AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

S. Hrg. 107–71

# NOMINATIONS OF ANGELA B. STYLES, STEPHEN A. PERRY, AND JOHN D. GRAHAM

## HEARING

BEFORE THE

COMMITTEE ON
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

ON THE

NOMINATIONS OF ANGELA B. STYLES TO BE ADMINISTRATOR OF THE OFFICE OF FEDERAL PROCUREMENT POLICY AT THE OFFICE OF MANAGEMENT AND BUDGET, STEPHEN A. PERRY TO BE ADMINISTRATOR OF THE GENERAL SERVICES ADMINISTRATION, AND JOHN D. GRAHAM TO BE ADMINISTRATOR OF THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS AT THE OFFICE OF MANAGEMENT AND BUDGET

MAY 17, 2001

Printed for the use of the Committee on Governmental Affairs

# NOMINATIONS OF ANGELA B. STYLES, STEPHEN A. PERRY, AND JOHN D. GRAHAM

S. Hrg. 107–71

# NOMINATIONS OF ANGELA B. STYLES, STEPHEN A. PERRY, AND JOHN D. GRAHAM

# HEARING

BEFORE THE

## COMMITTEE ON GOVERNMENTAL AFFAIRS UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

ON THE

NOMINATIONS OF ANGELA B. STYLES TO BE ADMINISTRATOR OF THE OFFICE OF FEDERAL PROCUREMENT POLICY AT THE OFFICE OF MANAGEMENT AND BUDGET, STEPHEN A. PERRY TO BE ADMINISTRATOR OF THE GENERAL SERVICES ADMINISTRATION, AND JOHN D. GRAHAM TO BE ADMINISTRATOR OF THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS AT THE OFFICE OF MANAGEMENT AND BUDGET

MAY 17, 2001

Printed for the use of the Committee on Governmental Affairs

U.S. GOVERNMENT PRINTING OFFICE

73–393 PDF WASHINGTON : 2002

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON GOVERNMENTAL AFFAIRS

FRED THOMPSON, Tennessee, *Chairman*
JOSEPH I. LIEBERMAN, Connecticut, *Ranking Democrat*

TED STEVENS, Alaska
SUSAN M. COLLINS, Maine
GEORGE V. VOINOVICH, Ohio
PETE V. DOMENICI, New Mexico
THAD COCHRAN, Mississippi
JUDD GREGG, New Hampshire
ROBERT F. BENNETT, Utah

CARL LEVIN, Michigan
DANIEL K. AKAKA, Hawaii
RICHARD J. DURBIN, Illinois
ROBERT G. TORRICELLI, New Jersey
MAX CLELAND, Georgia
THOMAS R. CARPER, Delaware
JEAN CARNAHAN, Missouri

HANNAH S. SISTARE, *Staff Director and Counsel*
ELLEN B. BROWN, *Senior Counsel*
PAUL R. NOE, *Senior Counsel*
JOHANNA L. HARDY, *Counsel*
SUSAN G. MARSHALL, *Professional Staff Member*
JOYCE A. RECHTSCHAFFEN, *Democratic Staff Director and Counsel*
LAWRENCE B. NOVEY, *Democratic Counsel*
JASON M. YANUSSI, *Democratic Professional Staff Member*
MICHAEL L. ALEXANDER, *Democratic Professional Staff Member*
DARLA D. CASSELL, *Chief Clerk*

# CONTENTS


| | Page |
|---|---|
| Opening statements: | |
| Senator Thompson | 1 |
| Senator Voinovich | 3 |
| Senator Collins | 21 |
| Senator Durbin | 24 |
| Senator Bennett | 28 |
| Senator Lieberman | 29 |
| Senator Carper | 30 |
| Senator Akaka | 31 |
| Senator Levin | 46 |


## WITNESSES

### THURSDAY, MAY 17, 2001


| | |
|---|---|
| Hon. Joe Barton, a Representative in Congress from the State of Texas | 1 |
| Hon. Ralph Regula, a Representative in Congress from the State of Ohio | 2 |
| Angela B. Styles to be Administrator of the Office of Federal Procurement Policy at the Office of Management and Budget | 6 |
| Stephen A. Perry to be Administrator of the General Services Administration | 11 |
| John D. Graham to be Administrator of the Office of Information and Regulatory Affairs at the Office of Management and Budget | 20 |


### ALPHABETICAL LIST OF WITNESSES


| | |
|---|---|
| Barton, Hon. Joe: | |
| Testimony | 1 |
| Graham, John D.: | |
| Testimony | 20 |
| Prepared statement | 150 |
| Biographical and financial information | 153 |
| Pre-hearing questions and responses | 175 |
| Additional pre-hearing questions and responses submitted by: | |
| Senator Lieberman | 191 |
| Senator Durbin with copies of correspondence from Philip Morris Management Corp. and Kraft General Foods, Inc. supplied by Mr. Graham | 248 |
| Post-hearing questions and responses submitted by: | |
| Senator Akaka | 303 |
| Senator Durbin | 308 |
| Senator Levin with attachments | 310 |
| Perry, Stephen A.: | |
| Testimony | 11 |
| Prepared statement | 93 |
| Biographical and financial information | 104 |
| Pre-hearing questions and responses | 122 |
| Regula, Hon. Ralph: | |
| Testimony | 2 |
| Styles, Angela B.: | |
| Testimony | 6 |
| Prepared statement | 67 |
| Biographical and financial information | 69 |
| Pre-hearing questions and responses | 77 |
| Post-hearing questions and responses submitted by: | |
| Senator Lieberman | 91 |

Page

## APPENDIX

Letter from Dr. Graham to Philip Morris Management Corp., dated October 25, 1993 ..... 266
Article dated May 7, 2001 from *Plastic News* entitled "Bush's OIRA appointee Graham could lend clout to plastics" (submitted for the record by Senator Durbin) ..... 349
Examples of Graham and Harvard Center Findings Contrary to Interests of Industries that Donated Restricted Funds for a Specific Project ..... 351
Chart of Graham quotes (submitted for the record by Senator Durbin) ..... 352
Letter from Dr. Graham to Senator Lieberman dated May 21, 2001 ..... 353
Letter from Mayada Logue, Scientist, Corporate Scientific Affairs, Philip Morris Management Corp., to Dr. Graham, dated January 22, 1991 with an attachment (submitted for the record by Senator Durbin) ..... 354
Letter from Dr. Graham to Philip Morris Management Corp., dated January 31, 1992 (submitted for the record by Senator Durbin) ..... 356
*Public Citizen* May 22, 2001 letter (response to the Finkelstein letter dated April 13, 2001) ..... 357
*Public Citizen* May 22, 2001 letter (response to an April 25, 2001 "Scholarly Response to Public Citizen") ..... 360
*Public Citizen* May 22, 2001 letter (response to remarks made by Senator Bennett) ..... 364
Joan Claybrook, President, *Public Citizen,* prepared statement with an attachment ..... 366
Lisa Heinzerling, Professor of Law, Georgetown University Law Center, prepared statement ..... 403
"Safeguards at Risk: John Graham and Corporate America's Back Door to the Bush White House," *Public Citizen*, March 2001 ..... 422
"Civilizing the Sport Utility Vehicle," by John D. Graham, *Issues in Science and Technology,* Winter 2000–01 ..... 543

Letters of Support and Opposition of the Graham Nomination:
Ande Abbott, Director of Legislation, International Brotherhood of Boilermakers ..... 549
John Adams, President, Natural Resources Defense Council ..... 550
Gary D. Bass, Chairman, Citizens for Sensible Safeguards ..... 551
Gary D. Bass, Executive Director, OMB Watch ..... 553
Randy Block, Co-Convener, Gray Panthers of Metro Detroit ..... 555
Merrick Carey, CEO, Lexington Institute ..... 556
Philip F. Clapp, President, National Environmental Trust ..... 557
Benjamin Cohen, Senior Staff Attorney, Center for Science in the Public Interest, with attached letter sent to President Bush ..... 558
Frank B. Cross, Professor of Business Law, University of Texas School of Law ..... 561
David M. Cutler, Professor, Department of Economics, Harvard University ..... 564
Douglas H. Dority, International President, United Food and Commercial Workers International Union (UFCW) ..... 565
Hon. E. Donald Elliott, Professor (adj) of Environmental Law, Yale Law School, formerly General Counsel, U.S. EPA, with an attachment ..... 567
Harvey V. Fineberg, Office of the Provost, Harvard University ..... 581
Michael Finkelstein, Independent Consultant on Automobile Safety ..... 583
Former Federal Regulators ..... 585
Harvard Center for Risk Analysis (response to *Public Citizen* report) ..... 588
Pamela Williams, S.M., Sc.D., Environmental Health and Health Policy and Management Program in Environmental Science and Risk Management with an attachment ..... 592
Harvard School of Public Health Supporters, "Who is Professor John D. Graham? A Scholarly Response to *Public Citizen*" ..... 596
Harvard University Faculty ..... 611
David Hemenway, Ph.D., Professor of Health Policy, Director, Harvard Injury Control Research Center ..... 614
David Holtgrave, Ph.D., Professor, Department of Behavioral Sciences and Health Education and Department of Health Policy and Management, Emory University ..... 615
J. Bennett Johnston, Partner, Johnston and Associates ..... 616
Faculty members at Schools of Medicine and Public Health across the United States ..... 617

Page

Letters of Support and Opposition of the Graham Nomination—Continued
National Organizations requesting inquiry ..... 622
Charles M. Loveless, Director of Legislation, American Federation of State, County and Municipal Employees, AFL–CIO ..... 639
Melissa A. McDiarmid, M.D., M.P.H. ..... 640
J. Donald Millar, M.D., Don Millar and Associates, Inc., Consultant in Occupational and Environmental Health ..... 641
National Environmental Organizations ..... 642
National Organizations ..... 644
Maria I. New, M.D., Professor/Chairman, Department of Pediatrics, Weill Medical College, Cornell University ..... 645
Joseph P. Newhouse, Ph.D., Director, Division of Health Policy Research and Education, Harvard University ..... 646
Margaret S. O'Donnell, Stop Dioxin Exposure Campaign ..... 647
Office of Information and Regulatory Affairs (OIRA), former Administrators ..... 648
Brian O'Neill, President, Insurance Institute for Highway Safety ..... 651
*Public Citizen* article "Bush Nominee for Key Position Would Thwart Protective National Health, Safety and Environmental Safeguards" ..... 652
Willie L. Pelote, Sr., Political and Legislative Director, California American Federation of State, County and Municipal Employees, AFL–CIO .. 655
William "Bill" K. Reilly, former EPA Administrator ..... 656
Mark L. Rosenberg, M.D., M.P.P., Executive Director, The Task Force for Child Survival and Development ..... 657
Alan Reuther, Legislative Director, International Union, United Automobile, Aerospace and Agricultural Implement Workers of America-UAW ..... 659
William Samuel, Director, Department of Legislation, American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) ..... 661
Scholars of law, medicine, economics, business, public health, political science, psychology, ethics and the environmental sciences ..... 663
Bob Stallman, President, Farm Bureau ..... 670
Louis W. Sullivan, M.D., Chairman, Board of Trustees, Public Health Policy Advisory Board ..... 671
Cass R. Sunstein, Professor of Jurisprudence, University of Chicago, The Law School ..... 672
Katherine Swartz, Associate Professor, Harvard School of Public Health .. 674
Tammy Tengs, Sc.D., Assistant Professor, Department of Urban and Regional Planning and Director, Health Priorities Research Group, School of Social Ecology, University of California, Irvine with an attachment ... 675
Harry Teter, Executive Director, American Trauma Society ..... 683
James H. Ware, with an attachment ..... 685
Elizabeth M. Whelan, Sc.D., M.P.H., President, American Council on Science and Health ..... 688

# NOMINATIONS OF ANGELA B. STYLES, STEPHEN A. PERRY, AND JOHN D. GRAHAM

**THURSDAY, MAY 17, 2001**

U.S. SENATE,
COMMITTEE ON GOVERNMENTAL AFFAIRS,
*Washington, DC.*

The Committee met, pursuant to notice, at 10:02 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Fred Thompson, Chairman of the Committee, presiding.

Present: Senators Thompson, Collins, Voinovich, Bennett, Lieberman, Levin, Durbin, Carper, and Akaka.

## OPENING STATEMENT OF CHAIRMAN THOMPSON

Chairman THOMPSON. The Committee will come to order, please. I think we will go ahead and get started.

This morning we are holding a hearing to consider the nominations of Angela Styles to be Administrator of the Office of Federal Procurement Policy; Stephen Perry to be Administrator of the General Services Administration; and Dr. John Graham to be the Administrator of the Office of Information and Regulatory Affairs at the Office of Management and Budget.

I understand that we have some Members of Congress and Senators here today to introduce these nominees. I will begin with Congressman Joe Barton. Glad to have you with us, Congressman.

## TESTIMONY OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. Mr. Chairman, I appreciate the opportunity to be here before you, and Senator Voinovich, and the other Members of your Committee. It is my pleasure to introduce to this Committee Angela Barbee Styles. She is a young woman who I have known for over 10 years. Her father was one of my three chairmen in my first campaign for political office for U.S. Congress back in 1984. Angela helped some in that campaign in a volunteer capacity. She was attending college at the time. She later decided to take a break from her college duties and worked for me for over a year in my legislative shop here in Washington. She handled some fairly major issues. She was very bright, very personable, and very dedicated.

She then decided to go back to college, went back to the University of Virginia. She graduated with distinction, went on to graduate school later on at the University of Texas at Austin, where she graduated with honors.

She has been in Washington for a number of years now, most recently with a private law firm where her expertise was in con-

tracting with the Federal Government. She is now married, has one child, I think a second child on the way. In fact, I think she is 9 months' pregnant, so this had better be a short hearing, Mr. Chairman. [Laughter.]

Mr. BARTON. I am trained as an emergency——

Chairman THOMPSON. You notice we have her first.

Mr. BARTON. I noticed that. I would hate to have to show my skills as a volunteer ambulance driver and try to help deliver a new U.S. citizen in this hearing. But she is very well qualified. She would have the highest recommendation from any individual that she had worked with, and I would hope that this Committee would give her a positive recommendation and an expeditious review to the full Senate.

Chairman THOMPSON. Thank you very much.

Senator Voinovich, I believe you have an introduction.

Senator VOINOVICH. Thank you, Mr. Chairman. At this time, I know it is not according to our protocol, but I would like to yield to the dean of the Ohio delegation, Congressman Ralph Regula, to begin the introduction of Steve Perry.

Chairman THOMPSON. Congressman Regula.

## TESTIMONY OF HON. RALPH REGULA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Mr. REGULA. Well, thank you, and thank you for your time and courtesy. I am here to speak on behalf of Stephen Perry, a senior vice president for human resources for the Timken Company. It is approximately a $3 billion company, operating in approximately 22 countries. So it gives you a measure of the responsibilities he carries as the vice president of this company.

In 1991, he was appointed by our then-Governor Voinovich to be a member of his cabinet and Director of the Department of Administrative Services for the State of Ohio. So I know, Senator, you know very well of his excellent service to the State of Ohio.

He has a master of science degree from Akron University and an MBA from Stanford University Graduate School, attended the University of Michigan, executive development. I could give you a whole list of all the things in which he has been involved. Just let me say that he is a great citizen of our community, highly respected, involved in a great number of community activities—the Stark Foundation and as a trustee of the Professional Football Hall of Fame.

I am pleased, in fact, proud to introduce Steve Perry and recommend him for the job of the head of General Services Administration because I know the kind of service he has given to our community. His professional service on behalf of the Timken Company has been outstanding, and, of course, as Senator Voinovich knows, he did a great job on behalf of the State of Ohio. And his experience in Ohio fits very well with the responsibility of heading up GSA.

Chairman THOMPSON. Mr. Congressman, thank you very much. I know you gentlemen have a very busy schedule, and you are welcome to stay as long as you can. But I know that you probably need to leave, so thank you very much for being with us.

Mr. BARTON. Thank you, Senator.

Mr. REGULA. Thank you.

Chairman THOMPSON. Senator Voinovich.

**OPENING STATEMENT OF SENATOR VOINOVICH**

Senator VOINOVICH. Mr. Chairman, it is a pleasure to join with Congressman Regula in introducing to the Committee, President Bush's nominee for the position of the Administrator of the General Services Administration, my good friend Stephen Perry, of Canton, Ohio.

Steve, I would like to extend a warm welcome to you and your lovely wife, Sondra, and thank you for your willingness to serve your country in a demanding position. I am delighted that you have once again accepted the call to public service. I would also like to thank you, Sondra, for the sacrifices you and your family made when Steve served in Ohio State Government and will likely make during his tenure at GSA.

Mr. Chairman, as you know, the position of GSA Administrator is probably best described as being the Federal Government's landlord and purchasing agent all rolled into one. The GSA Administrator is responsible for an annual business volume of $16 billion. Although filling the role of Administrator can be a daunting task, I believe, without question, that Mr. Perry is the right individual for this important position.

Mr. Chairman, I have personally worked closely with Steve Perry for a number of years. In February 1991, during my first term as Governor, I was pleased to appoint Mr. Perry to my cabinet as Director of the Ohio Department of Administrative Services, a position he filled until March 1993. He successfully managed this large department which is responsible for providing enabling services to State agencies in a manner similar to that of the GSA at the Federal level, including construction and maintenance services for Ohio's public buildings and leased facilities, procurement of supplies and services, and telecommunications services.

As the director of the department, Mr. Perry played a key role with the Governor's Operations Improvement task force—essentially, a Statewide top-to-bottom audit of State programs designed to improve the efficiency and effectiveness of each department and agency in State Government.

Further, he served as my designee on the Managing for the Future task force, conducting a 12-month study to develop recommendations for the most efficient and effective operation of Ohio's higher education system. In 1993, I appointed Mr. Perry to a 9-year term on the Ohio Board of Regents, where he has had a leadership role in implementing these recommendations and other improvements statewide.

Mr. Perry also helped me initiate Ohio's Total Quality Management program, which included working closely with unionized State employees. In my view, if Federal agencies are ever going to improve their operations, not only do they need to adopt modern business practices, but they need to make sure that unionized employees are involved in the process as well. I am glad that GSA will have an Administrator with experience in these areas.

In addition to his extensive government service, Mr. Perry has had significant general management experience during his 37-year

career with the Timken Company. After serving with distinction in my cabinet, he rejoined the company in 1993 as vice president, and in 1998 he was named senior vice president for human resources, purchasing, and communications.

His experience in both the public and private sector is going to be a tremendous asset to GSA. I have seen many skilled private sector managers stumble when given high-level government positions because they are not familiar with how government works. This is not going to be a problem for Mr. Perry.

In light of the Federal Government's pressing need for effective managers, especially in the critical areas of human capital and procurement, I can think of few individuals more experienced and more qualified to assume the leadership of GSA than Mr. Perry.

Steve, I look forward to working with you, and I thank you, Mr. Chairman, for holding this confirmation hearing this morning.

[The prepared opening statement of Senator Voinovich follows:]

PREPARED OPENING STATEMENT OF SENATOR VOINOVICH

Thank you, Mr. Chairman, it is my great pleasure to join Congressman Regula in introducing to this Committee, President Bush's nominee for the position of Administrator of the General Services Administration, my good friend, Mr. Stephen A. Perry of Canton, Ohio.

Stephen, I would like to extend a warm welcome to you and your lovely wife, Sondra, and thank you for your willingness to serve your country in a demanding position. I am delighted that you have once again accepted the call to public service. I would also like to thank you, Sondra, for the sacrifices you and your family made when Steve served in Ohio State Government, and will likely make during his tenure at GSA.

Mr. Chairman, as you know, the position of GSA Administrator is probably best described as being the Federal Government's landlord and purchasing agent all rolled into one. The GSA Administrator is responsible for an annual business volume of $16 billion. Although filling the role of Administrator can be a daunting task, I believe, without question, that Mr. Perry is the right individual for this important position.

Mr. Chairman, I have personally worked closely with Stephen Perry for a number of years. In February of 1991, during my first term as Governor of Ohio, I was pleased to appoint Stephen to my Cabinet as Director of the Ohio Department of Administrative Services, a position he filled until March of 1993. He successfully managed this large department which is responsible for providing enabling services to State agencies in a manner similar to that of GSA at the Federal level, including construction and maintenance services for Ohio's public buildings and leased facilities, procurement of supplies and services, and telecommunications services.

As Director of the Department of Administrative Services, Mr. Perry played a key role with the "Governor's Operations Improvement" task force; essentially, a statewide top-to-bottom audit of State programs designed to improve the efficiency and effectiveness of each department and agency of State Government.

Further, he served as my designee on the "Managing for the Future" task force, conducting a 12-month study to develop recommendations for the most efficient and effective operation of Ohio's higher education system. In 1993, I appointed Mr. Perry to a 9-year term on the Ohio Board of Regents, where he has had a leadership role in implementing these recommendations and other improvements statewide.

Mr. Perry also helped me initiate Ohio's total quality management program, which included working closely with unionized State employees. In my view, if Federal agencies are ever going to improve their operations, not only do they need to adopt modern business practices, but they need to make sure that unionized employees are involved in the process as well. I am glad that GSA will have an Administrator with experience in these areas.

In addition to his extensive government service, Mr. Perry has had significant general management experience during his 37-year career with The Timken Company. After serving with distinction in my Cabinet, he rejoined the company in 1993 as vice president, and in 1998 he was named senior vice president for human resources, purchasing, and communications.

His experience in both the public and private sector is going to be a tremendous asset to GSA. I have seen many skilled private sector managers stumble when given high-level government positions, because they are unfamiliar with how government works. This is not going to be a problem for Mr. Perry.

In light of the Federal Government's pressing need for effective managers—especially in the critical areas of human capital and procurement—I can think of few individuals more experienced or qualified to assume the leadership of GSA than Mr. Perry.

Stephen, I look forward to working with you, and I thank you, Mr. Chairman, for holding this confirmation hearing this morning.

Chairman THOMPSON. Thank you very much.

Before we turn to the nominees, Senator Durbin, did you have any opening comments?

Senator DURBIN. No.

Chairman THOMPSON. All right. Let's turn to the nominees, and we will begin with Angela Styles, to be Administrator of the Office of Federal Procurement Policy at OMB.

The mission of the Office of Federal Procurement Policy is to provide overall direction of government-wide procurement policies, regulations, procedures, and forms for executive agencies to promote economy, efficiency, and effectiveness in the procurement of property and services by the executive branch. This Committee has a longstanding interest in and jurisdiction over the Federal procurement system and has been primarily responsible for statutory improvements like the Federal Acquisitions Streamlining Act and the Clinger-Cohen Act and continuous oversight of the procurement process.

Unfortunately, improvement in the procurement system has been slow in coming. One of our primary allies in the effort to ensure that within the procurement system industry sellers and government buyers offer and acquire, respectively, maximum value for the taxpayer is the Office of Federal Procurement Policy.

I was pleased to see several initiatives already announced by the new administration. Forcing more competition in the many activities performed by the government, requiring more performance-based contracting, and insisting that we utilize the power of the Internet to streamline our procurement are just some of the things that are already underway. These initiatives, when implemented, will reap millions in savings and bring greater efficiency to government operations.

Angela Styles has the experience and background to take on these challenges. In addition to substantive experience in government, both on the Hill and on behalf of the State of Texas, Ms. Styles has hands-on experience representing clients with real government procurement problems, with increasing focus in recent years on disputes involving cost accounting standards, compliance, and allowability of costs under Federal contracts.

The Committee welcomes you, Ms. Styles.

Ms. Styles has filed responses to a biographical and financial questionnaire, answered pre-hearing questions submitted by the Committee, and had her financial statements reviewed by the Office of Government Ethics. Without objection, this information will be made a part of the hearing record, with the exception of the financial data, which is on file and available for public inspection in the Committee's office.

Our Committee rules require that all witnesses at nomination hearings give their testimony under oath. Ms. Styles, would you please stand and raise your right hand? Do you solemnly swear to tell the truth, the whole truth, and nothing but the truth, so help you, God?

Ms. STYLES. I do.

Chairman THOMPSON. Thank you very much. Please be seated.

At this point I would like to give Ms. Styles an opportunity to introduce anyone who is with her here this morning.

Ms. STYLES. I would like to introduce my husband, Scott Styles.

Chairman THOMPSON. Thank you. Welcome. Glad to have you with us this morning.

Any further opening remarks by anyone? If not, we will turn to Ms. Styles and receive any statement that she might have for us.

**TESTIMONY OF ANGELA B. STYLES[1] TO BE ADMINISTRATOR OF THE OFFICE OF FEDERAL PROCUREMENT POLICY AT THE OFFICE OF MANAGEMENT AND BUDGET**

Ms. STYLES. Thank you, Mr. Chairman and Members of the Committee. It is an honor to be here. I owe a special thanks to Congressman Joe Barton for his thoughtful introduction and a debt of gratitude for his continued support throughout my professional life. I am honored and grateful for his support today.

Second, but, I must confess, most importantly, I want to thank my husband, Scott, for his steadfast support throughout my career. Today is a particularly special occasion because it is also our wedding anniversary. I cannot imagine a better husband and father or one person that could possibly have been more tolerant and understanding of my legal career and now my commitment to public service.

Mr. Chairman, I also want to express my gratitude to the Committee for the expeditious consideration of my nomination. Your staff has shown me extraordinary courtesy by moving through the process quickly. I appreciate their time and preparation as well as the opportunity to further develop the working and personal relationships that I have had with several members of your staff over the past few years.

I am deeply honored and privileged by the President's nomination to be Administrator of the Office of Federal Procurement Policy and am looking forward with great anticipation to providing leadership and fostering an atmosphere of professional and excellence in acquisition policy.

Over the past decade, the Federal acquisition system has undergone significant and continual reform. This reform movement has achieved many laudable goals, most important of which government customers now receive the goods they need in a fraction of the time it took a decade ago. However, as with any reform movement, confusion has often dominated the process. I have been and continue to be concerned that the efficient procurement model, coupled with significant implementation confusion, has compromised

[1] The prepared statement of Ms. Styles appears in the Appendix on page 67.
The biographical and financial information of Ms. Styles appear in the Appendix on page 69.
Pre-hearing questions and responses appear in the Appendix on page 77.
Post-hearing questions and responses appear in the Appendix on page 91.

concepts fundamental to our system of government and our system of procurement.

We must never forget that we are procuring $200 billion a year in goods and services for the Federal Government with taxpayer dollars. Because we are spending the public's money, there are some goals that cannot be compromised in the name of efficiency. The real challenge for OFPP in this administration will be to balance the obvious benefits of increased efficiencies with the maintenance of fundamental concepts of competition, due process, integrity, and transparency. Indeed, OMB has already started working towards these goals with management initiatives relating to competitive sourcing and performance-based service contracts.

The next 4 years will be important years for our procurement system. I look forward to the prospect of working with you and other Members of Congress on these difficult acquisition issues.

Thank you, Mr. Chairman and Members of the Committee, for the opportunity to appear before you and for the time you have given me. I am happy to answer any questions you might have.

Chairman THOMPSON. Thank you very much. As I indicated earlier, the Committee submitted some substantive pre-hearing questions to the nominee, and the nominee has also met with Committee staff, as you have indicated, to discuss a variety of issues of Congressional interest regarding this office.

Your written responses to the written questions will be placed in the record.

I will start with questions that we ask all nominees. Is there anything that you are aware of in your background which might present a conflict of interest with the duties of the office to which you have been nominated?

Ms. STYLES. No.

Chairman THOMPSON. Do you know of anything, personal or otherwise, that would in any way prevent you from fully and honorably discharging the responsibilities as Administrator of OFPP?

Ms. STYLES. No, sir.

Chairman THOMPSON. Do you agree without reservation to respond to any reasonable summons to appear and testify before any duly constituted Member of Congress if you are confirmed?

Ms. STYLES. Yes.

Chairman THOMPSON. All right. Ms. Styles, in a March 9, 2001, memorandum to agency heads, OMB Deputy Director Sean O'Keefe stated that agencies should set goals to make greater use of performance-based contracts. As you know, part of our government-wide procurement amendment to the DOD Authorization Act last year included language to provide for performance-based contracts, but there is apparently disagreement among the agencies regarding the requirements to qualify as a performance-based contract.

Do you think agencies will be able to meet this goal set out in Mr. O'Keefe's memo? And what benefits do you think might be derived from such contracts?

Ms. STYLES. I certainly hope that the agencies can meet these goals. Part of the problem right now, I think, as I identified in my responses to the written questions, is that there is no agreement among the agencies on what qualifies as a performance-based contract. NASA, for instance, thinks cost reimbursement type con-

tracts are performance-based contracts. Other agencies don't agree with that.

Chairman THOMPSON. How would you define a performance-based contract?

Ms. STYLES. I think there may need to be more than one definition for performance-based contracts. You have contracts on the low-risk end of the spectrum, which would be fixed-price contracts for something like janitorial services. I think we could define a performance-based contract, as it has been defined in the past, to include incentives to be stating what you want performed as opposed to the specific steps to get there.

On the high-risk end of the spectrum, I think we should—we need to work a little bit harder to maybe take out some of the incentives. Obviously it's not going to be fixed-price contracts when you're talking about a cost reimbursement contract.

I think we need to work on definitions that can fit the specific situations. There may be an overriding definition that can fit low-risk and high-risk contracts, but I think we also need to make sure that we don't forget high-risk contracts or cost reimbursement type contracts when we're making that definition.

Chairman THOMPSON. In the interest of economy and efficiency, Federal Government buyers are placing increased emphasis on the use of multi-agency contracts. When properly developed and used, these contracts may enable Federal agencies to further leverage the government's buying power and satisfy agencies' contractual requirements. Agencies have been successful in marketing their many government-wide contracts to other Federal agencies.

There has been some concern that agencies are using these vehicles to short-cut competition. What are your views on the use of these government-wide contracts? And how will you ensure that they are used for the benefit of the government's leveraged buying power and at the same time maintain competition?

Ms. STYLES. I am very concerned about the proliferation of these types of contracts. The best analogy that I can make is for me to go out and buy a car. The most efficient and easiest way for me to do that is to go to the Ford dealership down the street and tell them I want the new 2002 Ford Explorer with the third-row seat. But that doesn't mean I'm getting the best price for that car. There are other dealerships in town. There are dealerships in Texas. There are dealerships in California.

From a procurement—and the most cost-effective way for me to actually buy that car would be to go to one inexpensive service that scours the country for the cheapest 2002 Ford Explorer, and I may be getting that car from New Mexico. It may take me 2 or 3 weeks, but I got the best price for the exact same car that I would have paid more for at the Ford dealership down the street.

Contracting officers face a similar situation, but they don't have the mechanism, they don't have the centralized mechanism or somebody that's going to scour the agencies' acquisition contracts or the types of contracts to find out what the best deal they can get or to find out the best vehicle for contracting for what they want.

A contracting officer looks at the situation. He will go to essentially the Ford dealership down the street, the easiest place to buy

the goods or service that he needs. There is no centralization of these government-wide acquisition contracts. There's no one place he can go to to find all of the contracts for whatever particular goods or service he's looking for. So there's no assurance—in fact, there's no assurance whatsoever that we're getting the best deal, that there's any competition, and I think in the end the taxpayers are probably paying a great deal more money for the convenience of going to the Ford dealership down the street.

Chairman THOMPSON. Do you have any ideas for improving that situation?

Ms. STYLES. I think we need to centralize the contracts that we're looking at, at least some centralization of where to go to look for the contracts. In the long term, I think we also need to be taking a look at the user fees on these contracts also.

Chairman THOMPSON. Thank you very much. Senator Voinovich.

Senator VOINOVICH. I am interested to hear you talk about centralization. If you are going to go in that direction, you better make sure that you have some really efficient people, because from my experience in government, it takes forever and a day to get anything done when you have had centralized purchasing. I think that is something that needs to be guarded against.

The other thing that I would like to share with you is that so often there is an attitude that programs to provide incentives to minority business and small business are more socially oriented rather than bottom-line. I recall while I was mayor of the city of Cleveland that we participated in a Federal program that was aimed at attracting more people to compete for work with the Defense Department. When that program was announced, there were accusations that it was going to be a rip-off and it wasn't the right thing to do. It happened to specifically deal with torpedoes. We really promoted the program while I was mayor, and we got a lot of people to be interested in providing parts of torpedoes that had previously been purchased through the "good-old-boy" network.

I will never forget it as long as I live. This major torpedo company, after it was all said and done, saved $14 million as a result of going to the northeastern Ohio area and giving some folks an opportunity to compete for those Federal contracts.

There was also in place something called a Maybank amendment, but I don't know if that is still around in terms of purchasing. You had to give the contract to the lowest and the best bidder. I lobbied very hard, and this was at a time in the early 1980's when unemployment was large in urban areas, 20 percent in my city. We lobbied through a provision that said that if you were in a labor surplus area where they had high unemployment, that if the person applying for the work was within 5 percent of the low bid, that they would get the work. So once we got it through, I said now we have to take advantage of it.

The interesting thing is this: By opening it up to a lot more people—we created an office called the "Make it in Cleveland" program with the Greater Cleveland Growth Association. It is something you should look into. They went out and looked at people that could compete for these contracts, particularly in the Defense Department. Long story short, we got a lot of contracts, and in no case did we ever have to take advantage of the 5 percent provision. The

contracts from Ohio were the lowest bid. But there was kind of a closed set-up, that only the people that were wired got the business. And I am just bringing that to your attention because so often there is an attitude that some of these "social welfare" programs are going to cost us more money and we've got to worry about the bottom line. Well, I am saying that the ones I have had experience with have been terrific, and I would hope that you would look into those.

The last thing I would like to discuss with you—and I would like your comments—is how familiar are you with the quality of the individuals that you are going to be dealing with in some of the departments in terms of procurement?

Ms. STYLES. I am relatively familiar with people that I have worked with at the Department of Defense. I have had clients and we have negotiated a number of agreements with the Department of Defense, many of them being contracting officers, defense corporate executives and the like.

Senator VOINOVICH. What about the quality of their work?

Ms. STYLES. The ones I have dealt with have been very high quality, although I will qualify that with saying that most of the clients I worked with are the larger defense contractors. So I think you would expect their contracting officers or their defense corporate executives to be probably the best.

Senator VOINOVICH. I have held hearings on the human capital crisis, and we had a hearing on the Commission on U.S. Security in the 21st Century. I would suggest that you read the testimony from Dr. Schlessinger, and from Admiral Trane, and familiarize yourself with it, because they have basically concluded that we are in a serious situation, particularly in the Defense Department, in terms of the quality of individuals that are there. I think one of the major problems that you are going to be confronted with is the quality of people who are in those departments and the prospect that many of them are going to be retiring before the year 2004 or will be eligible for retirement.

Ms. STYLES. I agree, and I think as we move to more competitive sourcing under A–76, the procurement people, the contracting officers are going to become increasingly more important. And I think we need to focus more training and recruitment in that area.

Senator VOINOVICH. I would urge you, anybody in OMB—and my observation is we haven't had any "M" in OMB—that there be a specific line item for training in the Federal Government. There is no training line item, even today in the budgets that are being submitted. I have asked the same question, and they don't have it in their budgets. You should have training in those budgets. Without it, those departments can't be competitive. Many of the individuals are going to leave if they don't have an opportunity to improve their skills.

Ms. STYLES. I agree.

Chairman THOMPSON. Thank you very much. I always learn more about State and local government by listening to Senator Voinovich. Someday I am going to learn why the city of Cleveland needs torpedoes. [Laughter.]

We will get into that later. Senator Durbin.

Senator DURBIN. I have no questions, but the Chairman will also know, when he visits Cleveland, he can visit Voinovich Park, which I have seen in Cleveland.

Thank you very much, Mr. Chairman.

Chairman THOMPSON. Thank you very much.

I might point out Senator Lieberman and I have sent a letter to OMB on the human resources problem, that we are very concerned about that Senator Voinovich mentioned. So I am sure that you will be talking to each other about that with your folks in OMB.

That is all the questions I have. We expect to act on your nomination promptly. We thank you for being here. We thank you for offering yourself to public service, and you are obviously a very qualified, knowledgeable person, and we appreciate your being here today.

Ms. STYLES. Thank you for having me.

Chairman THOMPSON. Thank you very much.

We will now proceed to the nomination of Stephen A. Perry, to be Administrator, General Services Administration. The GSA Administrator is responsible for managing the agency that supports the work of the Federal Government. It provides work space, equipment, supplies, procurement services, and other assistance to other Federal employees. Therefore, it is extremely important for the Administrator to be well versed in government operations.

Mr. Perry brings that experience to this position through his work as part of Senator Voinovich's—then-Governor Voinovich—cabinet as Director of the Ohio Department of Administrative Services, and his role as senior vice president, human resources, purchasing, and communications at the Timken Company.

In light of the Federal Government's need for effective managers, Mr. Perry seems to be very qualified to assume the leadership of GSA. Mr. Perry has filed responses to a biographical and financial questionnaire, answered pre-hearing questions submitted by the Committee, and had his financial statements reviewed by the Office of Government Ethics. Without objection, this information will be made a part of the hearing record, with the exception of the financial data, which is on file and available for public inspection in the Committee's office.

Committee rules require that all witnesses at nomination hearings give their testimony under oath. Mr. Perry, would you please stand and raise your right hand? Do you solemnly swear to tell the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. PERRY. I do.

Chairman THOMPSON. Thank you very much. Be seated, please.

At this point I would like to give Mr. Perry an opportunity to introduce anyone here today with him he might want to introduce.

## TESTIMONY OF STEPHEN A. PERRY[1] TO BE ADMINISTRATOR OF THE GENERAL SERVICES ADMINISTRATION

Mr. PERRY. Thank you, Senator Thompson. Mr. Chairman and Members of the Committee, it certainly is an honor for me to be

[1] The prepared statement of Mr. Perry appears in the Appendix on page 93.
The biographical and financial information of Mr. Perry appear in the Appendix on page 104.

have been nominated by President Bush to serve as Administrator of General Services, and it is also an honor for me to have this opportunity to talk about that subject with this Committee today. With your permission, Mr. Chairman, I would first like to take a moment, though, to say thank you to Senator Voinovich and to Congressman Regula, not only for the kind words that they said this morning, but more particularly for their friendship over the years and for the kindness that they have extended to Sondra and me and many other constituents, I am sure, back in our home State of Ohio. I also want to take this opportunity to thank Senator DeWine, who could not be here this morning because of his work on the Judiciary Committee, but he has certainly been very helpful and supportive of me in this instance and throughout my experience working in public service.

I sincerely appreciate the support and counsel that these gentlemen have given me over the years, and other members of the Ohio delegation have done the same. I understand that by supporting my nomination to lead GSA, each of them is saying something about the trust that they would place in me, and I want each of them to know, particularly you, Senator Voinovich, and I would like each of the Members of this Committee to know, that if I am confirmed, I pledge to continually strive to be worthy of your trust.

Mr. Chairman, I certainly agree with you and other Members of the Committee regarding the very important role and responsibility that General Services Administration has in achieving effective and efficient government services on behalf of the American people. It certainly is very clear to me that the quality and timeliness of the work done by GSA in providing services to the other Federal agencies has a direct and significant impact on the ability of those other agencies to achieve their respective missions. The challenge for GSA is to achieve and sustain itself as a high-performance organization, committed to continuous improvement of the services that it provides to meet the needs of its customer agencies, and thereby improve government services rendered directly to the public.

Mr. Chairman, I am very excited about the possibility of joining the team at GSA in this very important work. I am excited because I believe strongly in President Bush's aspiration to apply solid general management practices as the means to significantly improve government services for all Americans. I am excited because of the very interesting managerial challenge that will be involved with such a large and complex organization, and I am also excited to have this opportunity to be so involved in public service. I know that achieving and sustaining high-performance and a continuous improvement culture at GSA will be a very big job. I know it will have its hardships and frustrations. I know it will require long hours and some sacrifice by me, and certainly by Sondra and by others at GSA. I know that the administration and this Committee have high performance expectations for GSA.

From what I have learned, I believe that the people at GSA will accept the challenge for high-performance, and I am confident that I can help the GSA team make it happen. Mr. Chairman, as I thought about this hearing this morning and what I might say in this brief opening statement, I felt it might be useful to the Committee if I said a few words about my views on achieving and sus-

taining high performance in such an organization. Obviously, accomplishing this will require a number of things on behalf of people both outside and inside the agency, and I wanted to take a moment to mention just a few of these items.

First, I know that it is going to require very effective communication in all that we do. Constructive dialogue is critically important to get everyone involved on the same page and pulling in the same direction. Pardon me. I will have to ad lib. One example of a particular item of effective communication that perhaps we should spend some time on in the next few months, I believe, is in the area of the communication that GSA has with members of Congress and particularly with their staffs, and the same thing is going to be true with respect to communication that GSA has with the administration, and, there again, particularly with a staff of OMB.

In fact, communication can be improved. I have had the opportunity to meet with some of the Congressional staff already, and talk about ideas that they have for making that improvement. I look forward to working together with them to make that happen. Second, in addition to improving communication, as I just mentioned, achieving and sustaining high-performance at GSA will require developing an intimate working relationship with each of our customer agencies, so that we can work well together with them to develop the most effective and efficient approach to satisfy their needs.

The third item I would mention, that is necessary for achieving high-performance at GSA, will be to develop a very close working relationship with our suppliers. That is the way in which we can develop win-win approaches to developing the best value proposition for our customer agencies.

Fourth, it will require organizational capability building. We need to do this in order to have the people in place that are capable to achieve the mission that we have set out to achieve, and this brings us to the discussion that Senator Voinovich raised with respect to managing our human capital.

We must have a strong human capital management process throughout government. I am speaking particularly as it would relate to GSA. In this case, we must first determine the skills and competencies needed to achieve our specific goals for the coming years. We need to document that, understand what it will take to get us where we want to go. After having done that, then we need to identify the gap that exists between what is needed for success and what we have in place today. As we have identified that gap, then we need to execute the staffing plan that will bridge that gap by developing talent, by providing training, by recruiting people with the specific skills that GSA will need to achieve its goals.

Mr. Chairman, the last item I will mention in this area of achieving and sustaining performance at GSA is a very, very critical one, and it is the need to have what I call a strong performance management process throughout the agency. I think the guidelines in the Government Performance and Results Act, or GPRA, will serve as the framework for this work. Our performance management process will be built on the foundation of shared GSA values and missions, along with clearly-articulated goals and performance ex-

pectations. You can be sure that among the fundamental values will be integrity, customer service and accountability for results.

We will work very hard to see that each individual on the GSA team understands his or her role and responsibility, and just as importantly as understanding, we will work to see that they are strongly committed and aligned with each other to achieve the powerful force necessary for high-performance and to successfully achieve the GSA mission. We will have clear performance expectations. We will work with our oversight committees and the OMB staff to make sure that is the case.

We will have performance measures, so that we can be held accountable for our results. We will be proactive in taking corrective action as necessary to stay on course; and finally, the performance management process will provide for rewards and recognition to the people of GSA for their achievements. Mr. Chairman and Members of the Committee, as I said earlier, I know that achieving and sustaining high performance and continuous improvement at GSA will be a very big job. I believe that I do have the relevant experiences in business and in State Government which will enable me to be a strong contributor to the success of the GSA team in achieving the things that we have discussed here today.

It would be an honor and a privilege for me to serve our country in this capacity as Administrator of GSA, and so I respectively ask for your support of my nomination. Thank you very much, and I would be happy to answer any questions.

Chairman THOMPSON. Thank you very much. As I indicated earlier, the Committee submitted some substantive pre-hearing questions to the nominee,[1] and the nominee has also met with the Committee staff to discuss a variety of issues of Congressional interest. Your written responses to the questions will be placed in the record, and I will start my questioning with questions we ask of all nominees.

Is there anything that you are aware of in your background which might present a conflict of interest with the duties of the office to which you have been nominated?

Mr. PERRY. No, sir, there is not.

Chairman THOMPSON. Do you know of anything, personal or otherwise, that would in any way prevent you from fully and honorably discharging the responsibilities of the Administrator of GSA?

Mr. PERRY. No.

Chairman THOMPSON. Do you agree with reservation to respond to any reasonable summons to appear and testify before any duly constituted committee of Congress, if you are confirmed?

Mr. PERRY. Yes, I do.

Chairman THOMPSON. Mr. Perry, as you know, the GSA's Inspector General and the GAO have identified a number of management challenges that inhibit GSA's ability to achieve its mission, and this Committee has asked all agencies continually to set goals for solving many of these problems. As GSA's authorizing committee, we have a particular interest that you use the Results Act. You referred to GPRA, the Results Act, a few moments ago, but we really

[1] Pre-hearing questions and responses of Mr. Perry appear in the Appendix on page 122.

need you to use that to report to us on the extent to which you are solving them.

I am informed that the GSA, with some reluctance, has begun to report on its major management challenges in its performance report—as you know, the Results Act requires annual performance reports—as to whether or not we are actually achieving the goals we set out to achieve. We are trying to get to a performance-based government here, instead of looking at inputs, how many hours we spent or how many pieces of paper we shuffle. We are looking for results. Are we getting the job done that we were set up to do? These reports help us do that.

However, rather than setting concrete goals for addressing the problems, some of these GSA reports simply report on activities that they are undertaking to solve the problems. For example, regarding what the Inspector General calls GSA's information technology problem, GSA simply reports that they are working hard to improve. So I am going to ask you to really focus on that. We just had the Mercatus Center give us a report on the latest round of reports submitted, and they are all over the lot. Some agencies are doing a lot better job than others, and I think it depends more than anything else on what kind of leadership they are getting from the top, and whether or not the heads of these agencies prioritize that and think it is important.

We think it is important, and we are going to be coming back to you time and time again, to make improvements, not only in your department or in your agency, but in the way you report your improvements. You sound, from your opening statement, like you fully appreciate that, without my even having to ask the question.

Mr. PERRY. Yes, Senator, I absolutely do, and that is why I did allude to that in my remarks, because I think the guidelines provided in the Government Performance and Results Act really do represent some elements of best management practices in that regard. It does talk about setting challenging, but achievable, goals; goals that are important to your customers, not necessarily goals that mean something only to people inside the organization. It also talks about doing that in a collaborative way, by that, I mean having dialogue so that people inside the organization understand the importance of the goal, and hopefully, in the course of that dialogue, really develop some personal commitment to achieve the goal; and as that happens, you do need to have, of course, in place a process to measure progress, the willingness to take corrective action if it is necessary to make sure you stay on track, and then, at the end of the day, you do have the data that measures whether or not you have moved the needle in the right direction, and that's what leads to accountability and continuous improvement.

Another point, which I also alluded to, is that in the course of developing this initial plan and in the course of developing the initial performance measures by which we shall hold ourselves accountable, that is the point in time when GSA and the oversight committees, and people involved both on the Congressional side and the administrative side, need to be clear and on the same page. It should not be that GSA develops goals in a vacuum and then works on them. It should be that GSA develops goals that there is some consensus about, that these are the right things, so that we

make sure we are doing what is viewed by everyone as the right thing. So I subscribe to that wholeheartedly. That will be the place where we will begin to work, day one.

Chairman THOMPSON. Well, it looks like the agency is getting, maybe slowly, on the right track. I mentioned the Mercatus Center at George Mason University that does this annual assessment every year, and pointing out the importance of the job that you are about to take, it says the following: It says, "Because of the nature of GSA's role in the government, which is to serve other agencies' business needs, improving its own processes often automatically benefits its customers in the Federal Government and presumably citizen taxpayers. The connection between what GSA does and the expected result is obvious. This report gives tangible evidence of savings to its customers. The story is not told at the highest level, but at the performance goal level, the impact is clear." So they have been able to document, through this reporting, and this last one anyway, some savings to its customers. So it looks like you have some good people over there working on this already.

Mr. PERRY. I would agree with that, Senator. In fact, there are a couple areas where the goals are really well-measured. I will mention public building service. There are certainly some other challenges in that area, but they had a specific goal as to how many days it would require to place an agency in leased space, once they had made the request, and there was dramatic improvement, even though the IG's report shows that they did not achieve the goal they set, the improvement was dramatic, and I think that is what engenders inside the people in the organization that winning, and you win a little bit and then you win a little bit more and then you win a little bit more, and before you know it, you become a high-performance organization dedicated to that kind of performance.

Chairman THOMPSON. That is right. The direction is what is important, and agencies should not be afraid to set high goals for fear of missing their goal and somebody is going to criticize them. I think it is much more impressive to set high goals, and, whether you meet them or not, you are making progress toward achieving them. It sounds like that is what you are doing. GSA's government property auction site allows agencies to conduct online sales of everything from computer equipment to government vehicles. The commercial market provides the same service on the Internet sites, such as eBay and others. While having multiple sources for this type of activity is not uncommon, what is uncommon is the recent statement by a GSA official, who said GSA will go after the private sector government auction Federal business. Are you prepared to work with GSA's managers to better understand what capabilities should be developed in-house, and what should be contracted out? I think some in the government contracting community may think that GSA is duplicating the efforts of the private sector by developing technology within the agency, rather than taking advantage of commercially-developed solutions at a lower cost. Are you familiar with this issue, and what do you think about it?

Mr. PERRY. I am not intimately familiar. I know a little bit about it, and I can talk about it in general terms. On the one hand, I would certainly say at the outset that there are many things that

GSA does which may be available to be done commercially, on the outside, and I think we ought to carefully consider those opportunities every time they exist. Where it is in the best interest of our customer agency to work with outside commercial organizations, we should do that, and I think a lot of that is already done. Specifically, with something like the property disposal web site, part of what I have heard anecdotally is that the private-sector companies would be interested in the more lucrative parts of that, and not in the whole batch of it.

So what you would have remaining is GSA having to dispose of the things which are much more difficult to dispose of, and still having to develop the same web site to do it. So that would argue in favor of keeping the package together, so that you get the economies of scale. On the other hand, if there were a private-sector supplier out there who, in fact, would say, "No, I will step up and I will take the whole package, I will take the plums and I will take the prunes together, and we will provide something that is better than what could be done by Federal agencies," then I say clearly we ought to go in that direction. That is one of the things I will have to——

Chairman THOMPSON. You are obviously up on the issue, and it just requires good management judgment, which I am sure you will provide.

Senator Voinovich.

Senator VOINOVICH. Mr. Chairman, I just want to say that I hope that all of the President's nominees are as qualified and experienced and capable, and have the potential that Mr. Perry has. I think that your statement was very well put together, and I would like to say to you, Mr. Chairman, and to Senator Durbin, that in 2 years, this agency that Mr. Perry will head up will be a model, and one we can look to in terms of benchmarking some other agencies in the Federal Government.

Chairman THOMPSON. He is not doing you any favors, is he, Mr. Perry?

Mr. PERRY. He is setting those high challenges, like you advised.

Senator VOINOVICH. I would not be saying this if I did not think he was capable of doing it. I would just mention to you, as I said to Ms. Styles, that we do have a human capital challenge, and I was very pleased in your remarks that you talked about really looking at the skills and needs, and the shaping of your agency, to make sure that you can respond to the challenges currently and in the future. I would suggest to you that you look at your budget, find out whether or not some of the incentives that you need are currently in that budget, to retain people that you have and to attract other people into the agency. Also, one other important ingredient is the whole issue of training, which you are very, very familiar with.

I will say to you that, from what I have picked up, there are some concerns between the management of that agency and their labor unions, and I would be interested to see how you handle that situation. One other area that came before this Committee was the whole controversy over the qualifications of the people who provide the security in our buildings throughout the country. It appeared to me that there was a feeling among many people, that part of

your operation was not getting the same kind of attention that some other parts of the agency were getting. So those are two areas I think you need to look at pretty quickly, to see if there is something that can be done to deal with it.

Mr. PERRY. Thank you, Senator. I certainly will do that. I would like to just comment quickly, in the case of security, providing safe workplaces for Federal employees is of paramount importance. Part of what we have to understand is what is the duty and responsibility that we will place on those individuals? In other words, to some extent, that duty is to provide secure access to the building, and safety in that sense. There is another aspect that some talk about, which would be more in the line of police work, even investigative work. We have to define, first of all, what it is that we are responsible to do in that regard. Both of those things would have great implications with respect to the capability of our existing staff, or only the former portion of that, and that has to be worked out.

I know that one change has already been made with respect to the management oversight of that activity. It is now in the public buildings services, and the responsibility is there for that individual to work with the people in all the regions, to make sure that we are applying consistent practices, and that was not the case before. So it is an item of great concern, given the nature of the world in which we live and the possibility for bad acts within Federal buildings. So it is something we will pay attention to very early on.

Senator VOINOVICH. Thank you.

Chairman THOMPSON. Thank you very much. Senator Durbin.

Senator DURBIN. Mr. Chairman, I will only note that in his biography, it says that Mr. Perry was a stockroom clerk at Timken in 1964, and now he is a Senior Vice President. So I do not think that Senator Voinovich's projected success of your service is exaggerated. I wish you the best.

Mr. PERRY. Thank you, Senator. Thank you very much.

Chairman THOMPSON. We will act promptly on your nomination, Mr. Perry. Thank you very much for your service to your State and to your country, and we appreciate your being here and your willingness to serve. We look forward to acting on your nomination. Thank you very much.

We will now turn to the nomination of John Graham to be Administrator of the Office of Information and Regulatory Affairs at OMB. OIRA, as we refer to it, is the statutory office within OMB.

The administrator is the head of this office. OIRA was established in 1980 by legislation developed by this Committee, to address policy issues Congress was concerned were being neglected by the Executive Branch. Specifically, OIRA is charged with being a leader on regulatory reform, including implementing statutory requirements, reducing unnecessary paperwork and red tape, reviewing information policy and guiding statistical policy proposals. The decisions and actions of the OIRA Administrator are extremely important to the public, and these decisions should be made by an extremely capable and dedicated individual. Dr. Graham fits this profile.

He has been a professor of Policy and Decision Sciences at the Harvard School of Public Health since 1991, and director for the

Harvard Center for Risk Analysis. Like many other universes, such as Johns Hopkins, University of Pennsylvania, Washington University at St. Louis, Carnegie Mellon, George Mason and others, Harvard, through the Center for Risk Analysis, has researched analytical methods by which policy makers can make more reasoned regulatory decisions. Like these other research centers, the Harvard Center strives to continue its work through a diversity of supporters, including the university, government, and the private sector. As the government's share of research and development has decreased, universities have relied more and more on private support for crucial research. A survey by Committee staff indicates that research universities receive a substantial portion of their research dollars from industry, beyond monies from private foundations and non-profits. It is not uncommon for centers doing similar work as the Harvard Center to receive about 40 percent to 60 percent of their funding from the private sector.

It can be argued that much of the Harvard Center's work and the work of many other programs would not be possible without support from the private sector. A review by my staff and letters to the Committee indicate that the Harvard Center stands above many other centers because it has developed specific rules governing the researchers at the Center on conflicts of interest and financial disclosure, to ensure the integrity of the work. Many other centers surveyed relied solely on university-wide, or department policies, to address ethics concerns.

Dr. Graham's background highly qualifies him for this position. While as an academic and researcher, he was able, as all researchers do, to explore new ideas and methods related to his field. He could argue about what theories worked or did not work. That is what academia and research is all about. The Committee has received many letters pertaining to this nomination from leaders in environmental, health and regulatory policy. There are many outstanding letters of support for Dr. Graham, including letters from William Riley, former EPA administrator and head of an environmental group, as well as a letter signed by all five of the former administrators of OIRA, from both Democratic and Republican administrations. I am confident that Dr. Graham will effectively be able to make the transition from academia to government service, and that he will be able to use his background to bring more insight to the issues that confront OIRA every day.

Dr. Graham has filed responses to a biographical and financial questionnaire, answered pre-hearing questions submitted by the Committee, and had his financial statements reviewed by the Office of Government Ethics. Without objection, this information will be made a part of the record, with the exception of the financial data, which is on file and available for inspection in the Committee's office.

Our Committee rules require that all witnesses at nomination hearings give their testimony under oath. Dr. Graham, would you please stand and raise your right hand? Do you solemnly swear to tell the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. GRAHAM. I do.

Chairman THOMPSON. Please be seated. Dr. Graham, do you have anyone with you today that you would like to introduce?

**TESTIMONY OF JOHN D. GRAHAM[1] TO BE ADMINISTRATOR OF THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS AT THE OFFICE OF MANAGEMENT AND BUDGET**

Mr. GRAHAM. I do, indeed, sir. My wife, Susan, and daughter, Katy; my parents, Tom and Eileen Graham; and my sister and her husband, Sue and John Shefsley and their daughter, Sarah Shefsley; and my wife's parents, Leo and Gloria Warner.

Chairman THOMPSON. All right. Thank you very much. You are all very welcome here this morning.

Senator Voinovich, did you have any opening comments?

Senator VOINOVICH. Yes, I do. Thank you, Mr. Chairman. I am pleased that the Committee on Governmental Affairs is considering the nomination of Dr. Graham to be the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget. Mr. Chairman, I view OIRA as a very important office in the Federal Government. Fortunately, President Bush has nominated an individual who has the experience, the knowledge, and the integrity to be a first-rate administrator. Dr. Graham, as you mentioned, is a tenured professor at Harvard University. He has published widely, managed the Harvard Center for Risk Analysis at the Harvard School of Public Health, and is considered to be a world-renowned expert in the field of risk analysis.

When I was active in the National Governors Association, I had the pleasure of meeting Dr. Graham and hearing his testimony about risk assessment and cost-benefit analysis. He is, hands down, one of the most qualified people ever to be nominated for this position. Mr. Chairman, as you know, I served as Governor of Ohio for 8 years, and I know what it is like to operate in an environment of scarce resources, where tough choices have to be made on resource allocation among a State's various programs. In many instances, new Federal regulations have a habit of costing State and local governments tremendous sums of money to implement. That is why, many years ago, I was one of the four or five governors that pushed the passage of unfunded mandate relief legislation here on the Federal level; and, as Members of this Committee know, there was a provision in unfunded mandates relief legislation, that any regulation that was over $100 million had to be looked at in terms of risk assessment, cost-benefit, to determine whether or not it met the test.

That is why it is important that we have an OIRA Administrator who understands the significance of sound regulations and usefulness of cost-benefit analysis when determining how the Federal regulations will be applied to our State and local governments. As one who was very involved in development, as I mentioned, in unfunded mandates, it is important that the Administrator work to encourage agencies to consult with State and local governments

[1] The prepared statement of Mr. Graham appears in the Appendix on page 150.
The biographical information of Mr. Graham appears in the Appendix on page 153.
Pre-hearing questions and responses appear in the Appendix on page 175.
Additional pre-hearing questions and responses appear in the Appendix on page 191.
Post-hearing questions and responses appear in the Appendix on page 303.

while developing new Federal rules. It is also important that OIRA administrator produce accurate cost-benefit analysis for major Federal regulations. I am confident Dr. Graham will bring a reasoned approach to the Federal regulatory process. Dr. Graham is widely respected and his nomination has received support, and I am not going to go into them, Mr. Chairman, because you have already mentioned that.

I would mention, though, that he is so well-qualified that the last five OIRA Administrators, Democrats and Republicans alike, wrote to our Committee that, "We are confident that John Graham is not an opponent to all regulations, but rather is deeply committed to seeing that regulations serve broad public purposes as effectively as possible." These five individuals know what it takes to be an effective Administrator, because they have done the job themselves. Dr. Graham does have the skills and the qualifications to be a responsible steward of the public interest, and I agree with their assessment.

Before I conclude, Mr. Chairman, I would like to raise another point about Dr. Graham's nomination. While there has been strong support for his nomination from a variety of sources, I am familiar with the criticisms of Dr. Graham and the Harvard Center for Risk Analysis regarding their corporate funding. I see this criticism, frankly, as unfounded. The Harvard Center for Risk Analysis has a comprehensive disclosure policy, with the Center's funding sources disclosed and the Center's annual report on their web site. If reporters, activists or legislators want to know how the Harvard Center is funded, the information is publicly available.

It is well-known that the Harvard Center has substantial support from both the public and private sectors. The Harvard Center also has an explicit public conflict of interest policy. As for Dr. Graham, he has a personal policy against accepting personal consulting income from companies, trade associations and other advocacy groups.

Dr. Graham, I want to thank you for your willingness to serve your Nation. Your background and your experience have prepared you well to become the next Administrator of OIRA.

Thank you, Mr. Chairman.

Chairman THOMPSON. Senator Collins.

**OPENING STATEMENT OF SENATOR COLLINS**

Senator COLLINS. Thank you, Mr. Chairman, and good morning, Dr. Graham. I look forward to this hearing on Dr. John Graham's nomination to be the Administrator of the Office of Information and Regulatory Affairs. Along with most Members of this Committee, I have been able to work with Dr. Graham on such issues as the regulatory reform legislation that drew bipartisan cosponsorship from a diverse group of Senators. Dr. Graham's credentials for this position are stellar, and it would be hard to imagine anyone better qualified than he for this important position.

OIRA is responsible for reducing government paperwork and ensuring that regulations are drafted in a manner that will achieve their goals, but without unnecessary costs and increased risk. Dr. Graham has been a leader in the application of sophisticated research tools, such as risk analysis, that let us accomplish such reg-

ulatory rationalization in a far more effective manner. The risk analysis tools used by Dr. Graham and his colleagues help avoid regulatory paralysis and enhance public safety and welfare. It would be difficult to find a person better qualified to use these tools for the public's good than Dr. Graham, a professor at the Harvard School of Public Health and the founder of the Harvard Center for Risk Analysis.

In the years since its establishment, the Center has provided invaluable research on regulatory health and safety issues. As the Chairman has noted, Dr. Graham's nomination has been endorsed by a wide range of organizations, scholars and former OIRA Administrators. Mr. Chairman, I think it is unfortunate that a few groups have decided to oppose Dr. Graham's nomination, not by engaging in debate about his beliefs and positions, but rather by attacking his personal character and that of his academic colleagues at Harvard. Rather than discussing the merits of his analysis, his critics have somehow called into question his character and his judgment, because, like most academic institutions, the Harvard Center accepts private donations from industry groups.

Those who make such criticisms clearly know little about the Center. The Harvard Center, after all, receives considerable public funding, too, and has tougher conflict of interest policies than that of Harvard University as a whole. The Center is funded by both private industry and by the government's own regulatory and research agencies, including such organizations as the Environmental Protection Agency, the National Science Foundation, and the National Cancer Institute. Measurement of the effectiveness and efficiency of government regulations simply makes good sense, and it is ludicrous to suggest that rigorous analysis of government laws and regulations is somehow against the public interest, but to undertake such a study is all that Dr. Graham has done.

After all, Dr. Graham is hardly an opponent of well-crafted, commonsense regulation. He sounded the alarm, for example, of the deteriorating quality of indoor air quality in this country, a subject that had been virtually forgotten in our debates over clean air standards. Dr. Graham has also been an advocate of such conservation measures as the higher gasoline tax and tax credits for those who purchase vehicles utilizing a variety of energy-saving devices. I agree with him on one of those proposals and not on the other. I do not think we ought to have a higher gasoline tax, but my point is that he has been a supporter of efforts that would increase regulations in some areas. He has also been a supporter of efforts to regulate particulate matter.

In closing, Mr. Chairman, let me just make a few brief observations. Were Dr. Graham not strongly in favor of effective safety regulations, the American Trauma Society and the Task Force for Child Survival and Development would not have sent strong letters in support of his nomination, but they did. Were Dr. Graham not strongly in favor of effective regulations to protect Americans' health, the President of the American Council on Science and Health would not have informed me that Dr. Graham would be an outstanding OIRA Administrator, but she did. Were Dr. Graham not superbly qualified for this position, he would not have drawn the praise of every former administrator legally permitted to give

it, and he would not have won endorsements from scholars of all political persuasions and from many different disciplines, but he has.

Mr. Chairman, I am confident that, at the end of the day, the American people will be impressed, not only without Dr. Graham's qualifications and experience, but also with his willingness to leave academia for public service.

Thank you, Mr. Chairman.

[The prepared opening statement of Senator Collins follows:]

OPENING STATEMENT OF SENATOR SUSAN M. COLLINS

I look forward to this hearing on Dr. John Graham's nomination to be administrator of the Office of Information and Regulatory Affairs. Along with others on this committee, I have been able to work with Dr. Graham on such issues as the Thompson-Levin regulatory reform bill—legislation that drew the cosponsorship of a diverse group of Senators in both parties.

Dr. Graham's credentials for this position are stellar, and it would be hard to imagine anyone better qualified for the job. OIRA is responsible for reducing government paperwork and ensuring that regulations are drafted in a manner that will achieve their goals, without unnecessary costs and increased risk. Dr. Graham has been a leader in the application of sophisticated tools, such as risk analysis, that let us accomplish such regulatory rationalization in a far more effective manner. Far from being "paralysis through analysis," the risk-analysis tools used by Dr. Graham and his colleagues help *avoid* regulatory paralysis and enhance public safety and welfare. And it would be difficult to find a person better qualified to use these tools for the public good than Dr. Graham, a professor at the Harvard School of Public Health and the founder of the Harvard Center for Risk Analysis. In the years since its establishment, the Center has provided invaluable research on regulatory health and safety issues.

I am pleased to note that every single person, whether Republican or Democrat, ever to hold the position of OIRA administrator—every person, that is, except for two who are now federal judges and are quite properly prohibited from making such endorsements—have signed a letter to you, Mr. Chairman, and the Ranking Member, on Dr. Graham's behalf. In this letter, they urge us to act expeditiously, and with an open mind because, in their words, "we are confident that [Dr. Graham] is not an 'opponent' of all regulation but rather is deeply committed to seeing that regulation serves broad public purposes as effectively as possible." This statement from the people who know the job best is clearly a powerful indication of Dr. Graham's capability. It also highlights the non-ideological, nonpartisan, scholarly approach he will bring to OIRA.

Mr. Chairman, it is unfortunate that a few groups have decided to oppose Dr. Graham's nomination not by engaging in debate about his beliefs and positions but by attacking his personal character, and that of his academic colleagues at Harvard. Rather than discussing the merits of his analysis, his critics have tried to insinuate that he is somehow "corrupt" because, like most academic institutions, the Harvard Center accepts private donations from industry groups.

Those who make such criticisms clearly know little about the Center. The Harvard Center, after all, receives considerable public funding too, and has tougher conflict-of-interest policies than that of Harvard University as a whole. The Center is funded both by private industry and by the government's own regulatory and research agencies, including such organizations as the Environmental Protection Agency, the National Science Foundation, and the National Cancer Institute.

Measurement of the effectiveness and efficiency of government regulations makes good sense. And it is ludicrous to suggest that rigorous analysis of government laws and regulations is somehow against the public interest. But to undertake such study is all that Dr. Graham has done.

After all, Dr. Graham is hardly an opponent of well-crafted, common-sense regulation. He has sounded the alarm, for example, over the deteriorating quality of *indoor* air quality in this country—a subject that has been virtually forgotten in our debates over clean air standards. Dr. Graham has also been an advocate of such conservation measures as the higher gasoline tax and tax credits for those who purchase vehicles utilizing a variety of energy saving devices. He was also a supporter of efforts to regulate particulate matter. Are all of these the positions of a man whose scholarly views have been "captured" by private industry? Clearly not.

In closing, Mr. Chairman, allow me to make a few observations:

- Were Dr. Graham not strongly in favor of effective safety regulations, the American Trauma Society and the Task Force for Child Survival and Development would not have sent strong letters in support of his nomination—but they did.
- Were Dr. Graham not strongly in favor of effective regulations to protect Americans' health, the President of the American Council on Science and Health would not have informed me that Dr. Graham would be an outstanding OIRA administrator—but she did.
- Were Dr. Graham not superbly qualified for this position, he would not have drawn the praise of every former OIRA administrator legally permitted to give it, and he would not have won a rousing chorus of endorsements from scholars of all political persuasions and from many different disciplines—but he has.

Mr. Chairman, I am confident that, at the end of the day, the American people will be impressed not only with Dr. Graham's qualifications and experience but also with his willingness to leave academia for the public service.

Thank you, Mr. Chairman.

Chairman THOMPSON. Thank you very much. I don't know whether to call on the Ranking Member or the gentlemen that has been here longer.

Senator LIEBERMAN. I yield.

Chairman THOMPSON. All right. Senator Durbin.

**OPENING STATEMENT OF SENATOR DURBIN**

Senator DURBIN. Thank you, Mr. Chairman.

Dr. Graham, thank you for joining us today. I am happy that you came by my office and we had an opportunity to meet. I have not made any secret of the fact that I am going to oppose your nomination, and I hope, during the course of asking questions here, you will understand the misgivings I have about your appointment to this position. I do not think many people understand the importance of this position, but there are some who do. This position has been characterized as really the gatekeeper for rules and regulations related to public health and safety in our Nation.

In the testimony of Joan Claybrook, that was before this Committee, she has stated, "In theory, the OIRA director should serve as an honest broker, reviewing regulatory proposals from Federal agencies and deferring to agency expertise on the most technical and scientific matters. Federal safeguards on industrial chemicals, fuel economy standards, air and water pollution, tobacco regulation, implementation of a Patient's Bill of Rights, and virtually every other issue that is critical to human and environmental health fall under the office's purview."

She goes on to say, "Under the Paperwork Reduction Act, no government agency can gather information from 10 or more entities, a request which is often essential for research that justifies regulation, without the approval of this office. Through these mechanisms, OIRA can slow, stall, weaken or stop regulatory proposals and final rules that the regulated industry opposes."

How does industry view this appointment? Well, an article [1] in *Plastic News,* May 7, 2001, is headlined: "Bush's OIRA appointee, Graham, could lend clout to plastics," and they go on to say, "The job sounds boring and inside the Beltway, but the office can wield tremendous behind-the-scenes power, because it acts as a gate-

[1] Article from *Plastic News* dated May 7, 2001, appears in the Appendix on page 349.

keeper of Federal regulations ranging from air quality to ergonomics. It has the power to review them and block those that it chooses to."

They go on to say in this article, "The Harvard Center for Risk Analysis, which Graham founded and directed until Bush nominated him, gets a significant part of its $3 million annual budget from plastics and chemical companies." This is all from the *Plastic News* article: "The Center's donor list reads like a Who's Who of the chemical industry," and they go on to list some of the sponsors of Dr. Graham's institute. Graham is well-thought of by the plastics industry. Persons from that industry said, "The Bush Administration intends to make OIRA more important than it was in the Clinton Administration, elevating it to its intended status." This gentleman, Mr. Freeman, says, "They have a big stick if the President in office allows them to use it, and if they have someone in the office who knows how to use it." I ask this article be made part of the record, Mr. Chairman.

Chairman THOMPSON. It will be made part of the record, without objection.

Senator DURBIN. Mr. Chairman, I am troubled by a number of the things that Dr. Graham has done in his professional career. I think he has, in many aspects of his job, trivialized environmental problems that face our Nation. I hear from my constituents every day about their environmental concerns. The number one web site in the Federal Government at the EPA is the web site that parents visit every day to see if there is an ozone or smog warning, because they have children who are asthmatic. I know about these families. I think virtually all of us know someone who is suffering from asthma. When you talk about regulations relative to air pollution, regulations which Dr. Graham will ultimately review and stop if he disapproves, we can understand it is literately a matter of life or death.

When a rural couple wonders about their tap water and whether our national drinking water standards for arsenic and other chemicals will give them adequate protection, the final word may rest with Dr. Graham, if he wins this appointment. From a shopper in Chicago, writing to me about pesticides on food, to families all across America, they may not know what OIRA stands for, but decisions made in that agency will affect their lives. I have detected an attitude in Dr. Graham's work and writings that troubles me greatly. He has made the case that a little bit of dioxin might be good for you; that pesticide residues on food should not be taken all that seriously, that reducing smog might be a mistake because it would let in more damaging rays from sunlight; that banning DDT might have been a mistake; that environmental regulations can actually cause deaths, rather than prevent them.

I know you are going to find some of the things I have just said incredible. I will present some of Dr. Graham's actual quotes and will give him a chance to respond to them during the course of this hearing. I would like to ask that the entire statement be made part of the record, and save my remaining time for questions, Mr. Chairman.

Chairman THOMPSON. It will be made part of the record, without objection.

[The prepared statement of Senator Durbin follows:]

PREPARED STATEMENT OF SENATOR DURBIN

The word most often used to describe the office to which Professor Graham has been nominated—the Office of Information and Regulatory Affairs—is "obscure". Few are aware of OIRA, or of just how powerful the position of "regulatory czar" really is. But this office—this senior White House staff position—exercises enormous authority over every major federal regulation that the government has under consideration. Because of this, the OIRA Administrator must have a commitment to even-handedness, objectivity, and fair-play in analyzing and presenting information about regulatory options.

John Graham came by my office a few weeks ago for a courtesy visit, which I appreciated. Before that meeting I reviewed his extensive public record, his many articles, speeches and the numerous times he has testified before this and other Congressional committees.

It is Professor Graham's public record that troubles me—these many statements over the years that have minimized and trivialized environmental problems and have been dismissive of public concerns. His research work was worrisome—research that seemed to stretch the available information out of shape, in order to repeatedly reach the conclusion that we don't need regulations for air pollution or water pollution or pesticides. I'm troubled, as well, by the number of times Professor Graham worked too closely with industrial funders of his work, in order to advance a specific agenda at the expense of objective scholarship and the public interest.

I'd like to lay out in more detail a few of the areas that are of particular concern to me.

TRIVIALIZING ENVIRONMENTAL PROBLEMS

I hear from my constituents every day about their environmental concerns. From the young mother whose son has asthma, and can't go out to play on smoggy days. From a rural couple wondering about their tap water, and whether our national drinking water standards for arsenic will give them adequate protection. From a shopper in Chicago writing to me about pesticides on foods. I take every letter, every call, every concern very seriously.

I detect a very different attitude at work in Professor Graham's writings and statements. He has made the case that a little bit of dioxin might be good for you . . . that pesticide residues on foods are not a serious health threat . . . that reducing smog might be a mistake because it would let in more damaging rays from sunlight . . . that banning DDT might have been a mistake. That environmental regulations can actually *cause* deaths, rather than prevent them.

I'm not sure how someone holding those views could look at a regulatory proposal to reduce the levels of arsenic in drinking water and decide that it would be a good thing for society to do. Following Professor Graham's logic, a little bit of arsenic may be good for us as well.

It's not just environmental issues either. Professor Graham's work has been broad ranging, to say the least. In one study he concluded that safe housing regulations can lead to excess deaths. In another, he found that the use of cell phones while driving—which, by his own estimates cause 1,000 deaths per year—shouldn't be regulated since the benefits of cell phones outweigh the costs.

And I'm also troubled by what strikes me as a very dismissive attitude towards the American people. According to John Graham, we are "paranoid", "neglectful", "dysfunctional", and generally ill-informed and over-emotional. In one article, Professor Graham talked about America's "emotional gush" in the aftermath of the high school shootings in Littleton, Colorado, arguing that it might divert us from the real dangers that our children face.

Violence in schools is one of the real dangers that our children face, every day.

PUBLISHING MISLEADING, ANTI-REGULATORY RESEARCH

I also have concerns about the nature of many of Professor Graham's research projects. They all seem to support—sometimes directly, sometimes indirectly—the message that government regulations are a bad idea. And many of his results simply strain credibility. Regulations are killing 60,000 people a year through a process he calls "statistical murder"! Environmental regulations are forcing our country to spend million, billions . . . even *trillions* of dollars to save a single life! Saving five lives would cost us our entire Gross Domestic Product. I just don't see how any legitimate scientific analysis can reach these exaggerated conclusions.

And others have the same problem. Lisa Heinzerling is a well-respected Law Professor at Georgetown University who submitted testimony to today's hearing. I commend her testimony to all my colleagues, and wish that Professor Heinzerling were here to deliver it in person. She writes that the claims Professor Graham has made regarding the cost of regulations, in terms of both dollars and human life, are "exceedingly problematic, for three basic reasons. . . ."

—"they misrepresent the output of the current regulatory system;"
—"ignore many of the benefits of Federal regulation;"
—"and rest on controversial moral judgments about whose life is worth saving."

This last point is particularly troubling, because it involves the practice of "discounting" human life in exactly the same way economists discount money—a life saved or a dollar earned today is much more valuable than a life saved or a dollar earned in the future. Discounting makes sense for dollars. But it only trivializes the value of the lives of our next generation, and creates a built-in bias against environmental regulations meant to provide protections over the long term.

Dr. Heinzerling points out a fact in her testimony that startled me. Of the most expensive environmental programs that Professor Graham identified in his research, none of them were ever implemented! Where he says we spend hundreds of billions of dollars, we actually spend zero dollars, because these are programs that do not exist.

I asked the Congressional Research Service to look into the most expensive program that Professor Graham identified—chloroform standards that cost $99 billion for each year of life saved. Their response—this was a "hypothetical" case study never proposed, nor even considered for proposal.

There are organizations that absolutely love research results that show billions of dollars being wasted by unnecessary environmental regulations—groups like the Cato Institute, the Heritage Foundation, and the American Enterprise Institute, all of whom have made use of Professor Graham's results to strengthen their anti-regulatory arguments.

And perhaps this may be the result of how they've used the information, rather than his research itself, but the end result has been to inject a great deal of misinformation into the regulatory reform debate about what the true costs and benefits of Federal regulations actually are.

CONFLICTS OF INTEREST

Which leads me to the last area of concern: How the work Professor Graham does so neatly supports the very agendas of the organizations that support his work. There have been troubling charges of conflict of interest. Many of Graham's own colleagues from Harvard University have written this Committee alleging:

". . . a persistent pattern of conflict of interest, of obscuring and minimizing dangers to human health with questionable cost-benefit analysis, and of hostility to governmental regulation in general. . . ."

Some of the specific instances cited include soliciting funds from Philip Morris at the same time Professor Graham was writing a chapter on tobacco risks he invited Philip Morris to review in draft form. He returned funds received from Philip Morris as a violation of University ethics policy, yet solicited and received funds from Kraft Foods, a subsidiary of Philip Morris. His research on cell phone use while driving, critics charge, is patently designed to please the corporate sponsors of the study.

These concerns are broadly shared, which is why this nomination—to what would ordinarily be an obscure and non-controversial position—has generated so much opposition. Groups opposing this nomination include advocacy groups such as NRDC and OMB Watch, as well as labor unions, academics, health professionals, and public health organizations like the Center for Children's Health and the Environment at the Mount Sinai School of Medicine in New York.

We need to hear more about these possible conflicts in the course of this hearing. Professor Graham, I look forward to the opportunity to engage you on these issues.

Chairman THOMPSON. Senator Bennett.

Senator BENNETT. Thank you, Mr. Chairman.

**OPENING STATEMENT OF SENATOR BENNETT**

Dr. Graham, we welcome you here. I have read Joan Claybrook's presentation.[1] I have also read the refutation of that presentation submitted by David Hemingway, Ph.D., Professor of Health Policy, and Director of the Harvard Injury Control Research Center. If I may quote from Dr. Hemingway's cover letter of that refutation, not that this should be dispositive, but unfortunately, in this arena, this has to be said, "I am a public health professional and a Democrat. I agree with John's conclusion on many issues and disagree on some, but I have always respected his science and his integrity. I think the current administration in Washington has made some terrible decisions. However, I believe the appointment of John Graham is one of its best ones. John will serve the Nation well. I do not know of a more appropriate person to be appointed to oversee regulatory issues at OMB."

Joan Claybrook spends most of her time quoting newspaper articles. There is no indication that her special-interest group, *Public Citizen*, has ever examined, to the degree that David Hemingway, a colleague at Harvard, has examined the actual work of this nominee. She spends a great deal of her time complaining about those who have contributed money to Harvard University, on the grounds that by contributing money, they have somehow poisoned the well at Harvard and every professor who teaches there. I would be more impressed if, in her special-interest group, Joan Claybrook would disclose her sources of funds. We have no idea who paid for the statement she compiled and put together, what other special-interest groups have combined behind the cloak of her special-interest group to launch this assault on the integrity of this nominee.

She and her colleagues have every right to attack the integrity of the nominee, but we as Senators must pay attention to those who know him best and to those who know the job best. Those who know the job best have unanimously endorsed this nominee, including those who held the job under President Clinton. Those who know the nominee best, his colleagues at Harvard, have unanimously endorsed this nominee. I was unaware that Harvard was part of the vast right-wing conspiracy, but apparently it is, in some circles here.

Finally, Mr. Chairman, I remember when Joan Claybrook and *Public Citizen* told us of the tremendous number of deaths that would occur on the highway if the Congress were to raise the speed limit. Congress allowed the speed limit to be raised and the deaths did not materialized. As a matter of fact, the number of deaths per mile driven went down after the speed limit was raised. So I feel that we are seeing an attempt here to attack a public citizen in the name of public citizens, who, if he is confirmed, will render superb service.

Will he be right every time? Of course not. None of us is, including, if I may be so bold, even me. But given the track record that he has accomplished in his academic life, given the endorsement that has been given him by his colleagues at a university that some suggest is our leading university in the United States, given the record of integrity that has been endorsed by those who have per-

[1] The prepared statement of Joan Claybrook appears in the Appendix on page 366.

formed this job under different Presidents and in different political atmospheres, I think it is incumbent upon this Committee to give a strong vote for this nominee, and send him to the floor with our endorsement.

Thank you, Mr. Chairman.

Chairman THOMPSON. Thank you very much. Senator Lieberman.

Senator LIEBERMAN. Thanks, Mr. Chairman. First, I want to object to Senator Bennett's conclusion that Harvard is our leading university.

Chairman THOMPSON. I am glad you are sticking up for Vanderbilt. I appreciate that. [Laughter.]

Senator BENNETT. I will be happy to recant that statement.

Senator LIEBERMAN. We think of Vanderbilt as the Yale of the South.

**OPENING STATEMENT OF SENATOR LIEBERMAN**

Senator LIEBERMAN. Thanks, Mr. Chairman. Well, we could use a little levity today.

Thank you, Dr. Graham. This, as my colleagues have said, is a very important nomination because of the importance that OIRA holds in our governmental system. It is, as Senator Durbin said, very little-known, but casts a very large shadow and footprint across the workings of our government, particularly in what I would call the protective aspect of our government. I mean, after all, we, in the Legislative Branch, adopt laws which presumably are an attempt to express our values, to draw lines between what is right and wrong, what is acceptable and unacceptable, what is desirable and undesirable in our society, and we leave many of the details, because it is impossible to cover every situation through law, through legislation, that may be effective, and we leave the details to the regulatory process.

Particularly in the protective aspect of government, which is one of our most important roles, that regulatory part of the process is critically important. And what do I mean by protective? The obvious, which is that there are dangers that face people in our society, in our country, every day, that are so large or in other ways so difficult for individuals to respond to, that the government has a responsibility to do so. And this is not big government, this is protective government, and I think, in many ways, though I cannot cite a particular public opinion survey on this, the most desired, accepted, and supported aspect of our government.

Let me be specific. We have talked about environmental protection as a broad, bipartisan ethic in our society. I think about the importance of protecting the environment, the critical role that government plays in that. The other aspect of what we call environmental protection, but is really people protection, which is protecting people from the adverse consequences of environmental pollution, whether it is, as Senator Durbin said, the impact on an asthmatic child or an older person with respiratory problems of air pollution, whether it is the dangers associated with polluted water, or, in another sense, the natural resource sense, the role that regulation plays in protecting some of the great natural treasures that the good Lord has given us here in the United States.

So this is a very important part of government, and OIRA is the gatekeeper. It is at the center of this process. In recent years, OIRA has reviewed regulations to ensure that the agency has adequately defined the problem, considered non-regulatory alternatives, assessed available information on risks, costs and benefits, and consulted affected parties before those regulations can go forward to publication and full effectiveness. So this is an important position.

Because of what you have written and said, and, in some sense, done, so far as you have been an activist or involved in preparation of legislation, or testimony, your nomination has, I think, quite predictably become controversial, and based on your writings, because they do raise questions, it is a provocative nomination. It is, I think, all the more controversial at this particular moment because of the anxiety that is felt in different parts of our population in our country, about early first steps that the Bush Administration has taken with regard to protective regulations, beginning with a memo issued by the Chief of Staff to the President, Andy Card, the so-called Card memo, holding up a number of regulations that were issued by the Clinton Administration. And then some of the actual acts, the most controversial ones, such as the regulation with regard to the tolerable amount of arsenic in drinking water, and, of course, this is of wide concern, because the reason there is a limit placed is because at least some science and medicine says that arsenic in drinking water can cause cancer. So, in that context, based on your body of work and opinion, I think this nomination, your nomination, has actually raised more anxiety than it might have had those actions not preceded it.

But I think we have an obligation to try to be fair to you, and, I suppose, not to punish you because you have written or thought or spoken in ways that are different or provocative. I have always felt, as I presume most of my colleagues do, that our role in the advice and consent power in the Senate that the Constitution gives us is not to decide whether we would appoint a nominee, but whether the nominee is the appropriate choice for the position to which he or she has been nominated, and it is that standard that I am going to hold myself to as I consider your testimony today and the cumulative evidence that is presented to us about your nomination.

So I look forward to your testimony and to the question period, and I thank you very much for responding to the pre-hearing questions, voluminous as they were, that I and others submitted to you.

Thank you, Mr. Chairman.

Chairman THOMPSON. Thank you very much. Senator Carper, I believe you are next.

**OPENING STATEMENT OF SENATOR CARPER**

Senator CARPER. Thanks, Mr. Chairman, and to our nominee, welcome today. I don't know you, and I don't believe we have ever met, and I don't know a great deal about you. I have heard today from colleagues here whom I respect enormously who seem to feel that you are an excellent nominee. And I have heard from a colleague who I also respect enormously who has raised serious questions about your nomination.

I will be very brief. I just want to say that I think we all agree—I am sure you do as well—character is terribly important. There are few qualifications that are more important, maybe none, with respect to those who come before us for our consideration. Integrity, which is closely related to character, is just vitally important.

I hope in your comments today and in the opportunities we have with questions that you will just address very directly the concerns that have been raised about you, your character, and some of the work that you have been involved in in ways that will dispel some of the concerns that have been raised.

Again, we welcome you today and your family. We thank you for your willingness to serve, and we look forward to this hearing.

Chairman THOMPSON. Senator Akaka.

**OPENING STATEMENT OF SENATOR AKAKA**

Senator AKAKA. Thank you very much, Mr. Chairman. I wish to add my welcome to Dr. Graham and his family.

In 1986, Congress voted to make the Administrator of the Office of Information and Regulatory Review a presidentially appointed position. The action was taken because of the lack of transparency in the office's operations and an erosion of trust between OMB and Congress.

Given OIRA's wide-ranging authority over Federal regulation and information, there is a tremendous potential for abuse and a disregard for the technical expertise in decisions made by Federal agencies. The possibility of abuse remains, and the questions continue. How much weight should be given to cost/benefit assessment? And how should it be applied? Should all costs and benefits be lumped together in calculating cost/benefit ratios? Should distinctions be made between costs borne by industry versus private citizens or benefits gained by children as opposed to senior citizens?

It is in this light that I will view the nomination of Dr. John Graham. I want to know if he supports open and transparent reviews of rules and regulations and regular communications with Congress. I want to know if he would return OIRA to the 1980's when regulations went into a black hole and never came out again.

The regulations that OIRA reviews affect everyone in Hawaii and throughout the Nation. OMB and OIRA must be able to assure all stakeholders that their voices will be heard during the consideration of regulations. I want to be assured that transparency and accountability of the regulatory review process within OIRA, as supported by OMB Director Daniels during his confirmation hearing before this Committee, will be maintained. Openness and public participation must be the cornerstones of Federal rulemaking.

This is my statement, Mr. Chairman, and thank you very much.

Chairman THOMPSON. Thank you very much.

Senator Bennett, you made your comments earlier, didn't you?

Senator BENNETT. Yes. I have some questions at the appropriate time.

Chairman THOMPSON. All right.

Dr. Graham, let me start off by thanking you for offering yourself to public service and to the ordeal to which you are about to be introduced.

Certain questions, of course, have been raised concerning potential conflicts of interest that the Harvard Center might have, although the Harvard Center is almost unique in having specific conflict of interest rules for its Center. Questions have been raised about the fact that private money is taken for research, although all similar institutions, the most reputable institutions in the country, do so. Questions have been raised about the source of your funding, although you have a more extensive disclosure policy than any other institution that I know, at least as extensive or more than most, and certainly more than most of your critics have. So we will have a chance to address all of those.

I must say, in sitting here just thinking about it, it is kind of ironic for Congress to be criticizing someone for taking money from somebody and then passing judgment on interests that have to do with their business. We do that on a daily basis, and we have the benefit of reading in the newspaper every time we pass some policy decision who gave who the most money.

Now, even with campaign finance reform, that will still be the case because large amounts of money are involved. At the same time, we are making policy decisions with regard to those who just gave us the money. So I don't think we ought to get too high up on our high horse with regard to that.

Obviously, one of the things we have to do with regard to addressing that institutional situation that apparently these research centers find themselves in is to have rigorous disclosure. And it seems to me that the Harvard Center has that.

I was impressed, particularly among all of the favorable comments that you received, by one of Robert Litan, who is vice president and director of economic studies at The Brookings Institution, and a regulatory expert, who said, referring to you, "He's one of the most qualified people ever to be nominated for the job. He's drawing opposition from people who oppose cost/benefit analysis itself since he's the leading practitioner."

I want to talk a bit about this cost/benefit analysis. As you proceed, it is true that you, anyone in your position, would have somewhat of a burden to overcome because of recent events and the press treatment and so forth. After 8 years, the Clinton Administration on the way out the door put in certain regulatory requirements that even local Democratic officials in some cases would say would break their municipality if they were implemented, so it was obvious to me that they knew that a new administration would have to look at those things.

So you are having to look at them now, and you are getting the flack that comes from not just rubber-stamping whatever was done as they went out the door. I like to think that we all have the same interests in this country. We all have kids, and many of us have grandchildren, and all of us are concerned about the air that they breathe and the water that they drink. But we also realize that we make cost/benefit judgments every day. If we wanted to pay the price to save more lives, we wouldn't have automobiles on the streets. I don't think it is anti-safety but, rather, pro-safety to point out that seat belts or air bags are good things, but they can also kill children. And you might want to look at ways of doing that better.

We have had that experience. It is not anti-environment to say let's quit spending so much money on a water requirement that saves X number of lives and let's spend more money on a water requirement that saves more lives. Those are trade-offs, it seems to me, that are common sense and that we make every day. And you have had the audacity to put it up front and acknowledge that we do make those trade-offs and that they should be a part of the policy discussion. You have never been emperor or had the ability to put these things into effect, but you have candidly given the benefit of your research along with your colleagues. And most of these—I might point out, most of these reports that the Center has written, especially those with restricted funds, have been written with one or two more of your colleagues, the ones that you have been on, so very few of these things with restricted money have been things that you have done alone.

But, clearly, this cost/benefit analysis has stirred passionate disagreement, even though there seems to be a consensus on the use of regulatory analysis. Since the Carter administration, each President has required agencies to use regulatory analysis for important regulatory decisions. President Clinton's Executive Order on regulatory review looks a lot like President Reagan's.

Why the passionate disagreement, do you think, over these regulatory issues? And explain to us and to the public your view of the tools of risk assessment and cost/benefit analysis and why you think it is important for responsible regulatory policy?

Mr. GRAHAM. Senator, I had a short opening statement, and I wondered whether I should just pass it up and go to questions, or how do you want to do that?

Chairman THOMPSON. You should go ahead and give it. In fact, I am remiss in not calling on you to give it. So do that at this time, if you would.

Mr. GRAHAM. The good news is I am going to cut it in half given what has been said already.

Let me thank you, Chairman Thompson, Senator Lieberman, and Members of the Committee, for the opportunity to provide a brief opening statement. I am honored to be President Bush's nominee as Administrator of the Office of Information and Regulatory Affairs and look forward to the opportunity to work with each Member of this Committee. Some say that I am not practicing risk analysis in my own life since the risks of this job may end up exceeding the benefits. Yet I take a more optimistic view and aspire to working on behalf of the public to improve the regulatory system.

If I am confirmed as OIRA Administrator, I will be making a major change in my professional role and my responsibilities will be different. I will no longer be an academic, advancing provocative ideas, and will instead be responsible for enforcing the laws of the land as Congress wrote them. I will advise the OMB Director and the President on future legislation. I will implement the President's policies and advocate the President's priorities. I will also lead a team of fine analysts at OMB and work with Congress and the public on issues regarding regulation and information.

I see my chief role as to stimulate more analytical thinking about major regulatory decisions in the Federal Government—decisions that affect State and local governments, small and large busi-

nesses, and the public at large. My responsibilities will also include paperwork reduction, information policy, and statistical policy.

Mr. Chairman, the subject of openness in regulatory review at OMB has been a concern of this Committee for more than 15 years. Progress has been made in recent years, and I pledge to continue that progress while protecting the ability of OMB staff to do their jobs efficiently. If confirmed, I will work to achieve regulatory reviews that are timely, transparent, and rigorous. I understand that openness does not necessarily create agreement. Yet I also hope that we will find issues where the spirit of openness permits dialogue and a narrowing of policy disagreements.

Since my nomination in March, some have charged that I and the Harvard Center for Risk Analysis have a pro-business bias. I respectfully disagree. Sometimes the findings of our studies have supported the interests of sponsors, who happen to be business organizations. Sometimes the findings of our studies have supported strict regulation of business. And sometimes our studies offer public health insight but do not really affect business interests one way or another. Our Center has simply followed the scientific data and analysis, wherever they have happened to lead us.

Thank you for the opportunity to make this opening statement, and I hope we can proceed to questions.

Chairman THOMPSON. Thank you very much. Well, I will go back to my question, and that has to do with your explanation of the tools of risk analysis and cost/benefit analysis, why you think they are important, and why the passionate disagreement with regard to those issues that I described earlier.

Mr. GRAHAM. Senator, I see the purpose of these analytic tools, like risk analysis and cost/benefit analysis, not necessarily to create fewer regulations or more regulations, but to create a smarter regulatory system, one that can save more lives and protect the environment more effectively but at lower cost than we are currently doing now.

For 20 or 30 years there has been concern in the public interest community about these analytic tools, but I think what we have shown in our prior scholarship in this area, not just myself but other people in this field, is that these analytical tools can be a force for more protection at less cost than we're achieving today.

Chairman THOMPSON. You have written a lot about the need to make more efficient regulatory decisions. That sounds rather hard-hearted. Why do you think that is important when you are dealing with lives and safety of people?

Mr. GRAHAM. Right. Well, one way to think about this is that if we, as a society, don't invest our resources in life saving or in environmental protection in the areas where they can do the most good, then we have foregone the opportunity to spend those same resources to save more lives or do more for the environment.

Chairman THOMPSON. Is this based on the assumption that we as a Nation, regardless of what we say, are not willing to make unlimited resource commitments to every danger, every threat to safety in this country?

Mr. GRAHAM. Yes, sir. I am fond of telling my students that, if we have unlimited resources in these areas, there isn't any need

for risk analysis, there isn't any need for cost/benefit analysis, because we can simply tackle all these problems.

Chairman THOMPSON. Are equitable issues often important to the consideration of making regulatory decisions?

Mr. GRAHAM. Yes.

Chairman THOMPSON. Is considering efficiency inconsistent with considering fairness, for example?

Mr. GRAHAM. Well, I think that there are different dimensions of equity and fairness, and often times one needs to consult the underlying laws or statutes passed by Congress to understand what is the nature of the equity or fairness claim that Congress has insisted be honored. And once that is done, then one can look at what is an efficient way to accomplish the protection of fairness. So, yes, I think fairness and equity are important.

Chairman THOMPSON. All right. We have several Members here today, so we are going to proceed with Senator Lieberman.

Senator LIEBERMAN. Thanks, Mr. Chairman.

Dr. Graham, as you know, some who oppose your nomination have argued that your methodology essentially stacks the deck against many pollution control, employee protection, and other environmental measures. So to help me understand and evaluate their concern, I want to quote from an article that you wrote that was published in 1995 and then ask some questions off of it. And this is an article published by the National Center for Policy Analysis called "Comparing Opportunities to Reduce Health Risks: Toxin Control, Medicine and Injury Prevention."

In this article, you compare the cost effectiveness of a number of different kinds of public health programs, and as I read it, you reached two basic conclusions. First, you reported that the average toxin control program costs much more than the average medical or injury prevention program, and you gave as an example that we spend $115.6 million per year on benzene emission control during waste operations to save what you call 5 life-years—we can get into life-years a bit if you want—while the same spending, the same amount of money spent on collapsible steering columns in cars saves 1,684 life-years. Then the second conclusion that I see in the article is your recommendation that the private sector should not be required to spend so much money on these cost-ineffective requirements to control toxic pollution.

So I have a few questions that I want to ask off of that, and the first is that it seems to me that in comparing costs and benefits, your study doesn't seem to consider the question of whose costs and whose benefits.

I am going to go now to, I believe, advocacy that you made in an article, that OIRA should use its regulatory review authority to promote what you have called more rational priority setting. I think it is consistent with the article that I just quoted. As an example of this, you suggested that OIRA should promote arrangements where an oil refinery might be allowed to release more of a toxic pollutant in return for its commitment to fund AIDS prevention or violence prevention programs. Now, those are—I used the word earlier—very thought-provoking ideas, but the question I wanted to ask you to respond to is: How would such an approach help protect the health of, for instance, a family who lives next to

the oil refinery? In other words, in making what is—well, in one sense is an apples-and-oranges comparison, but a comparison of different kinds of threats, even if your analysis leads you to think that one is more cost efficient than the other, or there is a trade-off, for instance, between the health of someone living next to an oil refinery affected by air pollution and the health of someone suffering from AIDS or injured by violence, what answer does society give to the victims who, as a result of your cost/benefit analysis, we would not help?

Mr. GRAHAM. That is a very complicated and well-framed question, and I will try to give a short answer, which is, I do think you can make a fairness or equity objection to the idea of allowing some of the additional emissions at the plant in exchange for the violence prevention and AIDS prevention.

The only qualification I might make is that, if you could save a sufficiently large number of lives from violence prevention and from AIDS prevention, even in the neighborhoods near that facility, you might be able to persuade people that it is worthwhile. But I think basically your argument is correct that you can make an equity objection against that kind of trade.

Senator LIEBERMAN. Yes, that is my concern, and that in some senses the rational priority setting that you have advocated is, dare I say, too rational or so rational that it becomes to those who don't make it past the cost/benefit analysis cruel or uncaring or inhumane.

The study that I referred to earlier seems to suggest that our willingness to forego increased protection in the safety and medical areas is a reason not to protect ourselves against toxins. So let me ask you specifically, as we consider your nomination: Would you, if you became the Admistrator at OIRA, reject a rule, for example, submitted by the Environmental Protection Agency because you concluded that there were more cost-effective ways to save lives in other areas unrelated to the particular rule that was submitted to you for review?

Mr. GRAHAM. Well, Senator, I think it would possibly depend upon the underlying statutory and legal framework that the agency is operating under when they make that proposal. It may be that it is not even relevant, that they could, in fact, save lives through doing something very different or another part of the Federal Government could save more lives. If they're operating from a statutory framework that says they're going to address this particular drinking water problem or clean air problem, then I think it's OIRA's responsibility to review the proposal in the context of that legal or statutory framework.

Senator LIEBERMAN. So that you would not apply the kind of cost/benefit analysis that you have advocated in your writings and statements in that case?

Mr. GRAHAM. I think that the kind of priority setting—and I refer to it as risk-based priority setting—that I have advocated, I see it as more appropriate in the front end of both the legislative and the regulatory process. I don't see it as appropriate after an agency has already made a determination that an area is a priority, a rule is being developed. I think it's a little late in the game

to try to be constructive at that point by saying, well, you should be writing some other regulation.

Now, there are ways under the Executive Order, the existing Executive Order, to stimulate the front-end priority setting I'm talking about.

Senator LIEBERMAN. Tell me what you mean by the front end of the regulatory process. I understand what you meant about the legislative process in considering these kinds of trade-offs, but what do you mean by the——

Mr. GRAHAM. Well, under the Executive Order, there are requirements that agencies lay out their plans for regulation over the next year, for example, and there can be dialogue at that stage. There can also be decisions in the budgeting process as OMB works with agencies on how they're going to spend their resources. So those I think are areas where there is room for some discussion about these issues.

Senator LIEBERMAN. Let me approach the question of comparative risks or comparing risks, and if one risk seems to be susceptible to more cost-effective response, then you might pull away from responding to the other risk even though there are people whose health is being adversely affected by those risks.

You have said in some of your work that EPA often addresses the wrong priorities, such as one example you have given as outdoor air pollution where you believe that the worst risks involve indoor air pollution, for instance, from wood stove smoke.

However, I am obviously not the only one who would be troubled if you at OIRA were to encourage or even require EPA to weaken its regulatory initiatives for outdoor air pollution because you believe that the resources would be better spent on more efficient programs.

So let me ask you now whether you can provide assurances that you would not do this without express statutory authorization if you are confirmed as OIRA Administrator.

Mr. GRAHAM. Well, at the end of your comment and question, you asked about the need for express statutory authorization, and I guess I shouldn't suggest that I really know the legal necessities in that regard. I do want to respond to your basic point, though, with an example of a case where two agencies could be interested in clean air, say EPA interested in outdoor air and OSHA interested in indoor air. And there have been cases where a proposal by EPA to reduce outdoor air pollution caused some of the pollution to be captured and concentrated indoors and created a concern for the Occupational Safety and Health Administration.

I do think it's appropriate for the Administrator of the Office of Information and Regulatory Affairs to try to identify these potential conflicts between agencies and seek some kind of resolution.

Senator LIEBERMAN. I hear you, but barring that kind of direct conflict, can you assure us that, for instance, you would not question EPA regulations on outdoor air pollution because you conclude on your own cost/benefit analysis or risk analysis that it would be a better use of their resources to focus on indoor air pollution?

Mr. GRAHAM. I think this runs back to your previous question, which is where is the appropriate place in the process, the appropriate forum for risk-based priority-setting analysis. And I would

like to see it more at the front end, both legislative process and budgeting process and regulatory calendar at the beginning of the year. I don't think—once an agency has identified an area as a priority under its existing statutory framework, has proposed a regulation to OIRA, has invested that energy, I'm not sure at that stage it's appropriate to be engaging in the kind of dialogue you're talking about.

Senator LIEBERMAN. My time is up on this round. I guess I would say very briefly, before I get another chance to question you, that one of the concerns that has been raised is whether—almost as a result of both your orientation, your skeptical orientation about some regulations, and your intellectual acuity—that you would be asking so many questions, including at the front end, that there would be—and this is not my phrase, but others—that in the regulatory process of the Federal Government there would be what others have called paralysis by analysis. And I do think that it is a fair question, and on my second round, I am going to ask you that.

Thank you.

Chairman THOMPSON. Something we have some familiarity with, don't we?

Senator LIEBERMAN. Yes.

Chairman THOMPSON. Senator Voinovich.

Senator VOINOVICH. How familiar are you with the regulatory aspects of the unfunded mandates relief legislation and what do you think about them? Are you familiar with the current President's Executive Order, and what do you think of it? And then the last question is: Do you think that the former administration followed the provisions of both the unfunded mandates relief legislation, the regulatory portion of it, and the President's Executive Order?

Mr. GRAHAM. Well, let me just briefly comment on the Unfunded Mandates Act, which I understand to be a requirement that when the Federal Government imposes significant regulatory requirements on State and local governments, and it may cover private businesses as well, that there needs to be some analysis of what the costs and benefits are. And I have not studied in detail the actual implementation of the Unfunded Mandates Act. If I'm confirmed, it's definitely an area where I would like to spend some time actually looking at how well these analyses are done and determine their impact on actual decision making. I would elicit some feedback, for example, from State and local governments on how they feel the implementation of those provisions have been.

On the Executive Order, I have not engaged in any detailed study of how the existing Executive Order that was adopted at the beginning of the Clinton Administration, how, in fact, it's actually been implemented. So I can't really comment on that, and I don't have any plan to recommend any specific change to the Executive Order at this time.

Senator VOINOVICH. So you are not familiar with how they honored either the regulatory aspect of the unfunded mandates relief legislation or the Executive Order?

Mr. GRAHAM. I'm sorry. The first part of your question, how they did what?

Senator VOINOVICH. In terms of whether or not they honored the——

Mr. GRAHAM. The previous administration?

Senator VOINOVICH. The previous administration honored——

Mr. GRAHAM. I haven't done a careful study of how much they've honored it, no.

Senator VOINOVICH. Well, we have, and we have lots of testimony——

Mr. GRAHAM. I suspect you'll inform me.

Senator VOINOVICH. And if you get the job, I am going to at least share with you some of the concerns that we have had in terms of the provision that said any regulation over $100 million ought to be looked at from a cost/benefit point of view before it is implemented, and also the area of both President Clinton's and President Reagan's Executive Order in terms of cost/benefit analysis.

I just want to mention this: You are being attacked to a degree because some of the stuff that you have written and said was allegedly colored by contributions to your Center.

You have expressed concern, for example, that many chemicals in widespread use have not been tested for their cancer-causing potential. You objected to this practice and advocated a new approach of assigning default cancer potency numbers to chemicals until they are tested. And yet you have received money at the Harvard Center from chemical producers.

Particulate air pollution, another example is something that I am very interested in. You supported the work of the Harvard Center team making the case for increased regulation to find particles in outdoor air. You authored a commentary in the Harvard Center's newsletter highlighting the health risks of particulate exposure. And in spite of the fact that you received support from a wide range of industries, including energy, chemical producers, and manufacturers, global climate change—something we just had a major hearing on in another committee that I am a member of—you backed the hiring of a faculty member who is a specialist on the economics of global climate change and have written papers supporting the need for the United States and the world to take long-term actions to slow the rate of global climate change. And you said the United States should indeed take cost-effective steps to demonstrate our seriousness about the global climate issue and spur global policies. And you have received money from the wide range of industries, including manufacturers, energy producers and so forth. The same way with sports utility vehicles, you have indicated that there ought to be stricter safety measures and consumer tax credits for environmentally friendly vehicles, and you received money from the auto makers and the petroleum industry.

The point I am trying to make here is if you look at the record, you do the job that you are supposed to do in the most objective way that you possibly can. Do you want to comment on that?

Mr. GRAHAM. We tried. We try as hard as we can to maintain objectivity, regardless of whether the funding source is an industrial source or a governmental agency source. And I do want to add that our Center does get substantial funding from government agencies like the Environmental Protection Agency, the National Highway Traffic Safety Administration, the Department of Energy, the National Science Foundation, the Centers for Disease Control, and the U.S. Department of Agriculture. As the Center director, I

have aggressively sought to provide analytic support and advice to Federal agencies as well as to the private sector.

Chairman THOMPSON. Thank you very much. Senator Levin, did you want to make some opening comments?

Senator LEVIN. I will with my questions.

Chairman THOMPSON. OK. Senator Durbin.

Senator DURBIN. Thank you very much, Mr. Chairman.

Dr. Graham, when I look at your resume, I am curious. Do you have any degrees or advanced training in the fields of chemistry, for example?

Mr. GRAHAM. No, sir.

Senator DURBIN. Biology?

Mr. GRAHAM. No, sir.

Senator DURBIN. Toxicology?

Mr. GRAHAM. No.

Senator DURBIN. What would you consider to be your expertise?

Mr. GRAHAM. Well, I have a Ph.D. in public affairs from Carnegie-Mellon University with an emphasis in a field of management science called decision science. And at the School of Public Health I teach analytic tools and decision science, like risk assessment, cost-effectiveness analysis and cost/benefit analysis.

Senator DURBIN. No background in medical training?

Mr. GRAHAM. No. I do have a post-doctoral fellowship funded by the Environmental Protection Agency where I studied human health risk assessment and had research experience in doing human health risk assessment of chemical exposures.

Senator DURBIN. Does your lack of background in any of these fields that I have mentioned give you any hesitation to make statements relative to the danger of chemicals to the human body?

Mr. GRAHAM. I think I have tried to participate in collaborative arrangements where I have the benefit of people who have expertise in some of the fields that you've mentioned.

Senator DURBIN. But going back to the old television commercial, "I may not be a doctor, but I play one on TV," you wouldn't want to assume the role of a doctor or public health expert when it comes to deciding the safety or danger of exposure to certain chemicals, would you?

Mr. GRAHAM. Well, I think our Center and I personally have done significant research in the area of risk assessment of chemicals, and often times my role is to provide some analytical support to a team, and then other people on the team provide expertise in whether it be toxicology medicine or whatever.

Senator DURBIN. Based on that experience, have you come to a conclusion as to whether exposure to dioxin can increase a person's likelihood of cancer?

Mr. GRAHAM. My involvement in the dioxin issue comes primarily from serving on two committees of the Science Advisory Board of the Environmental Protection Agency, where I was asked to be a member of roughly a 20-member team of scientists, where we looked at the full body of data on human exposure to dioxin and the toxicity of dioxin, and the beliefs that I formed were as a consequence of those experiences.

Senator DURBIN. Let me return to the question. Based on that experience, do you believe that exposure to dioxin can increase your likelihood of cancer?

Mr. GRAHAM. Thank you for reminding me of the first part of the question. I think that at high dose in laboratory animals there's clear evidence that dioxin causes cancer.

Senator DURBIN. So do you—sorry. Go ahead.

Mr. GRAHAM. I was going to say, in humans I think that the database is more mixed and difficult to interpret.

Senator DURBIN. So do you believe there is a safe level of exposure or accumulation of dioxin?

Mr. GRAHAM. I don't know the answer to that question.

Senator DURBIN. I would like to bring up a quote which you have made on this subject. If you would put that up, please?[1] I show side by side here two quotes from you and quotes from other sources on the subject of dioxin. And I remind you that you have really told this panel that you don't have any special personal expertise when it comes to the impact of chemicals on the human body. Your statement to the EPA Science Advisory Board, November 1, 2000, you said, "It's possible that measures to reduce current average body burdens of dioxin further could actually do more harm for public health than good." And then you went on to say—and this is at the same time—"I think there would also be merit in stating not only that TCDD"—which is dioxin—"is a carcinogen, but also I would put it in the category of a likely anti-carcinogen."

Now, that is compared to what others have said on the right. The National Institutes of Health: "Dioxin is a known human carcinogen." And from EPA: "Exposure to low levels of dioxin over long periods (or high-level exposure at sensitive times) might result in reproductive or developmental effects. Those could include weakened immune responses and behavior changes in offspring."

Can you explain to me, are you suggesting in your second statement there that dioxin can either cure cancer or stop cancer when you call it an anti-carcinogen?

Mr. GRAHAM. There are several studies available that show that as dioxin exposures are lessened in both human populations and in animals, that actually the carcinogenic effect that you see at high doses disappears, and there does appear to be evidence of an actual decline in cancer incidence. So there are some studies that suggest that.

Senator DURBIN. And this would—I am going to ask you, does this lead you to conclude, then, that we should not be aggressively trying to stop the release of dioxin in the environment and the exposure of American citizens to dioxin?

Mr. GRAHAM. No, sir. In fact, in my service on these committees, I have been aggressive at pointing out that there is actually more compelling scientific information around a variety of non-cancer adverse health effects. Some of the reproductive and developmental effects that you have, I think appropriately, quoted on that chart, which would provide a sufficient rationale to continue reducing exposures to dioxin, even if the cancer risk issue were not settled.

[1] The chart appears in the Appendix on page 352.

Senator DURBIN. But isn't it true, Dr. Graham, that at the Harvard Center where you work, you have testified rather consistently to reduce the levels and standards when it comes to dioxin, for example, in the State of Maine, when you represented Georgia Pacific and they talked about release of dioxin from paper and pulp mills?

Mr. GRAHAM. I believe, Senator, in the early 1990's I served as an expert witness for several law firms representing pulp and paper companies. And I did not serve as an expert on the biology or the toxicology or the risk of dioxin. I served as an expert on the question of what are the different ways that the term "acceptable risk" is dealt with in public policy, what is the notion of a significant risk or acceptable risk, for example, in EPA decision making.

Senator DURBIN. I will, of course, defer to the record, and I will look at it again. But I recall your testimony in the State of Maine was relative to the State standard for dioxin.

Mr. GRAHAM. It was in the context of the dioxin deliberation, yes.

Senator DURBIN. You were representing George Pacific, where we know that the pulp and paper industry is a source of dioxin in the environment. Is it not?

Mr. GRAHAM. I think so.

Senator DURBIN. You think so?

Mr. GRAHAM. Yes. You are talking about the effluent into the water.

Senator DURBIN. Right.

Mr. GRAHAM. Yes.

Senator DURBIN. Do you think so or do you know?

Mr. GRAHAM. Now that you remind me, I know so.

Senator DURBIN. Thank you.

Who supports your position that lowering the level of dioxin actually decreases the incidence of cancer?

Mr. GRAHAM. I can give you a copy of the studies that I referred to in the Science Advisory Board deliberations, and I would be happy to share those with you. And this issue was discussed collectively within the Committee, and there was spirited dialogue, I can assure you, after I introduced those particular studies. Some of the scientists criticized them. Other ones said that they're valid.

Senator DURBIN. You were on the EPA Science Advisory Board, if I am not mistaken.

Mr. GRAHAM. Correct.

Senator DURBIN. And they deliberated for some 10 years on questions related to dioxin. Is that true?

Mr. GRAHAM. Yes, I think they have been studying dioxin in one way or another for probably longer than that.

Senator DURBIN. And are you still participating in that process?

Mr. GRAHAM. No. I resigned from the committee at the point of my nomination.

Senator DURBIN. And after your resignation, there was finally, after more than 10 years, a unanimous agreement from that board to release its report to the EPA. Are you familiar with it?

Mr. GRAHAM. I have not seen the report, no.

Senator DURBIN. So you can't tell us whether you would have signed on to that report or not?

Mr. GRAHAM. I can't.

Senator DURBIN. The report contains significant findings, among them, and I quote, "It is important that EPA continue to try to limit emissions and human exposure to the class of chemicals in view of their very long biological and environmental persistence," and they were referring to dioxin. So if you are at this new position at OIRA and this suggested policy comes before you, and you are to look at the issue of dioxin, are you going to hold to your belief that reducing levels of dioxin could actually reduce the incidence of cancer—or increase the incidence of cancer?

Mr. GRAHAM. I think that in the context of the deliberations I talked about, I was introducing two specific studies into a Science Advisory Board deliberation of a collaborative body. My assumption would be that at OIRA a lot of these issues would have already been ventilated at the agency and by the Science Advisory Board, and then that package would be coming to OIRA.

So I don't see myself in the process of interjecting my personal opinions about dioxin into the deliberation.

Senator DURBIN. Frankly, Dr. Graham, that is your job, to decide whether or not, for example, research will continue in given areas, whether regulations will be issued, and that is why it has given me great pause to consider you in this position, because when I look at some of your views—and I can tell you, quite frankly, I have never heard of anybody suggesting that dioxin somehow reduces cancer risk. It is just the opposite. It seems to be the vast body of knowledge that has been gathered on this chemical is exactly the opposite. And if you have said that publicly, as you have in the course of this consideration, you can understand why those of us who are concerned about issues like arsenic in drinking water may be concerned about having you at the helm to decide whether or not arsenic causes cancer or reduces the likelihood of cancer.

Do you have an opinion on that?

Mr. GRAHAM. No, sir.

Senator DURBIN. You have no opinion on whether arsenic is a dangerous chemical?

Mr. GRAHAM. I haven't had any experience in dealing with the arsenic issue, either at the scientific level or at the cost-effectiveness of control.

Senator DURBIN. Thank you, Mr. Chairman. I will wait for the next round.

Chairman THOMPSON. Thank you very much. Senator Bennett.

Senator BENNETT. Thank you. Dr. Graham, you have admitted you have no training and background in biology or medicine. Have you ever been to law school?

Mr. GRAHAM. No, sir.

Senator BENNETT. Have you ever studied languages?

Mr. GRAHAM. A little bit of German, but not much.

Senator BENNETT. The reason I raise that is because John Spotila, your predecessor, appointed by President Clinton and confirmed unanimously by the Senate, which means that all of the Members of the Committee here voted for him, is a lawyer who studied languages at Georgetown University before he went to the Yale Law School, and his government experience was a general counsel for the Small Business Administration.

Have you ever done any work on wage and price stability?

Mr. GRAHAM. No, sir.

Senator BENNETT. The reason I raise that is that Mr. Spotila's predecessor, appointed by President Clinton, Sally Katzen, is also a lawyer, whose government service included work on the Council on Wage and Price Stability. Do you consider that Mr. Spotila and Ms. Katzen were improperly confirmed by the Senate for this assignment, or do you think they were qualified?

Mr. GRAHAM. I think I'll let this Committee make that judgment.

Senator BENNETT. All right. Well, the Senate unanimously felt that in spite of the fact that they did not have any medical background or studies in toxicology, that their entire experience was in the legal field, that they somehow were qualified for this, and President Clinton appointed them and they were unanimously confirmed.

I want to move to an area that I have a particular interest in which deals with the future. In the year 2000, there were 586 computer security incidents reported by civilian agencies. Of these, 155 were root compromises. A root compromise, for those that don't understand the phrase, means that whoever got into the computer got all the way in and ultimately could take control of the system. You got down to the roots. And a root compromise means the intruder owns the system and controls it. That happened 155 times in the year 2000 in 32 different agency systems.

Now, I should stress that these are only the reported incidents. We do not know how often somebody got into one of those computers and got to root compromise level and then got out without being detected.

You are going to work for the Office of Management and Budget. We on this Committee have heard former Directors of OMB tell us they spent all their time on budget and they never got around to dealing with management.

And I think the ability of someone to break into the computers, compromise the database, and, if they wish, change, therefore, the results that come out is something that the Office of Management and Budget needs to deal with.

I understand you have some understanding of this kind of capacity, and I would like you to describe that for us to see if my understanding is correct. If my understanding is correct, that would be a further reason to want you in OMB as opposed to somebody who doesn't have any understanding of this particular challenge. Could you comment on this area?

Mr. GRAHAM. Well, I'm not sure I do know as much as you might think I know, sir. The particular area you're talking about hasn't been an area of my scholarship and my writing, so I don't want to overstate my competence in the area. So if you could focus the question a little bit more specifically, I'll do my best to respond to it.

Senator BENNETT. Well, have you ever looked at the question of computer security and preservation of the reliability of databases on which you depend?

Mr. GRAHAM. I do understand that the issue of computer security is extremely important in the Federal Government, both on the civilian side and on the national security side. And I understand that

OMB historically has had a particularly important role on computer security in the civilian side.

But I haven't had the opportunity—I've had maybe just one briefing or so from OMB staff on computer security issues, so I'm in a learning mode.

Senator BENNETT. All right. Well, I appreciate your paying attention to this because in the borderless world which we now live, the borderless economy, where people from countries or places unknown can get into government databases and at the moment we think, as they go after those databases, they are trying to take something out, the concern that I have is that at some point they are going to try to leave something behind. They are going to try to make changes in the database to affect, for whatever nefarious purposes, the decision making in the Federal Government.

To put in a military context, it would be the same thing as if our military had been able to get into Saddam Hussein's command and control system and change his orders to his troops without his knowing that they were doing that.

So that someone who had an interest in what was going on might want to break into American computers so that the data you receive as you make your decision as to cost/benefit analysis has been compromised, if not contaminated. And I would just suggest to you, looking ahead to the future, that you do a little bit of cost/benefit analysis on how the government is dealing with that issue, because it seems to me it is a whole lot cheaper to prevent it than it is to clean up after it if somebody has done that. And if I were someone who wished this country ill, I could think of no better way to terrify our population than to deal with our database that would cause improper decisions to be made about health and safety, because the database has been triggered with by some terrorist group or hostile nation state that wants to use this as a way to cause difficulty.

So I realize this has nothing to do with the clamor that has been raised about your nomination. I vented my spleen on what I thought was the character assassination attempt in my opening statement, and I want to focus now on some of the duties that you will have if you are confirmed. I expect you will be confirmed and trust you will be confirmed, and that is why I raise the issue.

Let me go to the issue that Senator Lieberman raised, which I find kind of interesting, that suggested that given your intelligence and your capacity, you might somehow break out of just reviewing the regulations when they get to you in your normal pattern as the watchdog there at OMB, but you would go to the front end, as you put it, and participate there in ways that Senator Lieberman felt might be inappropriate for you to do that. I think you are going to have enough to do at OIRA that you won't have to be called upon to do that.

But it strikes me that this is a complaint that may say you are overqualified for this job, you know too much, and we shouldn't have somebody who understands all of these things in that kind of a position.

Could you comment on your own sense of what the workload would be and whether, in fact, you would be tempted to do the things Senator Lieberman suggested and inject yourself into the

regulatory process prior to the time when a regulation comes to you for review?

Mr. GRAHAM. Well, I think that the experience that I've been told from the OMB OIRA staff, the career staff at the agency, is that once an agency has already formulated a position and has proposed a regulation and key officials have signed off on that and it goes to OMB, there is opportunity for OMB to have a review at that stage, but it is often more effective to have at least some dialogue with the agencies early on in the process, so that they can be sensitive to the kinds of concerns that are going to arise when it's ultimately reviewed at OIRA. And, in fact, sometimes you would save time and resources of both OMB OIRA and the agency if there was some initial dialogue on these issues.

Senator BENNETT. So that is the pattern that goes on now. Is that what you are telling us?

Mr. GRAHAM. I think that was the sentiment that was expressed by some of the career staff, but I haven't studied it enough in detail to know how often that happens now.

Senator BENNETT. But isn't the primary responsibility in the agency and not in OMB? Isn't your role a review role rather than an initiating role?

Mr. GRAHAM. Well, the Executive Order does have a review role, but it also has mechanisms provided in the Executive Order through the calendar and through the dialogue with agencies on the intent for their regulations and through the budgetary process for OMB to play a greater role in participating with the agencies.

Senator BENNETT. Thank you very much.

Chairman THOMPSON. Thank you very much. Senator Levin.

**OPENING STATEMENT OF SENATOR LEVIN**

Senator LEVIN. Thank you, Mr. Chairman. Let me add my welcome to you, Dr. Graham. My one experience with you was working on the regulatory reform bill with our Chairman, with Senator Voinovich, and with others, and I found you, during that experience, to be moderate and thoughtful. The positions that you took on cost/benefit analysis, on risk assessment were, I thought, positions which were constructive positions. You, for instance, did not argue that benefits had to justify costs in order that the regulations proceed, but that you ought to know whether benefits justify costs, and if they don't, then explain why one is regulating.

You took the position that benefits needn't be quantifiable, that if there is, for instance, a quality-of-life benefit, whether or not the air quality coming up over Lake Michigan interferes with a view of Lake Michigan, or whether or not an IQ could be affected by some particular substance in the air or water, that even though those benefits may not be quantifiable, that nonetheless they are worthy of being considered.

So I have found in my experience with you that you were a thoughtful and a moderate person who is willing to look at the importance of weighing costs and benefits, but not let that tail totally wag the dog.

Others obviously have raised concerns about your nomination based on their experience or their belief that they have knowledge of your background. And I want to explore a few of those concerns

with you today. I think it is important that you address a number of the concerns, and a number of them have been raised here already.

Senator Durbin asked you about some reports or about a statement you made relative to the anti-carcinogenic effects of a particular substance, and you made reference to a report or two on which you had based that conclusion. And I think it would be useful if you would submit those reports for the record so that we could see what the basis of your statement was.

We received a letter from some people who object to your nomination—the letter says, "Time and time again, Professor Graham has accepted money from industries while conducting research and policy studies on public health regulations in which those same industries had substantial vested interest." And my question to you is whether or not your policy relative to the receipt of funding for your studies has been approved by Harvard University. In other words, do they know of your policies and have they either approved, disapproved, or are they silent on them?

Mr. GRAHAM. The Center's procedures for dealing with both government and industry funding are regulated within the university—both at a university level and they are also reviewed at the dean's level in the School of Public Health, where my faculty appointment is. So, yes, they are aware of those practices.

Senator LEVIN. All right. We have received a letter, Mr. Chairman, from a professor of business law at the University of Texas whose name is Frank Cross,[1] and I am just wondering whether or not the various letters[2] both in support of the nomination and opposed to the nomination have been made part of the record. Have they already been?

Chairman THOMPSON. They are. Right.

Senator LEVIN. All right. Thank you.

If it has already been made part of the record, I will simply quote from one part of it, that "the Harvard Center has taken numerous steps to preserve its integrity and credibility, steps that surpass those taken by comparable research institutions, and documentation of these policies is publicly available on the Internet."

It also says the following, on page 2, that "the question of conflicts of interest provides an even more stark contrast" after the statement that the Harvard Center clearly provides more systematic financial disclosure to the public than the other institutions. And then the professor says this: "While many of the similar research centers have mission statements regarding their operations, none appears to have a separate and independent conflicts of interest policy."

Another statement which is made in the letter that I referred to by those who oppose your nomination is the following, that you have "consistently produced reports, submitted testimony to the Congress, and made statements to the media that have supported industry positions, frequently without disclosing the sources of his funding."

---

[1] Letter from Frank Cross appears in the Appendix on page 561.

[2] The letters of support and in opposition appear in the Appendix beginning on page 549.

I would like to ask you about disclosure of the sources of your funding and whether or not you indeed have consistently produced reports, submitted testimony to Congress, and made statements to the media that have supported industry positions without disclosing the sources. Has that happened with frequency? And if it has happened, should it happen? And what is your policy about that?

Mr. GRAHAM. Yes, Senator. For those reports or articles that the Center produces that were funded with a sponsored grant or a restricted grant for that purpose, the funder of that work should be disclosed on the publication itself.

If, however, the publication or report was produced under unrestricted funding, whether that unrestricted funding be from companies, from the university, from a trade association, or private individuals, then we rely on the general disclosure on our website and on our annual report to allow people to understand how our work is funded.

That is the basic approach that we have at the Center to disclosure.

Senator LEVIN. All right. So that if a report is a result of restricted funding, that source is supposed to appear on the report.

Mr. GRAHAM. That should be on the report, yes, sir.

Senator LEVIN. Has it ever happened that it did not appear on the report, do you know?

Mr. GRAHAM. I don't recall an example of where we failed to do that.

Senator LEVIN. All right. If you do find such an instance, would you let us know? There are an awful lot of reports, obviously. I have looked through the list of your reports. But perhaps somebody could do that and tell us whether or not there has been a report that has been produced by your Center which is the product of restricted funding where that source has not been reflected in the report.

In response to the written questions from Senator Lieberman, you said the following: "When publishing newsletters, the restricted grants are supposed to be noted on the publication. But when it's unrestricted, the Center relies on disclosure found on the Web and in our annual reports." But then you said the following, which is confusing to me, that "the Center discloses restricted sources of support for specific studies to the media and otherwise only discloses funding sources if asked to do so by the reporter."

Mr. GRAHAM. If we had a press release on one of our studies that was financed through restricted support, we would disclose on the press release that it was funded by a particular agency or company or trade association. If a reporter calls us, we don't have a general policy of affirmatively disclosing: Here are all the places where we get our money from. We rely on the journalist to ask us, and often they do.

Senator LEVIN. All right. There has been a question raised by one of the letters in opposition as to, again, the corporate sponsorship of your research. And one of the examples—the first example given related to air bags, and I would like to just ask you about that example.

Apparently you are a proponent of air bags. Your Center did a study in 1997 on the cost effectiveness of air bags, and the results of the study prior to peer review showed a cost of about $400,000 for each life saved for passenger-side air bags. And then after there was criticism of the study, the study was peer-reviewed. The results were significantly different, and the cost of each life-year saved after peer review then dropped to $61,000, and your conclusion was that that was within the acceptable range.

Now, the suggestion in that letter was that your preliminary finding of $400,000 per life saved was somehow skewed because of the funding that you received from industry. On the other hand, your report said that the research was supported in part by a grant from Centers for Disease Control and the Harvard Injury Control Center and the Harvard School of Public Health.

So I am trying to find out—it said "partly supported." Was the other part a general support or——

Mr. GRAHAM. That's correct.

Senator LEVIN. So the only restricted grants that went into that were from the ones that you identified?

Mr. GRAHAM. The air bag study would have been in the CDC, Centers for Disease Control in Atlanta, Georgia. That's my recollection.

Senator LEVIN. All right. And would they have any interest in skewing this to a $400,000 cost instead of a $61,000 cost?

Mr. GRAHAM. Not that I can think of, sir.

Senator LEVIN. All right. My time is up. Thank you.

Chairman THOMPSON. Thank you very much. Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Dr. Graham, I want to ask what, I think, is the fundamental question here, and that is: Do you let the source of your funding, whether it is from an industry group or a private individual or the university or government agencies, influence the findings and conclusions of your studies?

Mr. GRAHAM. No, Senator. I, as the Center director and my faculty colleagues, strongly believe that we need to pursue the design and analysis of our data and publish our results in the most objective manner possible, regardless of whether that would happen to serve the interests of a particular funder or not.

Senator COLLINS. Thank you. And, in fact, you have supported new regulation of the automobile industry that called for a redesign of air bags in order to protect children from injury or death when deployment suddenly occurs. Is that correct?

Mr. GRAHAM. Yes, that's correct.

Senator COLLINS. Could you tell us a little bit more about your work in that area?

Mr. GRAHAM. Yes. The National Transportation Safety Board meeting in 1997 that Senator Levin was referring to in his questions exposed a number of the issues around children and air bags. It stimulated our Center to form a working group of engineers, physicians, and decision analysts to look into the problem and suggest possible solutions. And we published those solutions in the journal *Pediatrics*. And one idea is the recommendation that vehicle manufacturers be expected to develop technology to sense

whether a child is in the front seat and not deploy the air bag if a crash occurs.

Senator COLLINS. Did the Automobile Manufacturers Association welcome those findings, and were they just delighted that you were calling for a redesign in the air bags?

Mr. GRAHAM. I do not recall specific reactions from particular companies.

Senator COLLINS. It is my understanding that the automobile manufacturers were not real happy about the findings of your survey because it was going to mean redesign work and additional expenses, which I think speaks to the fact that you do the research, and wherever it leads you, you publish those conclusions.

I would also like to ask, have you supported the development of new safety regulations for sports utility vehicles to prevent rollovers or to reduce the rate of their involvement in rollover crashes?

Mr. GRAHAM. Yes. In an article published in *Issues in Science and Technology,*maybe a year or 18 months ago, I argued that we ought to, as a country, develop a multi-year research and regulation program to reduce the rate at which sport utility vehicles roll over. And that program is consistent, but perhaps a little bit more aggressive than some of the legislation that has been passed by the Congress at the present time.

Senator COLLINS. Mr. Chairman, I have a copy of that article which Dr. Graham authored, entitled "Civilizing the Sport Utility Vehicle," and I would ask unanimous consent that it be made part of the record.[1]

Chairman THOMPSON. Without objection.

Senator COLLINS. Dr. Graham, have you also done work in the area of the EPA's low sulphur diesel rules as a strategy to allow for more fuel-efficient and cleaner diesel engines as well?

Mr. GRAHAM. Yes. In fact, I have a doctoral student, Edmond Toy, writing a thesis on that subject right now.

Senator COLLINS. And, again, this is another area where you believe that there could be improvements in the regulations that would produce environmental benefits?

Mr. GRAHAM. Yes, if we can bring the sulphur levels down in diesel fuel, it would increase the chances that diesel engine technology could meet the particulate and nitrogen dioxide standards that EPA applies. And if we could do that, diesel engines offer a lot of fuel efficiency and carbon dioxide benefits compared to conventional engine technology.

Senator COLLINS. Thank you, Dr. Graham.

Chairman THOMPSON. Is the Senator finished?

Senator BENNETT. Thank you, Mr. Chairman.

Senator Levin's citation of some letters——

Chairman THOMPSON. Excuse me. I am sorry. I asked if the Senator was finished. I take it you were.

Senator COLLINS. I was, yes.

Chairman THOMPSON. We are ready for another round now, I believe.

Senator BENNETT. Yes, and I was a little surprised. I am not next. [Laughter.]

---

[1] Article referred to appears in the Appendix on page 543.

Chairman THOMPSON. I am sorry. I hate to interrupt you midsentence here, but I guess we better go in order, which, coincidentally, starts with me. [Laughter.]

Senator LEVIN. Mr. Chairman, may I ask a question?

Chairman THOMPSON. Yes, sir.

Senator LEVIN. Can the record be kept open for questions for a reasonable period of time?

Chairman THOMPSON. Yes. Would 24 hours be sufficient?

Senator LEVIN. That would be fine. Thank you.

Chairman THOMPSON. Some of the issues that have been raised, first of all, concern the issue of your qualifications. One of the letters that was sent in criticized you for your lack of degree in hard sciences and giving your opinion on some of these areas that have been raised. And attached to that letter or signing on to that letter were several pages of academics, and I noticed most of them were lawyers. One of them is a professor of philosophy, another professor of philosophy, a professor of psychiatry, a professor of psychology, a professor of romance languages, and three professors of psychology. You are not doing well among the psychologists, Mr. Graham. [Laughter.]

Another professor of psychology, a chair of philosophy, associate professor of linguistic sciences, and another professor of psychology.

So they are entitled to their opinion, and their opinion is a part of the record, but I just say I believe that your qualifications in these areas probably are superior to some of the qualifications of your detractors.

I might point out that, on the other hand, we had a letter signed onto by at least twice as many academics, who are scholars working in environmental policy, health policy, and related fields. So I think that our record reflects pretty well, not only in terms of the background of the people who have sent in expressing their views, but also in terms of your comparison with your predecessor, as Senator Bennett pointed out. Your predecessors were lawyers who were appointed because they were good administrators. I think you bring some special skills to the position that we have not had in some time.

On the issue of your benefactors, there are several—let me get the list here. Several of the Senators here have referred to areas where your opinion, and those of your colleagues with whom you submitted these reports, went counter to those who had funded you with restricted funds, funds that went for a particular subject matter.

I am going to make a part of the record something that the staff compiled, and I emphasize this is a majority staff compilation, but I think it is quite impressive, and I think it will bear scrutiny.

In these following areas, we found where you and the Harvard Center reached opinions that were contrary to the interests of the industries that donated restricted funds for a particular project: Cancer risk from formaldehyde is one; cancer risk for chloroform; panel review of National Cancer Institute's Agricultural Health Study; study of using diesel versus compressed natural gas in transit buses; indoor air pollution; exposure to chemicals; untested chemicals; concern for highly exposed people; energy conservation; particulate air pollution; global climate change; sports utility vehi-

cles have been mentioned; health risks; and air bags have been mentioned.

I will not go into what you found, and I will not even mention all of the sponsors—a wide range of industries, energy, chemical, automobile manufacturers, chemical producers, tobacco company, and the petroleum industry. In each of these instances, you apparently, from our analysis, went against what would certainly seem to be the wishes and desires of the people involved.

So, if we get past the issue of, shall we say, skewing your reports to favor one side or another, then we have to get down to the merits of what you are actually dealing with in terms of these sometimes controversial subjects. I hope we are not getting to the point where we discourage scientists and academics from giving opinions, based upon research and based upon analysis of other research that has been done, even if it is sometimes controversial.

If you have a study that shows an increased risk of something, you will be embraced with open arms by everyone, including the Congress and the news media, and it allows us to emphasize our concern to citizens. But if you have a study that indicates that perhaps a particular risk has been overemphasized and resources would be better spent in another area, where the risk has been underemphasized, you are treading upon dangerous ground, and you will get very little comment, certainly, from any member of Congress about that because it is politically dangerous.

And I hope that we do not do anything to discourage our scientists and our people in academia from venturing into those grounds, and just have a good, open, honest debate about it, even if sometimes it goes contrary to commonly accepted or assumed notions.

Let me see if my understanding is correct concerning the dioxin issue. You were selected to serve on EPA's Science Advisory Board on Dioxin for both the 1995 and the 2000 reviews; is that right?

Mr. GRAHAM. Yes, sir.

Chairman THOMPSON. And you withdrew from the 2000 review when your nomination occurred.

Mr. GRAHAM. That is right.

Chairman THOMPSON. According to my information, in both reviews, you raised concerns that EPA may be exaggerating the cancer risk of low levels of dioxin exposure, but that you also said that the noncancer risks of dioxin exposure—damage to reproduction, development, immune system, and the endocrine system—merited greater attention by the EPA; is that correct?

Mr. GRAHAM. That is correct.

Chairman THOMPSON. And your writings show how risk analysis played an important part in reducing dioxin pollution from the pulp and paper industry in a cost-effective manner.

Mr. GRAHAM. Yes, that is true.

Chairman THOMPSON. We have made passing reference to peer review, which I think is one of the most important aspects of what we are dealing with here and that people need to understand. These reports are not something that you sketch out on the back of an envelope and get typed up the next day based upon your own notion solely, but that they are peer reviewed.

Will you discuss, in some detail, what that is, what it involves, and what part it plays in your work and especially with regard to the reports that have been referred to here today, the controversial ones. Perhaps they are the same as the noncontroversial ones, but what is the process?

Mr. GRAHAM. The commitment to peer review from the Center is to make sure that intellectual products that come out of the Center have been subject to peer review by qualified scientists. The level and intensity of peer review varies a lot, depending on the nature of the product itself.

For each issue of our newsletter, we try to make sure that at least two people within the Center review it before it goes out, and their names are actually put on the newsletter issue itself, as well as the authors of the newsletter issue. So I would say that is internal peer review, and it is the most modest level for the newsletter itself.

If we have a Center report that is not being published in a journal, we would typically apply at least internal review by our faculty colleagues, and in more complex or controversial cases, we would also get outside external peer review added to that.

Journal peer review practices, where a majority of our work is published, are variable, but they typically involve anonymous external peer review.

Chairman THOMPSON. How does that work?

Mr. GRAHAM. Well, in a journal setting, we would submit a paper to a journal, and then the editor of the journal would make a selection of appropriate reviewers, and their names and identities would not be disclosed to the authors of the papers.

Chairman THOMPSON. So you would have nothing to do with who is reviewing your work.

Mr. GRAHAM. For a journal peer review, but for the Center peer review, we in the Center would select those reviewers. So it is a different style.

Chairman THOMPSON. All right. I understand, since 1990, you have been on 97 studies at the Harvard Center.

Mr. GRAHAM. I guess if you counted our publications list since 1990, that sounds in the ballpark.

Chairman THOMPSON. My information is that virtually every study done with restricted funds, that is, for a particular subject, had three or more authors. Is that right?

Mr. GRAHAM. That sounds right.

Chairman THOMPSON. All right. My information is 45 of the studies have three or more authors, 27 had two, 25 of the studies had one author. Does that sound about right?

Mr. GRAHAM. I would be happy to check it for you, but it sounds in the ballpark.

Chairman THOMPSON. I am not holding you to the numbers. This is my information. But I think the point, the obvious point, is that we are dealing with a situation that is peer reviewed. The serious articles that go out, most of the ones we are dealing with that we see in the reports and so forth are peer reviewed by people other than anyone that you have any control over, that these articles that you are putting out for the most part, have others of your colleagues there at Harvard joining in, and it is all done pursuant to

a process in terms of conflicts of interest and disclosure and so forth is established by Harvard. This seems to be more extensive than other similar situations. Thank you very much.

Mr. GRAHAM. Just a brief clarification, Senator. The peer review process that we apply to our own publications is an internal process or external, where we pick the peer reviewer, whereas a journal, the editor would pick the reviewer. So there is a little bit extra assurance to some extent in a journal peer review process.

Chairman THOMPSON. Thank you very much. Senator Lieberman.

Senator LIEBERMAN. Thanks, Mr. Chairman.

Dr. Graham, at a Congressional hearing, you were asked how we should evaluate whether risks we hear about are real or exaggerated, and part of your answer—I think it may have been the beginning of your answer—is as follows: "Yes, the first thing I think we should keep in mind is if you are a risk assessor or a scientist in one of these Federal regulatory agencies, you don't usually have an incentive to find that an alleged hazard does not exist, because if you highlight the fact that a hazard exists, you may attract the attention of Congress and the media, and thereby garner public support and resources for your agency."

Do you stand by that statement?

Mr. GRAHAM. Did I say it as an incentive, do they have an incentive to do that?

Senator LIEBERMAN. Yes, "you don't usually have an incentive to find that an alleged hazard does not exist, because if you highlight the fact that a hazard exists, you may attract the attention of Congress and the media, and thereby garner public support and resources for your agency."

Mr. GRAHAM. I think that is plausible speculation.

Senator LIEBERMAN. Here is my concern, and it is this. In light of that statement and that attitude, can we assume that you would be able to give fair and unbiased review of rules developed by those same government scientists and analysts whose motivations, I think it is fair to say, perhaps even their professionalism, you question in that comment that you made to the hearing.

Mr. GRAHAM. Well, I think this actually comes from one of the written questions you submitted to me. And I do think that when I transition from a college professor to OIRA Administrator, I'm going to have to be a little bit more respectful of the public spiritedness and intentions of agency risk assessors. So I do hope to be sensitive to that.

Senator LIEBERMAN. Let me go on. In one of my written questions I raised—this goes back to environmental protection—I raised concerns that you have so consistently been critical of our national environmental laws, that it leads to a broader concern about how you would handle environmental protection and people protection from environmental pollution regulations. And your response said that I should look at your book, "The Greening of Industry."

And I did. And it does seem to me that the book ultimately reinforces the impression, my original impression, in this sense, that many environmental laws are based on certain rights, for example, that every American is entitled to breathe clean air and drink safe water. But your book seems to be an advocacy piece, supporting very fundamental revisions in those basic principles of our environ-

mental laws, and that is because of the heavy emphasis you give on the assessments and the cost-benefits that we have referred to earlier. And at one point I think you have indicated, you have said that these environmental laws should no longer be grounded in what you referred to as the people's "rights to environmental protection."

So I want to ask whether you would respond to a fear that I have heard from your critics, because of your writings and your statements, that there would be a danger that you would effectively eviscerate this principle that I think does underlie our environmental laws, that every American has a right to a clean environment, certainly insofar as it deals with their own health and safety, clean air and clean water—and I suppose, in fairness, I should say, regardless of whether there is a more cost-effective way to do something else, as we compared risks to people before.

I wonder if you would respond to that fear of your critics.

Mr. GRAHAM. I think it is an excellent question. There has been an intellectual dialogue and debate under way, certainly for 30 years in this country, over whether our environmental laws should be predominantly "rights-based" in their underlying structure, or whether they should be predominantly economics based in trying to achieve efficient solutions to environmental problems. And I think it's fair to say that in that intellectual debate, I have been in the camp of people who would like to see the environmental laws move in the direction of more sensitivity to economics and efficiency.

Having said that, if I become OIRA Administrator, I'm perfectly comfortable enforcing the environmental laws of the land as they are currently written, and a number of them are currently written much more in the rights orientation than in the economics orientation. But I think even in those areas where they are written with a rights orientation, there are pieces of those laws, for example, the implementation phases of the Clean Air Act, that allow for economics and efficiency considerations to have some role.

So I will try to be sensitive as OIRA Administrator to the exact statutory framework we're talking about when a rule is proposed to OIRA and that would influence the kind of review we would give it.

Senator LIEBERMAN. So what you are saying though, as you said correctly, is that your work has put you in the sort of economics/efficiency side of the debate with the environmental rights advocates, that—we do have a tendency here to pass laws based on the environmental rights theories and values—and you are saying that in reviewing regulations implementing such laws, such environmental-rights based laws, that you do not believe that your past tendency towards the economic efficiency side of the debate would inhibit you from approving regulations, carrying out the environmental-rights based laws?

Mr. GRAHAM. Right. In my role as a college professor and in my role as an advocate, I try to make a case for changing environmental laws in a direction that I feel is appropriate and reasonable. But in the context of being OIRA Administrator, I have a responsibility to enforce the laws as they are written. And a number of

them are written that way, in no small measure, because of your work, Senator Lieberman.

Senator LIEBERMAN. Well, I suppose I should say thank you. [Laughter.]

Dr. Graham, let me ask you about a very different aspect of your work if you go to OIRA, and that is the question we talked about briefly when you were in my office yesterday, and that is, the whole area of openness of OIRA, timeliness and accountability. This actually embraces the earlier reference I made to paralysis by analysis, whether either for reasons of ideology or just intellectual curiosity, your leadership there would have the effect of so delaying the movement of regulations through OIRA, that the rights of people who would be protected by those regulations would be compromised.

I want to go back to the first decade of OIRA's existence, when there was a history about OIRA reviewing regulations in secret, without disclosure of meetings or contacts. Rules would often languish, literally for years, as you probably know from your studies, with no explanation, and then be returned to the agencies with many required changes, which effectively not only compromised the rights of the presumed beneficiaries of those laws, but also frustrated the will of Congress in adopting the laws.

The last administration put provisions into effect through Executive Order 12866, which aimed at overcoming those problems. Public disclosure requirements, a 90-day period for OMB review, provisions to keep the regulatory agency informed and included, and provisions to prevent some entity outside of OMB from becoming a conduit for outside groups to try to influence the regulation off the record. Those assurances were quite hard won, and I believe it is essential that they be retained to avoid recurrences of the abuses that we saw earlier.

So I want to ask you for your commitment to retain those existing provisions, and to in fact, reflect them in your own administration of OIRA should you be there, on openness, timeliness and accountability. I just want to very briefly say these provisions include those for public disclosure, timely review, written explanation for any regulation returned to the agency, keeping agencies informed and involved in any OIRA context with outside parties, and the provision directing that only the OIRA Administrator may receive oral communications from those outside government regarding regulatory reviews. Can you give us such an assurance that you would continue such policies?

Mr. GRAHAM. That is another big, complicated question. And I guess the easiest thing to start with is to say that I think OMB Director Daniels and myself are both committed to the principle of openness and transparency in regulatory review. I don't think that we have reached a determination that any of the specific transparency requirements that are in the current Executive Order are necessarily inappropriate.

I happen to be aware of one particular GAO report that looks into one of the transparency requirements that you mentioned, where there was a dispute between OIRA and GAO about whether that particular transparency requirement was workable, but I don't feel that I know the details of that well enough to have a strong

opinion about that. But in general, I don't see any desire on the part of the administration to be going backward in the area of transparency and openness.

Senator LIEBERMAN. OK. My time is up. I do want to ask you to consider that Executive Order 12866, and just for myself, I would like very much to hear if you have any specific concerns about it prior to the time that we vote on the nomination, because I do think apart from the concerns that have been expressed about substance, the process here that goes on is critically important, and that is not a matter, obviously, of ideology or politics. So to the extent that you are able, I would personally be benefited by hearing whether you have any concerns, or in fact, whether after your review of that Executive Order, you are comfortable with it.[1]

Mr. GRAHAM. OK. I'll look into that.

Senator LIEBERMAN. Thank you. Thanks, Mr. Chairman.

Chairman THOMPSON. Thank you very much. Senator Voinovich.

Senator VOINOVICH. It is my understanding that in terms of disclosure, that because of your personal involvement, you have gone beyond the policy of Harvard University in regard to disclosure of people who contribute to your Center. Is that correct?

Mr. GRAHAM. We've gone beyond what are standard disclosure policies at a lot of institutions, at a lot of units both within Harvard and outside of Harvard.

Senator VOINOVICH. Senator Lieberman made reference to Executive Order 12866, and I referenced that earlier, but I did not have the statistics, and I now have them. There was a GAO review of what OIRA did in terms of some 110 rules that were economically significant under the Clinton Administration, under E.O. 12866, and they found that 78 out of 110 times, there was no cost benefit analysis produced by the administration. Because of that, I think there was some feeling in the community, the country, that perhaps the reason why they were not done was because if they were, the regulation coming from the agency might have not met the test.

And I think that one of the problems we have today is that there is a lot of suspicion about the transparency in the decision making. I support Senator Lieberman in terms of a transparency and openness so people know why you are doing the things that you are doing. But hopefully, you will get the job. If you do, there is going to be a lot of people out there saying, "Well, he is on the other side. He is for the polluters or the business or the industrial people." I think there was a strong feeling today in the country that the Clinton Administration was in the pocket of the extreme environmental groups, and they had sway over that administration.

I would like to know how you are going to assure all of us that we are not going to see, 3 years from now, a GAO study of your agency, that says out of so many economically significant issues, you have not done the job on many of them. How are you going to take care of that problem?

And I just want to mention one other thing that is so important. I have to believe that many lawsuits are filed in this country by one group or another because they think the people that are doing

[1] Responsive letter to Sen. Lieberman from Dr. Graham, dated May 21, 2001, regarding Executive Order 12866 appears in the Appendix on page 353.

the job are biased or in somebody's pocket or being influenced by them. The sooner that we can get away from that, I believe that we are going to move forward in terms of the environment, with a cleaner environment. I believe that instead of people settling their situations in lawsuits, that if they have trust in agencies, we can move forward and make some real progress.

Mr. GRAHAM. Well, let me just start by saying that if GAO reports like that are written under my tenure as OMB OIRA Administrator, I don't think Mr. Daniels is going to be very happy. So I'm definitely going to be looking very carefully at how we achieve the types of review that we need of each of those major regulations. That may involve a need to look into whether the organization itself is adequately staffed and has the adequate resources to provide the types of reviews, and I haven't had a chance to look at that in detail yet. But certainly that has to be looked into if we're serious about providing that level of review to that many regulations.

Senator VOINOVICH. How about the issue that Senator Lieberman made in terms of transparency? What are you going to do about that, so that people know that the fix is not on?

Mr. GRAHAM. Well, regarding the GAO report, I haven't made a firm conclusion yet, because I don't really feel I fully understand the dimensions of the issue, but I am concerned that you have a previous OIRA Administrator who tried to enforce the Executive Order saying that a transparency requirement in that Executive Order is not workable and feasible. I think that is something that needs to be looked at carefully.

And as I recall the basic requirement is showing how the rule was changed due to OIRA's activities, and the Administrator was arguing that it's often difficult to tell, after a dialogue with an agency, whether a change was due to OIRA's suggestion or the agency's suggestion and so forth.

Senator VOINOVICH. Well, again, I want to emphasize how important that is. I would hope that after your being there a couple of years, people would say that the guy really knows what he is doing, he is objective in what he is doing. You can argue maybe about what the result is, but it is being done objectively, and we understand that it is because information that you used or the reasons for your decision making have been made public, therefore will command the respect of objective reviewers including members of the U.S. Senate and the House of Representatives.

Mr. GRAHAM. Yes, Senator.

Chairman THOMPSON. Thank you, Senator Voinovich. Senator Durbin.

Senator DURBIN. Thank you, Mr. Chairman.

There have been a lot of questions asked of you, Dr. Graham, concerning conflicts of interest at the Harvard Center, and I would like to ask you, have you ever been asked by Harvard University to return any of the corporate funds that were given to the Center?

Mr. GRAHAM. Yes, sir.

Senator DURBIN. How many occasions?

Mr. GRAHAM. One that I recall.

Senator DURBIN. Can you tell me what that occasion was?

Mr. GRAHAM. That was an occasion where our Center solicited an unrestricted contribution from Philip Morris, and the Dean of the Harvard School of Public Health instructed me to return it.

Senator DURBIN. Was your Center involved in any kind of studies relative to tobacco at that time?

Mr. GRAHAM. Not that I recall, sir.

Senator DURBIN. Has your Center been, at any point in time, engaged in a study relative to the safety of tobacco?

Mr. GRAHAM. I think we have had a variety of pieces of work, either on tobacco explicitly or possibly comparing tobacco to other types of risks.

Senator DURBIN. Did you at any point review any Surgeon General reports on the warnings and safety of tobacco?

Mr. GRAHAM. I believe a colleague of mine, Evridiki Hatziandreu, M.D. and I jointly were involved in a project where we did review some Surgeon General's reports, yes.

Senator DURBIN. Why did Harvard University ask you to return the $25,000 from Philip Morris?

Mr. GRAHAM. My recollection is that the Dean of the Harvard School of Public Health felt that it was inappropriate for a school of public health to accept a gift, an unrestricted gift from a tobacco company.

Senator DURBIN. Why?

Mr. GRAHAM. I think that Dean Fineberg's, basic view—and this was a good while ago—was that tobacco is such a serious public health problem, that it's not appropriate for a school of public health to be accepting money from that type of organization.

Senator DURBIN. Do you agree with that?

Mr. GRAHAM. I argued against it at the time, and even today, I still have some reservations with that judgment.

Senator DURBIN. You made the original solicitation to Philip Morris, did you not?

Mr. GRAHAM. Correct.

Senator DURBIN. For the $25,000, which they sent you on January 22, 1992.[1] The records indicate on January 31, after the deans contacted you, you returned the Philip Morris check. Is that correct?

Mr. GRAHAM. Yes, sir.

Senator DURBIN. What was interesting about this—and I would like to make this letter part of the record[2]—was, you wrote them a very short letter and said, "I'm sending back the $25,000. Have Kraft Foods send it back to me."

Senator DURBIN. Kraft Foods is a subsidiary of Philip Morris, right?

Mr. GRAHAM. Kraft Foods is definitely a subsidiary.

Senator DURBIN. Did you see any ethical problem there, where you were told by the dean to get out of the pocket of Philip Morris, we do not want to be associated with it, and then you came back and said, "But have one of your subsidiaries send the $25,000 right back to me?"

---

[1] The letter dated January 22, 1992, from Philip Morris to Harvard Center appears in the Appendix on page 354.

[1] The letter dated January 31, 1992, from Harvard Center to Philip Morris appears in the Appendix on page 356.

Mr. GRAHAM. My recollection is that the dean and I discussed the issue of whether the subsidiaries of Philip Morris were inappropriate for unrestricted contributions. And the determination was that a contribution from—I think Kraft Foods in particular we discussed—would be acceptable according to the guidelines that he was developing.

Senator DURBIN. October 25, 1993,[1] you sent a thank you letter to Philip Morris for their donation to the research center of a desktop computer. Is that correct?

Mr. GRAHAM. I believe it was to Mayada Logue for a personal donation, yes.

Senator DURBIN. And so you were told by the university not to be affiliated or take money from the tobacco company. You said, "I will take it from a subsidiary." And the university, according to your testimony, has gone along with it. And then within a year, you are receiving a personal computer from the Philip Morris Company. Is that correct?

Mr. GRAHAM. I don't think that's correct. I think the donation of the personal computer was a personal donation, and not a donation of Philip Morris. And I don't recall my dean putting any restrictions on my ability as a professor to affiliate with people from Philip Morris.

Senator DURBIN. They gave a computer to you personally instead of money to the Center?

Mr. GRAHAM. No. The donation was a personal donation of Mayada Logue to the Harvard Center for Risk Analysis.

Senator DURBIN. What is Philip Morris's connection then?

Mr. GRAHAM. I don't know that there was. She was employed at the time by Philip Morris, and the thank you note, went back to her at her Philip Morris address, but the actual donation was a personal donation of Mayada Logue.

Senator DURBIN. I would like to go back to a point that was raised earlier about the fact that you do not have any qualifications or degrees in hard sciences, and I would like to make two points about that. First, I do not believe that is a prerequisite for this job, and I think predecessors certainly have not had that background. But you have held yourself out on a number of issues related to public health and science, and that is why you are being asked many of these questions today.

In terms of the letters in opposition to your nomination, they may include letters from psychologists and people in language sciences. They also include letters from 21 medical doctors, including one Nobel prizewinner, and a variety of Ph.D.s in public health and cell biology.

Now, the reason that is important is the next issue I would like to go to which relates to pesticides in food. Can I ask my staff to bring up some of the things that have been said about that particular issue.

I think it is fair to say that you have been dismissive of many of the public concerns about pesticides, and many of your funders, of course, are on your side on that. Your quote on the left says,

[1] The letter dated October 25, 1993, appears in the Appendix on page 266.

"The evidence on pesticide residues on food as a health problem is virtually nonexistent. It's speculation."

Here is what others have said. "Changes are needed to protect children from pesticides in diet." National Academy of Sciences.

Then we have Consumer's Union, which is not viewed as an advocate on either side really. "There is a 77 percent chance that a serving of winter squash delivers too much of a banned pesticide to be safe for a young child."

And then from the EPA. "EPA's risk assessment showed that methyl parathion could not meet the FQPA Safety Standard. The acute dietary risk to children age 1 to 6 exceeded the reference dose for the amount that could be consumed safely over a 70-year lifetime by 880 percent."

I am trying to reconcile, Dr. Graham, your conclusion that pesticide residue on food is virtually nonexistent as a health problem and is speculation, with the sources on the right, which come to the exact opposite conclusion. The obvious reason is that if you are appointed to this position, you will have food safety questions coming before you that may relate to pesticide residues. You have suggested to us that you are going to change your position when it comes to your views of people working in government developing these regulations, and when it comes to being rights-oriented rather than money-oriented when it comes to regulation. Are you going to change your views on the danger of pesticides on food, particularly for children?

Mr. GRAHAM. No, Senator.

Senator DURBIN. You do not believe there is a danger; it is pure speculation.

Mr. GRAHAM. I think there is actually a pretty heated debate within the scientific community on whether the pesticide residues on foods at their current levels represent a health risk.

Senator DURBIN. Let us go to methyl parathion. How much do you know about it?

Mr. GRAHAM. Not much, sir.

Senator DURBIN. Well, that is unfortunate, because that really makes the case. The decision was made because methyl parathion was being used as a pesticide on foods that kids were consuming. It was a danger to these children. And the Federal Government decided to change the uses of that pesticide, and ban it from certain foods where it might accumulate in children, causing health problems.

But from your point of view, they should not have done that, that was pure speculation; the health problem there was virtually nonexistent; is that correct?

Mr. GRAHAM. I haven't studied that particular example, sir.

Senator DURBIN. But you see, Dr. Graham, that is what troubles us. Arsenic in drinking water is a new issue for you. Methyl parathion is a new issue for you. You're not trained as a biologist or toxicologist. Yet, you make broad statements about the lack of health effects of pesticides, or dioxin being an anti-cancer chemical. I mean to think that we are going to entrust you with a position where you will be the gatekeeper on food safety, on pesticide levels on fruit and vegetables, when this government really tries to protect children, vulnerable children from what is a serious health

risk. That is why your lack of training in sciences related to this field, the fact that you have made some rather, I think, outrageous statements about science during the course of your professional career, and now seek to be the last word at OMB as to health and safety regulations, I hope you can understand that gives many of us some pause when we consider your candidacy.

Mr. GRAHAM. Senator, if EPA, for example, submits a proposal to OIRA that presents a strong case that children are going to be at risk if we don't lower exposures from pesticide residues, I think that is something I would certainly look at very carefully and very seriously in the context of the underlying statute and the terms of the executive order.

Senator DURBIN. But which John Graham are we dealing with here, the John Graham that says pesticide residues on food as a health problem is virtually nonexistent, or the John Graham that says he is going to be measured and objective and consider these things?

I think we have a lot of confirmation conversions here on Capitol Hill. And when we look at your background and the people who have supported you, and some of the statements you have made about dioxin actually eliminating cancer, and pesticide residue health threats to be virtually nonexistent, I hope you can see where many of us feel that putting you in this position is really a risk.

Mr. GRAHAM. [No response.]

Senator DURBIN. Thank you, Mr. Chairman.

Chairman THOMPSON. Senator Bennett.

Senator BENNETT. Thank you, Mr. Chairman.

Dr. Graham, you may take a place in history, alongside with Robert Bork. I have not seen such a concentrated effort to destroy the reputation of a man, who is considered by his peers to be of the highest integrity, highest objectiveness, willingness to take a risk and state positions outside the norm on the basis of your own research. I have not seen such an assassination since the time of Robert Bork.

Let me go to another letter. I began by quoting a letter from a fellow who had analyzed all of the statements in Joan Claybrook's statement. I will conclude by a fellow who has something also to comment on this effort. This is a letter addressed to the Chairman from Michael Finkelstein.

He identifies himself, "I am an independent consultant working on automotive safety, and have know Dr. Graham for more than 15 years. I first met him in the mid 1980's when he was doing research on air bags. Since then I have followed his work at the Harvard Center for Injury Control, and most recently at the Harvard Center for Risk Analysis. His academic credentials are outstanding, and there is little I could say that would add to his scientific accomplishments."

So far that is a garden variety endorsement of you, of which there are, as the Chairman has pointed out, literally hundreds. It is the next paragraph that caught my eye.

"Rather, the reason for this letter is to discuss Dr. Graham's integrity, both as a scientist and as a public health professional. The reason I feel compelled to write is that I discovered that a 1997 letter that I wrote was used by *Public Citizen* in their recent report

criticizing Dr. Graham's nomination as head of OIRA. Frankly, I was very surprised to see *Public Citizen* use my letter to criticize Dr. Graham. In fact, when a representative of *Public Citizen* contacted me to learn my views of Dr. Graham, I told them that I was strongly in favor of his possible appointment to any number of positions in the new administration."

So here is a man who is being quoted as an opponent of yours, who feels it absolutely essential to set the record straight by pointing out that he is a supporter. The interesting thing as to your credentials, in the conversations we have had here, comes in his explanation of his experience with you. He describes a presentation which you made, with which he had very strong disagreement. In other words, somewhat in the attitude of the Committee in some of the statements that have been made.

He says, "I felt that his analysis was flawed"—"his analysis" being your analysis—"and given the publicity surrounding Dr. Graham's preliminary conclusions, I wrote him a very strong letter, raising a number of technical problems that I had with his research, and in fact, during the peer review that his research received prior to his publication, apparently a number of reviewers raised many of the same questions. As a result, when the paper was published in the Journal of the American Medical Association, it had been substantially revised. Had Dr. Graham not presented his preliminary findings at the NTSB meeting, there would have been much less feedback from the safety community and the quality of the final published paper may have been diminished. Given the importance of the subject, Dr. Graham's presentation of his preliminary findings at the NTSB was reasonable. And while I disagreed with his conclusions, I certainly never questioned his motives for presenting that data. Further, when his research was subjected to the peer review process, he made a number of substantive changes which did in fact change his conclusions, and it is the paper published in JAMA that is used today to characterize air bag cost effectiveness."

In other words, what we have here from a man who was one of your critics, is a real-life example of your willingness to listen to other points of view, your willingness to accept peer review, and your willingness to change your conclusions when confronted with peer review that suggests that such a change is necessary. What we have here is a real-life example of a man who is open to criticism, open to review, and willing to make changes if he feels scientifically that those changes are required. In my view, that is the kind of a man we want as the head of OIRA.

Thank you, Mr. Chairman.

Chairman THOMPSON. Thank you very much. I think that is extremely important, Senator, because I think that what we are dealing with here in this job is very much process oriented. Your job is going to be to insure that the agency does a careful analysis of what it is dealing with. You are not being put in there to create new scientific findings, are you?

Mr. GRAHAM. No, sir.

Chairman THOMPSON. And you are an expert in regulatory analysis, that it is not uncommon for us to confirm people who have views. Anyone who has accomplished anything in life and lived a

few years, has views. And we confirmed an Attorney General, time before last, who was opposed to the death penalty. And I think every member of the Judiciary Committee and every member of the U.S. Senate, who supports the death penalty, voted for her confirmation, because she stated that she would apply the law that was on the books.

And I think a letter like this is testament to the fact that you are a person who is intellectually honest, and that you will apply the law and the regulations as you find them, but not be afraid to have an intellectual discussion about issues that are of importance to the public.

On the tobacco issue, my record reflects that you cited smoking as the No. 1 killer in America in over 100 species. Does that sound right to you?

Mr. GRAHAM. That's right, sir.

Chairman THOMPSON. Your Center finds smoking prevention programs to be cost effective; is that correct?

Mr. GRAHAM. Yes, sir.

Chairman THOMPSON. In one book, for example, you recommended that, "Physicians should be encouraged and trained to counsel all patients to stop smoking, an intervention with varied favorable cost effectiveness for all types of smokers." Your writings and Congressional testimony point to indoor air pollution generally, and secondhand smoke specifically as a significant health hazard; is that correct?

Mr. GRAHAM. Yes, sir.

Chairman THOMPSON. And that study was at least in part financed by tobacco companies, was it not?

Mr. GRAHAM. Well, if we're going to characterize Kraft Foods in that fashion, I guess that's true, but that's probably not fair.

Chairman THOMPSON. Well, I guess this is reflected in your tobacco sources, because my file indicates that tobacco-related companies constitute less than 1 percent of the funding for your Center. Would that comport with your recollection generally?

Mr. GRAHAM. Yes. I think Kraft Foods is the only company at issue.

Chairman THOMPSON. Tobacco related?

Mr. GRAHAM. Right.

Chairman THOMPSON. Thank you very much. Senator Lieberman.

Senator LIEBERMAN. I do not have any more questions, Mr. Chairman. If I have any, I will submit them for the record.

I mean, it is interesting, as I think about the hearing and several of the questions that I have asked this morning, and others have, Dr. Graham, you have referred to the transition you are making, if you are confirmed for this position, from academic to public administrator, and that would require—sensitivity was one word you used—and I do not mean to take it out of context, but a different kind of orientation than you had up until this time. And I think the question that remains, for me anyway, is whether you can make that transition. And that is exactly what I, myself, want to consider as I consider your testimony and the answers that you have given in the context of your background.

I must say again what I said at the outset, that if the Bush Administration had not taken actions early on, which raise questions

about this administration's attitude toward a whole range of protective regulations, then there would be much less anxiety and unease about your past statements and work in this area. If one can imagine such a prospect, if you had been nominated by President Clinton, for instance, I think there would be less anxiety, less concern, because of what seemed to be the clear orientation of that administration toward these protective regulations.

Anyway, I thank you for your testimony, and I promise you that I will give the fullest consideration to what you have said today and the answers you have submitted for the record previous to the hearing, and I would welcome any additional input you would care to give to me or other Members of the Committee, either in writing or in person, before the Committee votes. Thank you.

Chairman THOMPSON. Thank you very much. Senator Durbin.

Senator DURBIN. Thank you, Mr. Chairman.

Dr. Graham, you have used cost analysis on regulations and rules in your professional career, and it involves something called "discounting lives." Is that something, a statistical model that you have used to evaluate the cost of rules and regulations?

Mr. GRAHAM. Yes. Discounting is commonly used in cost effectiveness and cost benefit analysis, for both health benefits and economic benefits.

Senator DURBIN. Could you, in laymen's terms, explain what "discounting lives" means?

Mr. GRAHAM. Discounting lives involves applying a preference to saving lives now as opposed to saving lives in the future.

Senator DURBIN. And so that might lead you to conclude, as you have, that fire extinguishers in airplanes, or air bags or seat belts, because they would prevent accidents on a more immediate basis, would be of more value to society than some other rules and regulations that do not cost benefit out as well?

Mr. GRAHAM. I am not sure about the specific examples, but I think your general point is right, which is that the discounting factor will end up favoring regulations that have immediate benefit.

Senator DURBIN. And here—I guess this is where I get down to the problem, and Dr. Heinzerling, over at Georgetown Law School, has written about this as well. I do not subscribe to that point of view, and I voted against it when it has been proposed in this Committee. And the difficulty I have is this. Many of the things we are talking about—dioxin, arsenic, pesticide residue and the like—may not have an immediate impact on public health and mortality statistics, but it certainly will in the long term if you accept the premise that exposure to some of these chemicals does ultimately result in cancer. And so if it saves lives 10, 20 or 30 years from now, the statistical approach of discounting lives would place less value on it; it is not as important as dealing with today's problems and today's mortality tables. And I think that is why many of us, who think that there is an important responsibility to this government when it comes to environmental protection and public health, worry about putting someone in with such a strong bent toward discounting lives and the impact it will have on public health and safety.

Would you comment on that?

Mr. GRAHAM. Senator, I don't think that my convictions behind discounting future lives are any greater or less than is typical among decision scientists and economists who practice these analytic tools. I do think you're raising a very good point, that you may want to, on certain occasions, allow consideration of factors that are outside of the economic discounting framework to influence the regulatory choice, and I think that's a fair comment.

Senator DURBIN. Well, your critics have said, of course, that discounting lives really does work against environmental and long-term public health goals, because the savings are not immediate. We make a lot of decisions today that may have some benefit to our children or to their children, and I think we consider that a valuable part of our legacy. But if we are just measuring it by today's benefit, how much we can benefit immediately, I think the discounting lives approach diminishes that value.

I am going to close by just asking you for a general comment on a statement that you made in a book that you wrote, entitled "Making Sense of Risk, an Agenda for Congress", 1996. And you said in that book, "The public's general reaction to health, safety and environmental dangers may best be described as a syndrome of paranoia and neglect." What did you mean by that, Dr. Graham?

Mr. GRAHAM. We overreact to some risks, and we neglect others.

Senator DURBIN. And do you feel that you have taken a balanced approach on questions like dioxin and pesticides on foods?

Mr. GRAHAM. Yes, sir.

Senator DURBIN. Thank you. Thank you, Mr. Chairman.

Chairman THOMPSON. Thank you very much.

Does anyone else have anything further? If not, I am going to thank you, Dr. Graham, for being here with us today, and for volunteering for this important public service. We will act expeditiously on your nomination. Thank you very much.

We are adjourned.

[Whereupon, at 1:34 p.m., the Committee was adjourned.]

# APPENDIX

**STATEMENT OF ANGELA STYLES,**
**NOMINATED TO BE ADMINISTRATOR OF THE OFFICE OF FEDERAL PROCUREMENT POLICY**
**BEFORE THE**
**UNITED STATES SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS**

**MAY 17, 2001**

Good morning Mr. Chairman and members of the Committee. It is an honor to be here. I owe a special thanks to Congressman Joe Barton for his thoughtful introduction and a debt of gratitude for his continued support throughout my professional life. In 1987, Joe gave me my first job in Washington and taught me some of the most important lessons in my career. In spite of being a second term member of the House minority, Joe never lost sight of his goals and his commitment to public service. Most importantly, he taught me the power of perseverance and hard work. I am honored and grateful for his presence and support today.

Second, but I must confess, most importantly, I want to thank my husband, Scott, for his steadfast support throughout my career. Today is a particularly special occasion, because it is also our wedding anniversary. I cannot imagine a better husband and father, or one person that could possibly have been more tolerant and understanding of my legal career and now my commitment to public service.

Mr. Chairman, I also want to express my gratitude to the Committee for the expeditious consideration of my nomination. I keep opining, and probably accurately, that I am the only nominee that is 9 months pregnant. Your staff has shown me an extraordinary courtesy by moving through the process quickly. I appreciate their time and preparation, as well as the opportunity to further develop the working and personal relationships that I have had with several members of your staff over the past few years.

I am deeply honored and privileged by the President's nomination to be the Administrator of the Office of Federal Procurement Policy. Few people are afforded the tremendous opportunity to serve in an appointed capacity, and even fewer in policy positions with cognizance over issues about which they are profoundly dedicated. I am looking forward with great anticipation to providing leadership and fostering an atmosphere of professionalism and excellence in acquisition policy.

Over the past decade, the federal acquisition system has undergone significant and continual reform. This reform movement achieved many laudable goals. Most important of which, government customers now receive the goods they need in a fraction of the time it took a decade ago. However, as with any reform movement, confusion has often dominated the process. I have been and continue to be concerned that the "efficient procurement model" coupled with significant implementation confusion has compromised concepts fundamental to our system of

government and our system of procurement.

We must never forget that we are procuring $200 billion a year in goods and services for the Federal government with taxpayer dollars. Because we are spending the public's money, there are some goals that cannot be compromised in the name of efficiency. Since the beginning of this reform movement, over a decade ago, I have not seen a single serious examination of the effects of reform on competition, fairness, integrity, or transparency. As a result, I think we are seeing some serious competitive problems surface with the proliferation of government-wide contracting vehicles and acquisition of services. The real challenge for OFPP and this Administration will be to balance the obvious benefits of increased efficiencies with the maintenance of fundamental concepts of competition, due process, integrity and transparency. Indeed, OMB has already started working towards these goals with management initiatives relating to competitive sourcing and performance-based service contracts.

The next four years will be important years for our procurement system. I look forward to the prospect of working with you and other Members of Congress on these difficult acquisition issues.

Thank you, Mr. Chairman and members of the Committee for the opportunity to appear before you and for the time you have given me. I am happy to answer any questions you might have.

## BIOGRAPHICAL AND FINANCIAL INFORMATION REQUESTED OF NOMINEES

### A. BIOGRAPHICAL INFORMATION

1. Name: (Include any former names used.)

   Angela Barbee Styles (05/97 – present)

   Angela Jean Barbee (05/67 – 05/97)

2. Position to which nominated:

   Administrator, Office of Federal Procurement Policy

3. Date of nomination:

   April 23, 2001

4. Address: (List current place of residence and office address.)

   Home: ----------

   Office: Office of Management and Budget
   Washington, D.C. 20503

5. Date and place of birth:

   May 5, 1967 – Dallas, Texas

6. Marital status: (Include maiden name of wife or husband's name.)

   Married to Scott Buske Styles

7. Names and ages of children:

   ----------

8. Education: List secondary and higher education institutions, dates attended, degree received and date degree granted.

   University of Texas School of Law
   Attended: 08/91 – 05/94
   Degree Received: J.D. with honors 05/94

University of Virginia
Attended: 08/88 – 01/90
Degree Received: B.A. in History with distinction 01/90

University of Colorado
Attended: 08/85 – 05/87
No degree received

Highland Park High School – Dallas, Texas
Attended: 08/81 –05/85
Received high school diploma 05/85

9. Employment Record: List all jobs held since college, including the title or description of job, name of employer, location of work, and dates of employment. (Please use separate attachment if necessary.)

Counselor to the Director of OMB
Washington, D.C.
04/01 – present

Special Assistant to the Associate Administrator for Governmentwide Policy
General Services Administration
Washington, D.C.
03/01 – 04/01

Special Assistant to the Commissioner of the Public Buildings Service
General Services Administration
Washington, D.C.
01/01 – 03/01

Counsel
Miller & Chevalier, Chartered
Washington, D.C.
05/96 – 01/01

Associate
Baker & Botts, L.L.P.
Washington, D.C.
10/94 – 05/96

Law Clerk
Texas Attorney General's Office
Austin, Texas
03/94 – 06/94

Research Assistant
University of Texas School of Law – Professor Ernest Smith
Austin, Texas
03/94 – 06/94

Summer Associate
Figari & Davenport, L.L.P.
Dallas, Texas
07/93 – 08/93

Summer Associate
Baker & Botts, L.L.P.
Washington, D.C.
05/93 – 07/93

Summer Associate
Jenkins & Gilchrist
Dallas, Texas
05/92 – 07/92

Summer Associate
Figari & Davenport, L.L.P.
Dallas, Texas
07/92 – 08/92

Campaign Consultant
Blakemore & Associates
Houston, Texas
02/91 – 08/91

Programs Manager
State of Texas – Office of State-Federal Relations
Washington, D.C.
04/90 – 02/91

Legislative Assistant
Akin, Gump, Strauss, Hauer & Feld
Washington, D.C.
02/90 – 04/90

Legislative Correspondent
Congressman Joe Barton
Washington, D.C.
05/87 – 08/88

10. Government experience: List any advisor, consultative, honorary or other part-time service or positions with federal, State, or local governments, other than those listed above.

None

11. Business relationships: List all positions held as an officer, director, trustee, partner, proprietor, agent, representative, or consultant of any corporation, company firm, partnership, or other business enterprise, educational or other institution.

None.

12. Memberships: List all memberships and offices held in professional, business, fraternal, scholarly, civic, public, charitable and other organizations.

Member, State Bar of Texas
Member, District of Columbia Bar
Member, American Bar Association
Admitted to practice before the United States Court of Federal Claims
Admitted to practice before the United States Court of Appeals for the Federal Circuit
Member, National Republican Lawyers Association
Member, Viewpac
Member, Texas State Society
Member, Emmanuel Episcopal Church

13. Political affiliations and activities:

(a) List all offices with a political party which you have held or any public office for which you have been a candidate.

None.

(b) List all memberships and offices held in and services rendered to all political parties or election committees during the last 10 years.

None.

(c) Itemize all political contributions to any individual, campaign organization, political party, political action committee, or similar entity of $50 or more for the past five years.

George W. Bush for President - $1000
Jim Greenwood for Congress - $1000
Viewpac - $250

14. Honors and awards: List all scholarships, fellowships, honorary degrees, honorary society memberships, military medals and any other special recognitions for outstanding service or achievements.

Order of the Coif
Various academic scholarships at University of Virginia
Various academic scholarships at University of Texas School of Law

15. Published writings: List the titles, publishers, and dates of books articles, reports, or other published materials which you have written.

"Conforming Environmental Cost Allowability Determinations to CERCLA's No-Fault Approach," 98-7 *Government Contract Cost, Pricing & Accounting Report* 3 (Fed. Pubs., July 1998)

Quarterly Reports of Legislative Coordinating Committee, American Bar Association, Section of Public Contract Law (Published quarterly July 1998 – November 2000 in American Bar Association, Section of Public Contract Law council materials).

"Domestic Violence: Are All Men Potential Murderers?" 21 *American Journal of Criminal Law* 229 (Fall 1993)(reviewing book titled "Women Murdered by the Men They Loved" by Constance Bean).

16. Speeches: provide the Committee with four copies of any formal speeches you have delivered during the last 5 years which you have copies of and are on topics relevant to the position for which you have been nominated.

I have given numerous speeches, lectures, and informal talks on procurement policy, cost accounting issues, and legislative issues, but they were delivered from notes. I do not have any prepared texts.

17. Selection:

(a) Do you know why you were chosen for this nomination by the President?

I was chosen based on my extensive legal and legislative experience in the fields of procurement and cost accounting.

(b) What do you believe in your background or employment experience affirmatively qualifies you for this particular appointment?

Over a number of years, I have represented clients in numerous aspects of procurement law and litigation, including regulatory compliance, procurement fraud, bid protest, claim preparation, cost and pricing issues, defective pricing, accounting issues, contract disputes and claims, contract negotiation, litigation of complex corporate-wide

accounting and contract issues, and negotiation of broad corporate-wide advance agreements with the Defense Contract Management Command. Of particular importance because the Administrator of OFPP serves as chair of the Cost Accounting Standards Board, a significant portion of my legal practice focused on Cost Accounting Standards compliance, cost allowability, and cost allocation.

## B. FUTURE EMPLOYEMENT RELATIONSHIPS

1. Will you sever all connections with your present employers, business firms, business associations or business organizations if you are confirmed by the Senate?

   I have severed all connections with previous employers, business firms, business associations and business organizations.

2. Do you have any plans, commitments or agreements to pursue outside employment, with or without compensation, during your services with the government? If so, explain.

   No.

3. Do you have any plans, commitments, or agreements after completing government service to resume employment, affiliation or practice with your previous employer, business firm, association or organization?

   No.

4. Has anybody made a commitment to employ your services in any capacity after you leave government service?

   No.

5. If confirmed, do you expect to serve out your full term or until the next Presidential election, whichever is applicable?

   Yes.

## C. POTENTIAL CONFLICTS OF INTEREST

1. Describe all financial arrangements, deferred compensation agreements, and other continuing dealings with business associates, clients or customers.

   I have retained a Baker & Botts 401k Retirement Plan, but no further contributions will be made by Baker & Botts or myself

   I have retained a Miller & Chevalier Chartered 401k Retirement Plan, but no further contributions will be made by Miller & Chevalier or myself.

2. Indicate any investments, obligations, liabilities, or other relationships which could involve potential conflicts of interest in the position to which you have been nominated

   My husband has holdings in Air Products and Chemicals Inc., which he will divest within 90 days if I am confirmed.

3. Describe any business relationship, dealing or financial transaction which you have had during the last 10 years, whether for yourself, on behalf of a client, or acting as an agent, that could result in a possible conflict of interest in the position to which you have been nominated.

   For the past seven years, as an attorney in private practice, I have represented a number of clients in procurement related matters. Any representation that could result in a conflict is addressed in the attached letter to Darrell Johnson dated April 20, 2001.

4. Describe any activity during the past 10 years in which you have engaged for the purpose of directly or indirectly influencing the passage, defeat or modification of any legislation or affecting the administration and execution of law or public policy.

   a. General Chemical Group, Inc. – representation with respect to de-icing provisions of ISTEA legislation.

   b. SABIC – representation with respect to miscellaneous MTBE matters.

   c. E&J Gallo – representation with respect to product liability issues relating to alcohol and wine labeling matters.

   d. Wal-Mart Stores, Inc. – representation with respect to Internet tax matters.

5. Explain how you will resolve any potential conflict of interest, including any that may be disclosed by your responses to the above items. (Please provide copies of any trust or other agreements.)

   Please see attached letter to Darrell Johnson dated April 20, 2001.

6. Do you agree to have written opinions provided to the Committee by the designated agency ethics officer of the agency to which you are nominated and by the Office of Government Ethics concerning potential conflicts of interest or any legal impediments to your serving in this position?

   Yes.

## D. LEGAL MATTERS

1. Have you ever been disciplined or cited for a breach of ethics for unprofessional conduct by, or been the subject of a complaint to any court, administrative agency, professional association, disciplinary committee, or other professional group? If so, provide details.

   No.

2. Have you ever been investigated, arrested, charged or held by any federal, State, or other law enforcement authority for any violation of any federal, State, county or municipal law, regulations or ordinance, other than a minor traffic offense?

   No.

3. Have you or any business of which you are or were an officer ever been involved as a party in interest in any administrative agency proceeding or civil litigation? If so, provide details.

   No.

4. Have you ever been convicted (including pleas of guilty or *nolo contendere*) of any criminal violation other than a minor traffic offense?

   No.

5. Please advise the Committee of any additional information, favorable or unfavorable, which you feel should be considered in connection with your nomination.

   None.

## E. FINANCIAL DATA

Financial Data maintained on file in Committee offices.

## AFFIDAVIT

Angela Styles being duly sworn, hereby states that she has read and signed the foregoing Statement on Biographical and Financial Information and that the information provided therein is, to the best of her knowledge, current, accurate, and complete.

Angela B. Styles

Subscribed and sworn before me this 26 day of April, 2001

NOTARY PUBLIC
DISTRICT OF COLUMBIA

MY COMMISSION EXPIRES JANUARY 31, 2004

**Pre-hearing Questions for Angela Styles**
**to be Administrator for the**
**Office of Federal Procurement Policy**
**of the Office of Management and Budget**

## I. Nomination Process and Potential Conflicts

1. Why do you believe the President nominated you to serve as Administrator for the Office of Federal Procurement Policy (OFPP)?

I was chosen based on my extensive legal and legislative experience in the fields of procurement and cost accounting. Over a number of years, I have represented clients in numerous aspects of procurement law and litigation, including regulatory compliance, procurement fraud, bid protests, claim preparation, cost and pricing issues, defective pricing, accounting issues, contract disputes and claims, contract negotiation, litigation of complex corporate-wide accounting and contract issues, and negotiation of broad corporate-wide advance agreements with the Defense Contract Management Command. Of particular importance because the Administrator of OFPP serves as chair of the Cost Accounting Standards Board, a significant portion of my legal practice focused on Cost Accounting Standards compliance, cost allowability, and cost allocation.

2. Were any conditions, express or implied, attached to your nomination to be Administrator?

No.

3. Have you made any commitments with respect to the policies and programs which you will attempt to implement as Administrator? If so, what are they?

No.

4. Are there any issues involving OFPP from which you may have to disqualify yourself? If so, what system will you establish to carry these out?

Any potential conflicts of interest will be handled through the recusal process, in which I would remove myself from the action, and refer all activity to the next responsible official within the Office of Federal Procurement Policy or the Office of Management and Budget. I have notified the Designated Agency Ethics Official within OMB of certain former clients whose legal matters I handled while in private practice. In accordance with 5 CFR § 2635.502, for one year following the termination of my employment at the law firm of Miller & Chevalier, Chtd., I will not participate in any particular matter involving specific parties in which, to my knowledge, my former employer, Miller & Chevalier, Chtd., or my former clients, is a party or represents a party, unless I am authorized to participate.

My spouse is employed by Bergner, Bockorny, Castagnetti, Hawkins and Brain. Pursuant to 5 CFR § 2635.502, I will not participate in any particular matter involving specific parties in which Bergner, Bockorny, Castagnetti, Hawkins and Brain is or represents a party, unless I am authorized to participate. Furthermore, pursuant to 5 CFR § 2635.502, I will not participate in any particular matter involving specific parties in which any client of my spouse is or represents a party, unless I am authorized to participate. In addition, my spouse has agreed not to represent any client with respect to any particular matter before the Office of Federal Procurement Policy during my tenure.

## II. Role and Responsibilities of OFPP Administrator

1. What do you consider to be the mission of OFPP?

OFPP's mission, as defined by statute, is "to provide overall direction of Government-wide procurement policies, regulations, procedures, and forms for executive agencies and to promote economy, efficiency, and effectiveness in the procurement of property and services by the executive branch of the Federal Government."

2. What do you consider to be your basic role and responsibilities as Administrator?

If confirmed, my basic role and responsibilities as Administrator would be (1) the execution of OFPP's statutory mandates; (2) the fulfillment of the President's acquisition priorities; and (3) the provision of leadership to the acquisition community.

3. What challenges do you expect to face as the Administrator of OFPP?

Over the past decade, the federal procurement system has undergone significant and continual reform. While these reforms brought much needed efficiency, I am concerned that OFPP has not examined whether the "efficient procurement model" may have compromised competition, fairness, integrity, and transparency, including the promotion of small and disadvantaged businesses. The challenge for this Administration and OFPP will be to balance the obvious benefits of increased efficiencies with the maintenance of fundamental concepts of competition, due process, and transparency.

4. How will you prepare for the new challenges of advocating on behalf of the taxpayers?

Serving as OFPP Administrator, if confirmed, will not be my first experience working in the public sector on behalf of taxpayers. On three separate occasions I have worked for either state or federal government in positions requiring an advocacy role. First, in the late 1980's I worked as a legislative aide for Congressman Joe Barton. In that position, I represented the interest of the citizens of the 6th congressional district of Texas. In the early 1990's, I worked in the Texas Office of State-Federal Relations where I analyzed federal formula and discretionary grants on behalf of the citizens of

Texas. Finally, in the mid-1990's, I worked in the Texas Attorney General's office researching legal issues for eminent domain proceedings.

As a general proposition and in light of my experience, I do not believe that special preparation for advocacy on behalf of the taxpayers is necessary. I believe that two essential qualities are necessary: (1) extensive knowledge of the federal procurement system; and (2) the moral integrity to make the correct choice.

5. Please describe any legislative experience you have with respect to procurement (including procurement reform), cost accounting and outsourcing issues.

For the past three years, I served as Chair of the Legislative Coordinating Committee for the American Bar Association's Section of Public Contract Law. In that capacity, I have spent in excess of 250 hours per year, on a pro bono basis, identifying and analyzing procurement legislation. Published portions of my work product for the American Bar Association have been supplied to the Committee. In addition to my published material, I chaired monthly committee meetings where I updated committee members on current legislation and led discussions on legislation of particular relevance to the procurement community. These monthly meetings were well attended by industry and government representatives.

Although not an exclusive list, during the 106th Congress, I analyzed and provided information on the following pieces of legislation:

a. Procurement provisions within the Fiscal Year 2001 Defense Appropriation (Public Law No. 106-259)
b. Truth in Regulating Act (H.R. 4924, S. 1198, H.R. 4744)
c. Fiscal Year 2001 Defense Authorization
d. Government Waste and Corrections Act (H.R. 1827/S. 3030)
e. Small Business Competition Preservation Act (H.R. 4945)
f. Government-wide procurement provisions within the Fiscal Year 2001 Treasury, Postal, and General Government Appropriation (H.R. 4871/S. 2900)
g. Legislation concerning moratoriums on privatization and outsourcing (H.R. 3766, S. 2841, H.R. 4722)
h. FAIR Act Amendments (H.R. 4103/S. 2242)
i. Debt Payment Incentive Act (H.R. 4181)
j. Federal Prison Industries legislation (H.R. 2558, H.R. 2551)
k. Small Business Federal Acquisition Simplification Act (H.R. 4943)
l. Small Business Competition Preservation Act (H.R. 4945)
m. National Small Business Regulatory Assistance Act (H.R. 4946)
n. Federal Agency Compliance Act (H.R. 1924)
o. Electronic Signatures in Global and National Commerce Act (Public Law No. 106-229)
p. Construction Quality Assurance Act (H.R. 4012)

q. Federal Contractor Flexibility Act (H.R. 3582)
r. Federal Agency Compliance Act (H.R. 1924)
s. Procurement Provisions within Consolidated Appropriations for Fiscal Year 2000 (Public Law No. 106-113)
t. Congressional Accountability for Regulatory Information Act (H.R. 3521)
u. H.R. 3469 (treatment of arsenal overhead costs)
v. Fiscal Year 2000 Defense Authorization (Public Law No. 106-65)
w. Y2K Dispute Resolution Legislation (Public Law No. 106-37)
x. Construction Industry Payment Protection Act (Public Law No. 106-49)
y. Regulatory Fair Warning Act (H.R. 881)
z. Regulatory Right to Know Act (H.R. 1074/S. 590)
aa. Regulatory Improvement Act (S. 746)
bb. Prompt Payment Improvement Act (H.R. 1208)
cc. Federal Procurement and Assistance Integrity Act (H.R. 1227)
dd. Subcontractor Protection Act (H.R. 1209)
ee. Paperwork Elimination Act (H.R. 439)

Although not an exclusive list, during the 105th Congress, I analyzed and provided information on the following pieces of major legislation:

a. The Fiscal Year 1999 Defense Authorization (Public Law No. 105-261)
b. Procurement provisions within the Fiscal Year 1999 Defense Appropriation (Public Law No. 105-262)
c. Procurement provisions within the Fiscal Year 1999 Energy and Water Appropriation (Public Law No. 105-245)
d. The Federal Activities Inventory Reform Act (Public Law No. 105-270)
e. The Year 2000 Information Disclosure and Readiness Act (Public Law No. 105-271)
f. Procurement provisions within the Fiscal Year 1999 Treasury, Postal, and General Government Appropriation
g. The International Anti-Bribery Act
h. Construction Subcontractors Payment Protection Enhancement Act (H.R. 3032).

6. What will be your top priorities and objectives as Administrator of OFPP?

If confirmed, my three top priorities will be execution of OFPP's statutory mandates, implementation of the President's procurement initiatives, and provision of leadership to the acquisition community.

a. Execution of OFPP's Statutory Mandates

Over the past several years, the mission of OFPP has become diluted by a variety of unfocused initiatives. If confirmed, my first priority would be to narrow the mission of OFPP by examining the activities currently undertaken, determining the initiatives

required by statute, and examining the non-statutory activities that further the statutory mission of OFPP.

b. Implementation of the President's Procurement Initiatives

Three acquisition goals have been clearly articulated by the Administration. If confirmed, the implementation of these goals would be a top priority.

i. Competitive Sourcing Goals

The President committed to opening one-half of the commercial positions listed on the Federal Activities Inventory Reform ("FAIR") Act agency inventories to competition with the private sector. In accordance with a memorandum from the Director of the Office of Management and Budget dated February 14, 2001, and a memorandum from the Deputy Director of the Office of Management and Budget dated March 9, 2001, departments and agencies were instructed to develop specific performance plans to meet a FY 2002 goal of completing public-private or direct conversion competitions on not less than 5 percent of the FTEs listed on FAIR Act inventories.

ii. Performance-Based Service Contracts

The March 9, 2001 memorandum from the Deputy Director of OMB set a Fiscal Year 2002 Performance-Based Service Contracting (PBSC) goal of using PBSC techniques for not less than 20 percent of the total eligible service contracting dollars.

iii. Electronic Procurement

The March 9, 2001 memorandum from the Deputy Director of OMB also set forth Fiscal Year 2002 goals for expanding the application of on-line procurement. Departments and agencies are required to post (a) all synopses for acquisitions valued at over $25,000 for which widespread notice is required and (b) all associated solicitations unless covered by an exemption in the Federal Acquisition Regulation on the government-wide point-of-entry website (www.FedBizOpps.gov). The President's commitment is to shift procurement to the Internet at the same rate as the private sector and to increase competition and accessibility.

c. Provision of Leadership to the Acquisition Community

One of the most important responsibilities of the Administrator of OFPP is to provide leadership for the Acquisition Community. If confirmed I intend to:

i. Ensure that the federal procurement system provides true accountability to the American people by protecting the

fundamental concepts of efficiency, competition, fairness, responsiveness, and transparency;

ii. Foster an atmosphere of professionalism and excellence in procurement management;

iii. Lead the professional and support staff of OFPP to meet the goals and challenges set out by statute and the President;

iv. Serve, as provided by statute, as Chair of the Cost Accounting Standards Board, and provide leadership in efforts to develop equitable Standards and rules governing cost accounting for contracts and subcontracts that are priced or reimbursed on the basis of cost; and

v. Consult on a regular basis with relevant committees of the House and Senate and to keep those Committees informed about OFPP's major initiatives and strategies.

7. What contributions do you feel that you can make to OFPP and the Office of Management and Budget (OMB)?

Although OFPP is a statutory office within the Office of Management and Budget ("OMB"), in past administrations, OFPP has not been well-integrated within either the management or budget functions of OMB. With my extensive knowledge of procurement, my personal relationships throughout the Administration, and my past legislative experience, I am in a unique position, if confirmed, to work towards the integration of OFPP and procurement policy within the management and budget functions of OMB.

## III. Policy Issues

1. With a significant portion of the acquisition workforce eligible to retire in the next few years, the Federal government must begin initiatives to recruit, develop, and retain its future acquisition workforce. After a decade of consecutive years of downsizing, we face serious imbalances in the skills and experience of our acquisition workforce. How will you respond to this challenge?

Because statistics reveal that the Federal government could be facing a significant number of retirements among contracting personnel in the next five to ten years, I am concerned about a human capital crisis. As both the Director and Deputy Director of OMB noted in their confirmation statements, a lack of good long-term workforce planning, and the integration of that planning with agency mission objectives, is a deficiency that the Government Performance and Results Act highlights and aims to correct. From what I have read and reviewed, OMB has made good progress in this area.

Last year, for example, OMB established a Priority Management Objective to ensure that Federal agencies plan strategically to maximize performance of their human capital resources in order to achieve program results about which the American people care. OMB also revised Circular A-11 to require agencies to address human resource management issues in both their budget submissions and strategic and performance planning documents. If confirmed, I will place a high priority on OFPP's role as it relates to the larger OMB role in continuing to ensure that procurement agencies make human capital management, as it relates to their contracting work force, an integral part of their executive management responsibilities.

2. Recent years have seen an explosion of government-wide and inter-agency contract vehicles. Some have praised these as simpler and more responsive vehicles for meeting agency needs while others have raised concerns that agencies are using these vehicles to short-cut competition requirements and are wasting taxpayer dollars.

   a. How will you ensure that these contracts are used to best leverage the government's buying power while satisfying contractual requirements and maintaining competition?

I am concerned that the uncontrolled proliferation of government-wide contracting vehicles has impeded competition and wasted taxpayer dollars. I am also concerned about competition in the award of task and delivery orders against these contracts, the charges administering agencies impose for these contracts, and the manner in which information about these contracts is disseminated to potential using agencies. Indeed, the system has devolved to such a state that I believe it is impossible for a single procurement official to be expected to locate and understand the numerous contracting vehicles available in any particular situation. Ultimately, I believe the Federal government is failing to fully utilize its tremendous buying power and the economies of scale.

I do not have a simple solution to this problem. If confirmed, I would work to find a solution that maintains the benefits of these simpler and more responsive government-wide contracting vehicles, while addressing the valid concerns that these vehicles are not leveraging the Federal government's buying power. At a minimum, the information relating to the availability and use of these vehicles must be centralized. In the longer term, the competition requirements and user fee aspects of these vehicles also should be examined.

   b. Regarding governmentwide and inter-agency contract vehicles, concerns have been raised about the proliferation of such vehicles – that these vehicles are becoming uneconomical because too little business is spread over too many contracts. Do you believe that OFPP should play a role in regulating the establishment of governmentwide and inter-agency contract vehicles, and, if yes, how would you conceive that role?

I do not envision a *per se* regulatory role for OFPP.

3. Over the past decade, the Federal government has significantly increased its acquisition of services. Annually, the government acquires nearly $130 billion of services, more than twice the amount spent on products. However, the GAO and others continue to find instances in which the government is not obtaining fair and reasonable prices, is avoiding competition, and is not otherwise assuring the government obtains best value.

a. Do you see these issues as being systemic across the government?

Yes.

b. In your view, what are the principal causes of these problems?

I see several inter-related issues that have led to weaknesses in service contracting. First, and perhaps foremost, the Federal government's basic systems, experience, and culture are oriented toward the acquisition of products. Services, by their very nature, are more difficult to describe and require the exercise of a greater level of judgment in the contracting process.

c. How do you suggest that agencies improve their capacity to acquire services, and what additional policies or legislative authorities do you believe are necessary to assist them?

The acquisition of services is a difficult issue that will not be easily resolved. The best course of action would be to take a holistic approach to the acquisition system by involving, improving, and better integrating the roles played by requirements and contracting personnel. Too often in the acquisition of services there is a failure to communicate adequately among the government acquisition team. Requirements personnel do their work; contracting personnel do their work; and, the two never fully integrate to address the specific service requirement as a whole. While the government has reduced "stove piping", there is room for improvement. The entire acquisition work force (I am specifically thinking of requirements personnel) must be educated about the positive role that can be played by contracting officials when they are involved early in the process. Contracting personnel can make an enormous contribution to the acquisition of services if they are involved when the requirement is being defined. Unfortunately, this involvement often begins too late. OFPP must work to ensure that contracting officials are involved early in the acquisition planning process, not at the point when the statement of work has already been defined, and all that remains are the solicitation and award phases of the acquisition process.

I do not believe that additional legislative authorities are necessary at this time to address the issues relating to the acquisition of services. With regard to other policy guidance that may be necessary, I will need to examine the issues more closely before I make any recommendations.

d. To what extent can the government leverage the best practices from the private sector?

The Federal government must continually remain abreast of private sector procurement practices. In the services area, there is much to be learned. The Federal government's best interests would be served by examining and studying how the private sector, and State and local governments contract for services. Their success stories should guide the Federal government in adapting best practices and techniques for possible application to Federal agency procurement methodologies.

4. One initiative that OFPP has proposed to help agencies become "smart buyers" of services is the use of performance-based statements of work. OFPP first put forward this initiative in 1991 and now, a decade later, the concept is poorly understood by many procurement professionals and little used within the government.

a. Why do you believe this is the case?

In part, I believe the problem with performance-based service contracts centers on a lack of clarity regarding the definition of what constitutes a performance-based service contract. Based on my experience, there is tremendous disagreement among agencies regarding the requirements to qualify a contract as a performance-based service contract. Previous attempts by OFPP to clarify the definition, including a "checklist" of minimum required elements for an acquisition to be considered performance-based, have been wholly unsuccessful. More generally, agencies have received little useful guidance regarding the transition to performance-based statements of work.

b. What are your views on the Administration's goal to increase the use of performance-based contracts to 20%?

I believe that the Administration's goal to increase the use of performance-based contracts is an important step. Only with performance-based contracts can we achieve better acquisition solutions for service contracts by fostering the creativity and initiative of the private sector. However, for this goal to be meaningful, OFPP and the agencies must agree on a common definition of a performance-based service contract.

c. More broadly, do you believe that OFPP needs additional authority or resources to foster more timely and broader adoption of procurement policy reforms it initiates?

I do not believe that additional legislative authorities are necessary at this time to address the issues relating to performance-based service contracts.

5. The Federal Acquisition Streamlining Act of 1994 defined "commercial services" as services that are "offered and sold competitively, in substantial quantities, in the commercial marketplace based on established catalog prices for specific tasks performed under standard commercial terms and conditions." Some have argued that this definition is too restrictive, limiting the government's access to innovative services or posing an administrative burden on the private sector.

   a. Do you believe the current definition of "commercial services" should be revised?

The definition of commercial services is a sensitive area, and people on both sides of the issue raise valid concerns. Nevertheless, I am not prepared to commit to an answer at this time. If confirmed, I will ask that the OFPP staff further study the matter.

   b. If so, what revisions would you propose?

See above response.

6. As you know, language was included in the National Defense Authorization Act for Fiscal Year 2000 which made much needed revisions to the underlying statute of the Cost Accounting Standards ("CAS standards"). The legislation modified the CAS standards to streamline their applicability, while maintaining the applicability of the standards to the vast majority of contract dollars that are currently covered. An outstanding issue is the organization of the CAS Board. Currently, the CAS Board is located in the Office of Federal Procurement Policy (OFPP) and chaired by the Administrator of OFPP. Many in the public and private sectors believe that the Board's placement in OFPP affects its ability to operate as an independent board and has led it into procurement policy considerations that are not appropriate accounting concerns. Concerns have been raised that OFPP's procurement policy mission is much broader than the maintenance of the CAS standards. What is your view on the placement of the CAS Board and who should chair it? Do you believe that Federal Employees Health Benefits Program carriers should be exempt from cost accounting standards?

After extensive contemplation of the relevant facts and arguments, I believe, for the present time, the CAS Board should remain within OFPP and be chaired by the Administrator of OFPP.

The Federal Employees Health Benefits Program (FEHBP) does not require a statutory exemption from CAS coverage. To the extent that modifications and/or waivers from CAS coverage are required to meet any issues raised by FEHBP contracting procedures, the administrative process should be adequate to resolve these matters.

7. Procurement reform legislation, specifically the Clinger-Cohen Act of 1996, authorizes the OFPP Administrator to conduct or sponsor a number of pilot programs to test alternative approaches for the acquisition of information technology. So far, we have seen little activity in this regard. What specific actions would take to invigorate the pilot program test authority of the Administrator?

I am open to specific suggestions or recommendations for use of the Clinger-Cohen test authority for the acquisition of information technology. Since I was not involved when earlier recommendations may have been made to OFPP, I cannot comment on whether the test authority has been wisely or unwisely utilized, or even to what extent recommendations for its use have been made. However, if confirmed, I will review the pilot test authority, and will be open-minded as to its use when sound suggestions for pilot tests are offered.

8. What are the next steps that the Congress needs to take to promote continued progress toward acquisition reform?

Congress should examine the balance between the improved efficiencies achieved through a decade of acquisition reform and the fundamental concepts of competition, fairness, integrity, due process, and transparency. Where appropriate, Congress should move forward with acquisition reform initiatives that continue to increase efficiency, using the private sector as a model where possible, but maintain other concepts fundamental to our system of government and our system of procurement.

9. What steps does the Executive Branch need to be taking to promote continued progress toward acquisition reform?

The Executive Branch should take steps similar to what I recommend Congress consider by examining the balance between the improved efficiencies achieved through a decade of acquisition reform and the fundamental concepts of competition, fairness, integrity, due process, and transparency. Where appropriate, the Executive Branch also should move forward with acquisition reform initiatives that continue to increase efficiency, using the private sector as a model where possible, but that maintain other concepts fundamental to our system of government and our system of procurement.

10. In an effort to greatly expand the use of public-private competitions pursuant to OMB Circular A-76, OMB Director Mitchell Daniels has indicated that he will ask the next head of OFPP to implement some short-term simplifications to the A-76 process pending the recommendations of the General Accounting Office's (GAO) "Commercial Activities Panel". The Department of Defense (DOD) has the most experience conducting these competitions; however, it has encountered many problems with respect to resources and other issues. Further, few agencies

have staff who understand the A-76 process enough to conduct a competition under it.

a. How do you expect to implement this task government wide while addressing the necessary resource, education and training issues?

On March 9, 2001, the Deputy Director of OMB issued a memorandum to agencies requesting the development of Performance Plans to implement the Administration's A-76 goals, including resource and training requirements. If confirmed, I would work with OMB and the agencies to ensure that these plans are implemented and the necessary resources are available.

b. How will you deal with the recommendations of GAO's Commercial Activities Panel, understanding that we do not know at this time what the recommendations will be?

If confirmed, I will carefully consider the recommendations and work to implement them where appropriate.

c. What adjustments to the A-76 process do you believe might be appropriate in the short-term? What adjustments do you believe might be appropriate in the long-term?

In the short term, OMB has been considering the cancellation of the existing Interservice Support Agreements Grandfather Clause found at Part 1, Chapter 2, paragraph A.5 of OMB Circular A-76. As currently written, reimbursable agreements that existed before October 1, 1997, can be continued and renewed without competition. Only new reimbursable agreements or expansions are subject to the competition requirements of the Circular. I believe competition for reimbursable work should be expanded to all reimbursable activities.

In the long-term, OMB should consider independently and fully engage the members of the GAO's Commercial Activities Panel in the development of both technical revisions and possible alternatives to current A-76 procedures.

d. GAO has reported that some agencies do not have adequate systems for tracking the costs and savings from contracts awarded pursuant to the A-76 process. Given that the Administration has promised an increase in the use of A-76, do you believe that agencies need to have systems in place to track the costs and savings of service contracting?

I believe the Federal government has sufficient information regarding service contract dollars spent by each agency, as well as detailed financial and performance tracking systems to monitor contract performance. Agencies also have a separate set of automated systems to track savings achieved following an A-76 competition, using the winning or losing bid as a base line. However, agencies do not have a recurring system

to adequately track A-76 savings over the long term. Nevertheless, the General Accounting Office, many agency inspectors general, and the Center for Naval Analysis consistently have concluded that savings from A-76 competitions are real in both the long and the short term. As long as the savings are real, I believe the Federal government should carefully weigh the costs of developing an automated system to precisely measure these savings on a recurring basis, against the benefits of a precise measurement.

11. The Administration has asked agencies to provide by June 30 information on inherently governmental work performed by federal employees. What do you intend to do with that information?

The Director of OMB has a statutory responsibility under the FAIR Act to review and consult with the head of each executive agency regarding the yearly list of activities that the agency has determined "are not inherently governmental." It is my understanding that as part of the 1999 and 2000 FAIR Act inventory reviews, OMB relied on an earlier request for data from the agencies (known as the Raines A-76 Inventory) that provided inherently governmental information by agency and function code. I believe that OMB's request for a separate and updated report on inherently governmental positions is consistent with OMB's previous request and will be used by the Director of OMB in fulfilling statutory responsibilities for review and consultation under the FAIR Act.

12. The Clinger-Cohen Act of 1996 authorized two pilot programs for share-in-savings contracts for information technology solutions. With these contracts, a contractor pays the up front costs of implementing a new system and is paid out of any resulting savings. The risk to the government is low, but the benefits can be great. To date, the Clinger-Cohen authority has not been used, although GSA recently worked with the Department of Education to award an IT share-in-savings contract to update its Student Financial Assistance systems. Do you support increased use of IT share-in-savings contracts throughout government? If so, what steps would you recommend to promote their use?

I am unfamiliar with specific share-in-savings recommendations that may have been made to OFPP or agencies in the past. I am enthusiastic about pilot programs that hold promise for improved agency performance and cost savings to taxpayers. If confirmed, I will ask the OFPP staff to work with their agency counterparts to remind them of the share-in-savings authority, and I will remind senior procurement executives to carefully consider using this authority for sound proposals.

13. What are your views on electronic procurement and what will you do to promote it during your tenure as Administrator?

The commercial marketplace has been using e-commerce tools and harnessing the powers of the Internet to improve how customers are served. The Government must do the same and leverage the investments made by the private sector, whenever possible.

The Federal government must resist the temptation to buy technology simply because it is available. Instead, e-commerce applications that offer opportunities to strengthen procurement processes must be pursued so that Government transactions with businesses -- small and large -- can become easier, more efficient, and less expensive for both parties. Recognizing that e-procurement initiatives are often cross functional in nature (affecting the interests of the acquisition, information technology and finance communities, among others), if confirmed, I would work with my OMB colleagues to promote a productive collaboration among effected stakeholders.

## IV. Relations with Congress

1. Do you agree without reservation to respond to any reasonable summons to appear and testify before any duly constituted committee of the Congress if you are confirmed?

   Yes.

2. Do you agree without reservation to reply to any reasonable request for information from any duly constituted committee of the Congress if you are confirmed?

   Yes.

## V. Assistance

1. Are these answers your own? Have you consulted with the OFPP or any other interested parties? If so, please indicate which entities.

   The answers are my own. Since receiving the questions from the Committee, I sought background information from OFPP staff.

## AFFIDAVIT

I, Angela Styles, being duly sworn, hereby state that I have read and signed the foregoing Statement on Pre-hearing Questions and that the information provided therein is, to the best of my knowledge, current, accurate, and complete.

Angela B. Styles

Subscribed and sworn before me this 9th day of May, 2001.

Bessie M. Jones Weaver
Notary Public
Commission Expires: August 14, 2004

**Questions from Senator Joseph I. Lieberman for Angela Styles**
**Nominee to be OFPP Administrator**

1. Currently, OMB Circular A-76, governing public-private competitions, does not require such competitions for new work, i.e., work not currently being performed by federal employees. Do you believe that the Administration, as it reviews the A-76 process, should take any steps to require public-private competitions for new work?

The Federal government should rely on the dynamics of competition to determine who should perform needed commercial support services. In addition, contract performance requirements should permit offerors to compete on a level playing field for the performance of work. I am concerned that a requirement to submit Federal offers for new work would represent a significant administrative burden at considerable cost to the taxpayer without a commensurate expansion of competition or probability of cost savings.

2. As you know, OMB has directed agencies to compete during FY02 at least 5% of the jobs currently performed by federal employees which are listed on their Federal Activities Inventory Reform Act ("FAIR Act") inventories. Do you believe the Administration should take any steps to require public-private competitions for any work currently performed by contractors?

I am very concerned that a requirement to submit a public offer for each and every contracted job would (1) be extremely burdensome, (2) be costly to the taxpayer, and (3) significantly delay the Federal government's ability in both the short and the long term to acquire needed support.

3. Last year, the Clinton Administration published a final rule to require contracting officers to consider a company's satisfactory compliance with tax, labor, employment, environmental, and other laws before awarding a contract. This rule was carefully considered: The rule was initially proposed on July 9, 1999 with a 120-day comment period. OMB received more than 1500 comments from business groups, contractors and others. As a result, the Administration withdrew the proposal, revised it, and issued another proposal on June 30, 2000 for an additional 60-day comment period. Hundreds of additional comments were received and considered. On December 20, 2000, a final rule was issued, which OMB was to begin implementing in January.

Instead, On January 31, GSA took the sudden step of recommending to agencies that they authorize "class deviations:" for this rule. In a recent legal opinion, the Congressional Research Service called this action likely unlawful. On February 20, I sent a letter, along with Senators Kennedy and Durbin, to OMB Director Daniels inquiring as to the legal basis for GSA's action. More recently, on April 3, GSA, DOD and NASA sought comments on the repeal of the rule, suspended it government wide and sought comments on this stay before we ever received a response to our inquiry.

We have only recently received an answer to our letter which I do not consider to be responsive to our concerns. For instance, rather than responding to the legal objections raised in the CRS memorandum, GSA's letter stated the obvious: that the process for granting deviations differs from the process for revising or rescinding regulations. Our letter also said that, legalities aside, it was unfair to suspend the rule, years in the making, without notice or apparent consideration of the views of all sectors of the affected public, that it was wrong to address only the interests of the agencies and their contractors without considering the effect on other interested parties and the public interest, and that the Contractor Responsibility rule is a moderate and sensible reform that should be implemented without delay. Rather than responding to these concerns, GSA's letter simply asserted that "the procedural requirements for granting agency wide deviations were fulfilled."

- What is your view of the Contractor Responsibility rule?

As you know, on April 3, 2001, the Federal Acquisition Regulatory Council requested public comments on a proposed rule which would revoke the December 20, 2000 final rule relating to contractor responsibility. Because that comment period remains open, I do not believe it is appropriate for me to comment on the rule-making.

- What is your view of the actions taken by GSA in January and April? Do you believe these actions were taken in the public interest? If so, please elaborate.

I believe it was appropriate for the FAR Council in April to request public comment on whether the rule should be revoked. I also believe the GSA's use of class deviation authority complied with the requirements of FAR section 1.404(a).

- Have you reviewed the legal opinion by the Congressional Research Service? If so, what is your opinion of it?

Sometime in February 2001, I briefly reviewed the Congressional Research Service opinion. I have not spent enough time reviewing the class deviation matter to have developed an opinion regarding the Congressional Research Service's legal analysis.

- What authorities do you believe govern class deviations?

Class deviations are governed by FAR 1.404.

4. Twice within the last five years, OFPP proposed to amend the cost principles in the Federal Acquisition Regulation sections 31.205-46 and 31.205-35 in order to exempt federal contractors from ceilings that limit the amounts that can be charged to the taxpayers for travel and relocation expenses, while continuing to cap travel and relocation expenses for federal employees. On both occasions, the proposal was withdrawn. What is your view of this proposal?

TESTIMONY OF

STEPHEN A. PERRY

NOMINEE FOR ADMINISTRATOR OF THE GENERAL SERVICES ADMINISTRATION

BEFORE

THE COMMITTEE ON GOVERNMENTAL AFFAIRS

U. S. SENATE

May 17, 2001

THANK YOU, SENATOR THOMPSON.

MR. CHAIRMAN AND MEBMERS OF THE COMMITTEE, IT CERTAINLY IS AN HONOR FOR ME TO HAVE BEEN NOMINATED BY PRESIDENT BUSH TO SERVE AS ADMINISTRATOR OF THE GENERAL SERVICES ADMINISTRATION.

IT IS ALSO AN HONOR FOR ME TO HAVE THIS OPPORTUNITY TO DISCUSS THAT SUBJECT WITH YOUR COMMITTEE TODAY.

WITH YOUR PERMISSION, MR. CHAIRMAN, I WOULD FIRST LIKE TO TAKE A MOMENT TO SAY THANK YOU TO SENATOR VOINOVICH AND TO CONGRESSMAN REGULA -- NOT ONLY FOR THEIR WORDS OF SUPPORT HERE THIS MORNING, BUT ALSO FOR THEIR FRIENDSHIP AND THE ASSISTANCE THEY HAVE PROVIDED TO ME AND TO MY FAMILY OVER THE YEARS, AND THEIR MANY OTHER CONSTITUIENTS BACK IN OUR HOME STATE OF OHIO. MY WIFE, SONDRA, AND I APPRECIATE IT VERY, VERY MUCH.

I ALSO WANT TO THANK OHIO CONGRESSMAN DAVID HOBSON, WHO IS HERE, ...AND I WANT TO THANK SENATOR MIKE DEWINE, WHO COULD NOT BE HERE THIS MORNING BECAUSE OF HIS WORK ON THE JUDICIARY COMMITTEE.

AGAIN, I SINCERELY APPRECIATE THE SUPPORT AND COUNSEL THAT THESE GENTLEMEN AND THE OTHER MEMBERS OF THE OHIO DELEGATION HAVE GIVEN TO ME AND THE TRUST THEY HAVE PLACE IN ME REGARDING THIS NOMINATION TO LEAD GSA.

I WANT EACH OF THEM TO KNOW AND I WANT EACH MEMBER OF THIS COMMITTEE TO KNOW THAT, IF I AM CONFIRMED, I PLEDGE TO CONTINUALLY STRIVE TO BE WORTHY OF YOUR TRUST.

MR. CHAIRMAN, I CERTAINLY AGREE WITH YOU AND THE MEMBERS OF THIS COMMITTEE REGARDING THE VERY IMPORTANT ROLE AND RESPONSIBILITY THAT THE GENERAL SERVICES ADMINISTRATION HAS IN ACHIEVING EFFECTIVE AND EFFICIENT GOVERNMENT SERVICES ON BEHALF OF THE AMERICAN PEOPLE.

IT IS CERTAINLY VERY CLEAR THAT THE QUALITY AND TIMELINESS OF THE WORK DONE BY GSA IN PROVIDING SERVICES TO OTHER FEDERAL AGENCIES HAS A DIRECT AND SIGNIFICANAT IMPACT ON THE ABILITY OF THOSE AGENCIES TO ACHIEVE THEIR RESPECTIVE MISSIONS.

THE CHALLENGE FOR GSA IS TO ACHIEVE AND SUSTAIN ITSELF AS A HIGH PERFORMANCE ORGANIZATION COMMITTED TO CONTINUOUS IMPROVEMENT OF THE SERVICES IT PROVIDES TO MEET THE NEEDS OF ITS CUSTOMER-AGENCIES AND THEREBY TO IMPROVE GOVERNMENT SERVICES RENDERED DIRECTLY TO THE PUBLIC.

MR. CHAIRMAN, I'M VERY EXCITED ABOUT THE POSSIBILITY OF JOINING THE GSA TEAM IN THIS VERY IMPORTANT WORK.

I'M EXCITED BECAUSE I BELIEVE STRONGLY IN PRESIDENT BUSH'S ASPIRATION TO APPLY SOLID GENERAL MANAGEMENT PRACTICES AS A MEANS TO SIGNIFICANTLY IMPROVE GOVERNMENT SERVICES FOR ALL AMERICANS.

I'M EXCITED BECAUSE OF THE VERY INTERESTING MANAGERIAL CHALLENGE INVOLVED WITH SUCH A COMPLEX ORGANIZATION.

AND, I'M EXCITED TO HAVE THIS OPPORTUNITY TO BE SO INVOLVED IN PUBLIC SERVICE.

I KNOW THAT ACHIEVING AND SUSTAINING HIGH PERFORMANCE AND A CONTINUOUS IMPROVEMENT CULTURE AT GSA WILL BE A VERY BIG JOB. I KNOW IT WILL HAVE ITS HARDSHIPS AND FRUSTRATIONS. I KNOW IT WILL REQUIRE LONG HOURS AND SOME SACRIFICES BY ME AND OTHERS AT GSA. I KNOW THAT THE ADMINISTRATION AND THIS COMMITTEE HAVE HIGH PERFORMANCE EXPECTATIONS FOR

GSA. I BELIEVE THE PEOPLE AT GSA WILL ACCEPT THE CHALLENGE FOR HIGH PERFORMANCE AND I AM CONFIDENT I CAN HELP THE GSA TEAM MAKE IT HAPPEN.

MR. CHAIRMAN, AS I THOUGHT ABOUT TODAY'S HEARING AND WHAT I MIGHT SAY IN THIS BRIEF OPENING STATEMENT, I FELT IT WOULD BE USEFUL TO THE COMMITTEE IF I SAID A FEW WORDS ABOUT MY VIEWS ON ACHIEVING AND SUSTAINING HIGH PERFORMANCE AT GSA.

ACCOMPLISHING THIS WILL REQUIRE A NUMBER OF THINGS FROM BOTH OUTSIDE AND INSIDE THE AGENCY. I WANT TO MENTION JUST A FEW:

FIRST, IT WILL REQUIRE EFFECTIVE COMMUNICATION IN ALL THAT WE DO.

CONSTRUCTIVE DIALOGUE IS CRITICALLY IMPORTANT TO GETTING EVERYONE INVOLVED ON THE SAME PAGE AND PULLING IN THE SAME DIRECTION.

WHILE THIS WILL BE TRUE IN EVERY ASPECT OF OUR WORK, PERHAPS ONE AREA WE SHOULD GIVE SPECIAL EMPHASIS TO IN THE NEXT FEW MONTHS IS TO DEVELOP AN IMPROVED APPROACH FOR GSA's COMMUNICATION AND INTERACTION WITH MEMBERS OF CONGRESS AND PARTICULARLY THEIR COMMITTEE STAFF.

THE SAME IS NEEDED REGARDING GSA's COMMUNICATION WITH THE ADMINISTRATION AND PARTICULARLY THE OMB STAFF.

THIS IMPROVED COMMUNICATION BY GSA WITH THOSE RESPONSIBLE FOR OVERSIGHT IS NECESSARY TO FACILITATE A DIALOGUE REGARDING OBJECTIVES, PRIORITIES, RESOURCES, PERFORMANCE MEASURES, AND OTHER MATTERS THAT WE NEED TO WORK ON COOPERATIVELY.

SECOND, IN ADDITION TO IMPROVING COMMUNICATION IN ALL WE DO AS I JUST MENTIONED, ACHIEVING AND SUSTAINING HIGH PERFORMANCE AT GSA WILL REQUIRE DEVELOPING AN <u>INTIMATE WORKING RELATIONSHIP WITH EACH OF OUR KEY CUSTOMER-AGENCIES</u> SO THAT WE

CAN WORK WELL TOGETHER TO DEVELOP THE MOST EFFECTIVE AND EFFICIENT APPROACH TO SATISFY THEIR NEEDS.

THIRD, HIGH PERFORMANCE WILL REQUIRE GSA TO HAVE A VERY CLOSE WORKING RELATIONSHIP WITH OUR SUPPLIERS AND TO USE A "WIN-WIN" APPROACH TO DEVELOPING THE BEST VALUE PROPOSITION FOR OUR CUSTOMER-AGENCIES.

FOURTH, IT WILL REQUIRE DEVELOPING THE ORGANIZATIONAL CAPABILITY NECESSARY TO ACHIEVE OUR MISSION. THIS MEANS HAVING A HUMAN CAPITAL MANAGEMENT PROCESS:
FIRST, TO DETERMINE THE SKILLS AND COMPETENCIES NEEDED TO ACHIEVE OUR SPECIFIC GOALS FOR THE COMING YEARS.

SECOND, TO IDENTIFY THE GAP BETWEEN WHAT WE NEED FOR SUCCESS AND WHAT WE ACTUALLY HAVE IN PLACE.

AND THIRD, TO EXECUTE A STAFFING PLAN TO DEVELOP, TRAIN AND RECRUIT PEOPLE WITH THE SPECIFIC SKILLS

AND COMPETENCIES NECESSARY TO SUCCESSFULLY ACHIVE OUR GOALS.

MR. CHAIRMAN, THE LAST ITEM I WILL MENTION FOR ACHIEVING AND SUSTAINING HIGH PERFORMANCE AT GSA IS ANOTHER CRITICALLY IMPORTANT ONE.

IT IS THE NEED TO HAVE A STRONG PERFORMANCE MANAGEMENT PROCESS OPERATING THROUGHOUT THE AGENCY.

THE GUIDELINES IN THE GOVERNMENT PERFORMANCE AND RESULTS ACT, OR "GPRA," WILL BE THE FRAMEWORK FOR THIS.

OUR PERFORMANCE MANAGEMENT PROCESS WILL BE BUILT ON A FOUNDATION OF SHARED GSA VALUES AND MISSION ALONG WITH CLEARLY ARTICULATED GOALS AND PERFORMANCE EXPECTATIONS.

YOU CAN BE SURE THAT AMONG THE FUNDAMENTAL VALUES WILL BE INTEGRITY, CUSTOMER SERVICE AND ACCOUNTABILITY FOR RESULTS.

WE WILL WORK HARD TO SEE THAT EACH INDIVIDUAL ON THE GSA TEAM UNDERSTANDS HIS OR HER ROLE AND RESPONSIBILITY AND IS STRONGLY COMMITTED AND ALIGNED WITH EACH OTHER TO CREATE THE POWERFUL FORCE NECESSARY FOR HIGH PERFORMANCE AND THE SUCCESSFUL ACHIEVEMENT OF THE GSA MISSION.

WE WILL HAVE CLEAR PERFORMANCE EXPECTATIONS AND PERFORMANCE MEASURES SO THAT WE WILL BE ACCOUNTABLE FOR RESULTS.

WE WILL BE PROACTIVE IN TAKING CORRECTIVE ACTION AS NEEDED TO STAY ON COURSE.

FINALLY, THE PERFORMANCE MANAGEMENT PROCESS WILL PROVIDE FOR REWARDS AND RECOGNITION TO THE PEOPLE OF GSA FOR THEIR ACHIEVEMENTS.

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE, AS I SAID EARLIER, I KNOW THAT ACHIEVING AND SUSTAINING HIGH PERFORMANCE AND A CONTINUOUS IMPROVEMENT CULTURE AT GSA WILL BE A VERY BIG JOB.

I BELIEVE THAT I HAVE RELEVANT EXPERIENCES IN BUSINESS AND IN STATE GOVERNMENT WHICH WILL ENABLE ME TO BE A STRONG CONTRIBUTOR TO THE SUCCESS OF THE GSA TEAM IN ACHIEVING THE THINGS WE HAVE DISCUSSED HERE TODAY.

I WOULD BE AN HONOR AND PRIVILEGE FOR ME TO SERVE OUR COUNTRY IN THE CAPACITY OF ADMINISTRATOR OF GSA AND SO, I RESPECTFULLY ASK FOR YOUR SUPPORT OF MY NOMINATION.

THANK YOU.

**4/18/01**

# BIOGRAPHICAL AND FINANCIAL INFORMATION REQUESTED OF NOMINEES

## A. BIOGRAPHICAL INFORMATION

1. **Name:**
   Stephen Alexander Perry

2. **Position to which nominated:**
   Administrator – General Services Administration

3. **Date of Nomination:**
   April 4, 2001

4. **Address:**

---

5. **Date and place of birth:**
   Sept. 14, 1945
   Canton, Ohio

6. **Marital status:**
   Married to Sondra Diane Perry (her previous married name is Earley and her maiden name is Tucker)

7. **Names and ages of children:**

**A. BIOGRAPHICAL INFORMATION – Continued**
**Stephen Alexander Perry**

**8. Education:**

Timken Vocational High School;
September, 1959 – June, 1963

University of Akron;
September, 1963 - December, 1970
Bachelor of Science in Accounting

University of Michigan Graduate School of Business Administration;
May 9 – June 4, 1982
Certification – Executive Management

Stanford University;
August, 1983 – June 17, 1984
Master of Science in Management

**9. Employment record:**

The Timken Company
Canton, Ohio
February 10, 1964 – March 30, 2001
(Except Jan., 1991- March, 1993, when I served in the Cabinet of then Ohio Governor George V. Voinovich as the Director of the Department of Administrative Services)

The Timken Company, (www.timken.com), headquartered in Canton, Ohio, is a leading international manufacturer of highly engineered bearings and alloy steel for automotive, industrial machinery, railroad, aerospace, mining and other industries. The Timken Company is the world's largest manufacturer of tapered roller bearings and mechanical seamless steel tubing. Timken has more that 50 manufacturing plants and 100 sales, design and distribution centers in 25 countries. Annual sales are $2.7 Billion and the company has 21,000 associates.

**A. BIOGRAPHICAL INFORMATION – Continued**
**Stephen Alexander Perry**

| | |
|---|---|
| Jan., 1998 – March 30, 2001 | The Timken Company<br>Senior Vice President – Human Resources, Purchasing and Communications |
| March, 1993 – Jan., 1998 | The Timken Company<br>Vice President – Human Resources, Purchasing and Communications |
| Jan., 1991 – March, 1993 | State of Ohio<br>Director – Department of Administrative Services |
| Aug., 1989 – Jan., 1991 | The Timken Company<br>Director – Purchasing & Logistics |
| Nov., 1984 – Aug., 1989 | The Timken Company<br>Director – Accounting & Controller |
| May, 1984 – Nov., 1984 | The Timken Company<br>Asst. to Vice President - Finance |
| Aug. 1983 – May, 1984 | Stanford University<br>Sloan Fellow – graduate school student |
| Aug., 1977 – Aug., 1983 | The Timken Company<br>Manager – Tax Department |

**A. BIOGRAPHICAL INFORMATION – Continued**
**Stephen Alexander Perry**

| | |
|---|---|
| May, 1973 – Aug., 1977 | The Timken Company<br>Assistant Chief General Accountant |
| Sept., 1970 – May, 1973 | The Timken Company<br>Accountant |
| June, 1966 – Sept., 1970 | The Timken Company<br>Junior and Senior Accounting Clerk positions and Supervisor Sales Section – Gen. Acctg. Dept. |
| Feb. 10, 1964 – June, 1966 | The Timken Company<br>Stationery Stock Room Clerk |

**10. Government experience:**
1991 – 1992, Director – Ohio Department of Administrative Services. Then Governor George V. Voinovich appointed me to serve in this Cabinet level position. As head of this agency, with 1,300 employees and a $1.4 Billion annual budget, I was responsible for providing support and enabling services to all other state agencies. This included architectural, construction and maintenance services for public buildings; purchasing supplies and equipment; computer center operations and telecommunications services; personnel services; collective bargaining; equal employment opportunity and minority business development programs. My responsibilities also included having a key leadership role in several of the Governor's initiatives including, the Operations Improvement Task Force and Total Quality Management Practices to improve the effectiveness and efficiency of all state agencies and the Committee on Managing for the Future of Ohio's Higher Education System.

**A. BIOGRAPHICAL INFORMATION – Continued**
**Stephen Alexander Perry**

1993 – 2001, Ohio Board of Regents.
Then Governor George V. Voinovich appointed me to a nine –year term on this nine-member Board which is responsible for coordinating the operations of Ohio's institutions of higher education. This includes administering a $6 Billion biennial state budget and operations and curriculum review for all colleges and universities in the state.

2000 – State of Ohio Management Improvement Commission.
Governor Bob Taft appointed me to serve on this Commission which was responsible to achieve improvement in the efficiency of state agencies. The Commission provided oversight to the work of a consortium of public sector and private sector people with skills and experience in business management process improvement.

1970-1985 – Board of Trustees, Stark County District Library.
During my years on this Board we expanded the reading outreach program to students throughout Stark County, Ohio. Also my years included three terms as Chairman (1983-85) during the period when we secured funding and constructing a new library building in downtown Canton.

**11. Business relationships:**
Officer, The Timken Company (March, 1993 – March, 2001)

**A. BIOGRAPHICAL INFORMATION – Continued**
**Stephen Alexander Perry**

12. **Memberships:**

Current:
Trustee, National Professional Football Hall of Fame (1993 to present)
Member, Ohio Board of Regents (1993 to present)
Member, Stark County Community Foundation Distribution Committee (2000 to present)
Member, Omega Psi Phi Fraternity, Kappa Tau Chapter (1970 to present)

Former:
Director, Labor Policy Association (LPA) (1993 to March 30, 2001)
Member, Manufacturers Alliance for Productivity & Innovation (MAPI) (1993 to March 30, 2001)
Member, National Association of Manufacturers (NAM) (1999 to March 30, 2001)
Member, Greater Canton Chamber of Commerce and Chairman of 1999 Hall of Fame Festival
Member, United Way of Central Stark County and Chairman of Annual Fund Raising Campaign in 1996.
Trustee, Stark County District Library (1970 to 1985)
Trustee, Canton Urban League (1968 to 1983)
Trustee, Canton Scholarship Foundation (1980 to 1991)
Trustee, Timken Mercy Medical Center (1984 to 1991)
Trustee, Stark Development Board Finance Corporation
Trustee, Canton Art Institute
Director, Alumni Society Board of Governors, University of Michigan Graduate School of Business Administration (1983 to 1988)
Director, Walsh University Advisory Board (1987 to 1991)
Trustee, Catholic Community League (1970 to 1975)
United Negro College Fund Stark County Campaign Chairman in 1986

**A. BIOGRAPHICAL INFORMATION – Continued**
**Stephen Alexander Perry**

**13. Political affiliations and activities:**

Republican Precinct Committeeman – Jackson Township; Precinct 12 Stark County, Ohio.
Co-Chair - Stark County Voter Registration Drive
Co-Chair – Stark County for George Bush for President Rally (1988)
Member, Stark County Republican Central Committee
Member, Stark County Republican Executive Committee
Member, Stark County Republican "Early Bird" Contributors
Participant, George W. Bush for President Fund Raisers (2000)
Political Contributions:

2001 (Jan. 1 – April 9, 2001)

| | |
|---|---|
| Stark County Republican Party | $1,500.00 |
| The Timken Company Good Government Fund | 300.00 |

2000

| | |
|---|---|
| Stark County Republican Party | $1,500.00 |
| The Timken Company Good Government Fund | 1,200.00 |
| Ohio Republican Party - Victory 2000 | 1,000.00 |
| Ohio Republican Party – National Convention | 1,500.00 |
| Mike Dewine for U.S. Senate | 500.00 |
| Ralph Regula for Congress | 100.00 |
| Mary Cain for Ohio House | 250.00 |
| Chris Thomas for Stark County Recorder | 250.00 |
| Citizens for Kirk Schuring | 100.00 |
| Richard Regula for Treasurer | 100.00 |

1999

| | |
|---|---|
| Stark County Republican Party | $1,500.00 |
| The Timken Company Good Government Fund | 1,200.00 |

**A. BIOGRAPHICAL INFORMATION – Continued**
**Stephen Alexander Perry**

1998

| | |
|---|---|
| Stark County Republican Party | $1,500.00 |
| The Timken Company Good Government Fund | 1,200.00 |
| Bob Taft for Governor | 1,000.00 |
| Tom Moyer for Ohio Supreme Court | 300.00 |
| Kirk Schuring for Ohio House | 100.00 |
| Black America PAC | 100.00 |
| John Dougherty for Stark County Commissioner | 100.00 |

1997

| | |
|---|---|
| Stark County Republican Party | $1,500.00 |
| The Timken Company Good Government Fund | 1,200.00 |
| George Voinovich for U.S. Senate | 1,000.00 |
| Mike Dewine for U.S. Senate | 500.00 |

1996

| | |
|---|---|
| Stark County Republican Party | $1,500.00 |
| The Timken Company Good Government Fund | 1,200.00 |
| Ohio House Republican Campaign | 150.00 |
| PAC for Manufacturing Competitiveness | 150.00 |
| Stratton for Ohio Supreme Court | 150.00 |
| Ralph Regula for Congress | 50.00 |

**A. BIOGRAPHICAL INFORMATION – Continued**
**Stephen Alexander Perry**

**14. Honors and awards:**

1976 – Omega Psi Phi Fraternity, Outstanding Graduate Basileus Award
1977 - Canton Junior Chamber of Commerce (Jaycees) Distinguished Service Award
1983 – Sloan Fellow, Stanford University
1985 – Canton Young, Gifted and Black Foundation, Outstanding Community Service Award
1991 – Ohio Republican Council, Akron/Summit County Chapter, Person of the Year Award
1995 - Kent State University, President's Social Responsibility Award
1996 - Kent State University, Stark Campus Alumni Council, Distinguished Alumni Award
1999 - University of Akron, College of Business Alumni Association, Dr. Frank L. Simonetti Distinguished Business Alumnus Award
1999 – Timken High School, Alumni Association, Distinguished Alumni Award
2000 – Stark County Christian Hall of Fame, Man of the Year Award

**15. Published writings:**

None.

**16. Speeches:**

None.

**A. BIOGRAPHICAL INFORMATION – Continued**
**Stephen Alexander Perry**

**17. Selection:**

The work of the General Services Administration (GSA) is critical to the success of other government agencies as they strive to achieve their missions to deliver services which improve the quality of life of people in America and the around the world. As GSA continuously improves its efficiency and effectiveness in meeting the agencies' needs for workspace, procurement and security services, it enables those agencies to be more successful in delivering needed services to their constituents.

GSA is one of the Federal Government's most commercial organizations since many of its key activities are very similar to activities of private sector organizations. Therefore, GSA's successful operation will be enhanced by more rigorous application of best practices developed in high performance organizations of the private sector.

I believe that my extensive background in accounting, finance, purchasing, associate relations, performance management, continuous improvement and general management as developed and applied during my 37 year career at The Timken Company and during my 2 years as Director of the Ohio Department of Administrative Services agency provides me with excellent qualifications to successfully carry out the duties and responsibilities of Administrator of GSA.

## B. FUTURE EMPLOYMENT RELATIONSHIPS
**Stephen Alexander Perry**

1. **Will you sever all connections with your present employers, business firms, business associations or business organizations if you are confirmed by the Senate?**

   Yes.

2. **Do you have any plans, commitments or agreements to pursue outside employment, with or without compensation, during your service with the government? If so, explain.**

   No.

3. **Do you have any plans, commitments or agreements after completing government service to resume employment, affiliation or practice with your previous employer, business firm, association or organization?**

   No.

4. **Has anybody made a commitment to employ your services in any capacity after you leave government service?**

   No.

5. **If confirmed, do you expect to serve out your full term or until the next Presidential election, whichever is applicable?**

   Yes.

## C. POTENTIAL CONFLICTS OF INTEREST
**Stephen Alexander Perry**

1. **Describe all financial arrangements, deferred compensation agreements, and other continuing dealings with business associates, clients or customers.**

Pension Plan Payments –
I retired from The Timken Company as of March 30, 2001, accordingly I will receive monthly pension payments from the company's Pension Plan for Salaried Associates.

401(k) Plan Assets –
I am entitled to distributions from the 401(k) Savings and Investment Pension Plan to which I have made contributions over the years and which were partially matched by The Timken Company. Assets are currently invested in Timken Company common stock, however this could be transferred to other investment options or withdrawn.

Timken Company Common Stock –
I plan to continue to own stock in Timken Company which I have purchased over a period of years of my employment there.

Stock Options for Timken Company Common Stock –
I have stock options for future purchase of Timken Company Common Stock which were awarded to me over the years as part of my basic compensation.

Health Insurance Benefit Plan –
I have elected to enroll in The Timken Company's Health Benefit Continuation Plan and pay premiums for the standard health care coverage for retirees. This plan will also cover my spouse.

**C. POTENTIAL CONFLICTS OF INTEREST – Continued**
**Stephen Alexander Perry**

Indemnification Agreement –
I will continue to be covered under this agreement with The Timken Company which provides for my defense in the event legal action is taken against me for actions I was a party to when I was an officer of the company.

Death Benefit Agreement –
I will continue to be covered under this agreement with The Timken Company which provides for payment to be made to my spouse upon my death equal to 2 times my annual base salary in effect at the time of my retirement on March 30, 2001, increased to offset estimated U.S. Federal income taxes. This agreement is not life insurance and has no cash value.

**2. Indicate any investments, obligations, liabilities, or other relationships which could involve potential conflicts of interest in the position to which you have been nominated.**

I do not believe I have any investments, obligations, liabilities, or other relationships which could involve potential conflicts of interest, however, to avoid any conflicts of interest or even the appearance of a conflict of interest, my letter of April 2, 2001, to the GSA Ethics Official provides that:

1. Relating to my investment in Timken Company Common Stock –
   While The Timken Company does not currently do business with GSA, it does manufacture and sell bearings and steel component parts to automobile and other manufacturers which could be incorporated into vehicles and other items purchased by GSA. Therefore I would disqualify myself from participating in any GSA matters that have a direct and predictable effect on the financial interests of The Timken Company.

**C. POTENTIAL CONFLICTS OF INTEREST – Continued**
**Stephen Alexander Perry**

2. Relating to uncompensated outside positions, pending confirmation, I will resign from the Board of the Pro Football Hall of Fame, the Ohio Board of Regents, the Labor Policy Association (LPA) and the Stark County Community Foundation.

3. **Describe any business relationship, dealing or financial transaction which you have had during the last 10 years, whether for yourself, on behalf of a client, or acting as an agent, that could in any way constitute or result in a possible conflict of interest in the position to which you have been nominated.**

   None.

4. **Describe any activity during the past 10 years in which you have engaged for the purpose of directly or indirectly influencing the passage, defeat or modification of any legislation or affecting the administration and execution of law or public policy.**

   On several occasions I have written letters to or otherwise communicated with Federal and State lawmakers to inform them of my views on legislative or regulatory matters and to urge them to consider this view when taking action on the matter.

   I have participated in meetings of Trade Associations and deliberated on the positive and/or negative impact of legislative and regulatory matters. In these meetings I have informed other participants of my views on the matters and urged the Trade Association to inform the public as well as Federal and State lawmakers and regulators about the matter.

**C. POTENTIAL CONFLICTS OF INTEREST – Continued**
**Stephen Alexander Perry**

**5. Explain how you will resolve any potential conflict of interest, including any that may be disclosed by your responses to the above items. (Please provide copies of any trust or other agreements.)**

I do not believe I have any investments, obligations, liabilities, or other relationships which could involve potential conflicts of interest, however, to avoid any conflicts of interest or even the appearance of a conflict of interest, my letter of April 2, 2001, to the GSA Ethics Official provides that:

1. Relating to my investment in Timken Company Common Stock – While The Timken Company does not currently do business with GSA, it does manufacture and sell bearings and steel component parts to automobile and other manufacturers which could be incorporated into vehicles and other items purchased by GSA. Therefore I would disqualify myself from participating in any GSA matters that have a direct and predictable effect on the financial interests of The Timken Company.

2. Relating to uncompensated outside positions, pending confirmation, I will resign from the Board of the Pro Football Hall of Fame, the Ohio Board of Regents, the Labor Policy Association (LPA) and the Stark County Community Foundation.

**6. Do you agree to have written opinions provided to the Committee by the designated agency ethics officer of the agency to which you are nominated and by the Office of Government Ethics concerning potential conflicts of interest or any legal impediments to your serving in this position?**

Yes.

## D. LEGAL MATTERS
**Stephen Alexander Perry**

1. **Have you ever been disciplined or cited for a breach of ethics for unprofessional conduct by, or been the subject of a complaint to any court, administrative agency, professional association, disciplinary committee, or other professional group? If so, provide details.**

   No.

2. **Have you ever been investigated, arrested, charged or held by any federal, State or other law enforcement authority for violation of any federal, State, county or municipal law, regulation or ordinance, other than a minor traffic offense? If so, provide details.**

   No.

3. **Have you or any business of which you are or were an officer ever been involved as a party in interest in any administrative agency proceeding or civil litigation? If so, provide details.**

   From March, 1993 until March, 2001, I was an officer of The Timken Company. In 2000, The Timken Company participated in the U.S. International Trade Commission review of Anti-Dumping Orders on imports of tapered roller bearings from various foreign countries. The Timken Company had been a party to unfair trade (dumping) cases which it had brought against these countries. The Timken Company is routinely involved in minor administrative agency proceedings and civil litigation. I have never been named personally in any proceeding or litigation involving The Timken Company, nor have I ever personally been a party in interest to any such proceeding or litigation.

   From February, 1991 until February, 1993, I served as the Director of the Ohio Department of Administrative Services (DAS). This agency had responsibility for reviewing employment actions taken by the Directors of

**E. LEGAL MATTERS - Continued**
**Stephen Alexander Perry**

various State agencies. In my official capacity as Director of DAS, I was named along with various agency Directors and other State government officials as a defendant in several administrative proceedings and one law suit involving claims of wrongful discharge of State government civil service employees from various State agencies. The employee claims were dismissed.

4. **Have you ever been convicted (including pleas of guilty or *nolo contendere*) of any criminal violation other than a minor traffic offense?**

No.

5. **Please advise the Committee of any additional information, favorable or unfavorable, which you feel should be considered in connection with your nomination.**

I have always endeavored to conduct my business and personal activities in a completely legal manner and in a manner which is consistent with the highest standards of integrity and ethics. I pledge to continue this practice in the position of Administrator – GSA, if confirmed by the U. S. Senate.

## E. FINANCIAL DATA
## Stephen Alexander Perry

Financial Data maintained on file in Committee offices.

## AFFIDAVIT

**Stephen Alexander Perry being duly sworn, hereby states that he has read and signed the foregoing Statement of Biographical and Financial Information and that the information provided therein is, to the best of his knowledge, current, accurate and complete.**

**Subscribed and sworn before me this 18 day of April, 2001**

**Notary Public**

EMILY A. KLINK
Notary Public, State of Ohio
My Commission Expires May 20, 2003

**Pre-hearing Questionnaire for the Nomination of Stephen A. Perry to be Administrator, General Services Administration**

## I. Nomination Process and Conflicts of Interest

1. Why do you believe the President nominated you to serve as Administrator of the General Services Administration?

   **President Bush has expressed the need to maintain strong general management and leadership skills in positions such as Administrator of the General Services Administration in order to continuously improve the overall performance of government services for all Americans. I believe President Bush nominated me to serve in this position because I have extensive experience in senior general management positions for large, complex organizations which included several areas similar to the duties and responsibilities of this position.**

2. Were any conditions, expressed or implied, attached to your nomination? If so, please explain.

   **No.**

3. What specific background and experience affirmatively qualifies you to be Administrator of GSA? Please describe your background and experience in relation to GSA's various roles, which, as you know, include procurement, information technology, public buildings, and management of the agency.

   **From 1993 – 2001, I was an officer of The Timken Company with responsibility for worldwide human resources management, global purchasing and corporate communications. My career at The Timken Company began in 1964 as a Stock Clerk and concluded as a Senior Vice President with my retirement on March 30, 2001 after 37 years. During my career at Timken, I gained valuable experience in successfully managing and leading large groups of individuals in a complex organization. The Timken Company is a leading international manufacturer of highly engineered bearings and alloy steel. The company has more than 50 manufacturing plants and 100 sales, design and distribution centers in 25 countries. Annual sales are $2.7 Billion and the company has 21,000 employees. The background and experience I gained at Timken which are most similar to the duties and responsibilities of the Administrator of the General Services Administration include purchasing, internal and external communications, marketing communications, government relations and public affairs, finance and accounting, human resource recruitment, training and development, employee relations, union relations and compensation management.**

**From 1991 – 1992, I was Director of the Ohio Department of Administrative Services (DAS). Then Governor George V. Voinovich appointed me to serve in his Cabinet as head of this agency, with 1,300 employees and a $1.4 Billion annual budget. In this position, I gained valuable background and experience similar to the duties and responsibilities of the Administrator of the General Services Administration, because as head of DAS I was responsible providing administrative support and a variety of enabling services to all other state agencies to assist them in achieving their agency missions. My duties and responsibilities included providing workspace for all State employees through the DAS - Division of Public Works which provided architectural, construction and maintenance services for public buildings and leased space from private sector companies. DAS also included the Division of State Purchasing for procurement of supplies and equipment and services, the Division of Computer Services for the State computer center operations and procurement of computer systems and telecommunications services and the Division of State Personnel Services which included recruitment, training, collective bargaining and compensation management. DAS also had programs in the areas of equal employment opportunity and minority business development. My responsibilities also included having a key leadership role in several of the Governor's initiatives including, the Operations Improvement Task Force and Total Quality Management Practices to improve the effectiveness and efficiency of all state agencies and I served as Governor Voinovich's designee on the Committee on Managing for the Future of Ohio's Higher Education System.**

**I believe that my background in accounting, finance, purchasing, associate relations, performance management, continuous improvement and general management as developed and applied during my 37 year career at The Timken Company and during my 2 years as Director of the Ohio Department of Administrative Services agency provides me with the background, experience and qualifications necessary to successfully carry out the duties and responsibilities of Administrator of the General Services Administration.**

4. Have you made any commitments with respect to the policies and principles you will attempt to implement as Administrator of GSA? If so, what are they and to whom have the commitments been made?

**No.**

5. If confirmed, are there any issues from which you may have to recuse or disqualify yourself because of a conflict of interest or the appearance of a conflict of interest? If so, please explain what procedures you will use to carry out such a recusal or disqualification.

**I do not believe there are any issues which involve actual conflicts of interest, however, to avoid any potential conflicts of interest or even the appearance of a conflict of interest, my letter of April 2, 2001, to the GSA Ethics Official provides that:**

- **Relating to my former employer and my investment in Timken Company Common Stock – While The Timken Company does not currently do business with GSA, it does manufacture and sell bearings and steel component parts to automobile and other manufacturers which could be incorporated into vehicles and other items purchased by GSA. Therefore I would disqualify myself from participating in any GSA matters that have a direct and predictable effect on the financial interests of The Timken Company.**

- **Relating to uncompensated outside positions –**
  **Pending confirmation, I will resign from the Board of the Pro Football Hall of Fame, the Ohio Board of Regents, and the Stark County Community Foundation.**

## II. Roles and Responsibilities of the Administrator, General Services Administration

1. How would you describe the mission of the General Services Administration?

**The mission of the General Services Administration is to provide expert solutions in providing effective work space, products, services and security for federal employees and thereby enable them to accomplish their agency missions of public service.**

2. What do you consider to be the role and responsibilities of the Administrator, GSA?

**A primary role and responsibility of the Administrator of the General Services Administration is to ensure that there is a strong shared vision of the agency's values and mission and to develop the organizational capability necessary to successfully achieve GSA's short-term and longer-term goals and objectives. This includes having effective dialogue among all associates of GSA and effectively communicating performance goals and expectations throughout the organization to enhance the understanding and commitment to achieving the agency's mission, goals and objectives. It includes establishing the appropriate organizational structure and staffing plan and then identifying and bridging the gap between the skills and competencies necessary for success versus the current skills and competencies of employees. It also includes allocating resources, and rigorously applying a performance management process with appropriate measures, rewards and recognition to motivate high performance and continuous improvement and accountability.**

3. What do you propose are the major challenges facing the GSA, and how do you propose to address them?

**Among the major challenges facing GSA are items mentioned in the recent audit reports of the Government Accounting Office (GAO) and the GSA Inspector General. This includes the need for continued progress in incorporating the practices outlined in the Government Performance and Results Act of 1993 (GRPA) to achieve outcome-orientated goals in key program areas including achieving cost-effective procurement, addressing the backlog of repairs and alterations to federal buildings, maintaining adequate security and increasing the use of technology, including e-government initiatives, into government operations.**

4. What are your priorities for the agency?

**Successful accomplishment of the mission of the General Services Administration should be measured in term of the high level of continuous improvement in efficiency and effectiveness we achieve in meeting the needs of our customer agencies, thereby enabling them to successfully achieve their missions of public service. My priorities for GSA will be to: 1) help develop a shared understanding and commitment to the agency's values and mission outlined above and to have each GSA employee take the initiative necessary to achieve our short term and longer term goals and objectives; 2) to help develop the skills and competencies of each individual and the overall organization's capability as necessary to successfully accomplish our performance goals and objectives; and 3) achieve this while maximizing the career success of each GSA employee.**

## III. GSA Operations

1. In your view, how well has GSA fulfilled its mission and what is your vision for GSA's future? What objectives would like to achieve during your tenure?

**Much of what I have read and heard about GSA in recent weeks, indicates that the agency is making good progress toward fulfilling is mission. At the same time, the audit reports of the GAO, the GSA Inspector General and reports of GSA management indicate areas where there is certainly room for more improvement. If I am confirmed by the U.S. Senate to serve as Administrator of the General Services Administration, I will work with the team at GSA to achieve the successful implementation of the needed improvements called for in the GAO, IG and GSA management reports mentioned above and those outlined in the Government Performance and Results Act of 1993 (GPRA). In addition, I will work to achieve an understanding of our mission throughout the agency as well as a strong commitment by all GSA employees to take the steps necessary to achieve it.**

2. How will you incorporate results management into your day-to-day leadership of the agency?

**Managing for results requires a comprehensive and coordinated performance management process which motivates every member of the team to execute their role in an efficient and effective manner. The success of the performance management process depends upon building a strong foundation with a clear articulation and dialogue about the agency's values, mission, goals and objectives. This dialogue among employees throughout the organization is critical to achieving the necessary understanding and commitment that is necessary to cause GSA employees to fully exert their talents and energies as necessary to achieve the goals and objectives of the agency. Managing for results also requires rigorous measurement of performance and appropriate reward and recognition for achievement as well as the willingness to take the corrective action needed when results are not being achieved. The critical few measurements for each area should be identified and tracked by the responsible people in each area daily, weekly, monthly, quarterly or as necessary to provide an early warning signal as to whether we are on target to achieve expected results.**

3. In recent years, GSA has made a commitment to reorganization and reinvention, separating its policy and oversight responsibilities from its service delivery operations. What is your opinion of the progress GSA has made, and how will you see to it that GSA continues this effort?

**I have not yet been able to observe the progress GSA has made on separating its policy and oversight responsibilities from its service delivery operations. This must be achieved in a manner which does not distract the organization from achieving the service delivery expectations of our customer agencies.**

4. A number GAO reports have highlighted the need for agencies to expend more resources on effective training and professional development programs to better equip federal employees for the workplace of the future. Based on your experience, what priority would you place on workplace development, and how would you emphasize the continuous learning in your agency?

**Based on my experience, I would definitely place a very high priority on developing the talents, skills and competencies of people in the organization and recruiting people with skills we need from outside the organization. There is no other way to improve our organizational capability to the level necessary for successful achievement of our mission, goals and objectives. Without the necessary talent, skills and competencies, we can't succeed. It is important to note that while the organization should facilitate this employee development process as needed for organizational success, each individual must also take responsibility for his or her own development as needed for personal career success.**

**Senator George Voinovich, Representative Tom Davis and others on Senate and House committees have expressed concern about the progress agencies are making in the education, training and succession planning for the federal workforce. One example of how the issue is relevant to GSA is in the procurement area. In 1996 the Clinger-Cohen Act required the Office of Federal Procurement Policy (OFPP) to establish standards for college level educational achievement and ongoing training guidelines for the acquisition workforce in civilian agencies, such as GSA, similar to those previously established for the Department of Defense acquisition workforce. Of GSA's nearly 2,700 contracting officers, only 31% have college degrees. GSA is in the process of establishing an office to ensure that appropriate education and training levels are achieved to improve the capability of GSA's acquisition workforce. Another example of how this issue is relevant to GSA is in the technology area. While GSA appears to have a good track record in the education level and ongoing training of Information Technology (IT) professionals, the current high demand for highly skilled IT workers is putting pressure on GSA's ability to attract and retain the talent needed in this area to develop and maintain the technology-based systems for government operations of the future. GSA must take**

**steps to enhance the nature of the career opportunity and quality of work life as necessary to improve recruitment and retention given the extraordinary market for IT skills.**

5. An agency needs senior leaders who are drivers of continuous improvement in order to become a high-performance organization. What do you feel is the best approach for motivating career employees, or any employees for that matter, to achieve excellence?

**I believe that a great part of what motivates employees to achieve high performance and continuous improvement is the degree to which they are personally committed and aligned with the values, mission, goals and objectives of the organization. This commitment and alignment is to be generated in the performance management process. This process includes a clear articulation of and dialogue about the organizational values, mission, goals and objectives which provides the opportunity for clarification, debate and buy-in by individuals. This builds the foundation for understanding, agreement, internalization, commitment and alignment. This is a strong driver of high performance and the extra intellectual and physical effort necessary to go beyond the minimum requirements of the job to continuous improvement. The overall performance management process includes sub-processes for the development of strategies, business plans, individual performance expectations, effective communication, teamwork, performance measurement and corrective action. In addition to these motivators for organizational success, high performance and continuous improvement is also driven by motivators for personal success or the reward and recognition process.**

6. Concerns have been raised that changes in how agencies achieve their mission objectives and that downsizing through attrition and voluntary separations have left some agencies with gaps in necessary skills and many workers who are eligible to retire in the next few years. In fact, human capital management is on GAO's "high risk" list as a major challenge facing the government. How do you envision GSA addressing this issue?

**This is to some extent covered in my answer to item III, 4 above. Senator Voinovich's hearings and articles regarding "The Crisis in Human Capital," call attention to the fact the organizational capability of many government agencies could be adversely affected by continued attrition and inadequate ability to recruit people with the skills and competencies needed. This is relevant to GSA where nearly half the employees will be eligible to retire in the next five years. Human capital management is a critically important at GSA, including recruitment, retention, training, maintaining a positive and productive work environment and competitive compensation, reward and recognition for high performance.**

7. The Governmental Affairs Committee is committed to ensuring the use of performance-based management in federal agencies. For performance-based management to be truly effective, the organization must adopt a culture that uses these management principles for day-to-day decision making rather than simply complying with annual reporting requirement. Some agencies have been more successful at accomplishing this cultural change than others. Do you believe GSA currently uses performance management to accomplish its mission? What changes, if any, do you believe are necessary to improve results through better use of performance management?

**I am a strong proponent of performance-based management. This approach is essential to achieving a high performance organization and a continuous improvement culture. I have not been able to observe whether GSA is currently being successful in using performance-based management to accomplish its mission. However, the June 2000, audit report by the GAO was somewhat critical of GSA's efforts in this area. The report indicated that GSA had less than optimal results because the data used to evaluate performance was unreliable and some of the performance measures selected were not good indicators of key performance areas of interest to customer agencies. GSA's approach should be reviewed for improvement in light of these findings.**

8. GAO and the GSA IG have identified longstanding management problems that hamper GSA's ability to accomplish its mission. In its analysis of GSA's FY 1999 Performance Report, GAO wrote that GSA had only "limited discussion of major management challenges." Some in Congress have insisted that agencies set concrete goals for solving many of these problems, especially when they hamper an agency's ability to accomplish its mission. Others believe that agencies can also develop and report on plans to address these concerns through alternative means. What will you do to motive GSA to address some of its longstanding management problems? How will you report to Congress on GSA's progress in addressing its major management challenges?

**The "major management challenges" must be understood in terms of how their resolution will contribute to achieving the values, mission, goals and objectives of GSA. An organization which is strongly aligned with and committed to its shared values, mission, goals and objectives will be motivated to resolve any impediment to their achievement. Since these items are "major management challenges," it may take an extended period of time to resolve them fully. Consequently, a comprehensive plan should be developed showing what is to be done, by whom and by when. The achievement of milestones should be closely monitored so that we can hold ourselves accountable for making progress as planned. This same plan and monitoring used for management purposes would serve as the basis for reporting progress to Congress.**

## IV. Information Technology

1. What steps do you plan to take to focus management attention on important IT issues, such as electronic government? What do you see as the goals of a digital government? How would you help bring them about?

   **The internet and electronic technology is revolutionizing the way work is done. The concept of e-government brings enormous opportunity for improving speed and efficiency of transactions and creating new business models to provide value for customer agencies to enable them to achieve their missions of service to citizens. The several councils within GSA and other agencies which have expertise in this area should conduct a coordinated review to develop a strategy and implementation plan for this area.**

2. Last year, GSA in concert with other agencies, launched a single federal web site, or portal, known as firstgov.gov. The site provides access to a range of federal services and information. How do you intend to improve the current version?

   **This single portal to make access to individual federal government agency web sites easier and more customer-friendly makes sense. I have not developed any pre-conceived notions for changing the current version, but certainly this single portal site should be reviewed from time to time to ensure that it does not become hard for users to navigate or slow.**

3. The Committee on Governmental Affairs has made governmentwide information technology security a priority agenda item. Currently, GSA works with civilian agencies in providing information technology security services and alerts. Given the importance of protecting federal systems from internal and external threats, how will you go about determining if GSA is meeting civilian agency needs? What changes, if any, would you make to the way GSA has approached information security?

   **Information technology security must continue to be a priority agenda item. The use of up-to-date electronic technology for detection and prevention of unauthorized attempts to gain access to information and physical security of information assets is essential. Employee training on security procedures and compliance reviews should be conducted regularly. Preventative and corrective actions should be taken as required. It is my understanding that GSA's Federal Technology Service is charged with assisting federal agencies in meeting the security challenges of an open systems environment. The National Plan for Information Systems Protection identifies the Assistant Commissioner for Information Assurance and Critical Infrastructure Protection, Federal Technology Service, as the Executive Agent for the Federal Sector, responsible for assisting Federal Departments and Agencies in the**

**implementation of best practices for information assurance across the Federal Government. In this role, the Office of Information Assurance and Critical Infrastructure Protection oversees a national level effort designed to make the Federal Government a model for information security and critical infrastructure protection. The effectiveness of this approach should be reviewed from time to time to determine if there are opportunities for improvement.**

4. In 1999, GAO reported that both the Federal Supply Service and Federal Technology Service officials cited the inability to recruit and retain top-level staff as a barrier to operating in a business-like manner. What will you do to ensure that GSA has the staff it needs to accomplish its mission effectively?

**Recruitment and retention of people with the needed skills and competencies will be maximized only if GSA is perceived as a "great place to work." The ingredients necessary to create and sustain this perception include having a positive and productive work environment, interesting and challenging work, career development opportunities and adequate reward and recognition. It also requires effective marketing communication about the opportunities at GSA and aggressive recruitment and periodic re-recruitment of current staff. Winning the "war for talent" is a daunting task today for both public and private organizations. The best results will come from having a well-defined business plan goals and objectives which is used to develop an organizational capability development plan which, in turn, yields a detailed staffing (development and recruitment) plan to be executed and continually updated.**

5. Federal agencies, like the private sector, are increasingly using the Internet to deliver programs and services. Congress, the Administration, and the public increasingly expect government to provide services similarly to the best run private sector companies. GSA is playing an active role in promoting E-government through several functions: The Office of E-government in particular works with Federal agencies, OMB, and others to identify opportunities for common policy and shared responsibility for addressing government-wide issues in electronic commerce; promotes electronic access and interaction between Federal agencies (both civilian and military) and citizens, businesses, and institutions, as well as foreign and State and local governments; and promotes electronic acquisition.

   a. What are the primary benefits you see for the American people for e-government?

   **As I mentioned in response to question IV, 1 above, the Internet and electronic technology is revolutionizing the way work is done. The concept of e-government brings enormous opportunity for improving speed and efficiency of transactions and creating new business models to provide value**

**for customer agencies and thereby enhance their ability to achieve their missions of service to citizens.**

b. What do you believe are the primary obstacles to moving e-government forward both for GSA and government-wide?

**Certainly one of the obstacles to be dealt with is having the people with the necessary skills and competencies in this rapidly changing technical area. Another obstacle to be avoided will be the temptation to try to design and install e-government in one big step. I believe it will be prudent to develop an approach which builds on the progress of past efforts and implements the changes in phases rather than attempting to design and implement a complete e-government process all at once. A phased approach will be more manageable and more affordable.**

6. E-government promises to create a more cost effective and efficient government with programs and services accessible to citizens based on their interests, rather than those of individual agencies. However, thus far, progress towards e-government at the federal level has been uneven. There is a perceived lack of coordinated leadership which has led many to support the idea of a Federal CIO in the Office of Management and Budget. Given GSA's ongoing work in this area, how would you envision GSA working with a Federal CIO to enhance e-government?

**Successful implementation and use of an initiative as far-reaching and highly technical as e-government will require coordinated leadership across many federal agencies which have expertise and responsibilities in this area. Coordinated leadership may very well be affected by the organizational structure used. I will welcome the opportunity to work with my Administration colleagues and the Congress to fashion an organizational structure for effective coordination for planning execution and accountability for results.**

7. Firstgov.gov is the one-stop web portal designed to provide citizens access to government information. FirstGov is a joint project of the federal government and the private FedSearch Foundation, which oversees the search engine that powers the site. The site enables citizens to search the full text of millions of government Web pages and is the first step towards a central portal for citizens to access government programs and services irrespective of which agency is involved. At the same time, efforts to create partnerships with the private sector have been limited.

a. What concerns have been expressed by the private sector regarding Firstgov.gov? Do you agree with these concerns and, if so, would you work to address them?

**Providing the myriad of services necessary to design and operate this site would be of great interest to private sector firms in this business area. GSA should explore opportunities to involve additional firms in public/private partnerships of other contract relationships.**

b. What are the strengths and weaknesses of FirstGov as a government-wide portal and single point of access for the American people?

**Providing easy access to federal department and agency web sites is very desirable for enhancing the efficiency and effectiveness of the government's requirement to provide valuable information and services to constituents.**
**Potential weaknesses, such as overloading sites with non-value content and failing to keep the site easy to access and navigate will be minimized by frequent assessments of customer satisfaction and ongoing updates to keep the sites current and relevant.**

c. Has the effectiveness of FirstGov.gov been limited by the current process of "passing the hat" among agencies to fund the project?

**I have not yet reviewed all the details of the current process for funding FirstGov.gov or planned changes to that process. Given the importance of this item, an appropriate funding process should be selected.**

8. GSA's Office of Intergovernmental Solutions is also working to promote e-government. The office has started what appear to be several initiatives designed to facilitate increased cooperation between federal, state, local, and county governments on e-government projects. These include the "Government Without Boundaries" project; Pi2 - to build "communities of practice" among officials across government; and an Inventory of online initiatives in the Federal government.

a. Please describe how these initiatives relate to the work being done in GSA's Office of E-Government.

b. What are the funding requirements necessary, if any, to effectively promote the kind of cross-government collaboration envisioned by these projects?

c. How can the Administration and Congress best provide support for these initiatives?

**My response to item IV, 8 - a, b and c above is limited because I have not yet reviewed all the details of the e-government initiatives of GSA's Office of Intergovernmental Solutions or GSA's Office of e-government. Coordinating the work of these groups and facilitating increased cooperation between federal, state and local governments on e-government initiatives appears to be the right approach. To determine how to best support the e-government initiative, the Administration and Congress should review and approve a comprehensive plan which outlines the major phases of development and implementation steps to be taken and the time schedule for completion.**

9. As early as August 1999, GSA reported on the emerging trend of "integrated service delivery" as governments at the state, local, and international level were beginning to reorganize themselves to provide multiple online transactions and services via a single "portal" or interface. GSA reviewed sites of governments around the world and found that many governments are restructuring processes before integrating services and providing them online.

a. What will be the likely long term effects of this trend on government organizations, structure, and functions?

b. What steps should our government take to best prepare for these changes?

**Integrated service delivery by governments at federal, state and local levels may be a useful way of improving efficiency and effectiveness and should be evaluated.**

10. In 1999, GSA apparently decided to discontinue the Information Technology Innovation Fund (ITIF). While some outstanding projects are continuing, no new monies are being collected or obligated from this account. This fund was created in FY1995 using management savings from the FTS 2000 long distance telecommunications program. It provided approximately $5.2 million annually in seed money for innovative IT projects designed to provide more efficient and effective delivery of service to the public and multiple agencies. Projects were expected to be self-sufficient within two years and to provide future reimbursement to the Fund where feasible. Even though this fund is now inactive, there continues to be a need to fund the kind of cross-agency IT initiatives that can increase efficiencies and reduce operating costs for agencies.

a. What are some of the key lessons from GSA's administration of the ITIF?

**The Innovation Fund is not a separate revolving fund, but only an account within the Information Technology Fund, which supports FTS' government-wide telecommunications and information technology activities. The Innovation Fund was funded by the rates in the long distance telecommunications program (FTS 2000), which was a mandatory source by statute. When the Innovation Fund was conceived, the Interagency Management Council (IMC) and GSA agreed to use a portion of the FTS 2000 rates as the funding source since all agencies were benefiting from the mandatory FTS2000 program. Now the FTS programs are competitive sources and their rates cannot support an additional cost for innovative cross-agency IT projects. Thus, the small remaining balance in the Innovation Fund has been set aside to support the already approved projects. Currently, GSA's Innovation Fund is not active.**

b. What current processes and sources of funding does GSA have in place to support innovative IT initiatives with cross-agency impact? How much is available and what is the mechanism for selecting and monitoring projects?

**In recent years, funding for interagency e-government initiatives has been obtained by soliciting support from agencies involved in the interagency councils. Approximately $16 million will be collected from agencies in fiscal year 2001 to support the activities of the CIO Council, the CFO Council and the Procurement Executives Council (PEC). In addition, Congress appropriated $2 million in fiscal year 2001 for e-government.**

c. Do you believe the absence of a centralized IT fund hinders the federal government's efforts to move forward with E-government?

**Even with the absence of a centralized IT Fund, funding for e-government initiatives seems to be forthcoming. President Bush's budget proposes $20 million in 2002, and the funding will grow to a total of $100 million over three years to support interagency e-government initiatives.**

## V. Procurement

1. What steps will you take to ensure that GSA provides procurement services to customer agencies which will help them successfully accomplish their mission goals? What steps will you take to be responsive to the diverse needs of customer agencies?

   **Providing excellent procurement services to customer agencies is a core competency of GSA and accordingly must be given a high priority to continue to receive the resources and training necessary. It appears that GSA has taken steps to be "customer-centric" and has established performance expectations and goals to provide customer satisfaction. This approach should be continued and enhanced as needed to assure that GSA is responsive to the diverse need of customer agencies.**

2. What changes, if any, would you make to the way GSA has approached procurement reform?

   **President Bush's Administration, through the OMB, Office of Federal Procurement Policy has indicated the need to make further improvement in the federal procurement process. Additionally, the Federal Acquisition Streamlining Act of 1994 specifies fundamental changes to be made to the government's procurement process. I would plan to work with my colleagues to develop and implement these required changes to improve efficiency, effectiveness and value to our customer agencies.**

3. President Bush's budget blueprint encourages agencies to use technology to reduce the cost of buying products. In other words he supports the expanded use of an electronic contracting process. How will GSA help agencies move to this paperless contracting process?

   **One good example of this is *e-buy*, a paperless electronic procurement program which is a component of the GSA *Advantage!* program. This initiative expands electronic contracting with cost-effective and time saving on-line purchasing by agencies.**

4. Last year's National Defense Authorization bill contained a requirement for GAO to convene a panel of experts to review the OMB Circular A-76 process which governs public-private competitions when the government wants to outsource a function. GAO has formed the "Commercial Activities Panel" to carry out this mandate. In addition, OMB Director Daniels has ordered a more short-term review of the process.

   a. What are your views on the A-76 process?
   b. How involved do you plan to be in the various reviews that are ongoing?

**President Bush's Administration, through the OMB memorandum of March 9, 2001, has indicated the desire to increase public-private competition to explore opportunities for outsourcing activities now performed by federal agencies. The memo directed that by September 30, 2002, all agencies are to complete competitions or direct conversions of at least five percent of their Full Time Equivalents (FTE's) performing Commercial Activities, as identified on the agencies' Federal Activities Inventory Reform Act (FAIR Act) inventories. Five percent of GSA's FAIR Act Inventory is 367 FTE's. The memorandum also restated President Bush's commitment to have public-private competition for at least fifty percent of agency FTE's. Fifty percent of GSA's 2000 FAIR Act Inventory is 3,669 FTE's. OMB has reported that the Circular A-76 process has successfully yielded cost reduction and value improvements in the past and should be re-invigorated. GSA will need to quickly develop an action plan and a time schedule to meet the requirements of this directive.**

5. GSA's Federal Technology Service and Federal Supply Service are being positioned to increase their share of the federal market in providing products and services. How will you ensure that these organizations are positioned to fully leverage the government's vast buying power? How will you ensure that these organizations have improved efficiency through identifying opportunities for shared services (e.g., personnel, contracting) while eliminating any redundant services? How will you ensure that these organizations are not competing with private industry?

**The combined purchasing volumes of the Federal Supply Service and the Federal Technology Service present an opportunity to take advantage of massive economies of scale. Moreover, aggregate technology purchases by GSA are likely to grow as the demand for IT products and services continues to increase. At this point, I have not yet reviewed these matters to the extent necessary to have developed a specific plan of action. However, I recognize the importance of this issue. If confirmed, this certainly will be a high priority area for me.**

6. Recent years have seen an explosion of government-wide and inter-agency contract vehicles. Some firms in the vendor community have expressed concern about the proliferation of such vehicles. They are concerned that these vehicles are becoming uneconomical because too little business is spread over too many contracts. Do you believe that GSA should play a role in responding to these concerns, and how would you conceive that role?

**At this point, I have not yet reviewed these matters to the extent necessary to have developed a specific plan of action.**

7. GSA charges federal agencies fees for using their interagency contracts. We understand that there may be variation in the fees being charged for similar services. We also are concerned that the fees being generated may substantially exceed the actual costs; and circumvent congressional oversight and control. Could you explain how these fees are being established to ensure that they recover the actual costs for managing and administering the multi-agency contracts?

**At this point, I have not yet reviewed these matters to the extent necessary to have developed a specific plan of action. I am aware that the he General Accounting Office, at the request of this committee, is evaluating the fees being charged on multi-agency contracts to determine if the fees are being established to recover the actual costs for managing and administering the contracts. If confirmed, I will review the GAO's findings and, if necessary, take appropriate action to ensure that GSA's policies and practices conform to the letter and spirit of the law.**

8. With a significant portion of GSA's acquisition workforce eligible to retire in the next few years, GSA must begin initiatives to recruit, develop, and retain its future acquisition workforce. After a decade of consecutive years of downsizing, we face serious imbalances in the skills and experience of our acquisition workforce. How will you respond to this challenge?

**I recognize the importance of this issue, including the fact that 44% of GSA's acquisition workforce will be eligible to retire in 2005. At this point, I have not yet reviewed these matters to the extent necessary to have developed a specific plan of action. As I mentioned in my response to item III, 4- I would definitely place a very high priority on developing the talents, skills and competencies of people in the organization and recruiting people with skills we need from outside the organization. There is no other way to improve our organizational capability to the level necessary for successful achievement of our mission, goals and objectives.**

9. The Clinger-Cohen Act of 1996 authorized two pilot programs for share-in-savings contracts for information technology solutions. With these contracts, a contractor pays the up front costs of implementing a new system and is paid out of any resulting savings. The risk to the government is low, but the benefits can be great. To date, the Clinger-Cohen authority has not been used, although GSA recently worked with the Department of Education to award an IT share-in-savings contract to update its Student Financial Assistance systems. Do you support increased use of IT share-in-savings contracts within GSA and throughout government? If so, what steps would you recommend to promote their use?

**I recognize the importance of this issue. At this point, I have not yet reviewed these matters to the extent necessary to have developed a specific plan of action. If confirmed, this certainly will be a high priority area for me.**

10. The federal government has increased its use of reverse auctions. Under these procedures, vendors bid online to offer the lowest price to sell their goods or services to the government.

a. The concept of reverse auctions is relatively new in government purchasing. What are the strengths and weaknesses of using this type of purchasing procedure?

b. There are currently no regulations that would provide consistency in reverse auction procedures among the agencies. Do you believe there should be?

c. To your knowledge, are small business participating in these auctions? Why or why not?

**Reverse auctions can be a very useful tool for improving the value of purchases for federal agencies and broadening the number of suppliers which have an opportunity to participate in federal contracts. These electronic on-line sessions to some extent represent an automation of the existing process. The same good procurement rules and practices which are used in conventional RFP and bidding procedures should continue to apply to this automated approach. Consequently, I would not expect current regulation to require significant conceptual revision. Training for suppliers will ensure that large and small business will enhance their opportunity to participate.**

11. GSA is advertising the availability of its multiple award schedules (listing multiple qualified vendors available for contracts with the government) on the sides of buses and in subway stations and commercial radio advertisements? Do you believe this is the most effective way to promote the use of these schedules?

**For marketing communication to be most effective, it should be channeled through the various mediums which will enable the message to reach the targeted audience with the frequency and content necessary to cause the desired reaction. Periodic reviews and surveys of users of the multiple award schedules will provide the facts to be analyzed to help determine if the approach mentioned above is effective or should be modified.**

## VI. Public Buildings

1. GSA's Public Buildings Service (PBS) is the largest real estate organization in the nation. With resources of about $6 billion a year, PBS constructs, leases, manages, maintains, and protects various types of federal property assets. Are there innovative real estate management approaches used in the private sector that you would like to see PBS use?

   **There are opportunities to expand the use of public/private partnerships in developing leased space for federal offices.**

2. The Public Buildings Service is currently faced with aging and deteriorating buildings and various obstacles that impede effective real property management and disposal. How do you plan to address these challenges?

   **Accurate data regarding the highest priority and a time schedule for completing repair and alteration work should be developed for review, approval and execution. Hopefully, this will be facilitated by GSA's newly developed, web-based building assessment system that is to provide information on the condition of all federal buildings including information for necessary to quantify the impact of repair and alteration investments for purposes of prioritization decision-making. Legislation (i.e., S. 2805 & H.R. 3285) has been proposed that would provide some additional funding and authorize use of public/private partnerships to renovate and modernize federal buildings.**

3. GSA must make a concerted effort to enhance the level of security for federal employees and federal buildings. With respect to this critical issue:

   a. What are the primary obstacles that must be overcome to improve security?

   **GAO and GSA Inspector General audits indicate that security operations have traditionally been hampered by the inconsistencies which flowed from the lack of direct line authority for the Federal Protective Service (FPS), inadequate number of security guards, inadequate training and the need to enhance pay and benefits to attract and retain required personnel.**

   b. What indicators are there in GSA's budget, strategic plans, or performance plans that this issue will be a priority for you and the Administration?

**In November, 2000, the GSA Administrator address one of the obstacles listed above by establishing direct line authority for all Regional Divisions of the FPS to report to the FPS Assistant Commissioner within PBS at the Central Office. Another obstacle is at least partially addressed as $1.2 Billion has been spent on building security since 1995, and the number of security guards has been nearly doubled to approximately 7,000. GSA has designated improving security as one of the "Big Nine" top performance measures for the Agency.**

c. Do you have any prior experience with respect to employee and building security issues?

**My responsibilities at The Timken Company included providing security for office buildings, manufacturing plants and assets through the use of our in-house security personnel and closed circuit TV and other monitoring devices.**

4. Last year Senator Lieberman and I introduced, by request, S. 2805, a bill to reform the way the government manages its federal property assets. As you know, the Federal Property and Administrative Services Act has not been overhauled since its passage in 1949. Will you work with this Committee to find ways to improve federal property asset management? Does the Administration plan to request that Senators Thompson and Lieberman introduce this legislation this year? If so, will the Administration work to resolve concerns expressed by some advocates for the homeless, as the Clinton Administration indicated it would do?

**Yes. The Federal Property and Administrative Services Act of 1949, the major law overseeing Federal assets, is over 50 years old and has never been significantly revised. Additionally, Act focuses on disposal as opposed a total asset management approach that considers the entire life cycle of property. If confirmed, I would certainly work with Senators Thompson and Lieberman and other members of Congress on improving the process for federal property asset management.**

5. GSA in past years has promulgated "Emergency Electricity Reduction Measures" or "Tactical Curtailment Plans" aimed at responding to national and regional energy shortages resulting from extreme summer temperatures and electricity supply shortages.

a. Given the extreme drought conditions in the Western United States and known supply problems in California and the West and potentially New York City, what are GSA's plans for curtailing federal energy demand for this summer, nationally and by region?

**At the present time, GSA is pursuing efforts to reduce energy consumption in all federal property. On May 3, President Bush instructed all federal agencies to reduce their peak hour electricity use in the state of California. In compliance with this directive, GSA will increase its energy conservation efforts by adding actions such as turning thermostats to 78 degrees, stopping escalators, and turning off non-essential electric lights. These and other energy saving measures must also be considered for other regions of the Nation.**

b. As Administrator, what will you do to make sure that the Federal Government is responsive to energy shortages during the summer or whenever, they occur?)

**To be responsive to energy shortages, we must become even more proactive in energy conservation by investing in energy efficient technologies and by use of appropriate procedures for heating, cooling and lighting federal facilities. From what I have read, GSA appears to be making good progress in the energy conservation effort. For example, GSA reports that from 1985 to 2000, energy consumption was reduced by 20% by use of efficient technologies and procedures. In addition, GSA is actively promoting the "Energy Star" label program to focus attention and stimulate results in this area.**

c. Since supply problems in major regions of the country, such as California, are expected to persist for several years, what is GSA doing to accelerate energy efficiency investments at Federal facilities in those regions where energy supplies are forecasted to be tight? And what are you prepared to do, as GSA Administrator, to try to accelerate federal conservation and demand management investments in these most challenged areas?

**If I am confirmed as Administrator of General Services, I will work with federal, state, and local officials to promote and implement strategic energy management solutions that ensure that energy consumption is further reduced.**

6. Executive Order 13123, promulgated in 1999, requires Federal agencies to reduce energy consumption in their facilities by 30% by 2005 and by 35% by 2010 against a baseline of 1985 levels. Additional goals are provided for industrial and laboratory facilities. GSA, as stated in its "Implementation Plan" for Executive Order 13123, is the Government's largest landlord.

   a. How much of the planned reductions has GSA already achieved, and will GSA meet the goals set out in the Executive Order and its Implementation Plan?

   b. What are your views about the goals in Executive Order 13123, such as the promotion of energy savings products and designs, reduction in greenhouse gases, and water conservation efforts?

**My response to item VI, 6 – a and b is somewhat limited because I have not yet reviewed all the details of GSA's work in this area, however, I know that energy conservation in buildings is a very important issue, not only for GSA and federal buildings, but for the entire Nation's public and private facilities. Recent energy shortages in California illustrate the fact that more progress needs to be made in this area. President Bush has made Energy Policy a priority for his Administration. Having recently worked in the Steel Industry, a high volume consumer of energy, I know how vital energy conservation is to our Nation's economy and the resulting quality of life for individuals. GSA will continue to have a significant role to play in achieving the energy conservation goals outlined in Executive Order 13123 and the additional requirements anticipated from President Bush's energy conservation expectations.**

## VII. Background and Experience

1. In 2000, you served as a member of the State of Ohio Management Improvement Commission. Last November, that panel issued 163 recommendations to make improvements in customer service and cost savings for state agencies. The American Federation of State, County and Municipal Employees (AFSCME) raised concerns about not being consulted as the recommendations were being developed, and that certain recommendations could negatively impact worker compensation, according to a press release issued by AFSCME (attached).

   a. What is your response to these concerns?

**The leadership of AFSCME in Ohio has an interest in improving customer services and cost savings for state agencies. Consequently, I believe they should be a participant in such studies and in the implementation of recommendations to enhance the agency's ability to achieve its mission of service to citizens while meeting the needs of the agency's employees to the greatest extent it can.**

   b. What will be your approach to labor/management relations if you are confirmed to head the General Services Administration?

**My approach to labor/management relations will be one which embodies understanding and respect of the role and responsibilities of the parties and a recognition that working together cooperatively is essential.**

   c. Describe your experience with organizations representing workers in your role as Director of the Ohio Department of Administrative Services as well as your work as senior vice president for the Timken Company.

**As Director of the Ohio Department of Administrative Services, I worked cooperatively with organizations representing State employees, including AFSCME, UFCW and FOP. I believe we accomplished a great deal to maintain a positive and productive work environment and to enhance the quality, timeliness, efficiency and effectiveness of service provided to agency customers. For example, I worked closely with Paul Goldberg, Ron Alexander and other leaders of AFSCME to go beyond the regular work of contract negotiation and contract administration to develop a collaborative approach. This included discussion of how we might refine and implement many of the Operations Improvement Task Force recommendations for improving operations and restructuring as necessary to achieve the dual goals of accomplishing quality work for the people of Ohio while maximizing the career success of employees. Similarly, at The Timken Company, our Labor Relations team works with the leadership of the United Steelworkers of America in an atmosphere that reflects our mutual respect for the roles and responsibilities of the**

**parties and in the interest of the Timken associates represented. Whether at the State of Ohio, The Timken Company or at the federal government, Labor/Management relations should be directed at the common goals of providing quality work for customers and constituents while maintaining a positive, productive and safe work environment where employees have the opportunity to maximize their potential for career success.**

2. As a member of the Governor's Operations Improvement Task Force, as well as the Ohio Board of Regents, you have played a leadership role in efforts to improve efficiency and effectiveness at the state level.

   a. What are some of the primary lessons you have learned in your efforts to improve efficiencies within government?

**Improving efficiencies within government is not exactly the same as might be the case with most private sector organizations, but there are many fundamental elements which are the same. For example, one of the necessary conditions is to have a positive and productive work environment. The foundation for this is in the commitment that the parties have to both organizational performance goals and goals for individual career success. High performance organizations are comprised of individuals who are committed to the values, vision, goals and objectives of the organization and the organization in turn, is genuinely committed to the success and well-being of each individual. The tensions which are generated when seeking to balance these commitments will not be destructive to organizational performance or individual career success as would be the case if one or the other commitment did not exist. When this foundation of a positive and productive work environment is in place, the organization can do a much better job of developing strategies, plans, goal and objectives and executing those plans to achieve results. Within government organizations it is important to recognize that there is a legislative and regulatory aspect of getting things done which is a very different from what private sector organizations deal with. Also there may be differing philosophical and political perspectives to be accommodated if possible. Still, if the values, vision, goals and objectives are shared by the people of the organization, high performance can be achieved.**

   b. What are some of the comparisons and contrasts you might anticipate with respect to fostering productivity improvements at the Federal and state levels?

**Fostering productivity improvements at the federal level as contrasted to the State level will have many of the same issues as mentioned above. I think the major contrast will be in terms of the fact that the federal size and scope is much larger.**

c. What is your philosophy concerning human capital improvement? What are the primary strategies you believe GSA should pursue to maximize the productivity of its workforce?

**Ongoing human capital improvement is essential to high performance, continuous improvement and maximizing the success of any organization. The required pace of human capital improvement is quickening beyond what traditional methods of keeping abreast of a persons area of expertise can handle. In this new information age the speed of information flow and the rapid implementation of new and faster technology make keeping up with the latest state of knowledge required to do one's job well is a daunting task. I mentioned above that high performance organizations are comprised of individuals who are committed to the values, vision, goals and objectives of the organization and the organization in turn, is genuinely committed to the success and well-being of each individual. It is also the case that high performance organizations are comprised of individuals who have the skills, competence and personal characteristics required to achieve the "stretch target" goals and objectives necessary to keep pace with the speed of change in today's world. The productivity of the GSA workforce will be maximized on the foundation of 1) a positive, productive and safe work environment; 2) clear strategic direction with shared vision, values, goal and objectives; 3) an effective organizational structure designed with clear accountability to maximize results for customers; and 4) staffing of positions with people developed or recruited to bring the skills and competencies required to achieve the organization's goals.**

3. Especially in the age of the Internet, many managers in the public and private sectors are struggling with how to effectively deploy information technology to accomplish organizational missions. The Internet is transforming the way organizations conduct their business, creating possibilities for entirely new methods of service delivery and business models. Managers at all levels are being forced to increase their own understanding of the role of information technology in order to provide effective enterprise wide leadership.

   a. Please describe your own understanding of the role and potential impact of information technology today and your background in this area.
   b. Can you provide examples which demonstrate your competencies in this critical area?

**Information Technology and the Internet have significantly changed the way work is done. This has created new opportunities for productivity improvement and new opportunities to accomplish tasks which would have been impossible just a few years ago. While I am not an information technologist by formal training, I recognize the importance of this area and the need for all employees to be able to**

**take advantage of it from an end-user perspective.**

3. A 1993 Columbus Dispatch article (attached) describes a situation in which the owner of a medical supply company was convicted of submitting $31,000 in false billings to the state for delivery of adult diapers to Medicaid recipients. You are mentioned in the article as the state official who was overseeing the relevant department at the time. Because this matter may have fallen under your purview while you were Director of Administrative Services for the State of Ohio, please describe any knowledge of or involvement you may have had in this matter.

**I did not have any direct involvement in this particular case. The Ohio Department of Administrative Services – Division of State Personnel may have entered into the contract for these purchases on behalf of one of the State agencies. It is unfortunate that a supplier lacked the business ethics and integrity to avoid fraudulent practices. It is good that the Division of State Purchasing was able to detect the fraud and take appropriate corrective action.**

## VIII. Relations with Congress

1. Do you agree without reservation to respond to any reasonable summons to appear and testify before any duly constituted committee of the Congress if you are confirmed?

   **Yes.**

2. Do you agree without reservation to reply to any reasonable request for information from any duly constituted committee of the Congress if you are confirmed?

   **Yes.**

## IX. Assistance

1. Are these answers your own? Have you consulted with GSA or any interested parties? If so, please indicate which entities.

   **The answers given to this questionnaire are my own and I take full responsibility for them. For the most part the answers are based upon my experiences and upon information I have read or heard about the operations of GSA. I did consult with and received helpful assistance from individuals at GSA, namely:**

   **Brian A. Jackson, Special Assistant – GSA Office Congressional and Intergovernmental Affairs**

---

## AFFIDAVIT

I, Stephen A. Perry, being duly sworn, hereby state that I have read and signed the foregoing Statement on Pre-hearing Questions and that the information provided therein is, to the best of my knowledge, current, accurate, and complete.

Subscribed and sworn before me this 3rd day of May, 2001.

Notary Public

NOTARY PUBLIC FOR SOUTH CAROLINA
My commission expires September 2 2007

**OPENING STATEMENT**
**FOR**
**JOHN D. GRAHAM**
**NOMINEE FOR ADMINISTRATOR**
**OFFICE OF INFORMATION AND REGULATORY AFFAIRS**

Thank you, Chairman Thompson, Senator Lieberman, and members of the Committee for the opportunity to provide a brief opening statement. I am honored to be President Bush's nominee as Administrator of OIRA at OMB and look forward to the opportunity to work with each of the members of this Committee. Some say that I am not practicing risk analysis in my own life, since the risks of this job may far outweigh the benefits. Yet I take a more optimistic view and aspire to working on behalf of taxpayers to improve the regulatory system in the USA.

Since 1985 I have taught risk analysis, risk communication, and cost-benefit analysis to graduate students at the Harvard School of Public Health. In 1990 I also launched the Harvard Center for Risk Analysis, where teams of faculty and students apply analytic tools to issues in medical technology, food safety, automotive safety, and environmental protection.

If I am confirmed as OIRA Administrator, I will be making a major change in my professional role and my responsibilities will be quite different. I will be responsible for enforcing the laws of the land as Congress wrote them. I will advise the OMB Director and the President on future legislation. I will implement the President's policies and advocate the President's priorities. I will lead a team of fine analysts at OMB, and work with Congress and the public on issues regarding regulation and information.

One of my chief roles will be to stimulate more analytical thinking about major regulatory decisions in the federal government -- decisions that affect State and local governments, small and large businesses, and the public at large. My responsibilities will also include paperwork reduction, information policy, and statistical policy.

Mr. Chairman, the subject of openness in regulatory review at OMB has been a concern of this Committee for more than 15 years. Progress has been made in recent years and I pledge to continue that progress while protecting the ability of OMB staff to do their jobs efficiently. If confirmed, I will work to achieve regulatory reviews that are timely, transparent, and rigorous. I understand that

openness does not necessarily create agreement. Yet I also hope that we will find issues where the spirit of openness permits dialogue and a narrowing of policy disagreements.

Since my nomination in March, some have charged that I and the Harvard Center for Risk Analysis have a pro-business bias. I respectfully disagree. Sometimes the findings of our studies have supported the interests of sponsors. Sometimes the findings of our studies have supported stricter regulation of business. And sometimes our studies offer public health insight but do not affect business interests one way or another. Our Center has simply followed the scientific data and analysis, wherever they happened to lead us.

Thank you for the opportunity to make this opening statement and I look forward to the opportunity to respond to questions.

## BIOGRAPHICAL & FINANCIAL INFORMATION Requested of Nominees

## A. BIOGRAPHICAL INFORMATION

1. **Name:** *John D. Graham*

2. **Position to which Nominated:**
*Administrator, Office of Information & Regulatory Affairs, Office of Management & Budget*

3. **Date of Nomination:** *March 2001*

4. **Address:** ----------
*Office: Harvard Center for Risk Analysis, Harvard School of Public Health, 718 Huntington Avenue, Boston, MA 02115*

5. **Date and Place of Birth:** *October 3rd, 1956 in Pittsburgh, PA*

6. **Marital Status:** *Married 22 years to Susan Patricia Woerner*

7. **Names and Ages of Children:**

---

8. **Education:**
*Carnegie-Mellon University, 1981-1983, Ph.D., Urban and Public Affairs, December 1983*
*Duke University, 1978-1980, M.A., Public Affairs, September 1980*
*Wake Forest University, 1974-1978, B.A., Economics and Politics, May 1978*
*North Hills High School, 1970-1974, H.S. diploma, June 1974*

9. **Employment Record:**
- *Professor of Policy & Decision Sciences, Harvard School of Public Health, Boston, MA, 1991 to present*
- *Associate Professor of Policy & Decision Sciences, Harvard School of Public Health, Boston, MA 1988 to 1991*
- *Assistant Professor of Policy & Decision Sciences, Harvard School of Public Health, Boston, MA 1985 to 1988*
- *Assistant Professor, School of Urban and Public Affairs, Carnegie-Mellon University, Pittsburgh, PA, 1984 to 1985*
- *Post-Doctoral Fellow, Harvard School of Public Health, Boston, MA, 1983 to 1984*
- *Pre-Doctoral Fellow, Brookings Institution, Washington, D.C., 1982 to 1983*
- *Staff Associate/Research Assistant, Committee on Risk & Decision Making, National Research Council, National Academy of Sciences, Washington, D.C., 1980 to 1981*
- *Summer Intern, Office of Management & Budget, Washington, D.C., Summer 1979*

**10. Government Experience:**

**List any advisory, consultative, honorary or other part-time service or positions with federal, State, or local governments, other than those listed above.**

- *U.S. Centers for Disease Control (Injury Study Section)*
- *Congressional Research Service, U.S. Library of Congress (Consultant)*
- *U.S. Environmental Protection Agency (Scientific Advisory Board)*
- *Independent Regulatory Review Commission, Commonwealth of Penna. (Consultant)*
- *National Highway Traffic Safety Administration, U.S. Department of Transportation (Motor Vehicle Safety Research Advisory Committee)*
- *U.S. Office of Management and Budget (Consultant)*
- *Radiation Research Program, U.S. Department of Energy (Advisory Committee)*
- *U.S. Department of Justice (Consultant)*

**11. Business Relationships:**

**List all positions held as an officer, director, trustee, partner, proprietor, agent, representative, or consultant of any corporation, company, firm, partnership, or other business enterprise, educational or other institution.**

*Air Products and Chemicals (Environmental Advisory Committee)*
*American Council for Capital Formation (Consultant)*
*American Enterprise Institute (Consultant)*
*American Industrial Health Council (Consultant)*
*American Water Works Association Research Foundation (Consultant)*
*Brookings Institution (Consultant)*
*Carnegie-Mellon University (Consultant)*
*Center for Indoor Air Research (Consultant)*
*Dow AgroSciences (Global Environment Advisory Council)*
*Environmental Policy Center (Risk Dialogue Group)*
*European Society of Oncology (Consultant)*
*Federal Focus (Consultant)*
*Gradient Corporation (Consultant)*
*Health Effects Institute (Consultant)*
*Industrial Economics (Consultant)*
*Independent Regulatory Review Commission, Commonwealth of Pennsylvania (Consultant)*
*Institute of Medicine, National Research Council, National Academy of Sciences (Consultant)*
*International Council on Metals and the Environment (Consultant)*
*International Institute of Synthetic Rubber Producers (Consultant)*
* *Ketchum Communications (Advisory Board of Consultants)*
*King and Spaulding Law Offices (Expert Witness)*
*Metcalf and Eddy (Consultant)*
*National Academy of Engineering, National Academy of Sciences (Consultant)*
*National Center for Policy Analysis (Consultant)*
*Pierce, Atwood, Scribner, Allen, Smith and Lancaster Attorneys at Law (Expert Witness)*
*Procter and Gamble Company (Consultant)*
*Public Health Policy Advisory Board (Distinguished Fellow)*
*Resources for the Future (Consultant)*
*2, 4-D Task Force (Consultant)*
*University of Virginia (Consultant)*
*Western States Petroleum Association (Consultant)*

*** No financial compensation provided.**

(I have had speaking engagements with numerous organizations. Ms. Hardy told me not to include speaking engagements since they are not considered business relationships.)

12. **MEMBERSHIPS:**

**List all memberships and offices held in professional, business, fraternal, scholarly, civic, public, charitable and other organizations.**

*"Accident Analysis & Prevention: An International Journal" (Editorial Board)*
*Advancement of Sound Science Coalition (Policy Advisory Board)*
*American Council on Science and Health (Board of Scientific and Policy Advisors)*
*American Enterprise Institute-Brookings Joint Center for Regulatory Studies (Advisory Board)*
*Annapolis Center for Environmental Quality, Inc. (Board Member)*
*Association for the Advancement of Injury Control (Board Member)*
*Biological Effects of Low Level Exposures (Advisory Committee)*
*Center for Policy Research, American Council for Capital Formation (Board of Scholars)*
*Center for Regulatory Improvement, Carnegie-Mellon University (Advisory Committee)*
*Enterprise for the Environment (Member)*
*Environmental Defense (Member)*
*Franklin Country Club (Member)*
*Harvard Club in Boston (Member)*
*"Injury Control and Safety Promotion" (Editorial Board)*
*International Food and Information Council Foundation (Board Member)*
*"Journal of Risk Research" (Editorial Board)*
*Mercatus Center, George Mason University (Advisory Board)*
*National Academy of Sciences, Committee on Risk Analysis (Advisory Board)*
*National Council on Radiation Protection and Measurement (Member)*
*National Research Council, NAS (Board on Environmental Studies and Toxicology)*
*National Research Council, National Academy of Sciences (Transportation Research Board)*
*Progressive Policy Institute (Project Advisor)*
*"Risk Analysis: An International Journal" (Editorial Board)*
*"Risk: Health, Safety, and Environment" (Editorial Board)*
*Risk Management & Decision Processes Cntr, Wharton Business School (Advisory Committee)*
*Society for Risk Analysis (President 1995-1996)*
*Wake Forest University (Board of Visitors)*

13. **Political Affiliations and Activities:**

***(a) List all offices with a political party which you have held or any public office for which you have been a candidate.***

*None.*

***(b) List all memberships and offices held in and services rendered to all political parties or election committees during the last ten years.***

*None.*

***(c) Itemize all political contributions to any individual, campaign organization, political party, political action committee, or similar entity of $50 or more for the past five years.***

- *$300 04/12/2000 Republican National Committee*
- *$100 11/15/1999 George W. Bush*
- *$100 06/28/1999 Elizabeth Dole*
- *$250 06/02/1999 Elizabeth Dole*
- *$250 09/23/1996 Republican National Committee*
- *$250 09/23/1996 Richard Zimmer*
- *$200 02/25/1996 Republican National Committee*

**14. Honors and Awards:**

**List all scholarships, fellowships, honorary degrees, honorary society memberships, military medals and any other special recognitions for outstanding service or achievements.**

- *1998, Annapolis Center's Annual Public Service Award for Achievements in Risk Communication to the American People.*
- *1991, Surgeon General Antonia Novello, M.D. presented the Centers for Disease Control's Award for Outstanding Service in Helping to Develop and Support the National Agenda for Injury Control.*
- *1991, Society for Automotive Engineers, Industry-Government Meeting's Outstanding Oral Presentation for "The Case for Motor Vehicle Injury Control."*
- *1984, "Journal of Policy Analysis and Management" Annual Herbert Salzman Award for Outstanding Paper (Co-recipient with Steven Garber for paper in Volume 3).*

**15. Published Writings:**

**List the titles, publishers, and dates of books, articles, reports, or other published materials which you have written.**

*Please refer to the attached copy of my curriculum vitae, pages 2 through 14, for a list of Books, Published Papers and Reports, Editorials or Commentaries, and Congressional and Administrative Testimony and Comments. I have delivered one copy of each item to Senator Lieberman's office and to Senator Thompson's office. I also included one copy of each issue of the Harvard Center for Risk Analysis (HCRA) "Risk in Perspective" series and a set of HCRA Annual Reports.*

**16. Speeches:**

**Provide the Committee with four copies of any formal speeches you have delivered during the last five years which you have copies of and are on topics relevant to the position for which you have been nominated.**

- *I have delivered "Making Sense of Risk" over 100 times during the last 10 years. The speech is typically delivered with slides but no formal text. I have enclosed transcripts from 1994 and 1998 versions of the speech, plus hard copies of slides used in 1998.*
- *An edited transcript of my remarks at a 1996 Heritage conference, "Making Regulatory Reform a Reality," is provided.*
- *A written version of my 1999 speech, "Endocrine Disruptors and 'the' Precautionary Principle," to the Japanese Ministry of the Environment is provided.*

**17. Selection:**

**(a) Do you know why you were chosen for this nomination by the President?**

*I believe I was chosen for this nomination because of my qualifications.*

**(b) What do you believe in your background or employment experience affirmatively qualifies you for this particular appointment?**

*I have over fifteen years of experience at Harvard teaching the tools of regulatory analysis, including risk assessment, decision analysis, cost-effectiveness analysis, and cost-benefit analysis. I have also studied and written about the decision making of federal regulatory agencies, especially CPSC, EPA, FDA, NHTSA, and OSHA, and have served on several agency advisory committees. In addition, I have learned about the workings of Congress through testimony provided at numerous congressional committee hearings and through dialogue with congressional staff and Members of Congress working on legislation. My managerial experience at the Harvard Center for Risk Analysis should assist me in performing the managerial tasks at OMB-OIRA.*

## B. FUTURE EMPLOYMENT RELATIONSHIPS

1. **Will you sever all connections with your present employer, business firms, business associations or business organizations if you are confirmed by the Senate?**

   *Yes.*

2. **Do you have any plans, commitments or agreements to pursue outside employment, with or without compensation, during your service with the government?**

   *No.*

3. **Do you have any plans, commitments or agreements after completing government service to resume employment, affiliation or practice with your previous employer, business firm, association or organization?**

   *I have resigned my position as Director, Harvard Center for Risk Analysis. However, I have retained my tenured professorship at the Harvard School of Public Health. Upon confirmation, I will be granted a two-year leave of absence from Harvard University. I am able to return to my tenured faculty position at the Harvard School of Public Health within two years of my Senate confirmation. I may be able to return to the position at a later date, but it is only guaranteed to remain as an option for me for up to 2 years from the time my leave of absence begins. During my leave of absence I will receive no compensation or benefits of any kind from the University.*

4. **Has anybody made a commitment to employ your services in any capacity after you leave government service?**

   *Except for the within 2 years commitment from Harvard University, explained in question 3, above, no one has made a commitment to employ my services in any capacity after I leave government service.*

5. **If confirmed, do you expect to serve out your full term or until the next Presidential election, whichever is applicable?**

   *I intend to serve as long as President Bush desires my services.*

## C. POTENTIAL CONFLICTS OF INTEREST

1. **Describe all financial arrangements, deferred compensation agreements, and other continuing dealings with business associates, clients, or customers.**

   *There are none.*

2. **Indicate any investments, obligations, liabilities, or other relationships which could involve potential conflicts of interest in the position to which you have been nominated.**

   *My investments are almost entirely in diversified mutual funds, except for small holdings of common stock in 3 companies: 150 shares of Procter and Gamble, 300 shares of Port Financial, our local bank, and 12 shares of Avaya. One of my daughter's accounts also holds 75 shares of Microsoft common stock. If it is deemed inappropriate for me to maintain any of these holdings, I will liquidate.*

3. **Describe any business relationship, dealing or financial transaction which you have had during the last ten years, whether for yourself, on behalf of a client, or acting as an agent, that could in any way constitute or result in a possible conflict of interest in the position to which you have been nominated.**

   *There are none.*

4. **Describe any activity during the past ten years in which you have engaged for the purpose of directly or indirectly influencing the passage, defeat or modification of any legislation or affecting the administration and execution of law or public policy.**

   *I have testified before Congressional Committees and Federal Agencies on numerous occasions. Please refer to the enclosed curriculum vitae, pages 13 and 14, for a list of my Congressional and Administrative Testimony and Comments. I have included copies of these testimonies and comments with this form. For the last four sessions, I have offered technical advice to House and Senate staff on regulatory reform legislation.*

5. **Explain how you will resolve any potential conflict of interest, including any that may be disclosed by your responses to the above items.**

   *I do not foresee any conflicts of interest. I approach regulation analytically, without preconceived notions of what action should be taken. If somehow there were a conflict of interest that I was unable to eliminate, I would recuse myself from the review of that regulation. If it is determined that any of my financial holdings may present a conflict of interest, I will liquidate those holdings.*

6. **Do you agree to have written opinions provided to the Committee by the designated agency ethics officer of the agency to which you are nominated and by the Office of Government Ethics concerning potential conflicts of interest or any legal impediments to your serving in this position?**

   *Yes.*

## D. LEGAL MATTERS

1. **Have you ever been disciplined or cited for a breach of ethics for unprofessional conduct by, or been the subject of a complaint to any court, administrative agency, professional association, disciplinary committee, or other professional group?**

   *Not to my knowledge.*

2. **Have you ever been investigated, arrested, charged or held by any federal, State, or other law enforcement authority for violation of any federal, State, county or municipal law, regulation or ordinance, other than a minor traffic offense?**

   *Not to my knowledge.*

3. **Have you or any business of which you are or were an officer ever been involved as a party in interest in any administrative agency proceeding or civil litigation?**

   *I have been involved in litigation only as a witness. In the early 1990s I testified as an expert witness on state water quality criteria in the State of Maine for the Law Firm of Pierce, Atwood, Scribner, Allen, Smith and Lancaster and in the states of Louisiana and Alabama for the Law Firm of King and Spaulding. These law firms were representing companies in the pulp and paper industry regarding dioxin emissions. I was also an expert witness for the United States Department of Justice in 1994 in a case against a company that misrepresented its status as a recycler, the Marine Shale Case, DJ File #90-11-2-204.*

4. **Have you ever been convicted (including pleas of guilty or *nolo contendere*) of any criminal violation other than a minor traffic offense?**

   *No.*

5. **Please advise the Committee of any additional information, favorable or unfavorable, which you feel should be considered in connection with your nomination.**

   *I am not aware of any other information that should be considered.*

## E. FINANCIAL DATA

Financial Data maintained on file in Committee offices.

### *AFFIDAVIT*

**John D. Graham, being duly sworn, hereby states that he has read and signed the foregoing Statement on Biographical and Financial Information and that the information provided therein is, to the best of his knowledge, current, accurate, and complete.**

**John D. Graham**

**Subscribed and sworn before me this** 9th **day of** April**, 2001.**

**Notary Public**

Commission Expires: Aug. 14, 2002

## Books

John D. Graham, Laura Green, and Marc J. Roberts, In Search of Safety: Chemicals and Cancer Risk, Harvard University Press, Cambridge, MA, 1988.

John D. Graham (ed.), Preventing Automobile Injury: Recent Findings of Evaluation Research, Auburn House Publishing Company, Dover, MA, 1988.

John D. Graham, Auto Safety: Assessing America's Performance, Auburn House Publishing Company, Dover, MA, 1989.

John D. Graham (ed.), Harnessing Science for Environmental Regulation, Praeger, Westport, CT, 1991.

John D. Graham and Jonathan B. Wiener (eds.), Risk versus Risk: Tradeoffs in Protecting Health and the Environment, Harvard University Press, Cambridge, MA, 1995.

John D. Graham (ed.), The Role of Epidemiology in Regulatory Risk Assessment, Elsevier Science, Amsterdam, NL, 1995.

John D. Graham and Jennifer K. Hartwell (eds.), The Greening of Industry: A Risk Management Approach, Harvard University Press, Cambridge, MA, 1997.

## Published Papers and Reports (* indicates peer reviewed)

1. James W. Vaupel and John D. Graham, "Egg in Your Bier?" Public Interest, Winter 1980, pp. 3-17.

2.* John D. Graham and James W. Vaupel, "The Value of a Life: What Difference Does It Make?" Risk Analysis, Volume 1, 1981, pp. 89-95; reprinted with revision, What Role for Government? eds., Richard Zeckhauser and Derek Leebauert, Durham, NC: Duke University Press, 1983, pp. 176-186; reprinted, Risk Benefit Analysis in Water Resource Planning and Management, ed., Yacov Y. Haimes, New York: Plenum Press, 1981, pp. 233-244.

3.* John D. Graham, "Some Explanations of Disparities in Lifesaving Investments," Policy Studies Review, Volume 1, 1982, pp. 692-704.

4.* John D. Graham, "On Wilde's Theory of Risk Homeostasis," Risk Analysis, Volume 2, 1982, pp. 235-237.

5.* John D. Graham and Patricia Gorham, "NHTSA and Passive Restraints: A Case of Arbitrary and Capricious Deregulation," Administrative Law Review, Volume 35, 1983, pp. 193-252.

6. John D. Graham, "Automobile Crash Protection: Institutional Responses to Self-Hazardous Behavior," Risk Analysis, Institutions, and Public Policy, ed., Susan G. Hadden, Associated Faculty Press, 1984, pp. 39-59.

7.* John D. Graham and Steven Garber, "Evaluating the Effects of Automobile Safety Regulation," Journal of Policy Analysis and Management, Volume 3, No. 2, 1984, pp. 206-224.

8.* John D. Graham and Max Henrion, "A Probabilistic Analysis of the Passive-Restraint Question," Risk Analysis, Volume 4, No. 1, 1984, pp. 25-40.

9. Robert W. Crandall and John D. Graham, "Automobile Safety Regulation and Offsetting Behavior: Some New Empirical Estimates," American Economic Review, Volume 74, No. 2, May 1984, pp. 328-331.

10.* John D. Graham, "Technology, Behavior, and Safety: An Empirical Study of Automobile Occupant-Protection Regulation," Policy Sciences, Volume 17, 1984, pp. 141-151.

11. John D. Graham, "The Failure of Agency-Forcing: The Regulation of Airborne Carcinogens Under Section 112 of the Clean Air Act," Duke Law Journal, February 1985, pp. 100-150; selected for republication in Land and Environment Law Review, ed., Stuart L. Deutsch, 1986.

12. John D. Graham, "Secretary Dole and the Future of Automobile Airbags," Brookings Review, Summer 1985, pp. 10-15.

13. John D. Graham, Howard Raiffa, and James W. Vaupel, "Science and Analysis: Roles in Risk and Decision Making," Risk Evaluation and Management, eds., Vincent Covello, Joshua Menkes, and Jeryl L. Mumpower, New York: Plenum Press, 1986, pp. 503-518.

14.* John D. Graham and Younghee Lee, "Behavioral Response to Safety Regulation: The Case of Motorcycle Helmet-Wearing Legislation," Policy Sciences, Volume 19, 1986, pp. 253-273.

15.* John D. Graham, "Cancer in the Courtroom: Risk Assessment in the Post-Benzene Era," Journal of Policy Analysis and Management, Volume 6, No. 3, 1987, pp. 432-438; reprinted in Environmental Risk Management: Is Analysis Useful? Air Pollution Control Assoc., Pittsburgh, PA, 1986, pp. 98-104.

16. John D. Graham, "Application of Decision Analysis to Mental Health," Medical Care, Volume 25, 1987, pp. 585-586.

17.* Evridiki Hatziandreu, John D. Graham, and Michael A. Stoto, "AIDS and Biomedical Research Funding: A Comparative Analysis," Reviews of Infectious Diseases, Volume 10, No. 1, 1988, pp. 159-167.

18.* William N. Evans and John D. Graham, "Traffic Safety and the Business Cycle," Alcohol, Drugs, and Driving: Reviews and Abstracts, Volume 4, 1988, pp. 31-38.

19. John D. Graham, Neil Hawkins, and Marc J. Roberts, "Expert Scientific Judgment in Quantitative Risk Assessment," Carcinogen Risk Assessment: New Directions in Qualitative and Quantitative Cancer Risk Assessment, eds. Ronald W. Hart and Fred D. Hoerger, Banbury Reports 31, New York: Cold Spring Harbor Laboratory, 1988, pp. 231-244.

20. John D. Graham, Book Review: "Assessing OSHA's Future," Journal of Policy Analysis and Management, Volume 7, No. 7, 1988, pp. 742-743.

21.* Neil C. Hawkins and John D. Graham, "Expert Scientific Judgment and Cancer Risk Assessment: A Pilot Study of Pharmacokinetic Data," Risk Analysis, Volume 8, No. 4, 1988, pp. 615-625.

22. John S. Evans, Neil S. Hawkins, and John D. Graham, "Uncertainty Analysis and the Value of Information: Monitoring for Radon in the Home," Journal of the Air Pollution Control Association, Volume 38, 1988, pp. 1380-1385.

23.* Milton C. Weinstein, John D. Graham, Joanna E. Siegel, and Harvey V. Fineberg, "Cost Effectiveness Analysis of AIDS Prevention Programs: Concepts, Complications, and Illustrations," in AIDS: Sexual Behavior and Intravenous Drug Use, edited by C. F. Turner et al., National Research Council, Washington, D.C., 1989, pp. 471-499.

24. Alon Rosenthal, Mary Jean Sawey, and John D. Graham, "Incinerating Municipal Solid Waste: A Health Benefit Analysis of Controlling Emissions," a report prepared under contract for the Congressional Research Service, April 21, 1989.

25.* Robert C. Crandall and John D. Graham, "The Effect of Fuel Economy Standards on Automobile Safety," Journal of Law and Economics, Volume 32, 1989, pp. 97-118.

26.* John D. Graham, "Communicating About Chemical Hazards," Journal of Policy Analysis and Management, Volume 8, No. 2, 1989, pp. 307-313.

27. * Joanna Siegel, John D. Graham, and Michael A. Stoto, "Allocating Resources Among AIDS Research Strategies," Policy Sciences, Volume 23, 1990, pp. 1-23.

28.* Scott K. Wolff, Neil C. Hawkins, Susan M. Kennedy, John D. Graham, "Selecting Experimental Data for Use in Quantitative Risk Assessment: An Expert-Judgment Approach," Journal of Toxicology and Industrial Health, Volume 6, 1990, pp. 275-291.

29.* Steven Garber and John D. Graham, "The Effects of the New 65 MPH Speed Limit on Rural Highway Fatalities: A State-by-State Analysis," Accident Analysis and Prevention, Volume 22, 1990, pp. 137-149.

30. Mary Jean Sawey, David R. Holtgrave, and John D. Graham, "The Potential Health Benefits of Controlling Hazardous Air Pollutants," Villanova Environmental Law Journal, Volume 1, 1990, pp. 473-490. Adapted from Congressional Research Service Report for Congress, "Health Benefits of Air Pollution Control: A Discussion," February 27, 1989.

31. John D. Graham and David R. Holtgrave, "Coke Oven Emissions: A Case Study of Technology-Based Regulation," Risk: Issues in Health and Safety, Volume 1, 1990, pp. 243-272. Adapted from a Congressional Research Service Report for Congress, September 20, 1989.

32. John D. Graham, "Cancer Risk Estimation and Prevention," in Air Pollution and Human Cancer (ed., L. Tomatis), European Society of Oncology, Springer-Verlag, Berlin, 1990, pp. 75-84.

33.* William N. Evans and John D. Graham, "An Estimate of the Lifesaving Benefit of Child Restraint Use Legislation," Journal of Health Economics, Volume 9, 1990, pp. 121-142.

34. Carol S. Shepherd and John D. Graham, "The Economic Costs of Injuries to Truck Occupants," Report to the National Highway Traffic Safety Administration, Harvard Injury Control Center, April 1990.

35.* George M. Gray and John D. Graham, "Risk Assessment and Clean Air Policy," Journal of Policy Analysis and Management, Volume 10, 1991, pp. 286-295.

36.* John D. Graham and David R. Holtgrave, "Predicting EPA's Forthcoming CO Standards in Light of New Clinical Evidence," Risk Analysis, Volume 11, 1991, pp. 325-332.

37.* William N. Evans, Doreen Neville, and John D. Graham, "General Deterrence of Drunk Driving: Evaluation of Recent American Policies," Risk Analysis, Volume 11, No. 2, 1991, pp. 279-289.

38.* William N. Evans and John D. Graham, "Risk Reduction or Risk Compensation? The Case of Mandatory Safety Belt Use Laws," Journal of Risk and Uncertainty, 1991, pp. 61-73.

39. Robert W. Crandall and John D. Graham, "New Fuel Economy Standards?" The American Enterprise, Volume 2, March/April 1991, pp. 68-69.

40.* John D. Graham, "Product Liability and Motor Vehicle Safety," in The Liability Maze: The Impact of Liability Law on Safety and Innovation, (ed., P. W. Huber and R.E. Litan), Brookings Institute, Washington, D.C., 1991, pp. 120-190.

41.* M.A. Ibrahim, G.G. Bond, T.A. Burke, P. Cole, F.N. Dost, P.E. Enterline, M. Gough, R.S. Greenberg, W.E. Halperin, E. McConnell, I.C. Munro, JA. Swenberg, SH. Zahm, and J.D. Graham, "Weight of the Evidence on the Human Carcinogenicity of 2,4-D," Environmental Health Perspectives, Volume 96, 1991, pp. 213-222.

42. John D. Graham, "Improving Chemical Risk Assessment, " Regulation, Fall 1991, pp. 14-18.

43. John D. Graham and George M. Gray, "Air Toxics: Characterizing the Risks," Toxic Air Pollutants from Mobile Sources. Proceedings of a U.S. EPA/A & WMA International Specialty Conference, Air & Waste Management Association, Pittsburgh, PA, 1992, pp. 43-52.

44.* John D. Graham, "The Safety Risks of Proposed Fuel Economy Legislation," Risk: Issues in Health and Safety, Volume 3, Spring 1992, pp. 95-126.

45. Alon Rosenthal, George M. Gray, and John D. Graham, "Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals," Ecology Law Quarterly, Volume 19, No. 2, 1992, pp. 269-362; reprinted in An Environmental Law Anthology (eds. Robert Fischman, Maxine Lipeles and Mark Squillace), Anderson Publishing Company, Cincinnati, Ohio, 1996, pp. 391-413.

46. John S. Evans, John D. Graham, George M. Gray, Adrienne Hollis, Barry Ryan, Andrew Smith, and Alison Taylor, "Summary of Workshop to Review an OMB Report on Regulatory Risk Assessment and Management," Risk: Issues in Health and Safety, Volume 3, No. 1, Winter 1992, pp. 71-83. Condensed from "OMB vs. the Agencies: The Future of Cancer Risk Assessment," Workshop to Peer Review the OMB Report on Risk Assessment and Risk Management," Harvard Center for Risk Analysis, June 1991.

47.* John D. Graham, Bei-Hung Chang, and John S. Evans, "Poorer is Riskier," Risk Analysis, Volume 12, No. 3, 1992, pp. 333-337.

48.* John D. Graham, Katherine D. Walker, Maurice Berry, Elizabeth F. Bryan, Michael A. Callahan, Anna Fan, Brent Finley, Jermiah Lynch, Thomas McKone, Haluk Ozkaynak, Ken Sexton, "Role of Exposure Databases in Risk Assessment," Archives of Environmental Health, Volume 47, No. 6, 1992, pp. 408-420.

49. John D. Graham, "A Public Health View of Environmental Regulation," Maine Policy Review, Volume 1, No. 2, 1992, pp. 34-38.

50.* William N. Evans, John D. Graham, and Doreen Neville, "Toward Humility in Statistical Interpretation," Risk Analysis, Volume 13, No. 1, 1993, pp. 21-22.

51.* John D. Graham, "Injuries from Traffic Crashes: Meeting the Challenge," Annual Review of Public Health, Volume 14, 1993, pp. 515-543.

52.* Bei-Hung Chang and John D. Graham, "A New Method for Making Interstate Comparisons of Highway Fatality Rates," Accident Analysis and Prevention, Volume 25, No. 1, 1993, pp. 85-90.

53. George M. Gray, Joshua T. Cohen, and John D. Graham, "The Challenge of Risk Characterization: Current Practice and Future Directions," Environmental Health Perspectives Supplements, Volume 101 (Suppl. 6), 1993, pp. 203-208 .

54. John D. Graham, "An Economic Perspective on Air Bag Regulation for Canada," Chronic Diseases in Canada, Volume 14, No. 4 (Suppl.) 1993, pp. sl25-sl28.

55. John D. Graham, "The Economics of Controlling Outdoor and Indoor Air Pollution," in Indoor and Outdoor Air Pollution and Human Cancer (ed., U. Veronesi), European School of Oncology, Springer-Verlag, Berlin, 1993, pp. 149-162.

56. Susan W. Putnam and John D. Graham, "Chemicals vs. Microbials in Drinking Water: A Decision Sciences Perspective," Journal of the American Water Works Association, Volume 85, 1993, pp. 57-61.

57. John D. Graham, "Incorporating Scientific Judgment into Quantitative Risk Assessment," The Toxicology Forum, Winter 1993, pp. 51-62.

58. George M. Gray and John D. Graham, "Intuitive Toxicology: Comments on Public Perceptions and the Role of Institutional Affiliation in Expert Opinions," Comments on Toxicology: A Journal of Critical Discussion on the Current Literature, Volume 4, 1993, pp. 501-504.

59.* Susan W. Putnam and John D. Graham, "Formaldehyde Science: From the Laboratory to the Regulatory Arena," in Keeping Pace with Science and Engineering, Myron F. Uman, ed., National Academy Press, Washington, D.C., 1993, pp. 189-220.

60. Jane Hoppin, P. Barry Ryan, and John D. Graham, Risk Assessment in the Federal Government: Questions and Answers, Harvard Center for Risk Analysis, 1993.

61. John D. Graham, "The Fate of the Maximally Exposed Individual Under the 1990 Amendments to the Clean Air Act," a paper presented to the Committee on Risk Assessment Methodology, National Research Council, National Academy of Sciences, August 1993.

62. John D. Graham, "Making Sense of Risk," AG in Perspective, Volume 1, No. 1, September 1993.

63.* John Evans, John Graham, George Gray, and Robert Sielken, Jr., "A Distributional Approach to Characterizing Low-Dose Cancer Risk," Risk Analysis, Volume 14, No. 1, 1994, pp. 25-34.

64.* Dana Gelb Safran, John D. Graham, and J. Scott Osberg, "Social Supports as a Determinant of Community-Based Care Utilization Among Rehabilitation Patients," Health Services Research, Volume 28, No. 6, 1994, pp. 729-750.

65. Susan W. Putnam and John D. Graham, "Environmental Regulation," Essay in The Encyclopedia of the Environment, Boston: Houghton Mifflin Company, 1994, p. 224.

66. John D. Graham, "Synopsis of the BELLE Conference on Chemicals and Radiation," in Biological Effects of Low Level Exposures: Dose-Response Relationships (ed. E.J. Calabrese), Lewis Publishers, Ann Arbor, MI, 1994, pp. 271-274.

67. John D. Graham and March Sadowitz, "Superfund Reform: Reducing Risk through Community Choice," Issues in Science and Technology, Summer, 1994, pp. 35-40.

68. John D. Graham, "Hammers Don't Cut Wood: We Need Pollution Prevention and Comparative Risk Assessment." in: Adam M. Finkel and D. Golding, eds., Worst Things First? The Debate over Risk-Based National Environmental Priorities, Johns Hopkins University Press, 1994, pp. 229-236.

69.* John S. Evans, George M. Gray, Robert L. Sielken, Jr., Andrew E. Smith, Ciriaco ValdezFlores, and John D. Graham, "Use of Probabilistic Expert Judgment in Uncertainty Analysis of Carcinogenic Potency," Regulatory Toxicology and Pharmacology, Volume 20, 1994, pp. 15-36.

70.* John D. Graham, "The Risk Not Reduced," New York University Environmental Law Journal, Volume 3, No. 2, 1994, pp. 382-404.

71.* Nancy E. Isaac, Bruce Kennedy, and John D. Graham, "Who's in the Car? Passengers as Potential Interveners in Alcohol-Involved Fatal Crashes," Accident Analysis and Prevention, Volume 27, No. 2, 1995, pp. 159-165.

72. John D. Graham, "The Future of Risk Regulation," in Strategies for Improving Environmental Quality and Increasing Economic Growth (eds., Charles E. Walker, Mark A. Bloomfield, and Margo Thorning), Center for Policy Research, American Council for Capital Formation, Washington, D.C., 1995, pp. 3-18. Reprinted in: John D. Graham, "The Future of Risk Regulation," Environmental Engineer, Volume 31, No. 2, 1995, pp. 22-33.

73. Katherine D. Walker, March Sadowitz, and John D. Graham, "Confronting Superfund Mythology: The Case of Risk Assessment and Management," in Analyzing Superfund: Economics, Science, and Law (eds. Richard L. Revesz and Richard B. Stewart), Resources for the Future, Washington, D.C., 1995, pp. 25-53. Originally presented at the New York University School of Law Conference, "Superfund Reauthorization: Theoretical and Empirical Issues," December 3, 1993.

74.* March Sadowitz and John D. Graham, "A Survey of Residual Cancer Risks Permitted by Health, Safety and Environmental Policy," Risk: Issues in Health, Safety and Environment, Winter 1995, pp. 17-35.

75. John D. Graham, "Edging Toward Sanity in Regulatory Risk Reform," Issues in Science and Technology, Summer 1995, pp. 61-66.

76.* Tammy 0. Tengs, Miriam E. Adams, Joseph S. Pliskin, Dana Gelb Safran, Joanna Siegel, Milton C. Weinstein, and John D. Graham, "Five Hundred Life-Saving Interventions and Their Cost-Effectiveness," Risk Analysis, Volume 15, No. 3, 1995, pp. 369-389.

77. John S. Evans , John D. Graham, and George M. Gray, "A Distributional Approach to Characterizing Low-Dose Cancer Risk," in Low-Dose Extrapolation of Cancer Risks: Issues and Perspectives (eds. Stephen Olin, William Farland, Colin Park, Lorenz Rhomberg, Robert Scheuplein, Thomas Starr, and James Wilson), ELSI Press, Washington, D.C., 1995, pp. 253-274.

78. Harvard Group on Risk Management Reform, (ed. John D. Graham), "Reform of Risk Regulation: Achieving More Protection at Less Cost," Human and Ecological Risk Assessment, Volume 1, No. 3, 1995, pp. 183-206. Adapted from HCRA report, March 1995.

79. John D. Graham, "Historical Perspective on Risk Assessment in the Federal Government," Toxicology, Volume 102, 1995, pp. 29-52. Originally published by Harvard Center for Risk Analysis, March 1994.

80.* Evi J. Hatziandreu, Jeffrey J. Sacks, Ruth Brown, William R. Taylor, Mark L. Rosenberg, and John D. Graham, "The Cost Effectiveness of Three Programs to Increase Use of Bicycle Helmets Among Children," Public Health Reports, Volume 110, No. 3, 1995, pp.251-259.

81. John D. Graham, Comparing Opportunities to Reduce Health Risks: Toxin Control, Medicine and Injury Prevention, National Center for Policy Analysis, Washington, D.C., 1995.

82. John D. Graham and Richard R. Monson, Benzene and Leukemia: Time for a Reassessment? a report for the Western States Petroleum Association, Glendale, CA, 1995.

83.* John D. Graham and Elizabeth A. Richardson, "Ranking Risk Inequities," Risk: Health, Safety & Environment, Volume 6, 1995, pp. 359-372.

84.* David R. Holtgrave, Maureen R. Qualls, and John D. Graham, "Economic Evaluation of HIV Prevention Programs," Annual Review of Public Health, Volume 17, 1996, pp. 467-488.

85. John D. Graham and James K. Hammitt, "Refining the Comparative Risk Assessment Framework," in Comparing Environmental Risks: Tools for Setting Government Priorities (ed. Terry Davies), Resources for the Future, Washington, D.C., 1996, pp. 93-109.

86.* Sandra J. Baird, Joshua T. Cohen, John D. Graham, Alexander I. Shlyakhter, and John S. Evans, "Noncancer Risk Assessment: Probabilistic Characterization of Population Threshold Doses," Regulatory Toxicology and Pharmacology, Volume 2, No. 1, 1996, pp. 79-102.

87.* Bruce P. Kennedy, Nancy Isaac, and John D. Graham, "The Role of Heavy Drinking in the Risk of Traffic Fatalities," Risk Analysis, Volume 16, No. 4, 1996, pp. 565-569.

88. John D. Graham, "Making Sense of Risk: An Agenda for the Congress," in Risks, Costs, and Lives Saved: Getting Better Results from Regulation (ed. Robert Hahn), Oxford University Press, New York, NY, 1996, pp. 183-207. Presented at the American Enterprise Institute conference on Risk Assessment and Public Policy, Washington, D.C., October 27, 1994.

89. Tammy 0. Tengs and John D. Graham, "The Opportunity Costs of Haphazard Social Investments in Life-Saving," in Risks, Costs, and Lives Saved: Getting Better Results from Regulation (ed. Robert Hahn), Oxford University Press, New York, NY, 1996, pp. 167-182.

90.* Sandra J. Baird, Joshua T. Cohen, John D. Graham, Alexander I. Shlyakhter, and John S. Evans, "Noncancer Risk Assessment: A Probabilistic Alternative to Current Practice," Human and Ecological Risk Assessment, Volume 2, No. 1, 1996, pp. 79-102.

91.* Tammy 0. Tengs, Gregg Meyer, Joanna E. Siegel, Joseph S. Pliskin, John D. Graham, and Milton C. Weinstein, "Oregon's Medicaid Ranking and Cost-Effectiveness: Is There Any Relationship?" Medical Decision Making, Volume 16, No. 2, 1996, pp. 99-107.

92. John Ashby, et. al., "Principles of Evaluating Epidemiologic Data in Regulatory Risk Assessment," Federal Focus, Inc., Washington, D.C., 1996.

93.* John D. Graham and Lorenz Rhomberg, "How Risks Are Identified and Assessed," Annals of the American Academy of Political and Social Sciences, Volume 545, 1996, pp. 15-24.

94.* Kimberly M. Thompson and John D. Graham, "Going Beyond the Single Number: Using Probabilistic Risk Assessment to Improve Risk Management," Human and Ecological Risk Assessment, Volume 2, No. 4, 1996, pp. 1008-1034.

95. Jennifer K. Hartwell and John D. Graham, "Strategic Options for the U.S. Coke Industry: Striving Toward Clean Air Act Compliance," Corporate Environmental Strategy, Volume 3, No. 3, Spring 1996, pp. 51-59.

96. Maria Segui-Gomez and John D. Graham, "Economic Evaluation of Motor Vehicle Injury Prevention Programs: Methodology Review," 40th Annual Proceedings, Association for the Advancement of Automotive Medicine, October 7-9, 1996, Vancouver, British Columbia.

97.* Bruce P. Kennedy, Nancy E. Isaac, Toben F. Nelson, and John D. Graham, "Young Male Drinkers and Impaired Driving Intervention: Results of a U.S. Telephone Survey," Accident Analysis and Prevention, Volume 29, No. 6, 1997, pp. 707-713.

98. John D. Graham, "Politique de Réglementation pour la Maîtrise des Risques et des Coûts Associés," Annales des Mines, Octobre 1996, pp. 37-42.

99.* John D. Graham, Kimberly M. Thompson, Sue J. Goldie, Maria Segui-Gomez, and Milton C. Weinstein, "The Cost-Effectiveness of Airbags by Seating Position," Journal of the American Medical Association, Volume 278, No. 17, 1997, pp. 1418-1425.

100. John D. Graham, "The Rise of Epidemiology in Risk Assessment," a paper presented at Guangzhou Medical College, July 15-17, 1997.

101. John D. Graham, "Legislative Approaches to Achieving More Protection Against Risk at Less Cost," University of Chicago Legal Forum, Volume 1997, pp. 13-58.

102.* John D. Graham, Phaedra S. Corso, Jill M. Morris, Maria Segui-Gomez, and Milton C. Weinstein, "Evaluating the Cost-Effectiveness of Clinical and Public Health Measures," Annual Review of Public Health, Volume 19, 1998, pp. 125-152.

103. Kimberly M. Thompson, Maria Segui-Gomez, and John D. Graham, "Learning from the Past: Revisiting Expert Judgments Related to the Lifesaving Potential of Air Bags," Probabilistic Safety Assessment and Management, A. Mosleh and R.A. Bari, eds., PSAM 4, Volume 3, Springer, NY, 1998, pp. 2107-2112.

104.* Toben F. Nelson, Bruce P. Kennedy, Nancy E. Isaac, and John D. Graham, "Correlates of Drinking-Driving in Men at Risk for Impaired Driving Crashes," American Journal of Health Behavior, Volume 22, No. 2, 1998, pp. 151-158.

105.* John D. Graham, Sue J. Goldie, Maria Segui-Gomez, Kimberly M. Thompson, Toben Nelson, Roberta Glass, Ashley Simpson, and Leo G. Woerner, "Reducing Risks to Children in Vehicles with Passenger Air Bags," Pediatrics (electronic edition) 1998, Volume 102, No. 1; URL: http//www. pediatrics. org/cgi/content/full/ 102/1/e3.

106.* Maria Segui-Gomez, Roberta Glass, and John D. Graham, "Where Children Sit in Motor Vehicles: A Comparison of Selected European and American Cities," Injury Prevention, Volume 4, 1998, pp. 98-102.

107. James K. Hammitt and John D. Graham, "The Economic Value of Reducing Health Risks: Risk Perception, Communication, and Contingent Valuation," in Risk Analysis: Opening the Process, Proceedings of the SRA-E 8th Conference, Paris, October 11-14, 1998, Volume 2, pp. 1021-1027.

108.* Maria Segui-Gomez, Jonathan Levy, and John D. Graham, "Airbag Safety and the Distance of the Driver from the Steering Wheel," Letter to the Editor in The New England Journal of Medicine, Volume 339, 1998, pp. 132-133.

109.* Roberta Glass and John D. Graham, "Kids at Risk: Where American Children Sit in Passenger Vehicles," Journal of Safety Research, Volume 30, No. 1, 1999, pp. 17-24.

110.* Toben F. Nelson, Dana Sussman, and John D. Graham, "Airbags: An Exploratory Survey of Public Knowledge and Attitudes," Accident Analysis and Prevention, Volume 31, 1999, pp. 371-379. Adapted from "The Airbag's Teflon Image: A National Survey of Knowledge and Attitudes," Harvard Center for Risk Analysis, March 17, 1997.

111.* John D. Graham, Kim M. Clemente, Roberta J. Glass, and Nicole Pasternak, "Measuring Confidence in Hazard Claims: Scientists vs. Laypeople," Technology, Volume 6, 1999, pp. 77-87.

112.* John D. Graham, Roberta J. Glass, Kim M. Clemente, and Nicole Pasternak, "Measuring Public Confidence in Hazard Claims: Results of a National Survey," Technology, Volume 6, 1999, pp. 63-75.

113.* Toben F. Nelson, Nancy E. Isaac, Bruce P. Kennedy, and John D. Graham, "Factors Associated with Planned Avoidance of Alcohol-Impaired Driving in High-Risk Men," Journal of Studies on Alcohol, Volume 60, No. 3, 1999, pp. 407-412.

114.* John D. Graham, Nancy Beaulieu, Dana Sussman, March Sadowitz, and Yi-Ching Li, "Who Lives Near Coke Plants and Oil Refineries? An Exploration of the Environmental Inequity Hypothesis," Risk Analysis, Volume 19, No. 2, 1999, pp. 171-186.

115.* James K. Hammitt and John D. Graham, "Willingness to Pay for Health Protection: Inadequate Sensitivity to Probability?" Journal of Risk and Uncertainty, Volume 18, 1999, pp 33-62.

116.* Eve Wittenberg, Toben F. Nelson, John D. Graham, "The Effect of Passenger Airbags on Child Seating Behavior in Motor Vehicles," Pediatrics, 1999, Volume 104, pp. 1247-1250.

117.* Maria Sequi-Gomez, Jonathon Levy, Henry Roman, Kimberly M. Thompson, Kathleen McCabe, and John D. Graham, "Driver Distance From the Steering Wheel: Perception and Objective Measurement," American Journal of Public Health, July 1999, Volume 89, No. 7, pp. 1109-1111.

118.* James K. Hammitt, Eric S. Belsky, Jonathan L. Levy, and John D. Graham, "Residential Building Codes, Affordability, and Health Protection: A Risk-Tradeoff Approach," Risk Analysis, Volume 19, No. 6, 1999, pp. 1037-1058.

119.* Kimberly M. Thompson and John D. Graham, "Validating Analytical Judgments: The Case of the Airbag's Lifesaving Effectiveness," Reliability Engineering and System Safety, Volume 66, 1999, pp. 57-68.

120. Maria Segui-Gomez and John D. Graham "Patterns of Injury Among Drivers Hospitalized in Level-I Trauma Centers: Have Frontal Airbags Made a Difference?" 44th Annual Proceedings, Association for the Advancement of Automotive Medicine, October 2-4, 2000 Chicago, Illinois, pp. 171-185.

121. John D. Graham, "Perspectives on the Precautionary Principle," Human and Ecological Risk Assessment, Volume 6, No. 3, 2000, pp. 383-385.

122.* G.M. Gray, B.D. Goldstein, J. Bailar, D.L. Davis, E. Delzell, F. Dost, R.S. Greenberg, M. Hatch, E. Hodgson, M.A. Ibrahim, J. Lamb, T. Lavy, J. Mandel, R. Monson, M. Robson, R. Shore, and J.D. Graham, "The Federal Government's Agricultural Health Study: A Critical Review with Suggested Improvements," Human and Ecological Risk Assessment, 2000, Volume 6, No. 1, pp. 47-71. Originally published by Harvard Center for Risk Analysis, December 1998.

123. Karen S. Lissy, Joshua T. Cohen, Mark Y. Park, and John D. Graham, "Cellular Phone Use While Driving: Risks and Benefits," Harvard Center for Risk Analysis, July 2000.

124. John D. Graham, "Making Sense of Risk," Risk Analysis, Volume 20, No. 3, 2000, pp. 302-306.

125. Roberta Glass, Maria Segui-Gomez, and John D. Graham, "Child Passenger Safety: Decisions about Seating Location, Airbag Exposure, and Restraint Use," Risk Analysis, August 2000, Volume 20, No. 4, pp. 521-527.

126.* John D. Graham and Maria Segui-Gomez, "Economic Evaluation of Injury Control," Injury Control: A Guide to Research and Program Evaluation (ed. Frederick P. Rivara, Peter Cummings, Thomas D. Koepsell, David C. Grossman, and Ronald V. Maier), Cambridge University Press, Cambridge, United Kingdom, 2001, pp. 270-282.

127.* John D. Graham, "Civilizing the Sport Utility Vehicle," Issues in Science and Technology, Winter 2000-2001, pp. 57-62.

128.* Maria Segui-Gomez, Eve Wittenberg, Roberta Glass, Suzette Levenson, Ralph Hingson, and John D. Graham, "Where Children Sit in Cars: The Impact of Rhode Island's New Legislation," American Journal of Public Health, Volume 91, No. 2, February 2001, pp. 311-313.

129. Fred Anderson, Mary Ann Chirba-Martin, Donald Eliot, Cynthia Farina, Ernest Gelhorn, John D. Graham, C. Boyden Gray, Jeff Holmstead, Ron Levin, Lars Noah, Katherine Rhyne, and Jonathan Wiener, "Regulatory Improvement Legislation," Duke Journal of Environmental Law and Policy, in press. Adapted from HCRA report, June 1999.

130. John D. Graham, "Technological Danger Without Stigma: The Case of Automobile Airbags," Risk, Media and Stigma, ed. Paul Slovic, in press.

131.* John D. Graham, "Decision-Analytic Refinements of the Precautionary Principle," Journal of Risk Research, in press.

132. Maria Segui-Gomez, Sue J. Goldie, Milton C. Weinstein, Kimberly M. Thompson, and John D. Graham, "Using Cost-Effectiveness to Evaluate Alternative Airbag Deployment Levels," Risk Analysis, submitted.

133. Maria Segui-Gomez, Janice C. Wright, and John D. Graham, "Economic Evaluation of Injury Prevention: The Need for Standardization," Accident Analysis and Prevention, submitted .

134.* Kimberly M. Thompson, Maria Segui-Gomez, and John D. Graham, "Validating Benefit and Cost Estimates: The Case of Airbag Regulation," Journal of Policy Analysis & Management, submitted.

135.* Timothy J. Carrothers, John S. Evans, and John D. Graham, "The Lifesaving Benefits of Enhanced Air Quality," Risk Analysis, submitted.

## Editorial and Commentary

John D. Graham and Katherine D. Walker, "Environmental Risks: Paranoia and Neglect," The World & I, Volume 7, 1992, pp. 48-54.

John D. Graham, "Time for Congress to Embrace Risk Analysis?" Risk Analysis, Volume 14, No. 2, 1994, pp. 139-142.

John D. Graham, "Regulation: A Risky Business," The Wall Street Journal, May 18, 1994, p. A14.

John D. Graham and Katherine D. Walker, "How Clean is Clean?" Health and Environmental Digest, Volume 8, No. 3, 1994, pp. 17-19.

John D. Graham, "The New Congress: A Strong Finish on Regulatory Reform," Risk Policy Report, August 23, 1996, pp. 31-33.

John D. Graham and Pamela Dziuban, "Why Important Stories Are Underreported," Nieman Report, Volume I (4), Winter 1996, pp. 27-28.

John D. Graham, Letter to the Editor re: "Is Regulatory Reform Dead? Should Anyone Care?" Regulation, 1996, p. 4.

John D. Graham, "Phantom Dangers in the (Mis)Info Age," Los Angeles Times, November 14, 1996.

John D. Graham, "Think, Don't Leap on Health Hazards," Newsday, November 26, 1997, p. A48.

John D. Graham, "Sen. Collins Right on Need to Reform Federal Regulations," Portland Press Herald, April 28, 1998, p. 12.

John D. Graham, "Environmental Policy: Five Themes for the Future," Environmental Management, January 2000, pp. 36-37.

Congressional and Administrative Testimony and Comments

John D. Graham, Testimony on Clean Air Act Amendments of 1990, "S.816: The Toxics Release Prevention Act of 1989," Subcommittee on Environmental Protection, Committee on Environment and Public Works, U. S. Senate, Washington, D.C., 101st Congress, Second Session, 1989.

John D. Graham, "Recommendations for Improving Cancer Risk Assessment," comments submitted to the National Academy of Sciences, California's Environmental Protection Agency and the U. S. Environmental Protection Agency, July 1, 1992.

John D. Graham, Testimony on S. 3373, "The Bullet, Death, and Family Dissolution Act," Subcommittee on Social Security and Family Policy, Finance Committee, U. S. Senate, Washington, D.C. 102nd Congress, Second Session, October 23, 1992.

John D. Graham, Comments submitted to Ms. Dorothy Strunk, OSHA, regarding Risk-Risk Analysis, October 23, 1992.

John D. Graham, Comments submitted to Mr. Orron Kee and Mr. Barry Felrice, NHTSA, regarding CAFÉ and Safety, January 4, 1993.

Susan Putnam, John D. Graham, George Gray, Sandy Baird, Katy Walker, and Kim Thompson, "Comments on EPA's Integrated Risk Information System," submitted to the U. S. Environmental Protection Agency, April 15, 1993.

John D. Graham, Testimony on Reform of the Delaney Clause, Subcommittee on Department Operations and Nutrition, Committee on Agriculture, U. S. House of Representatives, Washington, D.C., 103rd Congress, First Session, July 14, 1993.

John D. Graham, Testimony on Reform of the Delaney Clause, Joint Hearing, House Subcommittee on Health and Environment and Senate Committee on Labor and Human Resources, Washington, D.C., 103rd Congress, First Session, September 21, 1993.

John D. Graham, Testimony on "The Role of Risk Analysis in Environmental Policy Making," Committee on Energy and Natural Resources, U. S. Senate, Washington, D.C., 103rd Congress, Second Session, November 9, 1993.

John D. Graham, Testimony on "The Role of Risk Assessment in Environmental Protection," Subcommittee on Transportation and Hazardous Materials, Committee on Energy and Commerce, U. S. House of Representatives, Washington, D.C., 103rd Congress, Second Session, November 17, 1993.

John D. Graham, "The Role of Risk Analysis in Environmental Protection," Subcommittee on Environment, Energy, and Natural Resources, Subcommittee on Legislation and National Security, Committee on Government Operations, U. S. House of Representatives, Washington, D.C., 103rd Congress, Second Session, February 1, 1994.

John D. Graham, Testimony on Title III, H.R. 9, "Risk Assessment and Cost-Benefit Analysis of New Regulations," Committee on Science, U. S. House of Representatives, Washington, D.C., 104th Congress, First Session, January 31, 1995.

John D. Graham, Testimony on Title III, H.R. 9, "Risk Assessment and Cost-Benefit Analysis of New Regulations," Committee on Commerce, U. S. House of Representatives, Washington, D.C., 104th Congress, First Session, February 2, 1995.

John D. Graham, Testimony on S. 291, "Regulatory Reform Act of 1995," Governmental Affairs Committee, U. S. Senate, Washington, D.C., 104th Congress, First Session, February 15, 1995.

John D. Graham, Testimony on S. 123, S. 229, S. 333, and S. 343, "Impacts of Regulatory Reform on Environmental Law," Committee on Environment and Public Works, U. S. Senate, Washington, D.C., 104th Congress, First Session, March 22, 1995.

John D. Graham, Statement to the National Transportation Safety Board, Supplemental Restraint Panel, Washington, D.C., March 17, 1997.

John D. Graham, Statement to the National Transportation Safety Board, Effectiveness Panel, Washington, D.C., March 19, 1997.

John D. Graham, Testimony on S. 981, "Regulatory Improvement Act of 1997, " Committee on Governmental Affairs, U. S. Senate, Washington, D.C., 105th Congress, First Session, September 12, 1997.

John D. Graham, Testimony on "The Role of Risk Science in Decision Making," Committee on Science, U. S. House of Representatives, Washington, D.C., 105th Congress, June 10, 1998.

John D. Graham, Testimony on the Regulatory Improvement Act of 1999 (S. 746), Committee on Governmental Affairs, U. S. Senate, Washington, D.C., April 21, 1999.

John D. Graham, Testimony on "Reauthorization of the Clean Air Act," Committee on Governmental Affairs, U. S. Senate, Washington D.C., October 14, 1999.

John D. Graham, Testimony on "Biotechnology in the Year 2000 and Beyond," U. S. Food and Drug Administration, Washington, D.C., November 30, 1999.

John D. Graham, Testimony on "Comparative Risk Assessment and Environmental Decision Making," Committee on Environment and Public Works, U. S. Senate, July 27, 2000.

## Service and Awards

Member, Editorial Board, Injury Control and Safety Promotion (1999).

Member, Highway Safety Study, Strategic Transportation Research Committee, Transportation Research Board, National Research Council (1989-1991).

Member, Committee to Identify Measures that May Improve the Safety of School Bus Transportation, Transportation Research Board, National Research Council (1987-1988).

Co-Recipient (with Steven Garber) of the annual Herbert Salzman Award for the "Outstanding Paper" in Volume 3 of the Journal of Policy Analysis and Management (1984).

Member, Editorial Board, Risk Analysis: An International Journal (1989-2001).

Member, Editorial Board, Accident Analysis and Prevention: An International Journal (1990-1999).

Member, NHTSA Motor Vehicle Safety Research Advisory Committee, U.S. Department of Transportation, Washington, D.C. (1990-1993).

Member, Editorial Board, Journal of Risk Research (1990 to 2001).

Member, Editorial Board, Risk: Health, Safety and Environment (1990 to 2001).

Member, Board of Visitors, Wake Forest University (1991 to 1994).

Outstanding Oral Presentation, "The Case for Motor Vehicle Injury Control," Society for Automotive Engineers, Industry-Government Meetings (May 16, 1991).

Award for Outstanding Service in Helping to Develop and Support the National Agenda for Injury Control, CDC (April 25, 1991 - awarded by Surgeon General Antonia Novello, M.D.).

Member, Committee to Review the Structure and Performance of the Health Effects Institute, Board on Environmental Studies and Toxicology, National Research Council (1992-1993).

Member, Ad Hoc Committee on Risk Analysis, Advisory Body to the President of the National Academy of Sciences (1994).

President, the Society for Risk Analysis (1995-1996).

Member, Board of Scholars, American Council for Capital Formation Center for Policy Research (1995-2001).

Member, National Council on Radiation Protection and Measurement (1997-2001).

Member, Public Health Policy Advisory Board (1997-2001).

1998 Annual Public Service Award from the Annapolis Center for Achievements in Risk Communication to the American People.

## Personal Facts

Born October 3, 1956; Married to Susan W. Graham; daughters, Jennifer Ann and Kathryn Woerner; hobbies include golf and bridge.

Date: April 6, 2001

**Pre-Hearing Questionnaire for John Graham**
**to be Administrator of the**
**Office of Information and Regulatory Affairs,**
**Office of Management and Budget**

## I. Nomination Process and Conflicts of Interest

1. Why do you believe the President nominated you to serve as Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB)?

   I believe I was selected on the basis of my academic and professional background, experience, and qualifications.

2. Were any conditions, expressed or implied, attached to your nomination? If so, please explain.

   No.

3. What specific background and experience affirmatively qualifies you to be Administrator of OIRA? Please describe your background and experience in relation to OIRA's various roles, which, as you know, include regulatory review, reduction of paperwork burden, and government-wide policy on information resources management and information technology.

   I have taught the tools of regulatory analysis (risk assessment, cost-effectiveness, and cost-benefit analysis) at the Harvard School of Public Health since 1985. I have also written several books and several dozen articles on how the federal regulatory process works in practice and how it can be improved. On numerous occasions, I have testified before congressional committees on the need for regulatory reform and I have provided technical advice on regulatory reform legislation to members of the House and Senate in both parties. I have less direct experience in the paperwork reduction area but am broadly sympathetic with the need to reduce the burdens of paperwork faced by regulatees and regulators, subject to the need to meet regulatory requirements. In the information arena, I have some relevant training and publications in the field of value-of-information (VOI) analysis, a branch of decision science. VOI analysis is concerned with quantifying the value to society of information that is not currently collected or disseminated to decision makers and the public. VOI analysis is also concerned about the problem of "imperfect" information, including information of poor quality, relevance, credibility, and/or reliability. The VOI framework recognizes that collection of information is often costly, and thus the social benefits of information collection/dissemination need to be weighed against the costs.

4. Have you made any commitments with respect to the policies and principles you will attempt to implement as Administrator of OIRA? If so, what are they and to whom have the commitments been made?

No.

5. If confirmed, are there any issues from which you may have to recuse or disqualify yourself because of a conflict of interest or the appearance of a conflict of interest? If so, please explain what procedures you will use to carry out such a recusal or disqualification.

I do not foresee any such conflicts. If issues should arise, I will work them out with OMB's General Counsel and the appropriate ethics officials at OMB.

## II. Role and Responsibilities of the Administrator of OIRA

1. How do you view the role of the Administrator of OIRA?

As with the OMB Director, my role begins with ensuring that OIRA serves the President. I see this as requiring that OIRA provide support for the President in policy making from the development of regulatory policy and information policy, to the development of statistical policy. In that capacity, I serve as a key advisor to the Director and the President and members of the cabinet. I will work closely with heads of other agencies and Congress to achieve results. My role also requires that OIRA fulfill any number of statutory requirements, examples of which are the Paperwork Reduction Act, the Clinger-Cohen Act, and the Congressional Review Act.

2. What challenges currently face OIRA? How will you, as Administrator, address these challenges and what will your top priorities be?

The major challenges facing OIRA are to meet its tasks with quality analysis that is produced quickly. If confirmed, I would propose to address these challenges by working hard to understand the individual projects underway in OIRA, to see how OIRA is carrying these out, and to then decide what kinds of improvements may need to be made or new initiatives undertaken.

## III. Policy Issues

*Regulatory Review*

1. OIRA has between 20 and 25 staff members to do an enormous amount of regulatory work. They are supposed to take action with regard to 3,000 to 5,000 information collection requests each year from federal departments and agencies under the Paperwork Reduction Act; review the substance of hundreds of significant rules each year under the

executive order on regulatory review; and perform other executive order, statutory, and policy responsibilities. Do you believe that OIRA would benefit from more resources to carry out its regulatory review mission?

Working with the Director, I will review OIRA's staffing needs. I also welcome the views from this Committee on how to strengthen OIRA's paperwork and regulatory analysis and review functions.

2. How do you view OIRA's role in the regulatory review process? To what extent should OIRA operate as an independent reviewer of agencies' regulatory proposals, or defer to the agency submitting the rules?

The President has the basic responsibility to take care that the laws of the land are faithfully executed. Where discretion exists within existing laws, I believe that regulatory proposals by agencies need to be responsive to the President's policies and priorities. Thus, it is ultimately the President, not the Administrator of OMB-OIRA or agency heads, who make regulatory decisions. Both the agencies and OMB, all of which report to the President, as Chief Executive, are performing specified and important roles. In its regulatory review function, OMB-OIRA has a crucial process role to play in making sure that agencies and the President have relevant information about promising policy options and their associated risks, costs, and benefits. Where there are uncertainties about risks, costs, and benefits, OMB-OIRA has a responsibility to make sure that important uncertainties are disclosed to agency heads, the President, and the public.

3. To your knowledge, is the current Administration planning to issue a new Executive Order on regulatory review?

The Administration has pledged to continue a role for OIRA. However, I am not aware of any Administration plans to issue a new Executive Order on regulatory review.

4. Last year, Congress passed a permanent law requiring that OMB issue an annual report estimating the costs and benefits of federal regulation and providing recommendations to reform regulatory programs. What is your opinion of the reports that OMB has issued in the past under similar statutory mandates? In what respects will your approach to preparing these reports be the same as, or different from, the approach used by OMB in the past for preparing reports under similar statutory mandates? When can we expect the next report?

I have not read the previous reports in great detail nor become familiar with the challenges that underlie preparing these reports, so I am not prepared at this point to identify specific recommendations for improvement. I can say that, if confirmed, I will take very seriously

this responsibility for developing a complete and accurate accounting of the effects of federal regulations. I will make every effort to submit all required reports to Congress in a timely fashion.

*Federalism*

5. Is the Administration intending to develop a new executive order on federalism? What role do you envision for OIRA in working with State and local governments?

On February 26, President Bush issued a Memorandum for the Heads of Executive Departments and Agencies, establishing an Interagency Working Group on Federalism. He charged this Working Group, inter alia, with drafting a new Executive Order on Federalism, which will require departments and agencies to adhere to principles of Federalism, and with consulting with State and local officials on the issuance of this new Order.

If confirmed, I think it is important to establish a regular OMB dialogue with the major State and local interest groups, which represent State and local elected officials. Since State and local governments are our partners, I welcome input from these groups on regulatory issues. Among my earliest priorities, I intend to review OMB's annual report to Congress on implementation of the Unfunded Mandates Reform Act of 1995 to assess further steps which may be necessary.

*Paperwork Reduction*

6. What is your opinion of OIRA's record with respect to implementation of the Paperwork Reduction Act? If confirmed, what actions would you take to improve on the implementation of the Paperwork Reduction Act? Please address such issues as (i) providing guidance to agencies; (ii) policies on the relationship between agencies' burden-reduction goal and the government-wide goal; (iii) designating pilot projects under the Act to test alternative policies and procedures to minimize information collection burdens; (iv) developing a government-wide information resource management strategic plan; and (v) keeping Congress and congressional committees fully and currently informed of major activities under the Act.

The Paperwork Reduction Act (PRA) emphasizes that agencies need to strike a balance, collecting the right information to meet their statutory obligations and program responsibilities to the public, while not requiring information that is unnecessary, has

little practical utility, or is unreasonably burdensome. OIRA is to review and approve or disapprove agency efforts in this regard.

I am aware of the concerns about the recent track record in paperwork reduction, and I take this problem seriously. I will ask OIRA staff to identify each statutory responsibility under the PRA and the status of OIRA's compliance. I will then ask OIRA staff what resources are needed and what is a realistic timetable to achieve compliance. In that context, I will be able to focus more specifically on the issues you raise.

7. The Paperwork Reduction Act contemplated a 35 percent reduction in paperwork burden; by now, that burden has actually gone up since 1995. What are your views on the value of these statutory burden-reduction goals and the annual Information Collection Budget? Do the agencies have a point when they argue that their burden reduction efforts are foiled by new statutory information collection requirements? What, if anything, do you believe OIRA can or should do to accomplish more burden reduction?

The Paperwork Reduction Act (PRA) strikes a balance between the costs and benefits of government information. The PRA directs agencies to collect or create only information that is necessary for the proper performance of agency functions and that has practical utility. It seeks to maximize the usefulness of information collected, used and disseminated by the Federal government, while minimizing the Federal and private costs of providing and managing that information.

There is no question that there are costs to the public and to the government of obtaining and using information. It is my understanding that Federal agencies are expected to spend nearly $45 billion in FY 2002 on information technology to manage Federal information. Federal agency requests for information impose very substantial burdens on the public. Understand that Americans spent some 7.4 billion hours complying with such requests in FY 2000.

Through the PRA, OIRA must help agencies meet their obligation to the public by striking the proper balance. The PRA should not be used as grounds for denying the government the ability to collect from the public what it needs. On the other hand, collection of unnecessary or duplicative information imposes unjustified costs on the businesses or individuals that must respond, on the taxpayer, and on the economy as a whole. It should not occur.

The PRA calls upon the agency Chief Information Officers (CIOs) and OIRA to work together to reduce the aggregate paperwork burden from federal collection of information, increase the public benefit from the usefulness of such information, and minimize the cost of the collection of such information. The statutory burden reduction goals emphasize the importance of these efforts.

OIRA is continuing to make serious efforts in this area, reviewing individual paperwork collection proposals and producing an annual Information Collection Budget that identifies, agency by agency, the agency initiatives under way to reduce paperwork burden and improve the quality of Federal data collection. If confirmed, I would place renewed emphasis on a coordinated effort to produce better results in this regard.

*Information Technology*

8. The Paperwork Reduction Act of 1995 (PRA) and the Clinger-Cohen Act of 1996 (CCA) require that agencies institute comprehensive capital planning and investment approaches for maximizing the value of their IT projects. How can OIRA best ensure that agencies are successfully meeting these requirements?

   As I understand based on briefings from OIRA staff, capital planning and investment control is critically important to getting the most out of the government's IT investments. An agency that implements a capital planning and investment control process provides a framework for sound IT investment decisions based upon the agency's business needs and then assessing and managing the risks so that the systems program and performance benefits are realized successfully. I understand that OIRA is working with the Resource Management Offices and other statutory offices this spring and summer on these issues.

9. Under the CCA, the Director of OMB is charged with evaluating the results of agency IT investments and enforcing accountability– including increases or reductions in agency IT funding proposals– through the annual budget process. Recently Deputy Director O'Keefe stated that the Administration intends to "establish a series of specific results for each major IT project." In fact, agencies will be required to show "what they are budgeting for and how it is going to accomplish established performance criteria." What will OIRA do to enforce IT investment accountability?

   OIRA staff have briefed me on the fact that agencies have made mixed progress over the last several years in the areas of capital planning, enterprise architecture, performance management, IT security, privacy, and e-Government. The majority of agencies have some process for capital planning yet many are just beginning to develop an enterprise architecture, address IT security and privacy, and make the transformation to an e-Government. I have not yet studied the question of how OIRA should enforce IT investment accountability.

10. What has OIRA done to improve the resources and skills it has in place to conduct or oversee internal OMB analyses of agencies' major IT funding requests? Do you have any specific plans in this area?

    As you may know, OIRA has been provided with a number of new statutory responsibilities within the last few years. Working with the Director and Deputy

Director, I plan on reviewing OIRA's staffing needs and welcome the views from this committee on how to strengthen OIRA's ability to influence agencies on these important matters.

11. What are the major information resources management and information technology challenges facing the government and what steps do you plan to take to focus attention on these issues?

Making the transformation to a fully electronic government will be an important priority for OMB and the government. Our other major challenges include ensuring privacy and security as we build e-government. OMB has statutory and policy responsibilities in these areas. Also, I expect to work with the Director, the DDM, and other senior OMB officials to ensure that agencies implement the Government Paperwork Elimination Act, which requires electronic options for most agency transactions by October 2003.

12. President Bush's Fiscal Year 2002 budget calls for Federal agencies to work together to consolidate similar functions around the needs of citizens,and businesses through the use of the Internet. In your opinion, what role should OIRA play in helping agencies expand their use of the Internet to create a citizen centric government?

OMB is committed to overseeing a transformation to a citizen-centered electronic government. The President's budget called for an electronic government that is citizen centric, results-oriented, and market-based. Based on OIRA staff briefings, there appear to be three basic ways OMB and OIRA can encourage and oversee e-government to meet this vision.

- First, through the information collection approval process, OIRA should push agencies to use the Internet and electronic reporting as methods of burden reduction for the general public. This work can also support OIRA's role in overseeing the implementation of the Government Paperwork Elimination Act.

- Second, we should continue to encourage agency participation in key projects under the CIO Council, as well as the other councils, that encourage cross agency collaboration around citizen and business needs.

- Third, OMB must make funding structures work for electronic government initiatives. The President's FY 2002 Budget allocates $45 billion dollars for IT investments across the government. We must make sure that the money is spent in a way that maximizes value to the citizen and uses the Internet where possible. The President's budget also included a $100 million fund for innovative, cross-agency electronic government.

13. In 1999, Senators Thompson and Lieberman introduced, S. 1993, the "Government Information Security Act" which was later enacted as part of the National Defense Authorization Act for Fiscal Year 2001 (P.L. 106-398). This law provides a comprehensive management framework to ensure the protection of sensitive federal computer systems and places accountability for this framework at the highest levels of the Executive Branch.

    a. Where do information security and privacy fall among your management priorities and what are your specific plans for implementation of the new law?

    Information security and privacy are top priorities for the Administration. OMB and the agencies take the security and privacy of government programs, and its information, with more than 26,000 computer systems and 2 million desk top computers, very seriously. We rely increasingly on computer systems to support nearly every critical governmental function. We are now more interconnected than ever, operating in a shared risk environment, with growing interdependence. The integrity and availability of systems and, where appropriate, the confidentiality and privacy of information in those systems are today more important than ever.

    The requirements in the recently passed Government Information Security Reform Act of 2000 highlight this importance and reinforce how essential security of federal systems and its information is today.

    I understand that OMB has begun to take significant steps to implement the Government Information Security Reform Act, and, if confirmed, I intend to build on this foundation.

    b. How do you plan to link attention to information security and privacy issues to the budget process?

    I understand this work has already begun. As part of the FY 2002 budget process, OMB required that agencies provide information on how computer security and privacy are budgeted for as part of agency requests for information technology funding. In this way, agencies think of security and privacy up front as they plan for electronic government, not after an incident occurs. This policy is now part of Circular A-130, and fully integrates security and privacy into the framework of capital planning that the Clinger Cohen Act established.

14. Recently, Deputy Director O'Keefe reiterated the importance IT holds for the Administration saying: " Making the transformation to electronic government, I think, is critically important and it's on the top of the agenda of the new Administration." As you know, there are Members of Congress who believe the government should appoint a

Federal Chief Information Officer in order to successfully facilitate the transformation to an electronic government. What are your views on this issue?

There is general consensus that IT is a critical component to achieving a government that is better managed and more responsive to citizens. In order to accomplish these important goals, IT leadership will be paramount.

During the campaign the President proposed establishing the title of Federal CIO and formally vesting these responsibilities with OMB's DDM. Currently the DDM has general oversight for IT and IRM issues as part of their broad Federal management responsibilities. The President's proposal would ensure a senior level commitment to these issues.

As OIRA Administrator, I would expect to work closely with the DDM on these issues, especially as OIRA carries out important responsibilities on information policy with regard to the collection and use of that information under the PRA.

15. In March of this year, GAO issued a report entitled "Information Management: Progress in Implementing the 1996 Electronic Freedom of Information Act Amendments" (GAO-01-378) in response to a request by Senators Thompson and Leahy, and Congressman Horn. Among other things E-FOIA requires that there be electronic availability of certain government information and encourages on-line, public access through electronic reading rooms. Many of the agencies have taken steps to comply with the E-FOIA requirements and some have gone further. However, the GAO report shows that agencies still have a long way to go in fully implementing E-FOIA and employing appropriate IT tools to facilitate the process. Although the Department of Justice is the lead coordinating agency on implementing E-FOIA, OMB has played an active role.

a. What do you believe is OIRA's role, if any, in this process?

OIRA, under its Paperwork Reduction Act responsibilities, provided guidance to the agencies in 1998 that addressed fulfilling the requirement under the E-FOIA amendments for a paper and online FOIA index and guide. OIRA's role will continue, and OIRA will work with the agencies to address issues of electronic access to public information through e-government initiatives.

b. How can IT policies and initiatives help in this regard?

OIRA continues to work with agencies on issues of electronic dissemination and information access. From a policy standpoint, I understand that OIRA plans to focus on ensuring that OMB Circular A-130, "Management of Federal Information Resources," will update how FOIA is handled as part of Section 8(a), which addresses Federal information policy.

16. The Information Branch within OIRA, with a staff of about ten, is responsible for implementing vital and far-reaching information laws and policies. These include administering significant portions of the Paperwork Reduction Act and much of the Director's information technology capital planning and performance-based management functions under the Clinger Cohen Act, implementing information security responsibilities, and overseeing agency implementation of the Government Paperwork Elimination Act and the Privacy Act. The Information Branch also must implement Administration policies in these areas, such as promoting e-government. Does the Information Branch of OIRA have sufficient staff to perform its work well?

It is true that OIRA has been provided with a number of new statutory responsibilities within the last few years. Working with the Director, I plan on reviewing OIRA's staffing needs and welcome the views from this committee on how to strengthen OIRA's ability in this regard.

17. In the absence of an established federal CIO position, who within the executive branch is to provide government-wide direction to IT priorities and spending?

Currently the DDM has general oversight for IT and IRM issues as part of broad Federal management responsibilities. Integrating the CIO function with the DDM's other responsibilities, like working with the Procurement Executive's Council and the Chief Financial Officer's Council, would be directly linked to IT management issues. In addition, the DDM can integrate management issues as part of the budget process at a level that ensures management attention by agency heads. As OIRA Administrator, I would expect to work closely with the DDM on these issues

18. The Administrator of OIRA is responsible by law for implementing the Paperwork Reduction Act, which includes important provisions relating to information resources management and dissemination of information to the public. What specific experiences in your background have prepared you to work in these areas?

In my role as the Director for the Center of Risk Analysis at Harvard's School of Public Health, I had to deal with such issues as our web content, accessibility of data, and disseminating our Center's newsletter. I am well aware – granted on a smaller scale than the entire Federal government – that the management and dissemination of information about an organization's mission to the public is important.

19. OIRA staff have traditionally been tasked with implementing the information technology capital planning and performance-based management provisions of the Clinger Cohen Act. What specific experiences in your background have prepared you to work in these areas?

In my previous job, I had to make decisions about information technology investments for the Center in collaboration with Harvard's IT staff.

20. What role do you believe OMB should take in encouraging electronic government initiatives? How can OMB be most effective in encouraging cross-agency collaborative efforts?

OMB is committed to overseeing a transformation to a citizen-centered electronic government. The President's budget called for an electronic government that is citizen-centric, results-oriented, and market-based. I think there are three basic ways OMB and OIRA can encourage and oversee e-government to meet this vision.

- First, through the information collection approval process, OIRA needs to push agencies to use the Internet and electronic reporting as methods of burden reduction for the general public. This work can also support OIRA's role in overseeing the implementation of the Government Paperwork Elimination Act.

- Second, OMB needs to continue to encourage agency participation in key projects under the CIO Council, as well as the other councils, that encourage cross agency collaboration around citizen and business needs.

- Third, OMB is working on funding structures to facilitate electronic government initiatives. The President's FY 2002 Budget allocates $45 billion dollars for IT investments across the government. We must make sure that the money is spent in a way that maximizes value and uses the Internet where possible. The President's budget also included a $100 million fund for innovative, cross-agency electronic government.

21. OIRA staff have helped to formulate and implement government-wide electronic government initiatives. What specific experiences in your background have prepared you to work in this area?

In my previous job as Director, I helped developed the Center's website and urged effective linking to other organizations that address risk management. Through our website and these linkages, we used the Internet to make our program more effective in a manner that I believe is applicable to the work of many agency programs. We also used the Internet to improve the way that we provide information about coursework offered by the Center's faculty.

22. What specific experience do you have in the area of information security?

As you know, the recently passed Security Act vests responsibility for computer security to the DDM. I'm becoming more familiar with this issue and I look forward to working with the DDM on this matter.

23. The Paperwork Reduction Act requires the establishment of a government information locator service (GILS). Federal agencies are also under mandate under the GILS and the 1996 amendments to the Freedom of Information Act, known as E-FOIA, to make an index of their major information systems and to provide descriptions of their records locator systems. How will OIRA work to ensure agencies follow through on their statutory mandate to provide these and other finder tools and fulfill the public's right to know?

    OIRA staff have briefed me on this matter. I understand that it is important for agencies to provide information in a way that the public can find and use. I intend to review the issues surrounding GILS in addressing this need. OIRA continues to work with agencies in their development of tools that make information easier to find as part of e-government. I also understand that there is a view that categorization tools like GILS can play an important role in achieving this objective and I look forward to working on these issues.

24. Under the Paperwork Reduction Act, agencies must calculate the burden that agencies place on the public in responding to agency information requests. How do you see technology helping to identify ways to reduce burdens across the federal government in collecting necessary information from the public, improve the efficiency of reporting, and improve public access to crucial information? Are there any concerns associated with efforts to integrate information collection, management and public access activities? And how should we address those concerns?

    Technology offers great opportunities to improve the collection, efficient handling and dissemination of information by the Federal government. For example, information technology allows a Federal agency to collect information intelligently by asking questions and correcting erroneous responses on the spot -- thus saving the respondent and the agency time and expense later. Furthermore, IT allows agencies to share more information more efficiently. With careful attention to maintaining individual privacy and confidentiality, such sharing can reduce the need to collect information another time from the public. And IT is opening-up whole new ways for government to disseminate information to its citizens -- in the last 10 years we have gone from paper pamphlets to websites in providing information to the public. I intend to review how OIRA addresses these important issues.

25. The Clinger-Cohen Act mandated the creation of a Chief Information Officer position in every executive agency, and specified that this individual report directly to the agency head and have information resources management as his or her primary responsibility. In

a few agencies, the CIO position is held by an individual with many diverse responsibilities and titles, including CFO and Chief Management Officer. In other agencies, this person reports to another executive at a level below the agency head.

a. What do you see as the appropriate reporting relationship for the agency CIO? Is it acceptable for a department or agency CIO to have additional duties and responsibilities beyond information management and technology?

While there is no one-size-fits-all answer to how an agency CIO should operate, I think that the most appropriate relationship is one that affords the CIO sufficient authority to manage the agency's portfolio of information resources in a manner that supports the agency mission and fulfills its business requirements.

According to OIRA staff, most successful agencies have CIOs that focus on information management and technology as their primary responsibility, and also focus on computer security and the transition to electronic government. They key is for CIOs to operate as part of an integrated team with other senior management and program officials so that technology they oversee supports the accomplishment of agency missions, goals and objectives.

b. What should the role of an agency CIO be in implementing GPEA and e-gov initiatives within and between agencies?

Citizens are expecting a more accessible and more efficient government that cuts across agency boundaries. The CIO is accountable for the agency's entire portfolio of information resources. CIOs are also responsible for partnering with other executives within their own agency and other agencies in an effort to re-design business processes and offer better services to citizens.

c. Do you believe that most of the federal agency CIOs have adequate input and/or authority over the agencies' IT budget and spending?

I am not familiar with the specifics of how agencies structure the CIO role in their internal budget process. I plan to look into this issue and welcome any thoughts that the Committee may have.

*Privacy*

26. What role will OIRA play in developing and enforcing the Administration's privacy policies? Do you believe that more must be done to improve the privacy practices of the federal agencies?

OIRA will continue to play a critical role in privacy policy formation by virtue of its statutory duties under the Privacy Act of 1974, the Computer Security Act of 1987, the Paperwork Reduction Act of 1995, the Information Technology Management Reform Act of 1996 (the "Clinger-Cohen" Act), and the Government Information Security Reform Act of 2000. OIRA will work to improve and expand recent initiatives with respect to privacy in the Federal Government.

OIRA's leadership role with respect to the Government's privacy policy has evolved over the years, and I anticipate this will continue. Playing this role provides an important link between the government's own use of personal information and the government's regulation of the use of personal information by others. OIRA's statutory duties with respect to Federal privacy coupled with its regulatory and legislative review functions make it a logical place for oversight of privacy issues.

27. Do you believe that a government privacy commission could be helpful to inform the debate on government privacy practices?

OIRA staff have made me aware of this issue, but I have been unable to fully examine its' implications. I look forward to working with the Committee on this issue.

28. OMB has taken a fairly active role in attempting to protect individual privacy online. Do you foresee any changes to OMB's role, and are changes needed to the Privacy Act to adequately protect individual privacy online?

OMB has statutory responsibility for Federal privacy issues under the Privacy Act and the PRA. OMB has taken on a strong privacy policy role as well. I expect this to continue as privacy is a critically important issue to the evolution of the Internet and as we work with Congress on pending Internet privacy legislation.

29. What is your level of familiarity with the privacy issues implicated in the Privacy Act of 1974? How much experience do you have working on privacy issues of relevance to Privacy Act implementation?

While I have little experience with the Privacy Act itself, I have struggled with issues relating to privacy in my work at Harvard. I look forward to working with the Committee on these issues.

*Statistical Policy and Coordination*

30. What are your views on the role that OIRA can play in helping the Census Bureau plan for future census efforts?

I am informed by OIRA staff that OMB and other agencies are involved extensively in efforts to examine alternatives to the traditional decennial census process. The Interagency Council on Statistical Policy (ICSP), chaired by OMB's Chief Statistician and composed of the leaders of the Federal Government's principal statistical agencies, has worked closely with the Census Bureau to develop an approach that will provide demographic, social, economic, and housing data *annually* for geographic areas at the State and local levels.

I believe OMB should continue actively reaching out to State and local governments, industry, public interest groups, and academic experts to hear their concerns, and to benefit from their advice and expertise. I am also informed that OMB and members of the interagency committee will work closely with the Census Bureau's advisory groups, who represent important viewpoints and played an active role in Census 2000 planning.

31. No question provided.

*Management*

32. What will you do as OIRA administrator to assure effective leadership and management with OIRA? Please address such areas as results-oriented management, financial management, information and technology, and human resources. What specific background and experience will you bring to this task?

    If I am confirmed as OIRA Administrator, I am committed to providing strong and ongoing leadership to manage OIRA effectively. I will recruit talented and well-trained staff to fill vacancies in OIRA. My experience directing the Harvard Center for Risk Analysis is relevant since I have, on numerous occasions, addressed challenges in financial management, information technology, and human resources.

33. What are your views on the organization of OIRA and the allocation of resources among the various activities undertaken by the office? Do you have any plans to reorganize or reallocate the resources of the office?

    I have not yet formed any views on the resource-allocation and organizational issues mentioned in this question. If confirmed, I plan to review the effectiveness of OIRA's organizational structure to ensure that OIRA's many responsibilities are carried out as effectively as possible.

## IV. Relations with Congress

1. Do you agree without reservation to respond to any reasonable summons to appear and testify before any duly constituted committee of the Congress if you are confirmed?

   Yes.

2. Do you agree without reservation to reply to any reasonable request for information from any duly constituted committee of the Congress if you are confirmed?

   Yes.

## V. Assistance

1. Are these answers your own? Have you consulted with OMB or any interested parties? If so, please indicate which entities.

   The answers are my own. Since receiving the questions from the Committee, I sought background information from the OMB staff.

AFFIDAVIT

I, John D. Graham, being duly sworn, hereby state that I have read and signed the foregoing Statement on Pre-hearing Questions and that the information provided therein is, to the best of my knowledge, current, accurate, and complete.

John D. Graham

Subscribed and sworn before me this 24th day of April, 2001.

Jessie M. Jones Hearn

Notary Public

Commission Expires: Aug. 14, 2004

**Additional Pre-Hearing Questions Submitted by Senator Joseph I. Lieberman for Dr. John D. Graham, Nominee to Be Administrator, Office of Information and Regulatory Affairs**

## I. General

1. You have described the Office of Information and Regulatory Affairs (OIRA) as being responsible, within the Executive Office of the President, for the "political work of regulatory decision-making."[1] If confirmed as OIRA Administrator, do you intend to perform for the Bush Administration the "political work of regulatory decision-making"? Please explain the meaning of your comment and whether and exactly how you intend for OIRA to play a "political" role if you are confirmed as Administrator.

ANSWER

My chief responsibility is to pursue analytic rigor in regulatory deliberations. There are also important political or policy-level dimensions to the OIRA Administrator's role in regulatory decision-making. For example, the OIRA Administrator plays a role in resolving disputes about regulation between the Executive Office of the President and the agencies, in building interagency consensus when multiple agencies have an interest in a regulatory matter, and in working with the White House and the OMB Director to respond to congressional concerns about regulatory decision-making. If confirmed, I expect to play roles in these areas.

## II. Regulatory Review

2. Describing the current Executive Order on regulatory review, E.O. 12866, you have said "it has some flaws, and I'd like to see it stronger, but it also has some basic principles that are sound."[2] Please explain in detail what, in your opinion, are the flaws, in what ways would you like to see it stronger, and what basic principles are sound or unsound.

---

[1] J. Wiener and J. Graham, "Resolving Risk Tradeoffs," in J. Graham and J. Wiener (editors), Risk vs. Risk: Tradeoffs in Protecting Health and the Environment (1995), page 260.
[2] J. Graham, speech at Heritage Foundation Lecture No. 559, "Making Regulatory Reform a Reality" (Jan. 1, 1996).

ANSWER

The cost-benefit principles in E.O. 12866 are sound. A flaw in the Order is that it does not give adequate treatment to risk assessment, even though these assessments are important to benefit estimation and are more broadly significant in their impact on resource allocation in society. Another flaw is that it does not give much guidance on what regulators should do when there are major scientific uncertainties about the risks, costs, and benefits of alternative regulatory options. If confirmed, I will work with OIRA staff and others to decide whether and in what ways to address these flaws.

3. What is your opinion of OIRA's track record in the area of regulatory review? If confirmed, in detail what, if anything, would you plan to do differently?

ANSWER

I have not studied OIRA's historical track record and have not yet determined what things should be done differently.

4. Please describe the guiding principles that you think should govern regulatory review. For example, if the agency head to whom Congress assigned responsibility for issuing a regulation has decided that a particular rule is appropriate or required under criteria specified or permitted by law, under what, if any, circumstances should OIRA be able to delay or reject the regulation?

ANSWER

If the substantive content of a rule is required by law, OIRA's review role may be extremely limited. When a statute leaves policy discretion to the agency, the OIRA role is greater and the President's policies and priorities can be implemented to a greater extent. In some situations, recognizing the discretion available to the agency, OIRA may suggest modifications to a draft rule that should make it more effective and/or less costly. In other situations, OIRA may have questions or issues about the supporting regulatory analysis, which it will need to address with the agency. I expect that these matters will generally be resolved promptly, so that OIRA review can be concluded within the standard time frame. In some cases, though, an extension of the review period may be needed, or the draft rule may be returned for further consideration, in accordance with E.O. 12866.

5. In 1993 you testified favorably of "the renewed openness of the regulatory review process under the Clinton Administration."[3] Do you intend to maintain that openness, and, if so, exactly how will you do so? During the early years of regulatory review, OIRA came under heavy criticism from some Members of this Committee and others for the way in which OIRA conducted reviews of agency rules. Agency rules would languish at OIRA, sometimes for years, with little or no explanation to the public. In an attempt to address these problems, provisions were incorporated into E.O. 12866 to assure that regulatory review is timely, fair, accountable, and transparent. The E.O. sets up a 90-day period for OMB review of proposed rules and creates mechanisms for timely resolution of disputes. The E.O. also establishes public-disclosure requirements for both OMB and the agency. For example, disclosure guidelines apply to substantive communications between OIRA personnel and persons outside the executive branch. OMB must provide a written explanation for all regulations returned to the agency; the agency must publicly identify changes made after OIRA review; and documents exchanged between OMB and the agency must be made public.

   a. Will you support and assure continuation of these and other transparency and disclosure requirements in E.O. 12866, and the 90-day time-frame and dispute-resolution process for regulatory review set forth in E.O. 12866?

      ANSWER

      I am committed to overseeing a timely, fair, transparent, and accountable review process. I have not yet determined how the specific requirements and processes in Executive Order 12866 impact OIRA's day-to-day functioning and whether any changes are appropriate. If confirmed, I will also look into new ways to enhance further the transparency of OIRA review.

   b. What are your ideas to further improve the transparency of the OIRA review process (for example, by upgrading information on reviews through the OMB website)? Will you implement these ideas?

      ANSWER

      I would like to see OIRA make greater use of the Web to notify the public of OIRA's activities and to disseminate docket materials, though I will need to examine the resource implications of these moves. If confirmed, I intend to work

---

[3] J. Graham, "The Role of Risk Analysis in Environmental Policy Making," Testimony before the Senate Committee on Energy and Natural Resources, November 9, 1993. *See, also*, J. Graham, "Time for Congress to embrace risk analysis?" in Risk Analysis, vol. 14, no. 2 (1994), page 140.

with the OMB Director and OIRA staff to determine what improvements in transparency are feasible and affordable.

6. Will the new Administration establish, or do you or the Administration contemplate establishing, a regulatory-relief task force like the Council on Competitiveness set up during the first Bush Administration, to monitor agency rulemakings from outside of OMB? Many came to see the Council on Competitiveness, which did not have to disclose its dealings, as a backdoor conduit for regulated interests seeking to stop agency action. Will the Vice President or some other official outside of OMB be assigned responsibility over regulatory disputes among agencies? In either case, what means would you recommend and how will you act to maintain transparency and accountability, so that the entity or official would not become a "conduit" by which outside parties interested in a rulemaking could affect the regulatory review process at OIRA or the regulatory process at the agency off the record and without disclosure?

**ANSWER**

I am not aware of any Administration plans to implement a specific dispute-resolution mechanism, nor am I aware of a need to do so.

7. E.O. 12866 also states that one of its goals is to "reaffirm the primacy of Federal agencies in the decision-making process." This was in response to what many saw as the heavy-handedness of OIRA during earlier administrations. Technical and policy judgments that were originally made by the agencies with expertise and the mandate from Congress to make those judgments were then superseded by regulatory reviewers within OMB, who lacked the expertise and the statutory mandate to make those judgments in such areas as protecting the public health, the environment, and consumers. Do you agree that the regulatory agency to which Congress delegated responsibility for formulating and adopting the rule, rather than OMB, should have primacy in decision-making? If you agree, what assurances can you give that OMB will honor the primacy of agencies in the decision-making process? If you do not agree, what do you believe should be the respective roles of the agency and OMB?

**ANSWER**

The rulemaking agencies have been given the statutory authority to promulgate regulations. As the head of the Executive Branch, the President has the inherent authority to oversee agency implementation of statutes. Recent Presidents have accomplished this oversight through Executive Orders and OMB review of agency's proposed and final rules. The proposed and final rules are issued by the rulemaking agencies, not OMB.

8. What changes to E.O. 12866 or to applicable policies and guidance for implementing it does the Administration intend or contemplate, based on your discussions with Administration officials or other nominees, and what changes (other than what you have discussed above) would you recommend should be made?

**ANSWER**

I am not aware of any discussions of the Administration's plans on this matter and have not yet determined what I would recommend.

9. Would you commit to notifying and working with me and other interested members of the Senate Committee on Governmental Affairs (GAC) before the Administration makes any changes to E.O. 12866 or to applicable policies and guidance?

**ANSWER**

If confirmed, I will work diligently to keep the Committee informed and engage in dialogue, as appropriate.

### III. Paperwork Reduction

10. Some have criticized OIRA for not meeting the government-wide paperwork reduction targets in the Paperwork Reduction Act (PRA). To what extent do you believe the PRA, or OIRA's implementation of it, strike an appropriate balance between the benefits to the public and the burdens on the public that flow from data collection by federal agencies, and to what extent should the PRA or OIRA's implementation be changed?

**ANSWER**

I have not studied this matter in sufficient depth to have an informed opinion.

11. The PRA directs that OIRA review agencies' information-collection proposals strictly on the basis of the burden imposed on the public, with no consideration of the benefits of collecting the information. Government collection of information is needed, for example, to learn about and address risks to health, safety, and the environment, to collect taxes, to ascertain customer satisfaction under the government's customer-service programs, and even to enable agencies to report their progress in meeting goals under the Government Performance and Results Act. Given your advocacy of cost-benefit analysis generally, do you think it should be applied to paperwork requirements?

ANSWER

Yes, I think cost-benefit reasoning is appropriate in the paperwork arena. PRA directs OMB to balance the agency's need for information, the practical utility of the information to be collected, and the burden on respondents. Thus, both the benefits of the proposed collection, and its burdens, are considered.

12. At times OIRA has been criticized for using its paperwork clearance process to control substantive agency decision-making or policies. What are your views about the legality and appropriateness of using OIRA's paperwork authority for that purpose? Are there any circumstances where you would consider using the paperwork clearance process to control or alter agency decisions or policies? If so, please describe.

ANSWER

I have not studied this matter in sufficient depth to have an informed opinion.

## IV. Cost Benefit Analysis

13. E.O. 12866 requires: "Each agency shall assess both the costs and the benefits of the intended regulations and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs."

a. Do you support this formulation, or do believe that it should be changed?

ANSWER

I am comfortable with this formulation, yet open to hearing other suggestions as well. One area where I have a firm opinion is that the word "justify" is preferred to "outweigh" because justify would seem to better accommodate non-quantifiable considerations that are sometimes important in regulatory decision-making.

b. How do you believe this provision should be applied to statutory mandates under which Congress has directed that regulations should not be based on agencies' cost-benefit analysis? Will you in any way apply this provision to challenge the agency's policy judgments implementing such mandates?

ANSWER

No. E.O. 12866 states that this provision shall be applied "to the extent permitted by law." I will work with agencies to respect existing law as well as the Executive Order.

c. What costs and benefits cannot or should not be quantified, and how do you believe those costs and benefits should be addressed and accounted for by agencies? (Please provide representative examples.)

ANSWER

Given current analytic tools, it is often difficult to quantify the ecological and natural resource impacts of regulatory alternatives. When impacts can be identified but not quantified, regulatory judgment needs to be exercised by accountable decision-makers.

14. You believe in applying a cost-benefit test to regulations, and you have endorsed comparative risk assessments that make judgments about allocation of resources based on the comparative risks of different regulated activities and costs of controlling those risks.

a. To what extent is your approach consistent with the statutory mandates established in the environmental laws implemented by EPA? Please review each major EPA statute in this regard. Exactly what standards will you apply in reviewing regulations under environmental statutes that require "technology standards," or protection of public health with an adequate margin of safety, or "feasibility" standards, or protection of the environment? If an environmental technology standard, for example, satisfies the statutory criteria mandating such a standard, what assurance can you provide that you will not reject the standard because you conclude that it fails a cost-benefit test or is low priority under a comparative-risk test?

ANSWER

I do not know whether my approach is consistent with existing mandates and I do not have the requisite legal expertise to determine which environmental laws could accommodate some of the insights from comparative risk analysis and cost-benefit analysis. I can assure you that any efforts to move in this direction would be based on sound legal advice.

b. To what extent is your approach consistent with the statutory mandate established in the Occupational Safety and Health Act, which requires the Secretary of Labor to set the standard that "most adequately assures, to the extend feasible, on the

basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity. The paramount consideration under the Act is "the highest degree of health and safety protection for the employee." Exactly what standards will you apply in reviewing regulations under that Act? If an OSHA regulation satisfies the standard under the Act, what assurance can you provide that you will not reject the regulation because you conclude that it fails a cost-benefit test or is low priority under a comparative-risk test?

ANSWER

I am not an expert on OSHA, but recognizing the Supreme Court's BENZENE and COTTON DUST decisions, I can assure you that any efforts to move in this direction would be based on sound legal advice.

c. Generally, can you provide assurance that, in providing guidance and oversight to EPA, OSHA, and other agencies, you will support all applicable statutory mandates, however much you may personally disagree with them?

ANSWER

Yes.

15. Generally, how would you assign monetary value to the benefits of regulations that protect public health? To what extent can such benefits not be monetized or quantified?

ANSWER

OMB has already published some guidance on this subject that reflects significant bodies of academic thought in environmental and health economics. I would like to see this guidance document updated periodically. In my own analytic work, I have tended to favor cost-effectiveness approaches that do not entail valuing public health in solely economic terms. Yet I see value in fostering a variety of approaches to valuing public health benefits.

16. In 1996, you wrote that some costs and benefits remain difficult to quantify, and in addition that fairness and justice considerations may persuade us to adopt some rules that would "flunk" a strict net-benefit test; therefore, "a strict net-benefit test is ill-advised."[4] In 1997, you expressed a more time-limited view, writing that a strict cost-benefit test was not desirable "[a]t the present time," because some important categories of costs and

[4] J. Graham, "Making Sense of Risk: An Agenda for Congress," in R. Hahn (editor), Risks, Costs, and Lives Saved (1996), pages 199-200.

benefits, "for example, ecological consequences and impacts on privacy and personal freedom," could not be quantified and monetized "yet."[5] Were you implying in 1997 that monetization of all values and application of a strict cost-benefit test should be our objective? What is your view now? Will OIRA under your leadership work towards having all or most values affected by regulations, including ecology, privacy, and personal freedom, quantified and monetized? Will you work towards applying a strict cost-benefit test to them?

**ANSWER**

A strict net-benefit test is ill-advised because some consequences cannot yet be quantified (e.g., ecological and natural resource damages) and others may be best left unquantified (e.g., freedom, privacy, and justice). It is very difficult to predict what will be analytically feasible far in the future.

17. How do cost-benefit analyses account for fundamental facts about "whose cost" and "whose benefit"? Won't there always be times when it makes sense to impose pollution controls that may not pass a cost-benefit test, in order to correct a social injustice, such as when a factory is responsible for causing high levels of toxic emissions next to a residential neighborhood even if the number of people in the neighborhood is not large? In fact, don't many environmental safeguards seek to protect people from exposures such as this? In your opinion, how should a cost-benefit analysis take into account a statute based on the proposition that the costs of installing control technology should be borne by the industry that may be polluting, rather than allowing the public to bear the costs of breathing the polluted air?

**ANSWER**

A classical cost-benefit analysis is concerned only with the difference between benefits and costs, regardless of who wins and loses. Concerns about equity can be accommodated in a more practical cost-benefit test if, for example, equity impacts are considered a nonquantifiable benefit or cost. Alternatively, equity impacts might be considered a relevant policy consideration in regulatory choice that is simply not covered by cost-benefit analysis. In the example provided, there is certainly a concern about the elevated health risks experienced by residents living near factories.

18. The Harvard Group on Risk Management Reform, which you convened, stated that, although they believed that monetizing all costs and benefits makes the analysis more systematic, "the analysis can simultaneously be impaired because the diverse outcomes at

---

[5] J. Graham, "Legislative Approaches to Achieving More Protection Against Risk at Less Cost," in University of Chicago Legal Forum (1997), page 49.

stake might best be seen for themselves, rather than be converted into a unitary scale. For example, some of the goods involved in environmental policy — aesthetic values, the quality of life in a community, ecological values, health values, and distributional concerns — are qualitatively diverse, and should be allowed to be expressed as such. This point does not mean that cost-benefit analysis should not be undertaken, but it does mean that any good cost-benefit analysis should offer a disaggregated as well as monetized picture of the goods at stake."[6] Do you agree with the importance of offering a disaggregated picture of the values at stake in environmental and other regulatory policy? If so, how would you further and institutionalize this view at OIRA and government-wide?

**ANSWER**

Yes, disaggregated presentations of benefits and costs are often a useful supplement to aggregated presentations. I have not yet given careful consideration to how best to carry this out.

19. In your writings, have you advocated the use of the Quality-Adjusted-Life-Year (QALY) to measure the benefits of air pollution controls, rather than the Value of Statistical Life (VSL) approach?[7] The QALY approach deals in changes in expected years of survival, weighted by a measure of their health-based quality. It has been argued that the QALY method values the preservation of the lives of young, robust people far more highly than preservation of the lives of old, frail or sickly people, whereas the VSL approach assumes that saving the life of one kind of person is of equal value to saving the life of any other kind of person. It has further been argued that, in comparison to the VSL approach, the QALY method generally assigns a lower value to air pollution controls, because of the way QALY measures the value of saving the lives and health of the old and frail, and generally assigns a higher value to safety measures that tend to benefit younger, healthier individuals. Do you agree with this characterization of these valuation measures?

**ANSWER**

No, I think the issues are a bit more complicated than the characterization suggests. First, when implemented as economic theory suggests, the VSL approach does not assign the same value to each life saved but instead allows this value to vary depending upon factors such as the preferences and wealth of the people at risk. The QALY approach, in

---

[6]Harvard Group on Risk Management, Special Report, "Reform of Risk Regulation: Achieving More Protection at Less Cost," in Human and Ecological Risk Assessment, vol. 1, no. 3 (1995), pages 183, 194-195.

[7]*E.g.*, Carrothers, Graham, and Evans, "Valuing the Health Effects of Air Pollution," Risk in Perspective, vol 7, no. 5 (Harvard Center for Risk Analysis, July 1999).

contrast, assigns the same value to each healthy year of life, regardless of the wealth and preferences of the people at risk. Second, there are efforts to merge the VSL and QALY frameworks, drawing insights from both perspectives. Although these efforts are not yet ready for immediate application at agencies, progress is being made. Third, the QALY approach may assign higher values to pollution prevention than the VSL approach in cases where the lives of children are impacted by pollution. Finally, I do agree that any approach to valuation based on years of life saved will give greater weight to prevention of trauma than chronic disease because fatal cases of trauma tend to strike early in the lifespan while fatal cases of chronic disease tend to strike later in the lifespan. I do have a paper under review (with two co-authors) at a journal that applies the QALY approach to valuing reductions in outdoor pollution exposures.

a. Do you believe that the decision whether to employ the VSL measure, or the QALY measure, or, indeed, some other measure for assessing the benefits of a health or safety regulation, is a judgment regarding what the goals and values of the regulatory program should be? Should the appropriate choice require considering the particular statutory mandate and Congressional purposes applicable to a particular regulation or program?

ANSWER

Administrative agencies, in collaboration with OMB, will often have to make these choices because legislation generally does not direct the use of a particular value.

b. Who should decide what metric to use in measuring the benefits of lifesaving regulations, and on what basis, and through what administrative process? As OIRA Administrator, would you tell EPA and other agencies whether they should use the QALY method, or some other method, for valuing the benefits of regulations, or would that decision be made by the individual regulatory agency? Do you think different measures might be used to implement different statutory mandates, or would you require that the same measure or measures be used government-wide?

ANSWER

I have not studied this matter in sufficient depth to have a firm opinion.

20. A decision to discount the value of future benefits, and, if so, the decision to apply a steep discount rate, can very significantly reduce the estimated benefits of certain regulations, like many environmental regulations, that prevent long-term ecological harm and long-latency diseases like cancer. Discounting generally has much less downward effect on the calculated benefits of safety regulations, which tend to prevent more immediate injuries. Do you agree?

ANSWER

Yes, except it should be noted that discounting depresses the value of safety rules that prevent crippling injuries (e.g., paraplegia) that are associated with lifetime costs to the patient and society.

a. What are your views about whether to discount and what discount rate to use? Please describe the range of mainstream economic opinions on this subject, and where your own views fit within the range?

ANSWER

For intragenerational discounting, my impression is that real discount rates between 0 and 7% are worth analyzing. A recent Expert Panel commissioned by HHS chose 3% as a preferred central value. I am not aware of a consensus view on intergenerational discounting.

b. How would you apply discounting to regulations that protect future generations? Should we apply a method for calculating benefits under which the preservation of the lives of our children counts for less than preserving our own lives?

ANSWER

This is a very controversial area where I have not developed a firm opinion.

c. Do you believe the decisions whether to discount and, if so, what discount rate to use, involve judgments regarding what the goals and values of the regulatory program should be?

ANSWER

Legislation generally does not address the use of discount rates specifically, thereby leaving it a matter for policy discretion.

d. Considering the profound effect the discount rate can have on the calculated benefits of environmental and other regulations, who should decide on the discount rate, and on what basis, and through what administrative process? Do agencies now have some flexibility, in practice, to choose which discount rate to apply in valuing benefits for regulatory impact analyses for OIRA? As OIRA Administrator, would you continue that practice, or would you attempt to require that all agencies use the same discount rate for all programs?

ANSWER

I have no firm opinion on this matter and have not studied the discounting practices at various agencies.

21. How should cost-benefit analysis reflect the judgment made by Congress in some statutes that pollution-control technology should be "forced" — that is, that a pollution-control requirement will cause industry to devote its ingenuity to finding technological solutions? In these and other situations, how can current cost estimates reflect the changes that technological advances will bring?

ANSWER

In projecting the future costs of a technology-forcing rule, it may sometimes be appropriate to apply a cost-reducing learning factor derived from experience with previous rules. In order to put this idea into practice, research is needed to quantify the cost-reductions (or unexpected increases) experienced after enactment of previous regulatory programs.

22. a. Overall, exactly what changes have you contemplated or would you intend to make (in addition to any discussed above) in the guidance, policies, and practices issued or employed by OIRA, with respect to cost benefit analysis in agency rulemaking?

ANSWER

I have not formulated any plans in this area.

b. Would you commit to notifying and working with me and other interested Members of the Senate Committee on Governmental Affairs before making significant changes?

ANSWER

If confirmed, I will be diligent to work with the Committee, and will engage in dialogue, as appropriate.

**V. Risk Analysis, Comparative Risk Assessment, and Risk-Based Priority Setting**

23. You have advocated a strengthened role for the Executive Office of the President in overseeing the analysis and ranking of health, safety, and environmental risks government-

wide. As OIRA Administrator, would you seek to establish such a strengthened role under the Bush Administration?

ANSWER

I have not made any definite plans to move in that direction.

a. How do you believe such responsibilities should be allocated among *(i)* the Science Advisor to the President working through the Office of Science and Technology Policy (OSTP), *(ii)* OMB and OIRA, and *(iii)* other offices?

ANSWER

I have written that I believe that OSTP and OIRA should have distinct yet complementary roles in reviewing risk assessments and cost-benefit analysis, respectively. However, I am open to other ideas to buttress the review capabilities of the Executive Office of the President.

b. Would you recommend legislation to accomplish this? If so, what would be its provisions?

ANSWER

I have not developed firm opinions about whether legislation is the way to go.

c. To what extent could your recommendations be implemented without new legislation? Do you intend to do so, or to recommend that the Administration do so?

ANSWER

I do not know what could be done without new legislation. I have not developed specific plans in this area.

24. Please explain in detail what you believe should be OMB's and OIRA's role in overseeing regulatory risk analysis and risk priorities?

a. As OIRA Administrator, will you have OIRA issue guidelines on how federal agencies should conduct risk analysis?

ANSWER

I have not developed specific plans in this area.

b. Will OIRA review agency risk analysis determinations to assure compliance with the guidelines?

ANSWER

I have not developed specific plans in this area.

c. In conducting regulatory review, will OIRA review risk analyses supporting the regulations to assure compliance with risk analysis guidelines?

ANSWER

I have not developed specific plans in this area.

25. You have written: "In the regulatory review process, OMB should, in collaboration with OSTP, scrutinize rulemaking proposals and make sure that sound risk assessment practices are being employed by agencies. Special attention should be given to the proper use of analytic tools that have been under utilized or poorly utilized in the past, including quantitative uncertainty and variability analysis, risk-tradeoff analysis, and value-of-information analysis."[8] Please explain what each of these analytic tools is, on what basis you have concluded they have been under utilized or poorly utilized in the past, how you would, as OIRA Administrator, foster their proper use, and how that would improve regulation. (Insofar as you discuss certain of these tools in responding to other questions, there is no need to repeat here.)

ANSWER

Quantitative uncertainty analysis provides insight into how much confidence should be assigned to estimates of risk, benefit, and cost. Variability analysis provides insight into how many people or resources will be placed at different levels of risk, information important to identifying the populations at highest risk. Risk-tradeoff analysis entails estimating how much of risk A (if any) must be accepted in efforts to reduce risk B. Value-of-information analysis provides insight into whether regulators should act now, based on uncertain information, or defer a decision until specified research programs are undertaken and completed. The available literature describing the analytic practices of agencies does not yet reveal widespread use of these tools. An example of a constructive role for OIRA might be to cosponsor with an agency a workshop for analysts to learn the value and limitations of these tools.

---

[8] J. Graham, "Legislative Approaches to Achieving More Protection Against Risk at Less Cost," in University of Chicago Legal Forum (1997), page 55.

26. You have recommended that risk tradeoff analysis, in particular, should be "forcefully implemented" by OMB and OIRA.[9] You have explained that analysis of risk tradeoffs means that, when an agency develops a regulation to reduce one risk, the agency should identify and evaluate other risks that may be increased as a (usually inadvertent) side-effect of the regulation. You foresee what you call an "iterative process," whereby the agency developing a regulation analyzes risk tradeoffs, OIRA reviews and provides suggestions or instructions, and then the agency conducts further analysis or reanalysis.[10]

    a. How would you prevent this "iterative process" from becoming a prescription for "paralysis of analysis"? For example, do you believe that the analysis of risk tradeoffs should extend in the direction of what many experts would regard as speculative and indirect effects — such as macroeconomic effects, or the health and safety consequences of any marginal impact on wealth?

    ANSWER

    When thinking through the value of learning about speculative and indirect effects, the question becomes whether that information would have enough social value to justify the delay consumed in the extra analysis.

    b. Some researchers at HCRA subscribe to a "richer is safer" hypothesis, which views a marginal reduction in disposable income as causing a reduction in safety and health. Do you subscribe to this hypothesis, and would you require agencies to report and analyze a supposed harm to health and safety caused by any regulation that diminishes disposable income?

    ANSWER

    I have written several papers on this topic but have no specific plans to require agencies to perform "wealth-health" analyses.

27. Do you believe that there is a connection between regulatory costs and unemployment, and, if so, please explain.

    ANSWER

    I am not an expert on this matter, but I am skeptical for reasons described in my 1992 submission of comments to OSHA.

---

[9] J. Wiener and J. Graham, "Resolving Risk Tradeoffs," in J. Graham and J. Wiener (editors), Risk vs. Risk: Tradeoffs in Protecting Health and the Environment (1995), page 255.
[10] *Id.*

28. You wrote that the Clinton Administration under E.O. 12866 had "been inclined to tolerate" agencies not performing risk analyses for regulations implementing Congressional mandates that made such analyses irrelevant to the decision the agency was required to make.[11]

a. As OIRA Administrator, would you change that policy and begin rejecting agency rules that are not supported by full risk analysis, regardless of whether the analysis would be relevant to the agency's decision under its Congressional mandate?

ANSWER

I have no specific plans to move in this direction.

b. You discussed the example of EPA's development of technology standards for air toxics under the 1990 Clean Air Act. You found fault with EPA's decision (and OIRA's "tolerating" that decision) to develop those standards without first conducting full risk analyses to ascertain the benefits of the pollution reduction. But, in enacting the 1990 Act, didn't Congress adopt technology standards specifically so that EPA would adopt air-toxics controls promptly, without conducting risk analyses, thereby avoiding the delays that EPA had experienced under prior legislation which had mandated such analyses? Would a policy by OIRA to require risk analysis for such standards therefore flout Congressional intent?

ANSWER

As a legal matter, I am not certain whether legislation prohibited agencies from conducting risk assessments of air toxics.

c. You wrote it was a "misstep" for EPA to issue its air toxics regulations without first completing risk analyses, because now it will be harder for the agency to demonstrate the benefits of its regulations to Congress.[12] But under a statute like the Clean Air Act, would it be more responsive to the will of Congress for the agency to issue the regulations promptly, without holding them up while risk analyses are completed, and then subsequently to commission whatever analyses may be necessary to support future legislative or agency decision-making?

---

[11] J. Graham, "Making Sense of Risk: An Agenda for Congress," in R. Hahn (editor), Risks, Costs, and Lives Saved (1996), pages 184, 196.
[12] *Id.*, pages 198-199.

ANSWER

I see merit in this argument, but I also fear that the agency may never get around to collecting the information required to demonstrate the benefits of the air toxics program.

d. You have further argued that "the risk assessments of air toxics at EPA took years to complete under the Reagan Administration. The root cause of delays is a lack of courage or interest on the part of regulators, a problem that should be addressed through the appointments, confirmations and oversight processes, rather than through arbitrary restrictions on the quality and quantity of analyses performed by agency scientists."[13] You thus advise us that Congress should address concerns about regulatory delay through rigorous scrutiny of nominees and rigorous oversight. But if Congress also chose legislatively to restrict the analyses required before rules may be issued, should OIRA respect that decision, even if you believe that the problem should not be addressed that way?

ANSWER

OIRA should clearly respect the law.

e. What does the record of the air toxics program tell us about the relative advantages of a risk- or cost-benefit-based approach as compared to a program based on technology standards? From 1970 to 1990, the Clean Air Act included a risk-based air toxics requirement, and during those 20 years EPA managed to issue standards for just 7 hazardous air pollutants. During the 10 years after the 1990 Clean Air Act amendments, EPA has issued technology standards to control air toxics from dozens of industries, resulting in large reductions in hazardous air emissions. Do you agree with this description of the history, and what, in your opinion, does it tell us about the value of a technology-based approach compared to a risk-based approach?

ANSWER

I think the historical description is accurate. The problem is that now we do not have the information required to determine whether the benefits of regulating dozens of industries were sufficient to justify the costs.

29. The Harvard Group on Risk Management Reform, which you convened, recommended against OMB assuming more power over risk assessments. "Otherwise, suspicions could arise that OMB is forcing agencies to manipulate risk assessments in order to promote

---

[13] J. Graham, "Legislative Approaches to Achieving More Protection Against Risk at Less Cost," in University of Chicago Legal Forum (1997), page 51 (citation omitted).

OMB's risk-management preferences. Given OMB's historical role in regulatory review, we believe scientific accountability would be better assured through OSTP leadership of risk assessments."[14] One panel member wrote: "in order to maintain balance and independence, any such function must be lodged in an institutional context other than OMB-OIRA." Do yo agree? As OIRA Administrator, how would you address these concerns that OIRA might manipulate risk assessments in order to promote OMB's risk-management preferences?

**ANSWER**

I think this is a serious issue and, if confirmed, I will investigate a variety of alternatives for securing appropriate review of agency risk assessments, including better peer review at agencies, a new role for OSTP or a buttressed OIRA.

30. Do you believe OMB has sufficient authority under E.O. 12866 to do what you believe it should do in overseeing regulatory risk analysis, or would you want expanded authority by either executive order or statute? If the latter, exactly what additional authority under statute or executive order would you need or want?

**ANSWER**

I have not developed specific plans on this matter.

31. Could OIRA exercise such authority effectively with its current staffing or would its expertise in risk analysis and related scientific fields have to be buttressed?

**ANSWER**

I have not yet done a detailed analysis of OIRA's current staffing.

32. You have written that, to respond to concerns about excessive politicization of analytic functions, "[i]t is important that new power centers [in the Executive Office of the President should] publish their analyses for public criticism as well as work internally with government officials."[15] More generally, a member of the Harvard Group on Risk Management Reform reported: "Because of the indeterminacy of knowledge, and the need to respect non-scientific values such as equity," it is essential that increased oversight of risk assessment be "a means

---

[14]Harvard Group on Risk Management, Special Report, "Reform of Risk Regulation: Achieving More Protection at Less Cost," in Human and Ecological Risk Assessment, vol. 1, no. 3 (1995), page 193.

[15]J. Wiener and J. Graham, "Resolving Risk Tradeoffs," in J. Graham and J. Wiener (editors), Risk vs. Risk: Tradeoffs in Protecting Health and the Environment (1995), page 258.

of opening up the value components of technical analyses to more effective public review and control, not . . . a means of delegating political choices to unreviewable experts."[16] What procedures will you implement or recommend to assure that any centralized oversight of risk analysis is open to public criticism, review, and control?

ANSWER

I have not yet given this matter sufficient thought to offer an informed opinion.

33. You have recognized in your writing that requiring risk analysis does have the potential for contributing to "paralysis of analysis," and you have made several suggestions for addressing that potential problem. As OIRA Administrator, how exactly will you avoid "paralysis of analysis"? For example —

a. You have written that agencies generally should "tailor the intensity of analysis to the importance and complexity of the specific problems."[17] As OIRA Administrator, how would you institutionalize this principle?

ANSWER

I am not sure that the principle can be institutionalized, but I will certainly be sensitive to the need to manage analytical resources to limit and hopefully avoid "paralysis by analysis."

b. You have advocated application of the "value-of-information" methodology for determining when it is appropriate to undertake further studies in lieu of regulatory action. Please explain this methodology and how you would apply it as OIRA Administrator to avoid "paralysis of analysis."

ANSWER

If the benefits of further study are likely to be less than the costs (including delay of regulatory benefits) of deferred regulation, then the "paralysis of analysis" should be avoided. In many cases the "value of information" analysis may need to be performed intuitively or qualitatively.

---

[16]Harvard Group on Risk Management, Special Report, "Reform of Risk Regulation: Achieving More Protection at Less Cost," in Human and Ecological Risk Assessment, vol. 1, no. 3 (1995), Supplementary Statement of Sheila Jasanoff, page 201.
[17]J. Graham, "Making Sense of Risk: An Agenda for Congress," in R. Hahn (editor), Risks, Costs, and Lives Saved (1996), page 184.

c. To avoid "paralysis of analysis," you have also recommended that "Congress should provide adequate budgetary and technical resources for agencies to discharge their analytical functions."[18] You have also warned that, if those who advocate reforming the regulatory system were to cut EPA's budget, they would invite this rejoinder: "Look, they want to have more responsibility for EPA, but then they want to cut them. Isn't that an indication that they really want [regulatory] relief, that they don't really want reform."[19] From this perspective, what is your opinion of the Administration's FY 2002 budget proposal? An analysis by the Senate Budget Committee Democratic Staff (April 12, 2001) reports that, in addition to other cuts in environmental and natural resource programs, the Administration's budget "slashes science programs in the Interior Department and EPA, making it harder for the government to produce sound science to examine environmental problems."

i How might such budget cuts, if enacted, affect your ability to obtain the quality of environmental science and analysis that you would want as OIRA Administrator?

**ANSWER**

I have not been briefed in detail on EPA's budget and any impacts on analytical functions relevant to OIRA.

ii As OIRA Administrator, would you advocate within the Administration to increase funding for environmental science and other environmental programs?

**ANSWER**

I favor science programs that support an enhancement of EPA's risk assessment capabilities.

34. You have recommended that Congress should authorize the Director of OMB to promote risk-based priority-setting in the regulatory review process. How would you propose that this be done? To what extent could this be accomplished without specific authorizing legislation?

a. For example, you have written that, in regulatory review, OMB should "promote and evaluate agency use of alternative risk-reduction plans in order to advance rational priority setting."[20] You explained that an "alternative risk-reduction plan" is a plan

---

[18] *Id.*

[19] J. Graham, speech at Heritage Foundation Lecture No. 559, "Making Regulatory Reform a Reality" (Jan. 1, 1996).

[20] J. Graham, "Legislative Approaches to Achieving More Protection Against Risk at Less Cost," in University of Chicago Legal Forum (1997), page 55.

proposed by the regulated entity to reduce risk by a greater degree than compliance with the applicable regulation. "For example, an oil refinery might propose to fund promising AIDS-prevention and violence-prevention programs for a ten-year period . . . in a community where the refinery is located in exchange for reducing benzene emissions by only 60 percent instead of the mandated 90 percent."[21]

i As OIRA Administrator, would you recommend legislation of this sort? If so, what would be its provisions?

**ANSWER**

I have no specific legislative plans in this area.

ii To what extent could your recommendation be implemented without authorizing legislation? Do you intend to do so, or recommend that the Administration do so through Executive Order?

**ANSWER**

I do not know whether legislative authorization is required and have no specific plans in this area.

iii Have you ever published or otherwise developed a detailed proposal for administering and enforcing a regulatory program authorizing alternative risk-reduction plans such as your AIDS- and violence-prevention example?

**ANSWER**

I have published (with March Sadowitz) a rather detailed proposal in the context of Superfund reforms that promote community choice in risk reduction. The article was published in "Issues in Science and Technology," 1994.

b. In reviewing an agency rule, do you believe OIRA now has authority, or would you seek authority, to consider whether the rule is consistent with OIRA's views about appropriate priorities? For example, if EPA proposes regulations to further reduce air pollution emissions from power plants, as Administrator Whitman has indicated she may pursue, do you think it would be appropriate for OIRA to decide whether to reject such regulations in favor of: *(i)* A program to control indoor air pollution? *(ii)* A program to build better treatment centers for asthma-related illnesses? *(iii)* An increase in funding

[21] *Id.*, page 46.

for asthma-related prevention research? *(iv)* An alternative risk-reduction plan such as violence prevention programs?

ANSWER

I have no plans to implement risk-based priorities in this manner.

35. You have testified that regulatory agencies should demonstrate that they are focusing on the highest risk issues as part of their budget submissions. You have proposed that OMB should require agencies to engage in risk-ranking exercises, and OMB should use the risk-based information in responding to budget requests.

    a. What factors should be considered in determining appropriate rankings?

    ANSWER

    My paper with Dr. James Hammitt (1996) addresses this matter in some detail.

    b. To what extent would the ability to set such risk-based priorities across agencies (and even within some agencies) be constrained by the mandates in organic statutes (*e.g.*, the Clean Air Act, the Clean Water Act, the Occupational Safety and Health Act, etc.)? Would statutory requirements and their different risk mandates make inter-agency comparisons and priority-setting difficult, if not impossible?

    ANSWER

    Statutory constraints can be expected to limit the influence of risk-based priorities.

36. How would risk ranking such as you describe relate to processes under the Government Performance and Results Act?

ANSWER

The challenge is to develop risk-based measures of performance and results.

37. You have explained that there are different kinds and measures of risks:

    a. You have written: "The choice of metric can obviously affect the risk ranking: accidents will be considered relatively more important than cancer-causing chemicals if risk is measured by expected number of years of life lost rather than by the increase in mortality

probability, because accidents typically kill people at younger ages than do cancers."[22] In a risk-ranking system, who should choose the metric, on what basis, and through what administrative process?

**ANSWER**

A team of researchers at Carnegie-Mellon University has experimented with tools that permit citizen advisory groups to collaborate with risk analysts in choosing various metrics for risk ranking. Early risk-ranking exercises at EPA were controlled primarily by experts and/or senior agency managers. State and local risk-ranking exercises have shied away from a single metric and instead allowed participating scientists, citizens, and stakeholders to perform rankings in whatever manner seemed to work best. There is no single answer to the question.

b. Many environmental regulations and programs preserve ecology and natural resources as well as health. Should such regulations be ranked against other health and safety programs solely in terms of their respective life- and health-saving potential, which might well lead to the ecological purpose of the environmental regulation being disregarded? Or should the ecological function be taken into account in setting agency and government priorities? You wrote that "there is no accepted basis for comparing risks to ecosystems with those to human health," and a judgment whether a habitat destruction is a greater risk than toxic air pollution "reflects a combination of scientific and value judgments."[23] Exactly how, and by whom, and following what administrative process, do you believe the ranking should be conducted?

**ANSWER**

This is a very profound issue: how to weigh the well-being of people against ecosystem well-being. I have no special wisdom to offer.

c. In considering the significance of a risk to the public, it matters whether the risk is under a person's control, or whether it is forced on a person involuntarily or even without the person's knowledge. There are other matters associated with risk and risk-reduction, such as equity, human rights, privacy, and community preservation. Some essential values affected by regulation remain unquantifiable. Do you believe all of these different kinds of risks and values should be ranked on a single scale?

---

[22]Graham and Hammitt, "Refining the CRA Framework," in Davies (editor), Comparing Environmental Risks: Tools for Setting Government Priorities (Resources for the Future, 1996), page 96.
[23]*Id.*, pages 96 - 97.

ANSWER

A ranking does not necessarily require a unitary numerical scale. In many risk-ranking exercises, rankers simply put different problems in categories (e.g., high, medium, and low) based on a judgmental evaluation of multiple values.

38. Your recommendations about risk-related priorities appear to be based on the premise that, as a society, we can only provide protections against certain risks to health, safety, or the environment if we give up opportunity to protect against other risks. For example, do you believe we must choose between safeguarding people against hazardous air pollution and providing childhood vaccinations? Between improving indoor air quality and preserving natural resources and ecosystems? Please explain your views on this subject.

ANSWER

If society has unlimited resources to devote to risk reduction, then there is no need for risk-based priorities. Since the resources of the public and private sectors are limited, there may be a role for explicit risk-based priority setting within or even across agencies. If these priorities are established explicitly rather than implicitly, then a variety of good-government values are enhanced (e.g., transparency and accountability).

39. Would you commit to notifying and working with me and other interested members of the Senate Committee on Governmental Affairs before any significant changes are made at OIRA or elsewhere in the Administration regarding centralized oversight and review of how agencies conduct risk analyses and of how risk-based priorities are set ?

ANSWER

If confirmed, I will work diligently to keep the Committee informed and engage in dialogue, as appropriate.

## VI. Regulatory Accounting, Regulatory Budgeting

40. A rider attached to one of last year's spending bills established a permanent requirement that OMB prepare a regulatory "accounting statement" each year, reporting on the estimated total annual costs and total annual benefits of federal rules and paperwork. I and several other members of the Governmental Affairs Committee expressed significant concerns about this kind of requirement, which I would ask you now to address:

a. Concerns were expressed that the preparation of information for these reports not impose unreasonable new burdens on regulatory agencies, diverting their scarce resources away from fulfilling their own statutory mandates. This was not a problem under the previous Administration, because OMB asked agencies to provide estimates of costs and benefits based on existing analyses. Will you commit not to ask agencies to conduct, prepare, or revise analyses for the purpose of providing information to OMB for the accounting statement?

ANSWER

I have not studied this question in sufficient depth to have an informed opinion.

b. Concerns were expressed that this kind of report could be misleading by understating the benefits of regulations and overstating the costs. This is because many key values affected by a regulation to protect health, safety, and the environment, and particularly benefits, are difficult or impossible to quantify or monetize. Even though the legislation mandates that non-quantifiable costs and benefits be included, an accounting report can provide a distorted picture, because it aggregates and focuses attention on the numbers from individual cost-benefit analyses and may downplay and obscure the various statements of nonquantifiable benefits. Do you agree? How will you make sure that OMB's regulatory accounting statements do not place undue emphasis on the quantified and monetized values or downplay or obscure the unquantified?

ANSWER

I agree that both quantified and non-quantified benefits and costs should be reported, even though it may be difficult to achieve consensus on a single approach to reporting.

c. As discussed in earlier questions, the choices of methods for measuring and calculating quantifiable costs and benefits are based on explicit or implicit judgments of public policy and values, but those judgments can get obscured and buried when multiple cost and benefit estimates get aggregated into a single number or chart of numbers. Furthermore, the Harvard Group on Risk Management, quoted above, emphasized that the diverse outcomes of regulation — such as aesthetic values, quality of life in a community, ecological values, health values, and distributional concerns — are qualitatively different and should be expressed as such, rather than being converted into a unitary scale; and that diversity can be obscured when costs and benefits from multiple regulations are compiled and aggregated. Do you agree with these concerns about how an accounting statement can give a misleading and distorted picture, and, if so, what will you do minimize these problems?

ANSWER

I think a combination of aggregated and disaggregated reporting makes sense. Yet we must also be aware that the number of permutations of possible disaggregated reports is large.

d. Some have argued that estimating cumulative costs and benefits provides little of value for policymaking. Decisions about regulatory programs should be made rule-by-rule, and estimates of aggregate costs and benefits of other regulations should not alter the decision of whether a particular rule is warranted. Furthermore, OMB has emphasized that large gaps in data and lack of agreement on methodology make the analyses of limited use for decisions. Do you agree?

ANSWER

I have not studied these issues in sufficient depth to have an informed opinion.

e. The legislation requires OMB to obtain independent and external peer review of the accounting statements and reports and applicable guidelines. As you know, there is a wide range of opinion regarding how best to evaluate and characterize the costs and benefits of regulations and what recommendations to derive. How will you assure that a wide range of opinions is represented on these peer review panels and that the panels are balanced?

ANSWER

I have no specific plans on the design of peer review panels.

41. You have recommended that Congress should require the President periodically to propose to Congress a regulatory budget and program, providing a total budget for the costs incurred as a result of risk-regulation activities, including sub-budgets for particular agencies and programs, and listing and justifying specific risks that will be addressed by regulatory action under the budget.[24]

a. Please explain how this recommendation would work, and what are its advantages and disadvantages.

ANSWER

The basic idea is to stimulate explicit decision-making about limits on the overall and agency-specific costs that federal regulation imposes on the private sector and State and

[24] J. Graham, "Legislative Approaches to Achieving More Protection Against Risk at Less Cost," in University of Chicago Legal Forum (1997), page 51.

local governments. As a country, we currently have explicit decision-making about federal budgetary expenditures; why not have a similar process for expenditures induced by regulation?

The advantages of this approach are: (1) it would encourage Congress and the President to consider costs that are not reflected in the federal budget, (2) it would stimulate discussion about what overall degree of regulatory burden is desired in the USA, and (3) it would encourage specific agencies and programs to trim unnecessary costs from their regulatory programs, since such savings in their "Budget" would make room for additional rules with corresponding benefits. The disadvantages of this approach are: (1) it requires more investment of resources in tracking the costs of regulation, and (2) it may cause decision-makers to focus too much attention on costs compared to regulatory benefits.

b. As OIRA Administrator, would you propose such legislation?

**ANSWER**

I have no specific plans to propose such legislation.

c. To what extent could your recommendation be implemented without new legislation? Do you intend to do so, or to recommend that the Administration do so?

**ANSWER**

I have no specific plans to implement a regulatory budget.

d. You have written that the statutory requirement that OMB estimate and report the total costs and total benefits of regulation is "a modest step toward a regulatory budget."[25] Could you explain this comment? Will you use the regulatory accounting statement, or the process for its preparation, as a way to begin implementing, or laying the groundwork for implementing, a regulatory budget?

**ANSWER**

The accounting statement provides rudimentary, annual information on regulatory costs, which is information that is necessary to implement a regulatory budget plan. I have no specific plans to begin implementing a regulatory budget.

---

[25] J. Graham, "Legislative Approaches to Achieving More Protection Against Risk at Less Cost," in University of Chicago Legal Forum (1997), page 52.

e. If you intend to implement any portion of a regulatory budget and program, how would you address and minimize each of those concerns raised in the previous question in the context of regulatory accounting statements?

ANSWER

I have no specific plans to begin implementing a regulatory budget.

f. Would you commit to notifying and working with me and other interested members of the Senate Committee on Governmental Affairs before you or others in the Administration implement any portion of a regulatory budget and program?

ANSWER

I will certainly keep the Committee informed on this matter and engage in dialogue, as appropriate.

### VII. Regulatory Reform Legislation

Background for questions related to regulatory reform legislation: You have been a leading proponent of omnibus "regulatory reform" legislation to change the criteria and process by which regulations are adopted government-wide, including testifying at least three times before this committee in its favor. In advocating such legislation, you have described our existing health, safety, and environmental statutes, and the arguments in support of these statutes and against regulatory reform, in such terms as the following:

- Arguing for regulatory reform legislation, you identified the major environmental laws — specifically, hazardous waste laws, the Safe Drinking Water Act, the Clean Air Act, and the Clean Water Act — as embodying the "most egregious departures" from your key principles.[26]

- More recently, you told Congress that, because provisions of the Clean Air Act require "safe" levels of pollution, the resulting health protections are based on "mythology."[27]

---

[26] J. Graham, "Edging Toward Sanity on Regulatory Risk Reform," in Issues in Science and Technology (Summer 1995), pages 61, 64-65.

[27] J. Graham, Response to post-hearing question number 9, submitted to the Senate Committee on Environment and Public Works under cover of a letter dated January 3, 2000, following up on testimony at a hearing on Reauthorization of the Clean Air Act, October 14, 1999.

- You have argued that the American people "suffer" from a "syndrome of paranoia and neglect" about dangers to their health, safety, and environment; that regulatory reform can help "cure" that "syndrome," but that one impediment is that reform would require "challenges to various power structures in Washington, D.C., and elsewhere that have capitalized and prospered from the syndrome."[28]

- You have testified that, because our allocation of lifesaving resources places too much effort addressing some risks and not enough addressing others, a failure by Congress to enact regulatory reform legislation would be a "shocking display of 'statistical murder.'"

  As you know, regulatory reform legislation has not passed. The intent of this and several following questions is not to debate the pros and cons of regulatory reform legislation. Rather, the purpose is to explore how you would approach your responsibilities at OIRA under a statutory framework that does not include the regulatory reform you have endorsed.

42. If confirmed, you would be expected to faithfully oversee the implementation of statutes that you call "egregious," statutes applying health-protection principles you call "mythology," statutes enacted and preserved in response to what you call the public's "syndrome of paranoia and neglect," statutes that you suggest are protected by the influence of unnamed "power structures" thriving off of the public's irrationality. You have said that preservation of these statutes in their present form is an act of "statistical murder." Will you be able to faithfully oversee the implementation of environmental and other statutes, and be constrained by their provisions, no matter how much you may disagree with them? If, as you have said, you believe our current statutory arrangements amount to "statistical murder," will you feel tempted or justified in skirting the law in order to reduce your own complicity?

    ANSWER

    The answers are "yes" to the former question and "no" to the latter question.

43. What are the "power structures" you refer to in the quotation set forth above, and please describe the basis on which you concluded that they have "capitalized and prospered from the syndrome [of paranoia and neglect]" and that the reform you advocate is impeded because it would require "challenges" to these power structures? Can you demonstrate that, as OIRA Administrator, your dealings with these "power structures," as well as your dealings with various members of the public and officials within the government who may hold views about regulatory reform different from yours, would be responsive and open-minded?

    ANSWER

---

[28] J. Graham, "Making Sense of Risk: An Agenda for Congress," in R. Hahn (editor), Risks, Costs, and Lives Saved (1996), pages 184, 186, 188.

These power structures include the mass media, the activist community, government, industry, and even some academics. If I make this transition from college professor to OIRA Administrator, I can pledge that I will be responsive and open-minded to people who hold different views than my own. At the Harvard Center for Risk Analysis and the Harvard School of Public Health, I regularly collaborate productively with faculty, staff and students whose views on matters of public policy are different from mine.

44. In arguing for regulatory reform legislation, you singled out for criticism the 1990 Clean Air Act Amendments requiring regulation of "so-called 'hazardous air pollutants' by specified deadlines, regardless of whether the risks posed by the pollutants are significant or whether regulatory costs are reasonably related to benefits."[29] You wrote that, in enacting this and other similar technology-based standards of the environmental laws, Congress said, in effect: "You, industry, must change your technology because we, Congress, perceive there is a problem, although we may have no science or numbers to back our perception and no idea what the changes will cost you."[30]

a. Do you base your claim that Congress had "no science or numbers" to back our perception of the problem, and "no idea" of the costs to industry, on your review of the hearings and debates leading to the adoption of these statutes?

ANSWER

No, I based the claim on the fact that EPA risk assessments were not performed for the 189 hazardous air pollutants and cost-benefit analyses were not performed on the controls to be imposed on each of the affected industries.

b. Part of that legislative history includes your testimony on September 21, 1989, before the Senate Committee on Environment and Public Works, Subcommittee on Environmental Protection. You testified that people who live very close to industrial sources of air toxics may experience substantial elevations in lifetime cancer risk, "say, in the range of 12 in 100 to 1 in 1,000," presenting a serious equity issue that you said Congress should address. Accordingly, you recommended that Congress should adopt "technology-based standards for the first phase of pollution reduction [for air toxics]. We also need deadlines and so-called 'hammers' to accompany the technology-based standards."

i How do you reconcile this testimony with your subsequent criticism of the provisions adopted in the 1990 Act, and with your advocacy of "supermandates" to supersede these same provisions?

---

[29] J. Graham, "Edging Toward Sanity on Regulatory Risk Reform," in Issues in Science and Technology (Summer 1995), pages 61, 64.
[30] *Id.*, page 65.

ii How do you reconcile your 1989 testimony with your subsequent assertion, in support of regulatory reform legislation, that we in Congress had "no science or numbers" to back our perception that an air toxics problem even existed?

ANSWER

On both questions, I do not think reconciliation of the views is possible and thus it is satisfying to know that I did not make these statements on the same day. As I stated in my 1989 testimony, much of it is based on work that I published in the "Duke Law Journal" in 1985. In that article, my focus was incremental reform of a single environmental statute and I explicitly used political feasibility considerations as part of my argument in favor of technology-based standards and against continuation of purely risk-based or cost-benefit standards. I was also concerned that judicial interpretation of the "ample margin of safety" test could lead to zero-risk standards for carcinogens. Thus, I formulated a plan that I thought could garner substantial support from both industry and environmentalists, given the politics of the mid-1980s. Moreover, at that time I had not even contemplated the possibility of comprehensive regulatory reform legislation and supermandates.

As the regulatory reform movement picked up steam in 1994, gaining substantial bipartisan support, I began to brainstorm more ambitious reform ideas. I had become frustrated with how difficult and time consuming it was to perform statute-by-statute reform. For example, at that time, the efforts at Superfund reform were stalled and the efforts at OSHA reform were virtually impossible to get off the ground. At an AEI conference in October 1994, I proposed the idea of a "soft" cost-benefit mandate that would supersede the risk-management criteria in existing laws.

45. You have argued that regulatory reform legislation should establish a cost-benefit test for new regulations and should contain a "supermandate" overriding substantive provisions of existing laws passed by Congress.

a. As OIRA Administrator, would you advocate omnibus legislation that included "supermandate" provisions establishing a cost-benefit test that would override existing laws?

ANSWER

I have no specific plans to advocate such legislation.

b. If so, what cost-benefit test have you in the past considered, and what would you recommend regarding such a test?

**ANSWER**

The "benefits must justify costs" test in the E.O. 12866 is reasonable.

c. Would you advocate that OIRA should review agencies' rules under such a "supermandate" standard even without new legislation?

**ANSWER**

No.

46. In arguing in support of regulatory reform legislation, you have frequently cited and described a study examining 200 programs designed to advance human health in the United States. As you have described it, the study estimates that a re-allocation of lifesaving resources away from "cost-ineffective" programs (such as control of low-level exposures to air pollution from factories) to "cost-effective" programs (e.g. childhood immunization) could save an additional 60,000 lives per year in the United States, at no increased cost, or could save the same number of lives as we are currently saving, but at a cost saving of $31 billion per year. The study was conducted by your former student, Dr. Tammy Tengs, and was described in a book chapter you coauthored with her.[31]

You have cited this study in testimony before the Senate Governmental Affairs Committee at least twice. On February 15, 1995, testifying in favor of regulatory reform legislation, you cited the estimates of 60,000 additional lives saved or $31 billion saved each year to illustrate the magnitude of what you called "the inefficiency of current regulations." Testifying again before our Committee on April 21, 1999, you again described the study, cited the estimates of 60,000 lives and 31 billion dollars saved, and concluded: "In short, a smarter regulatory system can provide the public with more protections against hazards at less cost than we are achieving today."

Comment: The written versions of my 1995 and 1999 Senate testimony do not assert that all 60,000 lives could be saved by enactment of a particular regulatory reform bill.

a. In a recent news broadcast, Professor Lisa Heinzerling of Georgetown University stated that many, if not most, of the environmental regulations cited in the study never went into effect.[32] Is that true?

---

[31]Tengs & Graham, "The Opportunity Costs of Haphazard Social Investments in Life-Saving" In: Hahn (editor), Risks, Costs, and Lives Saved: Getting Better Results from Regulations (1996).
[32]Interview with Lisa Heinzerling, on National Public Radio, All Things Considered, April 13, 2001.

ANSWER

When I listened to this news broadcast, I thought Professor Heinzerling might have been referring to a 1995 paper that we wrote on 500 lifesaving programs. She is correct that the 1995 paper included some programs that were never implemented and some that were implemented. The 1996 Tengs and Graham chapter, the published version of the 60,000 lives estimate (which was originally part of Teng's 1994 Harvard doctoral dissertation), is based on a subsample of roughly 200 lifesaving interventions where we were able to obtain information on the degree to which the intervention was implemented in the United States. Keep in mind that, if the full sample of 500 had been analyzed, the inefficiency estimate would probably have exceeded 100,000 lives.

b. Your article indicated that such measures might have been included in the study "[because some degree of implementation can exist even in the presence of a 'no-go' decision."[33] Do you believe that a study of "cost-ineffective" regulatory proposals that were either rejected by the agency or never even taken seriously by the agency illustrates what you called "the inefficiency of current regulations" or the advantages of "a smarter regulatory system"?

ANSWER

No.

c. How many of the 60,000 lives saved and how much of the $31 billion saved in the study resulted from reallocating lifesaving resources from "cost-ineffective" regulatory proposals that were never implemented by a regulatory agency?

ANSWER

I do not know.

d. Were any of the "cost-ineffective" interventions in the study implemented by private action, without having been mandated or otherwise brought about by regulation?

ANSWER

I believe so.

---

[33]Tengs & Graham, "The Opportunity Costs of Haphazard Social Investments in Life-Saving" In: Hahn (editor), Risks, Costs, and Lives Saved: Getting Better Results from Regulations (1996), at page 170.

e. If so, do you believe that a study of such "cost-ineffective" non-regulatory interventions illustrates what you called "the inefficiency of current regulations" or the advantages of "a smarter regulatory system"?

ANSWER

No.

f. How many of the 60,000 lives saved and how much of the $31 billion saved in the study resulted from reallocating lifesaving resources from "cost-ineffective" interventions that were not regulatory measures at all?

ANSWER

I do not know.

g. How many of the 60,000 lives saved and how much of the $31 billion dollars saved in the study resulted from reallocating lifesaving resources from "cost-ineffective" regulations actually implemented by a regulatory agency, and moving the resources to "cost-effective" interventions?

ANSWER

I do not know.

h. What is the range of uncertainty of these estimates — that is, what are the minimum and maximum numbers of lives or amount of dollars that could have been saved by shifting resources away from "cost-ineffective" implemented regulations?

ANSWER

I do not know.

i. In your testimony presenting this study to the Governmental Affairs Committee, you cited two publications, one peer-reviewed and one not. The peer-reviewed article provided a "compilation of available cost-effectiveness data" and "reveals that there is enormous variation in the cost of saving one year of life," but does not attempt to add up the additional lives or dollars that could be saved from a more "efficient" allocation of

resources.[34] That effort, with the resulting estimate of 60,000 lives, or $31 billion, saved annually, was presented in a non-peer-reviewed book chapter.[35] Is that correct?

ANSWER

Yes.

j. Has the estimate of 60,000 lives or $31 billion ever been published in a peer-reviewed periodical?

ANSWER

No, but it was peer-reviewed by those non-authors who were also faculty members on Ms. Teng's dissertation committee.

k. Has it been presented in a writing submitted for publication in a peer-reviewed periodical?

ANSWER

No.

Comment: The Tengs and Graham, 1996 paper does perform some substudies that give some credence to Professor Heinzerling's concerns. If reallocations are allowed only within REGULATORY programs or only within TOXIN CONTROL programs, the efficiency savings are much less than 60,000 lives. However, it is important to remember that S. 291 (1995) and S. 746 (1997) also contained risk-based priority provisions, which could promote some NONREGULATORY programs in budgetary decisionmaking. It also must be remembered that the overall efficiency loss would have been larger than 60,000 if the universe of lifesaving programs had been studied rather than a subsample of 200.

47. In oral testimony regarding regulatory reform legislation before subcommittees of the House Commerce Committee in 1995, you were asked how one can tell which risks are real and which are exaggerated. In response, you said: "Yes, the first thing I think we should keep in mind is, if you are a risk assessor or a scientist in one of these Federal regulatory agencies, you don't usually have an incentive to find that an alleged hazard does not exist, because if you highlight the fact that a hazard exists, you may attract the attention of Congress and the media and thereby

---

[34]Tengs, Adams, Pliskin, Safran, Siegel, Weinstein, and Graham. "Five-Hundred Life-Saving Interventions and their Cost-Effectiveness" *Risk Analysis*, 15(3), 369-389, 1995.
[35]Tengs and Graham. "The Opportunity Costs of Haphazard Social Investments in Life-Saving." In: Hahn (editor), Risks costs and Lives Saved: Getting Better Results from Regulation. 1996.

garner public support and resources for your Agency."[36] Does this quotation describe what your approach will be as OIRA Administrator, and what your advice to others in the Administration will be, in working with agency risk assessors and scientists and in reviewing and evaluating their reports and recommendations? If not, how will your approach differ from what you said in the quoted statement?

**ANSWER**

As OIRA Administrator, I will assume, absent good evidence to the contrary, that each agency risk assessor is public spirited and does not behave in ways designed simply to maximize their program's budget or influence.

## VIII. Environmental Policy

48. In your statements and writings, you have frequently criticized EPA and the statutes it implements for addressing the wrong priorities. For example, in your July 27, 2000 testimony before the Senate Committee on Environment and Public Works, you said that: the Superfund resources have not been targeted at the riskiest sites or most cost-effective remedies; the highest Clean Air Act priorities are reducing remaining outdoor sources of pollution whereas scientific evidence suggests indoor sources (e.g., smoking, wood stoves, and others) are a more serious hazards; and EPA focuses too much on speculative hazards and not enough on unintended adverse impacts of regulation.

    a. Taking these views into account, please list and explain what efforts to control outdoor pollution you believe EPA should maintain or expand, and with what degree of emphasis, and what efforts EPA should contract or eliminate, during the next several years.

    **ANSWER**

    I have not performed the kind of study necessary to provide an informed answer to this question.

    b. Please describe how those priorities differ from EPA's actual priorities in recent years.

    **ANSWER**

---

[36]Joint hearings before the Subcommittee on Commerce, Trade, and Hazardous Materials and the Subcommittee on Health and Environment of the House Committee on Commerce, 104th Cong., 1st Sess., on title III of H.R. 9 (Serial No. 104-3, February 1 and 2, 1995) at pages 323 - 324.

Again, I have not performed such a study.

c. Please identify any instances when you advocated or supported a specific measure to control outdoor pollution, or a risk assessment supporting such measures, at a time when there was debate or uncertainty over whether the measure should be implemented or whether the risk assessment should be adopted. Please also include any situation where you endorsed or agreed with EPA's methodology and analysis supporting such a measure or risk assessment. (Please identify any relevant publications or statements where you expressed this position, and, if you have not already done so, please provide us copies.)

**ANSWER**

Prospective evaluation of outdoor pollution policies has not been a significant focus of my personal scholarship. In fact, most of my scholarship in environmental policy has consisted of retrospective case studies of the role of risk, science, and economics in previous decisions at EPA. Some of these case studies have been critical of EPA; some have offered a mixed reaction; and others have been favorable. The key books, which you already have, are Harnessing Science for Environmental Regulation (1991) and The Greening of Industry: A Risk Management Approach (1997). I think any fair reader of these books would conclude that (1) I am deeply interested in environmental policy (including policies that reduce outdoor pollution); (2) I am particularly interested in ways to introduce more scientific, economic, and engineering insight into environmental decision-making; and (3) I am not reluctant to praise or criticize EPA when the evidence justifies it.

I would offer two rather clear pieces of evidence that my work is not hostile to existing environmental laws and regulations. First, the 1997 book, in particular, shows EPA stimulating environmental progress UNDER EXISTING LAW through indepth case studies of (1) the deleading of gasoline, (2) the phase-out of chloroflourocarbons, (3) the regulation of dry cleaners, (4) coke plant pollution control, and (5) dioxin control at pulp and paper mills. The argument in the book is modest: It says that these case studies suggest that analysis can play an important role in guiding further environmental progress under modernized laws. Second, my 1995 testimony on the Dole bill, and the related testimony on HR 9 in the House, OPPOSED so-called "look-back" provisions that would have applied cost-benefit analysis retroacatively to existing rules. The "supermandate" that I advocated was applied only to new rules and the test that I recommended was a "soft" cost-benefit test rather than the "benefits outweigh costs" test found in the original Dole bill. The nuances that I have just described do not appear to be appreciated in some recent commentary about my previous record on environmental law and regulatory reform.

On outdoor air pollution, the Harvard Center for Risk Analysis (HCRA) has a multi-year effort underway to strengthen the analytic case for reduced outdoor concentrations of

small, respirable particles. As Center Director, I provided additional financial support –from unrestricted corporate gifts – to a team of faculty and students (led by Dr. John Evans) who have been building, with EPA support, a cost-benefit model of stricter regulation of particles. In addition to assisting this group financially, I have served on the dissertation committees of two doctoral students, T. J. Carrothers and Scott Wolff, who have prepared new approaches to benefit estimation and identified cost-effective controls that can be applied to power plants, industry, and motor vehicles. A new junior faculty member (J. Levy) with interest in particles was recently funded in part by HCRA. I have also encouraged a third doctoral student, Edmond Toy, to include particulate considerations as part of his broader evaluation of greener and safer sport-utility vehicles. In terms of advocacy, I have favored cost-benefit approaches over health-based approaches at the same time that I have stated that cost-benefit analysis will support additional controls on particulate air pollution (see my 1999 Senate testimony).

Finally, my most recent writing on greener SUVs (ISSUES, 2000-01), argues that a promising combination of EPA rules on emissions/fuels and consumer tax credits can accelerate the penetration of alternate fuels, hybrid engines, and advanced diesels in the US fleet. I argue that these developments will enhance fuel efficiency, reduce urban air pollution (including particulates), and contribute to carbon emission control. A distinctive feature of this article is a concern for making SUVs safer as well as greener, since regulation is also needed on a variety of safety concerns.

d. Please identify any instances when you expressed disagreement with or opposed a specific measure to control outdoor pollution, or a risk assessment supporting such measures, at a time when there was debate or uncertainty over whether the measure should be implemented or whether the risk assessment should be adopted. Please also include any situations where you disagreed with EPA's methodology and analysis supporting such a measure or risk assessment. (Please identify any relevant publications or statements where you expressed this position, and, if you have not already done so, please provide us copies.)

ANSWER

Again, prospective evaluation of outdoor pollution policies has not been a significant focus of my scholarship. I have been a constructive critic of the standard tools of chemical risk assessment that EPA applies to cancer and non-cancer health effects. These tools (1) conceal scientific uncertainty, (2) overemphasize cancer relative to non-cancer health risks, (3) understate the risks of chemicals that have not been tested in full-scale animal tests, (4) give too much weight to simplistic classifications (e.g., carcinogen or not), and (5) do not make adequate use of available knowledge and scientific judgment. I have gone beyond criticism. I have helped stimulate and finance six doctoral dissertations in this general area (N. Hawkins, A. Cullen, J. Cohen, A. Smith, K. Thompson, and S. Speddon) as well as a stream of peer-reviewed scientific publications

(some with me as a co-author and others by colleagues listed in HCRA's publication list). This line of work is not easy to characterize as pro- or anti- EPA or pro- or anti-environment because the advances are methodological in nature. HCRA's senior faculty believe it will be a decade or more before the impact of this methodological research on professional practice can be evaluated.

e. As Administrator of OIRA, do you believe it would be appropriate for you to reject a regulation to continue cleaning up outdoor air and to instruct EPA to redirect its efforts towards controlling indoor air?

**ANSWER**

No.

49. When applying a "precautionary principle" to environmental problems such as climate change, you wrote that there are "dangers in both ignoring the desire for precaution and taking the desire for precaution to an extreme."[37] You recommended that our priorities should not be based on "the expected value of risk reduction," but instead we should be especially precautionary, because "the nation or planet should be especially averse to health, safety, and environmental risks that have potentially catastrophic outcomes, such as some of the more dangerous outcomes of global climate change."[38]

a. If there is scientific consensus that anthropogenically caused global warming will have severe, irreversible consequences for our public health and environment, should we be more concerned that we might unwisely de-emphasize these problems?

**ANSWER**

Yes.

b. If the costs of implementing greenhouse gas abatement is not nearly as expensive as some may have previously projected, should the balance tip further in favor of the precautionary approach?

**ANSWER**

---

[37]J. Graham, "Perspectives on the Precautionary Principle," in Human and Ecological Risk Assessment, vol. 6, no. 3 (2000), pages 383, 384.
[38]Graham and Hammitt, "Refining the CRA Framework," in Davies (editor), Comparing Environmental Risks: Tools for Setting Government Priorities (Resources for the Future, 1996), pages 93, 100.

Yes, assuming there is scientific consensus on the severity of the problem (as stated in "a").

50. The Food Quality Protection Act (FQPA) of 1996 changed the way EPA regulates pesticides, creating a new safety standard – reasonable certainty of no harm – that must be applied to all pesticides used on foods. The law addressed the special risks that pesticides pose to infants and children by requiring EPA to make a specific finding that permissible pesticide residues on food are safe for infants and children. Do you agree that it is important to tailor such health-based regulations to protect populations — such as infants and children — that are particularly susceptible to exposure to known risks? What is your opinion of the FQPA provision on that subject?

**ANSWER**

Risks to susceptible populations should be accounted for in health-based regulations. I am aware of some concerns about implementation of the FQPA but have not studied the matter in detail.

51. You have written that "[p]roviding protection of human health . . . does not always ensure protection of nonhuman life forms and ecosystems,"[39] yet your comments on the comparative effectiveness of specific environmental programs always focus on risks posed to human health. Do you believe that regulations implementing environmental statutes such as the Clean Air Act and the Clean Water Act may be partially justified on the basis of their beneficial effects on ecosystems and natural areas?

**ANSWER**

Yes.

52. You have written and testified that you believe the science underlying EPA's decision-making is sometimes suspect. In your role at OIRA, would you seek to evaluate the science underlying the regulations that are presented to you? Or do you see such an inquiry as beyond the scope of your review?

**ANSWER**

If confirmed, I intend to look into a variety of options: (1) better peer review at agencies, (2) a new OSTP role, or (3) a buttressed OIRA role. I am open to suggestions in this important area.

---

[39] J. Graham, "Making Sense of Risk: An Agenda for Congress," in R. Hahn (editor), Risks, Costs, and Lives Saved (1996), page 192.

53. In your July 27, 2000 testimony before the Senate Environment and Public Works Committee, you suggested that the EPA's analysis of dioxin was deficient because it did not account for newly established reproductive and developmental risks. Do you still believe that EPA is underestimating the health risks associated with dioxin?

ANSWER

Yes, though the most recent draft dioxin risk assessment has an improved analysis of non-cancer health risks. At the 2000 SAB dioxin meeting, I urged EPA to give greater emphasis to a variety of non-cancer health risks of dioxin rather than place emphasis on the speculative case that low doses of dioxin cause a significant risk of human cancer.

54. In the July 27, 2000 testimony, you summed up your view of environmental protection in these terms: "The good news is that the last thirty years have witnessed dramatic progress in reducing pollution in the USA. The bad news is that many of the 'low-hanging fruit' have been picked and thus the costs of making further reductions in pollution from the same sources (e.g., factories, utilities, and motor vehicles) may prove to be substantial." In 1996, at a seminar convened by the Heritage Foundation, a news report quotes you as having advised advocates of regulatory reform that they should depict environmental regulations as an "incredible intervention" in the operation of society.[40] Are these two descriptions of our environmental programs consistent? If not, which description better reflects the spirit in which you would oversee environmental regulation as Administrator of OIRA?

ANSWER

The first quotation better reflects the spirit in which I would oversee environmental regulation as Administrator of OIRA. The "incredible intervention" quote was attributed to me by a trade press reporter but I believe another speaker on the panel may have been the source of this quote. I have copies of both the edited and unedited transcripts of my remarks at the Heritage conference and neither transcript includes this quote. In any event, I do not believe that environmental regulation should be depicted as "incredible."

## IX. Impartiality and Research Funding

The following questions are intended to describe some of the concerns expressed to the Governmental Affairs Committee by a number of public interest organizations and to give you an opportunity to respond to these concerns. Please feel free to add any facts that you may deem relevant even if not specifically called for by these questions:

---

[40] "Risk-Expert Graham as Political Guru: GOP Must Change Reg-Reform Pitch," in Air/Water Pollution Report's Environment Week (Business Publishers, Inc., Feb 2, 1996).

55. Concerns have been expressed to the Governmental Affairs Committee by a number of public interest organizations that your relationships with the industrial funders of the Harvard Center for Risk Analysis (HCRA) could compromise your ability to act independently and fairly as OIRA Administrator.

a. It was asserted that, as Director of the HCRA, for more than a decade you have raised a majority of the Center's funding from industrial interests that would be affected by the regulations and paperwork you would be reviewing and overseeing as OIRA Administrator. To what extent, if at all, is this true? Please describe the process by which the HCRA solicits and obtains funding from such interests and your role in the process.

ANSWER

In fiscal year 2000, the Center raised about 40% of its revenues in unrestricted gifts from companies and individuals, 30% in restricted government grants, 20% in restricted private grants, and 10% in unrestricted University support. I do not know the precise percentages for the Center's entire history (1989 - 2001) but, if both unrestricted and restricted industrial revenue are grouped together, it is probable that a majority of the Center's overall revenue was supplied by companies and trade associations. Throughout this period, the corporate funders were quite diverse, with no single company and no single industry accounting for the majority of this private revenue.

With regard to fundraising process, prospects were identified based on an assessment of the organization's likely interest in making a donation to a university-based center for risk analysis. The School's Development Office sometimes assisted in making this assessment, providing research to me on specific companies and foundations. Often prospects were identified by me or other faculty and students through speaking engagements or participation in conferences or scientific societies. Once a donor was recruited, a representative of that organization was typically asked to suggest other organizations that may be prospects. At the outset of the Center, the focus was on fundraising from Fortune 500 companies since they were considered likely to have donation programs.

A standard fundraising letter was used to initiate contact with a prospect. The letter described the Center's overall mission and major functions (training, research, and communications). The letter requested an unrestricted gift of a specified amount (varies in size depending upon prospect). Recent Center accomplishments and ongoing activities were described briefly. Information about current contributors and the Center's conflict-of-interest policy was mentioned. An annual report was typically enclosed. For new prospects, a personal visit from the Director may have been offered.

In the initial letter I always expressed an interest in learning more about the risk challenges faced by the prospect since this was a way for a university-based Center to stay in touch with the real world.

A follow-up call to the corporation was made by Center staff to determine whether the letter had been received, whether any additional information was required, and whether a funding decision had been made. Some regular donors requested a visit by the Center Director every two or three years and that request was generally granted. When checks were received they were deposited into the Center's unrestricted account and a thank you note was sent by the Dean to the donor.

b. Is there a formal or informal understanding that, as Director of the HCRA, you are expected to raise funds to support the Center? If so, please describe that understanding.

**ANSWER**

Yes. In 1989 I was told by Dean Harvey Fineberg and my Department Chairman, Dr. Robert Blendon, that the School did not have sufficient unrestricted endowment or unrestricted annual gifts to support a new Center. If I was to create a Center for Risk Analysis, which they encouraged, I would need to raise the necessary funds. Once the Center was launched, it was my responsibility to make sure that it was a fiscally viable enterprise. I enjoyed this challenge and pursued fundraising aggressively since I believed in the mission of the Center: to promote a more reasoned public response to health, safety, and environmental hazards.

c. In the course of your fundraising activities, have you ever shown potential funders that the research, educational, and advocacy activities performed by you and the Center may benefit these funders by helping to foster regulatory policies that are less harmful or more beneficial to their interests? Is this a regular practice? Do funders ever indicate to you that they are providing funds for that reason?

**ANSWER**

My primary case for private gifts to the Harvard Center for Risk Analysis is a good-government argument that, through risk analysis, government can achieve more public protection against risk at less cost than is being achieved under current arrangements. I generally leave it to the potential donor to decide whether and why they do or do not decide to give to HCRA. It is possible that I have, on occasion, advanced an argument that a gift to HCRA is in both a firm's interest and society's interest. However, I cannot recall a particular time when I made such an argument. The "good government" rationale is the one that motivated me to create the Center and devote over ten years of my life to building the Center.

d. You informed the Committee that you are taking a two-year leave of absence from the Harvard School of Public Health (HSPH). If you were to return to HSPH, either during or after that time, what is the likelihood that you would return to the HCRA? Have you had any discussions with Harvard officials about that subject? Do you have any formal or implicit understandings on the subject? If you did return to HCRA, what is the likelihood you would resume any activities raising contributions from industrial funders?

ANSWER

I have resigned my position as HCRA Director and recommended to the Dean that a new leadership arrangement be established. If I am not confirmed, I will take an unused sabbatical and then return to my tenured Professorship at Harvard to do some writing and teaching. If I am confirmed, I may also ultimately return to Harvard and possibly to HCRA to do writing and teaching. I have indicated to the Dean that, if I return to Harvard, I will not be interested in running HCRA. It is very hard for me to predict now whether, when I return to Harvard, I will do any fundraising from industrial organizations or regulatory agencies. It is certainly a possibility but I can pledge that I will not allow any such possibility to influence my independence, judgment, and fairness as the Administrator of OIRA. I understand that I will be subject to post-employment restrictions when I leave government service and I intend to abide by these restrictions.

e. Generally, do you believe that any of these matters could compromise your ability to serve as OIRA Administrator with the necessary independence and fairness? Please explain.

ANSWER

No. My job as HCRA Director entailed raising funds from both regulatory agencies and regulated firms and trade associations. If I am confirmed as OIRA Administrator, I will have a different job and can commit to being independent and fair in the execution of the OIRA Administrator's responsibilities.

56. Several newspapers have reported that you solicited funding for the HCRA from Philip Morris, but that accepting tobacco money violated the policy of the HSPH and you were directed by Harvard to return $25,000 to the company. It was further reported that a few months later the HCRA received a $20,000 contribution from Kraft General Foods, a Philip Morris subsidiary, and that the contribution was noted in a Philip Morris internal memorandum with the comment: "I hope we can continue to work with and support Dr. Graham's work."[41] Please explain the circumstances, including the following:

---

[41] Boston Globe, March 18, 2001, page A7; see also New York Times, March 25, 2001, page 1; Richmond Times Dispatch, April 1, 2001, page A-6.

a. Were you in fact directed to return this payment to Philip Morris? If so, why and by whom?

**ANSWER**

The Dean of the Harvard School of Public Health, Dr. Harvey Fineberg, directed me to return the check because the Dean believed that the School should not accept gifts from tobacco companies. I do not believe that there was a written policy to that effect at the time.

b. What role had you played in soliciting, or arranging for, this Philip Morris contribution?

**ANSWER**

I had mailed the standard fundraising letter to an appropriate official at Philip Morris.

c. Did you subsequently solicit and receive a contribution from Kraft Foods for the work of the HCRA? Please describe the circumstances, and explain why this contribution was treated differently than the contribution from Philip Morris.

**ANSWER**

Yes. In the discussion with Dean Fineberg that caused the return of the Philip Morris check, it was determined that the prohibitive policy would not apply to gifts from subsidiaries of tobacco companies, such as Kraft Foods. I do not recall the precise reasons provided for the difference in treatment.

d. Were there any other instances when university officials directed you to return any funds that had been contributed to the Center or for your own research? Did you ever voluntarily decline offered funding?

**ANSWER**

I do not recall any other instances of directed returns but I have voluntarily declined offers of funding to the Center on a variety of occasions. Two such incidents come to mind.

First, prior to the Kyoto protocol, a coalition of companies approached the Center about the possibility of sponsored funding of research and communications to highlight uncertainty about global climate change. After consulting with a faculty colleague who specializes in this area (J. Hammitt), we declined this offer because our Center's work on climate change was moving into the cost-benefit arena on the belief that global climate

change is likely. Second, a corporate member of the HCRA's Advisory Committee approached me, after EPA's new NAAQS proposal, about whether we were interested in sponsored research funding from companies on the PM/ozone question, particularly the causation question about health effects. After consulting with a faculty colleague who knows this area (J. Evans), we decided to decline this funding because we felt the critical unanswered questions were on cost-benefit matters, not causation of health effects.

57. Concerns have been expressed to this Committee by a number of public interest organizations regarding your service as a consultant to EPA's 1995 SAB Dioxin Reassessment Review Committee and, until your recent resignation, your membership on EPA's SAB Dioxin Reassessment Review Committee. These organizations expressed concern that the HCRA has received financial support from a large number of companies and industries that produce dioxin, and that this funding creates conflict between your obligation to serve as an objective expert as a consultant to the SAB and your real or perceived sense of obligation or supportiveness towards HCRA's funders.

    a. In connection with your service to EPA's SAB, were you obligated by statute or otherwise to disclose the funding received by the HCRA from companies that produce dioxin and any involvement you may have had in soliciting these funds? Are you aware of any complaints made publicly or privately that you should have disclosed? Please describe these complaints, who made them, and what is your response.

    ANSWER

    It is my understanding that SAB disclosure policy was developed pursuant to the Federal Advisory Committee Act. SAB committees have standing members and ad hoc consultants and my role in the dioxin review committees was as an ad hoc consultant. In this capacity I was required to disclose personal financial information in writing. SAB staff inform me that academics are generally not required to disclose in writing the sources of their grants and other funds to support their research and teaching. Moreover, the OGE-450 form that SAB distributes does not elicit information on institutional grants/gifts. However, there is a voluntary tradition at SAB that, at the outset of the first public meeting on an issue, members of the committee disclose orally the general nature of the funding sources for their work.

    SAB staff inform me that some members of the activist community have raised concerns about my participation due to the industrial funding that my Center receives. As I understand it, they believe that SAB should not have permitted me to serve because the Center receives funds from companies and trade associations that may have an interest in the outcome of the dioxin reassessment.

    My response is that the standard regarding conflict of interest that the activist community is advocating is a more stringent one than SAB appears to believe is required by FACA.

SAB staff inform me that they are worried that, if SAB were to lose all members and consultants with funding from interested sources, the technical quality of SAB committees might decline substantially. As a matter of law, I certainly do not know whether SAB's position is correct or whether the activist community has a stronger legal argument. When I accepted the invitation to serve on the committee, I had every reason to believe that SAB staff - who are generally familiar with my Center - had made a judgment that our Center's industrial funding does not constitute a conflict barring my participation.

There may also be a concern that I have a bias on this issue due to previous public statements I have made about dioxin. The position of SAB staff is that this kind of bias issue is addressed in committee composition, with balance achieved by appointing members with different biases. Obviously, there is subjectivity in making a determination as to whether a group of scientists has appropriate balance.

b. Please describe any companies or organizations potentially affected by the outcome of EPA's dioxin reviews that were funders of the HCRA or of your own research during the general period of your service to the Dioxin Reassessment Review Committees, or that you solicited for contributions during that period.

ANSWER

Virtually any company or trade association "could potentially be affected" by the outcome of EPA's dioxin review because (1) dioxins are ubiquitous in food and in the environment, and (2) EPA's dioxin review raises important precedent-setting issues in risk assessment and science-policy that may affect future assessments of other chemicals and products. I am aware that there are a variety of HCRA donors in the chemical, food, and paper industries that might be perceived to have a special interest in the dioxin issue, although I do not in fact know which segments of industry or which specific companies have the most significant commercial interest in the dioxin reassessment. The companies/organizations that HCRA solicited during the 1995-2000 period were from the same industries as HCRA's pre-existing donor base and thus the interest issues are the same. I would also like to add that the government agencies that support HCRA through sponsored research, certainly EPA and USDA, might also be judged to have an interest in the outcome of the dioxin reassessment.

c. Do you believe these relationships (if any) obligated you to make disclosures in connection with your service to EPA's SAB? If so, did you do so? Please explain why you believe you met any applicable obligations for disclosure.

ANSWER

In addition to the obligation to disclose personal financial information, which I satisfied in writing, I did feel obliged to disclose orally at the 2000 meeting the general nature of the funding that HCRA receives. My recollection is that I disclosed orally that (1) there is a mix of public and private funding for HCRA, and (2) there are gifts to HCRA from numerous companies and trade associations. I indicated that many were likely to have an interest in the outcome of the reassessment and I believe I may have mentioned several specific organizations by name. I also believe that I referred to our Center's web site or annual report for those who desired more information. There were activists at the meeting who kindly assisted me on the disclosure matter. Each time I spoke at the public meeting, activists would raise signs with the names of HCRA donors who the activist community believed were "dioxin producers". They presumably had taken the names of these companies and trade associations from HCRA's web site or annual report. Their activities were not disruptive to me and I think their concerns about conflict issues were strongly held.

d. Do you believe these relationships (if any) created a conflict between your obligation to serve as an objective expert as a consultant to the SAB and any real or perceived sense of obligation or supportiveness you may have had towards HCRA's funders? Please explain.

ANSWER

No. Scientists are routinely called upon to perform studies or interpret data objectively, even though their institutional funders might prefer one result over another.

58. Concerns have been expressed to the Governmental Affairs Committee by a number of public interest organizations regarding studies and other activities by you and others at the HCRA that these organizations assert lend support to the positions of industry funders of the Center regarding pending regulatory or legislative issues:

- The following were claimed to the Committee: HCRA received a $300,000 grant from AT&T Wireless Communications to assess the risks of using a cell phone while driving. In July 2000, Dr. Graham and others at HCRA published findings that cell phone use while driving does pose a risk, but the risk appears small compared to other daily risks. The authors urged that before government regulates cell phone use by drivers, better data on risks and benefits should be collected. The HCRA report was released one week after NHTSA held a public hearing on driver distraction and recommended that drivers pull over before using cell phones. The report was self-published by the HCRA, after review by 12 independent specialists selected by the Center. One of those specialists, who had earlier published a peer-reviewed article on the risk of car crashes when a driver uses a cell phone, was quoted in a news article as saying: "The difficulty with the Harvard study is that it provides no new data, gives no new expertise, provides no new analysis. . . . The conclusion comes across more like an editorial assertion than a logical

consequence."[42] The news article further reported that he "said Harvard researchers left the [HCRA] report open to conflict-of-interest questions because they didn't publish it in a scientific journal or take other steps to demonstrate the study's fairness."[43]

Comment: The AT&T grant was to cover benefits as well as risks. The first phase of the grant was predominantly a literature review on risks with some exploratory data collection on benefits; the second phase, now in progress, involves some original data collection on benefits. In contrast to the NHTSA suggestion that people pull over before using cell phones, the HCRA report urges more selective and prudent use of cell phones while driving until informed policies can be established. Some of the peer reviewers were internal and some were external to the Center. We selected the reviewer who criticized us publicly -- as well as several other reviewers -- precisely because we expected them to challenge our perspective and methods. In this particular case, we went beyond the requirements of our conflict-of-interest policy by commissioning both external and internal peer reviews.

- The following were claimed to the Committee: The American Farm Bureau (a trade association of farmers and ranchers) funded a study by HCRA of what would happen if EPA were to totally ban two entire classes of widely used pesticides. The HCRA report (Graham himself was not (listed as an author) stated that a complete ban was an "extreme scenario," but it had the virtue of simplicity for analytic purposes; and also a complete ban had been mentioned in the debate about EPA's implementation of the 1996 Food Quality Protection Act. The report found that the net risk could not be estimated, but predicted the ban would have adverse side effects, including perhaps 10 to 1000 premature deaths because increased food costs would reduce people's wealth, and generally wealthy people are safer and healthier. The American Farm Bureau then publicized the report's findings, both to criticize EPA and to promote legislation to change EPA's methods of evaluating pesticide risks.

  Comment: The release of this report did not adhere to HCRA's conflict-of-interest policy because the findings were released to the sponsor and then to the public without peer review. However, the report was subsequently published in a peer-reviewed journal without significant change in findings. Although I was not involved in this project, I accept responsibility, as the Director, for the fact that the Center's policy on peer review prior to release was not followed.

- The following were claimed to the Committee: HCRA has received unrestricted support from companies in the automobile industry. Graham's research supported a passive restraint air bag mandate in the early 1980s. However, in March 1997, in news appearances and testimony before the National Transportation Safety Board, Graham said new research convinced him that passenger air bags were not cost effective enough to justify being mandated, and he announced

---

[42]Jay Lindsay, Associated Press writer, "Harvard study says risks of driving with cell phone are overstated," Associated Press State and Local Wire (July 24, 2000).
[43]*Id.*

his new cost and benefit figures. Also in March 1997, the HCRA and Graham's Harvard Injury Control Center released a public opinion survey which found American's widespread support for air bags was founded in part upon bad information. These announcements occurred as NHTSA and OIRA were considering a proposed rule advocated by industry and others that would have allowed manufacturers to depower (i.e., install lower-power) air bags. Subsequently, in an article published in the peer-reviewed Journal of the American Medical Association, Graham's revised study found that driver-side air bags cost far less per life saved than his earlier estimate.

Comment: I was invited to serve on two panels at the March 1997 NTSB meeting, one devoted to broad policy concerns and one devoted to technical issues where airbag effectiveness and cost-effectiveness were discussed in some detail. Given public interest in the issue and the opportunity to receive constructive feedback from safety specialists, I decided to discuss orally the results of a draft HCRA cost-effectiveness study at the first panel and to provide more technical detail about the study orally at the second panel. I described our March 1997 findings as "preliminary" and I did not release or disseminate the draft paper to the public, in order to protect our publication prospects at JAMA. We did provide copies of the draft paper to scientists for peer comment. Later, my colleagues and I revised the paper based on the feedback received at NTSB and the comments from a reviewer at JAMA. The paper was published by JAMA in November 1997 in improved form based on the NTSB hearing comments and the reviewer's comments. The passenger airbag results were more encouraging than before because several technical improvements to the analysis were made.

Some have criticized me for speaking to the media about our preliminary results. Since the NTSB meeting was open to the public, and reporters were permitted to cover what was said, I knew my preliminary results might be covered anyway. Thus, I spoke freely with reporters before, during, and after the NTSB meeting about the preliminary cost-effectiveness findings and my growing uneasiness about the passenger airbag. I was seeking not a repeal of the passenger airbag mandate but a serious reexamination of policy by the safety community. In response to a question from the audience at the meeting, I noted that the disturbing risks of passenger airbags to children would justify reexamination of policy, even if the cost-effectiveness ratios for the passenger airbag were favorable.

My remarks about the passenger airbag prior to the meeting were used by a "USA Today" reporter to frame a front-page story suggesting that a leading backer of the airbag was having second thoughts. This story then attracted attention from television networks and other news outlets during the NTSB meeting. I was satisfied that this heightened publicity had a constructive outcome: It highlighted the need to improve public policy toward airbags through better regulation and better education of adult motorists and their children.

The public opinion survey about airbags was peer reviewed at HCRA prior to release and was later published in a peer-reviewed journal. The release of the survey was timed to coincide with the NTSB hearing; the release was not intended to influence NHTSA's actions on depowering.

a. Are the foregoing descriptions accurate? Is there anything you want to add?

**ANSWER**

Note the comments above.

b. Do you believe that receiving funding from interests affected by the research of the HCRA diminishes the credibility of the research results? Does such funding create any possibility of subtle bias in the work of the HCRA?

**ANSWER**

Some may judge the credibility of research findings based on whether the funding source has an interest in the results. If the Center is organized properly to do its work, even subtle sources of bias based on the interests of funders should be avoided or minimized. In the long run, I believe that unrestricted endowment funds are the best from a credibility perspective but they induce a risk that faculty and students will become less interested in the real-world problems facing government and industry.

Is there any "good" research money? Some conservatives would like the Center to stop accepting government grants, since they fear biases of our research toward the policy orientations of government agencies. Some liberals would like the Center to stop accepting corporate money (gifts and/or sponsored research) because they fear the Center will become biased by commercial interests.

My experience as Center Director was that the best strategy is a multiplicity of funding sources, a substantial percentage of unrestricted support, and a research process that emphasizes collaboration and peer review by analysts with differing disciplines and philosophical perspectives.

c. Have industrial funders played a role, either directly or through the HCRA Executive Council, in suggesting, establishing, or limiting research topics and priorities at the HCRA, or the timing of research or the timing or means by which results are announced?

ANSWER

HCRA's Executive Council needs to be distinguished from HCRA's Advisory Committee.

The Executive Council was formed two years ago in collaboration with the School's Development Office to assist the Center in building a long-term funding base (e.g., endowment) through individual donations. One of the purposes of individual donations is to reduce HCRA's dependence on corporate and governmental support. The Council is comprised of private individuals with a deep interest in risk analysis who provide strategic planning advice and development skills. Individuals recruited to serve on HCRA's Executive Council typically have philanthropic ability and inclination.

HCRA's Advisory Committee, which has existed since the Center's inception, is comprised of 30-40 scientists and professionals from government, industry, academia and non-profit organizations. They meet regularly to critique the Center's work, suggest new ideas for education and research, and highlight emerging issues and project opportunities. Professionals from some (but not all) companies that donate to HCRA serve on the Advisory Committee. Several books produced by the Center were direct outgrowths of project ideas generated at Advisory Committee meetings. HCRA-affiliated students use the Advisory Committee meeting as a forum to network and identify possible employers.

Research priorities at the Center are established through a mix of top-down and bottom-up mechanisms. Students may suggest topics and persuade faculty or the Center Director to support them. Faculty may win grants on topics of interest or persuade the Center Director to support a worthy project with unrestricted funds.

Industrial or public funders can directly influence priorities by approaching the Center with a proposal for a sponsored research agreement (a restricted grant). As the Center has become better known and developed a reputation for producing relevant, quality work in a timely fashion, the number of these approaches from outside funders has increased rapidly. At the suggestion of the Executive Council, the Center is trying to develop some explicit criteria and a process for deciding which approaches from would-be funders to accept. The Executive Council itself does not play a role in setting research priorities.

d. Is it of any relevance or concern to you and others at the HCRA how the results of research produced by you and others at the Center may be used by the Center's funders to affect administrative or legislative deliberations or public opinion in ways beneficial to their interests?

ANSWER

I respond only for myself. If the Center performs quality work on an important subject, there is no reason why sponsors or others should not use the results in ways that they see fit, assuming they are not distorting or misrepresenting the work.

e. Have you or others at HCRA adjusted the timing of research or announcements of results to accommodate the timing of administrative or legislative deliberations or decisionmaking? Have you or others at HCRA discussed such matters with funders whose interests might be affected?

ANSWER

When restricted grants are negotiated with public or private funders, deadlines for deliverables and timing of announcements are often an important, negotiable item. A funder may not be interested in a project if it cannot be completed and released by a specified time. The funder may have in mind an administrative or legislative deliberation. Yet the Center faculty member(s) may not feel they can deliver a quality product if the sponsor's desired schedule is too tight. Negotiations ensue. A sponsored research agreement will typically address timing of deliverables. There are also procedures for adjusting deadlines if both parties agree.

f. Do you or others at HCRA apply a formal or informal policy or practice regarding when to disclose any funding sources (including funding from industries that might be affected by the outcome or dissemination of your research) when issuing reports or making statements to the media, testifying at hearings, or advising governmental boards or the public?

ANSWER

When publishing newsletters, journal articles, books, or Center reports funded by restricted grants, the source(s) of the restricted grants are supposed to be noted on the publication. For products generated on unrestricted support, the Center relies on the disclosure found on the Web and in our annual reports.

The Center discloses restricted sources of support for specific studies to the media, and otherwise, only discloses funding sources if asked to do so by the reporter.

When testifying at hearings, Center faculty and staff are typically appearing as private citizens rather than Center representatives. No disclosure of Center funding sources is typically volunteered. Interestingly, when I testified before a

Senate Committee in 1995, one Senator obtained HCRA's funding sources from our annual report and had it included in the hearing record.

When advising government boards, faculty and staff typically respond to whatever disclosure questions are posed by the entity sponsoring the advisory session.

g. Do you or others at HCRA apply a formal or informal policy or practice regarding whether and when to submit research findings to independent and external peer review before announcing or publishing them?

**ANSWER**

The Center's policy, established in 1997, is to subject all intellectual products to peer review by qualified scientists. For the newsletter, "Risk in Perspective," internal peer review is generally considered adequate. For Center reports, internal review may be supplemented by external peer review when the issue is complex and significant to public policy. The Center will sometimes commission a panel of scientists to advise us on a particular issue or assist in preparing a report. The Center does not require that all Center products be published in peer-reviewed journals. If a paper or report is accepted for publication by a journal or book publisher, the Center generally considers that adequate peer review even though peer-review standards vary considerably. The vast majority of the Center's products are published in medical, scientific, methodological or policy journals.

h. According to the HCRA website, the Center publishes a complete list of sources of its unrestricted and restricted funds on the website and in its annual reports. Is that correct? Does HCRA also disclose to interested members of the public information about the dates and amounts of funders' contributions and, for restricted grants, the purpose for which each grant was given? If not, what is the reason for withholding this information?

**ANSWER**

The HCRA website and biennial report are supposed to provide a complete list of restricted and unrestricted sources of support. The list may be incorrect at any point in time due to a minor oversight or clerical error. For example, the AT+T Wireless grant was inadvertently omitted from the list of restricted support for a period, but this grant was disclosed on the Center report and related newsletter. New sources of support are added periodically, so the list at any given time may be a bit dated.

For unrestricted support, dates and amounts are not generally disclosed. As an organization competing with other organizations for gifts, the Center does not see it as in its interests to disclose dates and amounts. Although some donors disclose the amount of the donation, we have been told that some donors would prefer that amounts not be disclosed. The Center is currently looking into whether it should disclose more information about unrestricted gifts and whether the School and the University's lawyers would support more disclosure.

For restricted support, the Center provides only a list of sources on the Web. If people ask for specific information about a restricted grant from industry (e.g., amount, duration, purpose), the Center generally provides it. For example, the Center disclosed that the AT+T Wireless grant to HCRA was for the amount of $300,000. The Center also discloses information about purpose in the context of publications, where the source of the grant is noted. The Center is currently looking into whether more information about restricted grants should be placed on the Web.

As a rough check of the completeness of our web reporting, I asked the Center's web manager to cross check the annual report list (99-00) with the web list. She found the following omissions on the Web from the unrestricted list: American Insulation Manufacturers Association, Chlorine Chemistry Council (listed under "restricted"), Microban, Volvo, and Zeneca. The following omissions were found on the restricted list: Charles G. Koch Foundation, Health Canada, National Research Council, Office of Health Economics, Public Health Policy Advisory Board, Roche Global Pharmaceutical Research, and Wireless Technology Research Foundation. Corrections to the web site will be made if these errors are verified.

In 2000, the Center began to disclose an additional piece of information to provide numerical perspective: a percentage breakdown of Center funds by type of source. In fiscal year 2000, for example, the Center's revenue was comprised of unrestricted gifts from private sources (40%), restricted government grants (30%), restricted private grants (20%) and unrestricted University support (10%).

**AFFIDAVIT**

I, John D. Graham, being duly sworn, hereby state that I have read and signed the foregoing Statement on Pre-hearing Questions and that the information provided therein is, to the best of my knowledge, current, accurate, and complete.

John D. Graham

Subscribed and sworn before me this 3rd day of May, 2001.

Susie M. Jones Kenney

Notary Public

Commission Expires: Aug. 14, 2004

**Additional Pre-Hearing Questions Submitted by**
**Senator Richard Durbin for Dr. John D. Graham,**
**Nominee to be Administrator,**
**Office of Information and Regulatory Affairs**

1. **Question:** The latest OMB "Report to Congress on the Costs and Benefits of Federal Regulations", prepared by OIRA, concludes that the benefits of federal regulations generally outweigh the costs, perhaps by more than a ten to one ratio. Return on investment from environmental regulations may be even greater. OMB reports from prior years also found that benefits exceeded costs. If confirmed as OIRA Administrator, how would you propose reconciling these findings with the results of your own studies that indicate environmental regulations are very cost-ineffective?

   **Answer**: I have no reason to question the validity of the OMB "Report to Congress on the Costs and Benefits of Federal Regulations." I have never authored an original estimate of the overall benefits and costs of federal environmental regulations and thus do not believe that any reconciliation is required.

2. **Question:** In our meeting of April 25th, you mentioned indoor air pollution as an example of misplaced resources, that is, an environmental problem that should receive higher priority than it does, relative to other environmental issues. What research have you conducted at HCRA or elsewhere that leads you to this conclusion?

   **Answer:** I have not produced any original estimates of the relative risks of indoor air pollution. However, in the early 1990s, when conducting research on regulatory reform, I came across a variety of studies and publications in the literature that made a compelling case that indoor air pollution is a neglected environmental risk in the USA. Here are some key references to that literature:

   -JM Samet and JD Spengler (eds), Indoor Air Pollution: A Health Perspective, Johns Hopkins Press, Baltimore, MD, 1991;

   -National Research Council, Human Exposure to Airborne Pollutants, National Academy Press, Washington, DC, 1991;

   -Frank Cross, Legal Responses to Indoor Air Pollution, Quorum Books, 1990.

3. **Question:** You once testified before a Senate Committee (*Environment & Public Works 10/14/99)* that reducing smog levels might do more harm than good because less smog might mean more exposure to ultraviolet rays. Please elaborate on this remark. Do you think we've gone too far in reducing smog-causing air pollution, or do we need to do more?

**Answer:** I was referring to the DC Circuit's ruling in the PM/ozone case. The court was unanimous in its ruling that EPA had not adequately considered the claim about the possible countervailing health benefits of smog. I have not published any original work on the smog issue and do not have any opinions about policy directions.

4. **Question:** You have often written and spoken about environmental regulations that impose large costs and act as an "incredible intervention" on society. Please itemize the ten environmental regulations that have been fully implemented in the U.S., and that your research has shown to be the most expensive in terms of cost per life-year saved. Include the regulation (and FR citation), the cost per life year saved, and any other information that would assist me in understanding the context of these costs.

   **Answer:** With regard to the "incredible intervention" quote, please note my response to a related question (#54) posed by Senator Lieberman. It does not appear in either the edited or unedited transcript of my remarks at the relevant conference proceeding. I have never performed a major study of the cost-effectiveness of fully implemented environmental regulations. The Tengs and Graham (1996) study is a survey of the cost-effectiveness of lifesaving interventions and their degree of implementation, regardless of whether implementation was required by regulation.

5. **Question:** In your 1995 paper, "Comparing Opportunities to Reduce Health Risks: toxin Control, Medicine and Injury Prevention", (NCPA policy report #192), you cite the following example:

   "Spending $100 million per year on control of benzene emissions at rubber tire manufacturing plants might save one life-year over a 200-year period (i.e. $20,000 billion per life-year saved)."

   (a) Please explain the basis of this statement, including the regulatory analysis that was the source of the $100 million per year" cost figure and the "one life year over a 200-year period" figure, as well as the method by which you arrived at the figure of $20,000 billion per life-year save.

   **Answer**: The $20,000 billion figure is a typographical error that should be $20,000 million. The references and methods of calculation for the $20 billion figure are provided in the Tengs et al paper in Risk Analysis (1995). The $100 million expenditure is hypothetical. Given the $20 billion per life-year ratio, it would take 200 years to save a life year at a spending rate of $100 million per year.

   (b) Can you provide an estimate of how much money society has actually spent on this particular benzene control program?

**Answer:** I do not know how much money, if any, society has actually spent on this particular program.

6. **Question:** In a paper published by the National Center for Policy Analysis (Progressive Environmentalism: Principles for Regulatory Reform by Kent Jeffreys) the author cites your work as the basis for the following statement:

> Some regulations impose astronomical costs relative to the benefits they produce... The standard set for chloroform emissions at 48 pulp mills imposes over $99 billion in costs for each life-year saved. If this regulation allowed one person to live another 20 years, the implicit "cost" of saving that life would be about $2 trillion - about one-third the size of the U.S. annual GNP.

Has the author accurately represented your work? If not, in what way does it misconstrue your findings?

**Answer:** The math appears to be correct. I do not know the pulp-mill case well enough to comment on whether the example is being used properly by Jeffreys.

7. **Question:** One of your most well-known publications is "Five Hundred Life Saving Interventions and Their cost-Effectiveness." The database created for this report contained 587 interventions.

(a) Has the database been expanded since publication of your report in 1995? How many interventions are now included?

**Answer**: Dr. Peter Neumann of HCRA has built a new, closely related database that uses quality-adjusted life years instead of life years as the measure of program effectiveness. I do not know how many interventions are currently in his database.

(b) How many researchers have made use of the database? In what way? How many of these researchers are from institutions other than HCRA?

**Answer**: We have not kept track of users of the database. I am aware that similar databases have been developed and published by both Swedish and Japanese researchers using data from their home countries.

(c) This work was published in the journal, Risk Analysis, at a time when you were affiliated with the publisher of the journal, the Society of Risk Analysis. What was your affiliation with SRA at the time the work was published? Did you consider publishing elsewhere to avoid any appearance of conflict of interest?

**Answer**: I do not recall exactly when the paper was submitted for publication but, at the time, I was certainly a member of SRA, the journal's Editorial Board, and possibly an elected councilor in the Society. I did not consider publishing the work elsewhere, since it is the premier journal in the field, and the possibility of an appearance of conflict of interest did not cross my mind.

(d) Was this paper peer reviewed prior to publication?

**Answer:** Yes.

**Harvard Center for Risk Analysis (HCRA)**

8. **Question:** You have established two bodies at HCRA to provide advice and guidance to the work of the Center: an Executive Council and an Advisory council. Neither council has any members from public interest environmental groups or consumer groups.

(a) Why have you excluded such groups from any formal role at HCRA?

**Answer**: From 1989-2000 Alon Rosenthal, J.D., Sc.D. and Adam Finkel, Sc.D were active members of the HCRA Advisory Council. Alon is a graduate of the Harvard School of Public Health who launched a successful environmental advocacy organization in Israel (The Israel Union for Environmental Defense). He is currently based at Arava Institute for Environmental Studies in Israel and is well connected in both the Israeli and U.S. environmental movements. Adam Finkel, also a Harvard graduate, began his career at Resources for the Future and often advised public-interest groups on risk assessment issues. He was, for example, a key expert in the Alar case for the pro-NRDC/CBS side and often opposed me in regulatory reform policy debates. He left RFF several years ago to join OSHA. Inside the Center we have also had significant participation by students and staff who had experience with the activist community. Several doctoral students (e.g., A Cullen and A Smith) were advisors to public-interest groups while our Center hired full-time researchers (K. Walker and J. Hartwell) who had previously worked full-time in the public-interest community. I have also invited activists to speak at several conferences that I organized and their voluntary participation is always welcome. For example, our most recent conference on the "precautionary principle" in Washington, DC drew significant participation from Greenpeace USA.

The Executive Council is comprised of private individuals with a deep interest in risk analysis who also have philanthropic ability and inclination. No such individual from the public-interest community has yet been identified by the School's Development Office.

(b) If confirmed as Administrator of OIRA, would you be receptive to meeting with, and receiving input from such organizations on a regular basis?

**Answer:** Yes.

9. **Question:** In the work done at HCRA, do you establish priorities in the same manner that you recommend for the federal government, that is, by a formalized process of identifying the greatest risks and focusing most of your resources on these?

**Answer:** At several meetings of the HCRA Advisory Council, we have undertaken formalized priority-setting exercises where each advisor and staff/student votes for preferred project priorities. We treated these exercises as a stimulus for deliberation as well as advice to the faculty and the Center Director. The outcomes of the exercises were not binding but they did produce useful insights.

10. **Question:** In your recent HCRA report, "Cellular Phone Use While Driving" there is no mention in the body of the report of an estimate of the annual number of fatalities that occur as a result of the use of cellular phones while driving. Yet, Appendix I to the report does contain such data, and indicates about 1,000 fatalities per year occur as a result of cell phone use [406 fatalities to individuals not in the vehicle driven by a cell phone user + (6.4 fatalities per million drivers using cell phones x 84.8 million drivers using cell phones) = 406 + 543 = 949 fatalities per year].

(a) Is our understanding of the data correct, in that it indicates almost 1,000 deaths per year due to use of cell phones while driving?

**Answer**: Yes.

(b) Isn't this an important finding, and one that should be included in report highlights and summaries with appropriate qualifications?

**Answer**: The Executive Summary of the report does not include any numerical estimates of risk (individual or societal) because, although the existence of hazard is clear, the available data to quantify this risk are highly uncertain.

(c) Why is this result relegated to an Appendix?

**Answer**: Researchers in the Center tend to prefer quality-adjusted life years (QALYs) lost instead of lives lost as a measure of societal risk because (a) it accounts for the number of years of life lost and (2) it incorporates information on nonfatal injuries that impair quality of life. QALYs lost is presented in the text in Section 6 (33,000 QALYs lost per year) and serves as an important input to the cost-effectiveness calculation.

(d) What statistical methods were used to conclude "there does not appear to be any simple association between fatalities and national phone subscriptions" (pg 25).

Was any type of statistical association identified?

**Answer:** The phrase on page 25 was intended to convey that no association is apparent from visual inspection. Several univariate and multivariate time-series models were also estimated to determine the association between cell-phone subscriptions and national fatality counts. No significant associations were found. The results of these analyses were not reported because, for the reasons cited in the text, these "ecological" analyses were considered too inconclusive to suggest safety or risk.

**Professional**

11. **Question:** Please summarize the degrees you have received and the type of work you did as an undergraduate, graduate and doctoral student. Do you consider yourself a scientist?

    **Answer:** At Wake Forest (BA) I was a double major in politics and economics. At Duke (MA) I studied public affairs with an emphasis on quantitative approaches to health policy, taking a special interest in decision analysis. At Carnegie-Mellon (Ph.D.) I studied urban and public affairs with a special interest in risk, economic, and decision analysis. My post-doctoral fellowship at the Harvard School of Public Health provided training and research experience in health risk assessment. I consider myself a scientist insofar as decision analysis, a branch of management science, is considered a science. Harvard refers to me as "Professor of Policy and Decision Sciences." I do not have formal training in the hard sciences (e.g., biology, chemistry, and physics) or engineering.

12. **Question:** If confirmed as OIRA Administrator, would you recuse yourself from regulatory issues pertaining to companies or industries from which you have received funding in the past?

    **Answer:** I have executed the necessary ethics undertakings that are appropriate for my situation based upon my proposed duties. These undertakings will begin upon confirmation and appointment as Administrator, OIRA, and will include resignations from various outside positions, recusals, divestitures and a leave of absence from Harvard University. Based upon these undertakings, I have been told I am in compliance with applicable laws and regulations governing conflicts of interest.

13. **Question:** Please provide a copy of any correspondence you have had with Phillip Morris or Kraft Foods regarding the work of the Harvard Center for Risk Analysis.

    **Answer:** I asked Jenny Bell, HCRA's administrator, to retrieve any correspondence between HCRA and Philip Morris and Kraft on the work of the Harvard Center for Risk Analysis. She uncovered the attached materials.

I also had some technical correspondence with professionals at Philip Morris in the early 1990s but I no longer have copies of that correspondence.

14. **Question:** What percentage of your publications have been published in peer review literature? When publishing the findings of a study, what criteria do you use to decide if the publication should appear in the peer reviewed literature or not?

**Answer**: Of my 129 published papers and reports, about 70 were published in what might be considered "peer reviewed" journals. The nature and intensity of peer review at journals varies considerably. I have no explicit, formal criteria for making a decision about whether to submit a paper to peer reviewed or non-peer reviewed outlets. As a practical matter, many of the non-peer reviewed pieces were (a) commissioned by the publication, (b) reviews that contained no new data or analysis, or (c) policy-oriented discussion papers.

**Harvard Center for Risk Analysis**

202-637-1500

October 21, 1991

David L. Greenberg
Vice President, Government Affairs
Philip Morris Companies, Inc.
The Colorado Building
1341 G Street, NW, Suite 900
Washington, DC 20005

Dear Mr. Greenberg,

The Harvard Center for Risk Analysis was created in August 1989 to promote a reasoned public response to health, safety, and environmental hazards. Currently, America devotes a major share of national resources to minor health risks while neglecting relatively serious health risks. Our mission is to advance public health by incorporating the principles of risk analysis into training programs, scientific research, and public policy. The enclosed Center Annual Report highlights the principles that govern the Center's deliberations and the nature of our activities.

During our first year, we offered a reasoned, independent voice to the political debate in Washington about air toxics legislation. In particular, we exposed some serious weaknesses in the federal government's risk assessment process while pinpointing some drawbacks to writing simplistic risk numbers into law. For the future, we advocated a scientific approach to the assessment of the residual health risks from air toxics. Although the "risk debate" in Congress is far from resolved, it is apparent that improvements in risk assessment will be necessary within the next ten years to assure sound implementation of the upcoming amendments to the Clean Air Act.

In our second year, we played a pivotal role in the congressional debate on fuel economy standards. In particular, we have urged consideration of the safety risks associated with smaller vehicles. We continue to emphasize this theme.

Currently, we have major projects underway in carcinogen classification, risk assessment, public health priorities, and the use (and misuse) of risk numbers in environmental legislation. Looking beyond the urgency of the clean air and fuel economy issues, people are beginning to recognize that our nation's approach to managing health risks is deeply flawed. The Center seeks to participate in a longrun national effort to enhance public discussion about risk. Our strategy is to train young professionals how to think about risk in a balanced way, to target limited technical and human resources at the most important problems, and to participate vigorously in public policy debates about risk.

The Center has been launched primarily with gifts from the following corporations: the Amoco Company, Bethlehem Steel Corporation, British Petroleum, Chevron Corporation, The Coca Cola Company, Dow Chemical Company, Eastman Kodak Company, Exxon Corporation, General Electric Corporation, General Motors, Inland Steel Industries, Merck & Company, Mobil Oil Corporation, the Monsanto Company, Pepsico Incorporated, Rohm and Haas Company, Texaco, Union Carbide Corporation, and Westinghouse Corporation. Government support has also been provided by the Centers for Disease Control, the U.S. Department of Transportation, and the National Science Foundation. The Center is now looking to a broader base of industrial sources to supply critical funding for the years ahead.

In the course of establishing the Center, we have collaborated with leaders of other risk-related organizations. Paul Portney of Resources for the Future, Roger McClellan of CIIT, and Thomas Grumbly of Clean Sites provided helpful advice. We owe a special debt to Vincent Gregory, retired chairman of Rohm and Haas Company, who helped us create a vision for the Center while persuading skeptics at Harvard of the merit of our mission.

I would like the opportunity to meet with you personally to discuss the future of the Harvard Center for Risk Analysis. In particular, I am requesting $25,000 in financial support in 1992 and 1993 that can help the Center expand its public policy activities. It is important for me to learn more about the risk-related challenges that you face.

Please do not hesitate to call me directly if you have any questions about the Center. I will call in the next month to determine when we might be able to get together.

Thank you in advance for your consideration.

Sincerely,

John D. Graham

John D. Graham, Ph.D.
Director, Center for Risk Analysis
Professor of Policy and Decision Sciences

PHILIP MORRIS
MANAGEMENT CORP.
120 PARK AVENUE, NEW YORK, N.Y. 10017 · TELEPHONE (212) 880-5000

January 22, 1991

Dr. John D. Graham, Director
Center for Risk Analysis
Harvard School of Public Health
677 Huntington Avenue
Boston, MA 02115

Dear John:

Enclosed is a check in the amount of $25,000 payable to the Center for Risk Analysis, Harvard School of Public Health.

Philip Morris Companies Inc. welcomes this opportunity to contribute to your program.

Returned
1/31/92

Sincerely,

Mayada Logue

Mayada Logue, Scientist
Corporate Scientific Affairs

804-274-2921

Enclosure

Harvard Center for Risk Analysis

January 31, 1992

Mayada Logue
Scientist
Corporate Scientific Affairs
Philip Morris Management Corporation
120 Park Avenue
New York, NY 10017

Dear Mayada,

As we discussed, I have enclosed the check Philip Morris recently sent to the Center. I appreciate your understanding of the situation and hope that some arrangement can be made with Kraft. Thank you for your help.

Sincerely,

John

John D. Graham, Ph.D.
Director
Center for Risk Analysis

PHILIP MORRIS MANAGEMENT CORP. 153959
120 PARK AVENUE, NEW YORK, NY 10017-5592 01/21/92 62-20/311

Citibank,Delaware : 1 Penn's Way New Castle, DE 19720

NET AMOUNT

PAY EXACTLY*********25,000*DOLLARS AND 00 CENTS *********25,000.00**

TO THE ORDER OF
*HARVARD SCHOOL OF PUBLIC HEALTH
CENTER FOR RISK ANALYSIS
677 HUNTINGTON AVENUE
BOSTON, MA 02115

AUTHORIZED SIGNATURE

⑈153959⑈ ⑆031100209⑆ 388285 16⑈

Harvard Center for Risk Analysis

June 1, 1992

Dr. Enrique J. Guardia
Vice President
Scientific Relations
Kraft General Foods, Inc.
250 North Street
White Plains, NY 10625

Dear Dr. Guardia,

Thank you very much for the opportunity to meet you and discuss the challenges in food safety and pesticide regulation. I also appreciated the opportunity to discuss the Center for Risk Analysis and to explore the possibilities of financial support from Kraft for the projects we are working on. HCRA is committed to becoming an informed and active voice in the food safety debate.

Please don't hesitate to contact me if I can be of assistance to you.

Sincerely,

John D. Graham, Ph.D.
Director
Center for Risk Analysis

Harvard School of Public Health • 677 Huntington Avenue • Boston, MA 02115

KRAFT GENERAL FOODS

DR. ENRIQUE J. GUARDIA
VICE PRESIDENT
SCIENTIFIC RELATIONS

August 12, 1992

John D. Graham, Ph.D.
Harvard Center For Risk Analysis
Harvard School of Public Health
677 Huntington Avenue
Boston, MA 02115

Dear John:

I just finished responding to your letter, and in my mail was the check for HCRA.

This $20,000 check from Kraft General Foods is a contribution of $10,000 per year for the next two years to support the work of the Center, in general, and your contributions to the food safety debate (Pesticides).

I would like to meet from time to time to discuss topics of mutual interest.

As I said before, there are a great many issues of importance to our family of companies that involve Risk Analysis, and we are delighted to have you and your group as engaged and unbiased participants in the debate.

Regards,

Rick

EJG/pc
Enclosure

3650648

KRAFT GENERAL FOODS, INC.

64-1278
611

NATIONSBANK OF GEORGIA, N.A.
ATLANTA, DEKALB COUNTY, GEORGIA

| DATE | CHECK NO. | NET AMOUNT |
|---|---|---|
| 08/03/92 | 01867374 | $*****20,00 |

'AY

Not Valid After Six Months From Issue Date

WENTY THOUSAND DOLLARS AND 00 CENTS

TO THE ORDER OF
HARVARD CTR FOR RISK ANALYSIS
HARVARD SCHOOL PUBLIC HEALTH
677 HUNTINGTON AVE
BOSTON MA 02115

George P Burdell

COUNTERSIGNATURE REQUIRED OVER $100,000
VOID IF COLORED BACKGROUND IS ABSENT

⑈01867374⑈ ⑆061112788⑆ 011 32 166⑈

PHILIP MORRIS
MANAGEMENT CORP.
120 PARK AVENUE, NEW YORK, N.Y. 10017-5592 • (212) 880-5000

THOMAS J. BORELLI, PH.D.
DIRECTOR
SCIENCE AND ENVIRONMENTAL POLICY

August 26, 1993

Dr. John D. Graham
Harvard School of Public Health
677 Huntington Avenue
Boston, MA 02115

Dear Dr. Graham,

I am responding to your letter sent to Mr. Michael A. Miles regarding the Harvard Center for Risk Analysis.

As a major manufacturer of consumer products, Philip Morris Companies Inc. has a strong interest in the public policy debate on pesticides. Accordingly, we are interested in finding out more about your plans concerning this important public policy issue.

I will discuss your proposal with Dr. Guardia of Kraft-General Foods and one of us will contact you in the near future.

Sincerely,

Thomas J. Borelli

Thomas J. Borelli

cc: M. Miles
R. Guardia

Harvard Center for Risk Analysis

335.250

September 7, 1993

Dr. Enrique Guardia
Vice President
Kraft-General Foods
250 North Street
White Plains, New York 10625

Dear Dr. Guardia:

Recently I received a letter from Thomas Borelli expressing interest in our pesticide policy studies and mentioning that you or he would contact us in the near future. His question about our plans concerning this important policy issue comes at an opportune time since we are currently drafting Testimony to be presented at the Joint Hearing on this matter of the House Subcommittee on Health and Environment and the Senate Committee on Labor and Human Resources. Accordingly, I am sending you a copy of a draft of my testimony and would much appreciate receiving your comments on it. Since the Joint Hearing is scheduled for September 21 your suggestions, if any, should be sent as soon as possible.

I will look forward to hearing from you.

Sincerely,

John D. Graham

John D. Graham, Ph.D.
Professor of Policy and
Decision Sciences

cc: Thomas J. Borelli

Harvard School of Public Health • 718 Huntington Avenue • Boston, MA 02115
tel 617-432-4497 • fax 617-432-0190

**Harvard Center for Risk Analysis**

## Facsimile Transmission Sheet

Date: Sep 8 93 Total No. of Pages: 1 (including cover)

Name: Dr. Enrique Guardia

914 335 6845

From: Professor John Graham
The Center for Risk Analysis

Tel. No.: 617-432-4497
Fax No.: 617-432-0190

Message:

Rick

Sorry about the confusing letter sent to Philip Morris. I have a new staff person who was not aware of our previous difficulties accepting Philip Morris money. I also neglected to tell her that we already have a two year commitment from Kraft. Please just ignore the letter and pass the word along to Tom. Sorry for the confusion.

John

P.S. Comments on my draft congressional testimony, which should arrive in the mail soon, are welcome.

*If you do not receive the entire document, please call:*
*(617) 432-4497*

Harvard School of Public Health · 677 Huntington Avenue · Boston, MA 02115

Harvard Center for Risk Analysis

Personal donation
GDL
5/14/01

October 25, 1993

Ms. Mayada Logue
PM USA
120 Park Avenue
Fourteenth Floor
New York, NY 10017

Dear Ms. Logue,

We cannot thank you enough for your gracious donation. Our continued growth in personnel brings with it a steady need for more computers. Your 286/16 with 1MB RAM and the 3.5 and 5.25 disk drives, complete with the 14" VGA color monitor, keyboard, modem 2400, and mouse has made one of our analysts extremely happy -- she no longer must share a computer!

Thank you for thinking of us.

Sincerely,

John D. Graham

John D. Graham, Ph.D.
Director
Center for Risk Analysis

Harvard School of Public Health • 718 Huntington Avenue • Boston, MA 02115

November 19th, 1993

Kraft General Foods, Inc.
Dr. Enrique J. Guardia
Vice President
Scientific Relations
250 North Street
White Plains, NY 10625

Dear Dr. Guardia:

We appreciate Kraft General Food's support in 1993 to the Harvard Center for Risk Analysis (HCRA). Your support has enabled us to accomplish our mission - to foster a reasoned public response to health, safety, and environmental risks. Our mission has been achieved with public policy projects, communications activities, and reform of professional and scientific training programs. In this letter, we are requesting continued financial support from Kraft General Foods, Inc. which will permit HCRA to expand our public policy activities.

HCRA's philosophy is that public health priorities should be rearranged to reflect the insights of science-based risk analysis. Risk analysis principles provide a useful framework for separating the serious health threats from the trivial risks. Moreover, the risk analysis framework fosters critical thinking about allocation of scarce resources and the weighing of important risk-risk tradeoffs. Since 1989 HCRA's philosophy has exerted significant impact on national policy discussions.

We anticipated that the safety of pesticide residues on foods wouldl emerge as a significant legislative issue. HCRA participated in the legislative discussions by placing the risks of pesticide residues in a larger public health context. Big health problems need to be distinguished from small and non-existent health problems. Our experience with the Clean Air Act suggests that many Members of Congress and their staffs are likely to be ill-informed about the safety of foods and the extreme assumptions that form the basis of estimates of cancer risks due to pesticide residues. Enclosed for your review please find my testimony to Congress on this issue.

Now In our fifth year, we continue receive unrestricted contributions from over thirty Fortune 500 companies that are listed alphabetically in the attachment to this letter. HCRA has also obtained restricted grants for project support from the American Industrial Health Council, the Department of Health and Human Services, the Environmental Protection Agency, the National Science Foundation, and the Department of Transportation.

HCRA values Kodak Corporation's support and confidence in our work. I would like the opportunity to meet with you and discuss the Center's future. In particular, I would like to request the continued contribution of $25,000 in 1994 to support the Center's increased public policy activities.

Thank you in advance for your consideration and support. I will call your office in the weeks ahead to determine if any questions need to be answered. Enclosed for your information please find copies of HCRA's recent newsletters and the 1993 Annual Report.

Thank you very much in advance for your consideration.

Sincerely,

John D. Graham, Ph.D.
Director

JDG/sg
enc: 1992 Annual Report
7/93 Testimony

Harvard Center for Risk Analysis

August 12, 1994

Dr. Enrique J. Guardia
Vice President
Scientific Relations
Kraft General Foods, Inc.
250 North Street
White Plains, NY 10625

(914) 335-2500
mail going to Terrytown
Patty out [illegible]
call Fri or next week
(914) 335-6350
left message.

Dear Dr. Guardia:

As you know, the mission of the Harvard Center for Risk Analysis is to promote a reasoned public response to potential health, safety and environmental hazards. We accomplish this mission by incorporating a risk-analysis perspective into public policy debates, scientific research, and education and communications programs. Looking to the future, we are requesting a contribution of $20,000 from Kraft General Foods that will allow us to expand our public policy activities.

The last year has been particularly productive and rewarding for HCRA. We testified on the importance of risk analysis before seven House and Senate committees and met personally with leaders from both the Congress and the Clinton Administration on the need for risk-oriented legislation.

In the communications area, we worked with John Stoussel of ABC News on the one-hour, prime-time show, "Are We Scaring Ourselves to Death?" (April 21, 1994), which brought the theme of "comparing risks" into the homes of an estimated 30 million Americans. Our bimonthly newsletter, Risk in Perspective, now reaches an audience of 8,000 opinion leaders, journalists, and elected officials.

On the scientific front, we completed our probabilistic analysis of the carcinogenic potency of chloroform, which demonstrates how a single, worst-case number can be replaced by a distribution of potency values that reflect the weight of the scientific evidence. Our new scholarly book, Risk versus Risk: Confronting Tradeoffs in Health and Environmental Protection, will be published by Harvard University Press in 1995. Recently, the results of our Lifesaving Priorities Project were covered prominently in the Wall Street Journal (July 6, 1994) and stimulated over 500 requests for additional information.

In the coming year, we intend to build on our current activities as well as begin to address new issues. Our current projects are described in the enclosed HCRA annual report. We are also developing new projects on chlorine, electric and magnetic fields, pharmaceuticals, pest control, and food biotechnology. If there are major issues facing Kraft General Foods that HCRA should consider addressing, I would be happy to meet personally with you or your colleagues to discuss whether and how HCRA might be of assistance.

We appreciate Kraft's previous support and confidence in our work. Your 1994 contribution will be added to the growing number of corporations, foundations and public agencies that support HCRA. In 1989 HCRA was launched with contributions from a handful of corporations. We now receive contributions from several foundations, several agencies of the federal government, and over 35 Fortune 500 companies (attachment).

Thank you very much in advance for your consideration of this request. If you have specific questions, please do not hesitate to contact me. I am certainly willing to make a visit to White Plains in order to explain what our nation needs to do to achieve a more reasoned public response to health, safety and environmental hazards. My assistant, Mary Esther Otts (617-432-4342), will contact you in the weeks ahead to determine if you desire any further information to support this request.

Sincerely,

John D. Graham
Professor and Director

JDG/meo
Enclosure

## HCRA 1993-1994 CORPORATE CONTRIBUTORS

Aetna Life & Casualty Company
Alcoa Foundation
Amoco Corporation
Ashland Oil Inc.
Atlantic Richfield Corporation
ARCO Chemical Company
Bethlehem Steel Corporation
BP America Inc.
Chemical Manufacturers Association
Chevron Research & Technology Company
CIBA-GEIGY Corporation
The Coca-Cola Company
The Dow Chemical Company
E.I. DuPont de Nemours & Company
Eastman Chemical Company
Edison Electric Institute
Electric Power Research Institute
Exxon Corporation
Ford Motor Company
Frito-Lay
General Electric Company
General Motors Corporation
Hoechst Celanese Corporation
ICI Americas Inc.
Inland Steel Industries
International Paper
Kodak
Kraft General Foods
Mobil Oil Corporation
Monsanto Company
New England Power Service
Olin Corporation
PepsiCo Inc.
The Procter & Gamble Company
Rohm and Haas Company
Texaco Inc.
Union Carbide Corporation
USX Corporation

KRAFT GENERAL FOODS

GARY A. HENDERSON, Ph.D.
DIRECTOR
SCIENTIFIC RELATIONS

September 20, 1994

Dr. John D. Graham
Professor and Director
Harvard Center for Risk Analysis
Harvard School of Public Health
718 Huntington Avenue
Boston, MA 02115

Dear Dr. Graham:

Rick Guardia passed along your letter of August 12, 1994 concerning support for the Harvard Center for Risk Analysis. Kraft General Foods is pleased to be able to provide the attached check for $20,000 to further the work related to health and safety hazards. The work is important to ensure public policy debates include a clear risk analysis perspective.

Please substitute my name for Rick's name on your distribution lists for information concerning the program. Also attached is a tax form which should be completed and returned.

Sincerely,

GAHenderson

GAH/pc
Attachment

5610312

# KRAFT GENERAL FOODS, INC.

64-1278
611

PAY NATIONSBANK OF GEORGIA, N.A.
ATLANTA, DEKALB COUNTY, GEORGIA

| DATE | CHECK NO. | NET AMOUNT |
|---|---|---|
| 09/13/94 | 03717799 | $*****20,000.00 |

Not Valid After Six Months From Issue Date

TWENTY THOUSAND DOLLARS AND 00 CENTS

TO THE ORDER OF

HARVARD SCHOOL OF PUBLIC HEALTH
OFFICE OF CONTINUING EDUCATION
718 HUNTINGTON AVE
BOSTON MA 02115

George P Bundell

COUNTERSIGNATURE REQUIRED OVER $100,000

VOID IF COLORED BACKGROUND IS ABSENT

⑈03717799⑈ ⑆061112788⑆ 011 32 166⑈

HARVARD SCHOOL OF PUBLIC HEALTH
Department of Health Policy & Management

677 Huntington Avenue, Room 420
Boston, MA 02115

432-4499
Fax: 432-4494

**MEMORANDUM**

To: OFS
From: Dawn Elliott-Linehan
Date: September 30, 1994
Subject: Check receipt

Re: Kraft General Food's check numbers 03717799 in the amount of $20,000.

Please deposit the enclosed check in John Graham's account 72-090-3653.

Thank you very much.

cc: M.E. Otts

# KRAFT GENERAL FOODS

CHARITABLE CONTRIBUTION ACKNOWLEDGMENT
Internal Revenue Code Section 170(f)(8)

Upon receipt of the contribution, please complete this acknowledgment form and return it in the self-addressed stamped envelope.

Federal Tax ID Number: 04-210-3580 501(c)(3) Status: Yes ☑ No ☐
Donee Name and Address: President and Fellows of Harvard College / Harvard University / Radcliffe College
Harvard Center for Risk Analysis
718 Huntington Avenue, Boston, MA 02115
Telephone Number: (617) 432-4497

☑ Cash Contribution Amount: $ 20,000
☑ Check Date: 9 / 13 / 94

Goods or services were not provided to Kraft General Foods, Inc. in consideration for this contribution. If goods or services were provided, please check box and include a description and estimated value of the goods or services.
Consideration Provided: ☐

Non-Cash Contribution: Please provide the quantity and a description of property. Attach separate sheet(s) if necessary.

Goods or services were not provided to Kraft General Foods, Inc. in consideration for this contribution. If goods or services were provided, please check box and include a description and estimated value of the goods or services.
Consideration Provided: ☐

☐ Quid Pro Quo contribution amount over $75.

Total Cash Contribution Amount Received: $_____
Less Value of Goods or Services Provided: ($_____)
(e.g. Dinners, luncheons, theater tickets, etc.)
Please itemize and attach separate sheet(s) if necessary.

The above information accurately represents the value of the charitable contribution received from Kraft General Foods, Inc.

Print Name: Mary Esther Otts Date: 9/30/94

Signature: Mary Esther Otts Title: Administrator

Return to: Kraft General Foods, Inc.

Harvard Center for Risk Analysis

September 30, 1994

Gary A. Henderson, Ph.D.
Director
Scientific Relations
Kraft General Foods, Inc.
250 North Street
White Plains, NY 10625

Dear Dr. Henderson,

I am writing to acknowledge with thanks Kraft General Foods gift of $20,000 for the Harvard Center for Risk Analysis. HCRA continues to promote a reasoned public response to health, safety, and environmental risks by addressing the current issues in risk analysis. Kraft's support is crucial to the Center's continued success in achieving our goals, and we certainly appreciate your confidence in our work.

Enclosed for your review please find our most recent Annual Report. Per your request all future information regarding our center will be directed to your attention.

Sincerely,

John D. Graham, Ph.D.
Director

JDG/meo

cc: Dr. Enrique J. Guardia

HARVARD SCHOOL OF PUBLIC HEALTH

Harvey V. Fineberg, Dean

16 November 1994

Gary A. Henderson, Ph.D.
Director, Scientific Relations
Kraft General Foods, Inc.
250 North Street
White Plains, NY 10625

Dear Dr. Henderson:

I am delighted to acknowledge Kraft General Foods' recent grant of $20,000 in support of the Center for Risk Analysis directed by Dr. John D. Graham at the Harvard School of Public Health.

The Harvard Center for Risk Analysis has achieved a reputation for excellence in its approach to health, safety and environmental risks. We are particularly proud of the work being done by Dr. Graham and greatly appreciate support from Kraft for this vitally important program.

On behalf of Dr. Graham and all of us at the School, I send my sincere appreciation for your ongoing interest and confidence in our work.

Sincerely,

Harvey

Harvey V. Fineberg

HVF/eb

cc: John D. Graham, Ph.D.

677 Huntington Avenue Boston, Massachusetts 02115 617 432-1025 Fax: 617 277-5320

Harvard Center for Risk Analysis

TO: Gary A. Henderson, Ph.D.
Kraft General Foods
Telephone: (914) 335-6020
Facsimile: (914) 335-6239

FROM: Mary Esther Otts MEO
Telephone: (617) 432-4497
Facsimile: (617) 432-0190

DATE: December 21, 1995

RE: HCRA Contribution Request
Kraft General Foods, Inc.

VIA: Facsmile - Total Pages (4)

Attached is a copy of Dr. Graham's contribution request letter dated August 31, 1995. Per your request, I have checked our files and confirmed no record of a response to this request.

I will be out of the office until January 4, 1996. In the meantime, please contact Melissa Rocha (617) 432-4497 should you need additional information.

Thank you for your time and consideration.

Harvard Center for Risk Analysis

August 31, 1995

Gary A. Henderson, Ph.D.
Director Scientific Relations
Kraft General Foods, Inc.
250 North Street
White Plains, New York 10625

Dear Dr. Henderson:

As you know, the mission of the Harvard Center for Risk Analysis is to promote a reasoned public response to health, safety, and environmental hazards. We accomplish this mission by bringing a "risk analysis" perspective to public policy debates, scientific research, and education/communications activities. We appreciate the previous contributions that Kraft General Foods, Inc. has made to HCRA. Looking to the coming year, we are requesting a contribution of $20,000 from Kraft General Foods, Inc. that will allow us to expand our activities.

For HCRA, the past year has been exciting and satisfying. On public policy issues, HCRA faculty and staff testified before six congressional committees in Washington, DC on the need for regulatory reform legislation. In the process, we have built useful working relationships with members of the new Congress and their staffs.

Our message has been that better use of analytic tools by agencies can provide the public with more protection against genuine hazards at less cost to the private and public sectors than is being accomplished under current laws. This same message was also delivered in selected state capitals (including Albany, New York and Harrisburg, Pennsylvania) where reform coalitions are building. The enclosed publication, "Reform of Risk Regulation: Achieving More Protection at Less Cost," provides an excellent overview of HCRA's perspective on these issues. While it is not yet clear what new laws, if any, will emerge from this Congress on these issues, we believe that our efforts have begun to legitimize risk analysis in the eyes of key policymakers from both political parties.

In the scholarly arena, we are working with a longer time horizon to advance the analytic tools of risk analysis. Our scholarly book, Risk Versus Risk: Tradeoffs in Health and Environmental Protection (Harvard University Press, Cambridge, MA, 1995), proposes a new analytic approach to identifying and weighing hazards that are caused by well-intentioned efforts to reduce risks. Case studies in the book address topics ranging from drug approval at FDA to toxic chemical regulation at EPA.

HCRA's longterm methodologic research program is balanced by shorter-term projects on specific hazards and/or technologies of current concern. The following topics are currently research priorities at HCRA: environmental estrogens, violence, electric and magnetic fields, drinking and driving, chemical carcinogens, automobile airbags, environmental equity, medical devices, and prescription drugs. We are interested in your suggestions about which subjects should (or should not) be a HCRA priority.

On the education and communications front, HCRA's activities go far beyond new and revised course offerings for Harvard degree students. We participate regularly in continuing education programs aimed at journalists (e.g., those risk-oriented courses designed by the Foundation for American Communications) and disseminate our bi-monthly newsletter, Risk in Perspective, to over 12,000 professionals in government, business, the mass media, and non-profit advocacy organizations. We have been particularly effective in building relationships with TV and newspaper reporters that have led our message to appear in prominent stories run by the major television networks and the New York Times, Washington Post, Los Angeles Times, and numerous trade publications.

We recognize that philanthropic resources are limited and that HCRA is competing against other worthy causes. We are proud to report that HCRA, which was established in 1989, now receives financial support from over 35 Fortune 500 companies, several trade associations, various agencies of the federal government, and several private foundations. Our objectivity is strengthened by this diversity of funding sources, the caliber of our advisory committee, and our reputation for recruiting faculty, staff, and students on the basis of intellectual merit. For your information, I have taken the liberty of enclosing a copy of HCRA's 1994 Annual Report.

Thank you very much in advance for your consideration of this request. I am certainly willing to make a visit to White Plains if that would be informative. My assistant, Mary Esther Otts, will contact you in the weeks ahead to determine if you might desire any additional information to support this request.

Sincerely,

John D. Graham mea

John D. Graham, Ph.D.
Director

JDG/meo

Enclosures

## HARVARD CENTER FOR RISK ANALYSIS 1993-1995 CORPORATE CONTRIBUTORS

Aetna Life & Casualty Company
Alcoa Foundation
American Automobile Manufacturers Association
American Petroleum Institute
Amoco Corporation
Ashland Oil Inc.
Atlantic Richfield Corporation
ARCO Chemical Company
BASF
Bethlehem Steel Corporation
BP America Inc.
Chemical Manufacturers Association
Chevron Research & Technology Company
CIBA-GEIGY Corporation
The Coca-Cola Company
The Dow Chemical Company
DowElanco
E.I. DuPont de Nemours & Company
Eastman Chemical Company
Edison Electric Institute
Electric Power Research Institute
Exxon Corporation
Ford Motor Company
Frito-Lay
General Electric Company
General Motors Corporation
The Goodyear Tire & Rubber Company
Hoechst Celanese Corporation
ICI Americas Inc.
Inland Steel Industries
International Paper
Kodak
Kraft General Foods
Mead Corporation
Minnesota Mining and Manufacturing Company
Mobil Oil Corporation
Monsanto Company
New England Power Service
Olin Corporation
Oxygenated Fuels Association
PepsiCo Inc.
Pfizer
The Procter & Gamble Company
Rhône-Poulenc, Inc.
Rohm and Haas Company
Texaco Inc.
Union Carbide Corporation
Unocal
USX Corporation

Kraft Foods

MEO

Gary A. Henderson, Ph.D.
Director
Scientific Relations

March 19, 1996

Dr. John D. Graham
Harvard School of Public Health
718 Huntington Avenue
Boston, Massachusetts 02115

Dear John,

Attached is a check for $20,000.00 to further the risk analysis activity of the center. Kraft is pleased to provide the contribution to encourage programs in the important area of promoting a rationale response to health and safety hazards. It was good to meet you at the recent Kraft Scientific Relations staff meeting in Washington.

Also attached is a Charitable Contribution form to be completed and returned.

Sincerely,

Gary Henderson/pc

GAH/pc
Attachment

c: Laura Hayes

MULTI-TONE AREA OF THE DOCUMENT CHANGES COLOR GRADUALLY AND EVENLY FROM DARK TO LIGHT WITH DARKER AREAS BOTH TOP AND BOTTO

6474565 KRAFT FOODS, INC. 64-1278
611

NATIONSBANK OF GEORGIA, N.A.
ATLANTA, DEKALB COUNTY, GEORGIA

| DATE | CHECK NO. | NET AMOUNT |
|---|---|---|
| 03/04/96 | 04542196 | $*****20,000.0 |

Not Valid After Six Months From Issue Date

:ENTY THOUSAND DOLLARS AND 00 CENTS

THE
:DER

HARVARD SCH OF PUBLIC HEALTH
.
718 HUNTINGTON AVE
BOSTON MA 02115

George P Bundell

VOID IF COLORED BACKGROUND IS ABSENT

⑈04542196⑈ ⑆061112788⑆ 011 32 166⑈

THE ORIGINAL DOCUMENT HAS A REFLECTIVE WATERMARK ON THE BACK. HOLD AT AN ANGLE TO VIEW WHEN CHECKING THE ENDORSEMENT.

# Kraft Foods, Inc.

CHARITABLE CONTRIBUTION ACKNOWLEDGMENT
Internal Revenue Code Section 170(f)(8)

Upon receipt of the contribution, please complete this acknowledgment form and return it in the self-addressed stamped envelope.

Federal Tax ID Number: 042-103-580 501(c)(3) Status: Yes ☑ No ☐
Donee Name and Address: President and Fellows of Harvard College
Harvard Center for Risk Analysis
Telephone Number: (617) 432-4497

☐ Cash Contribution Amount: $ 70,000.00
☐ Check Date: 3/4/96

Goods or services were not provided to Kraft Foods, Inc. in consideration for this contribution. If goods or services were provided, please check box and include a description and estimated value of the goods or services.
Consideration Provided: ☐

☐ Non-Cash Contribution: Please provide the quantity and a description of property. Attach separate sheet(s) if necessary.

Goods or services were not provided to Kraft Foods, Inc. in consideration for this contribution. If goods or services were provided, please check box and include a description and estimated value of the goods or services.
Consideration Provided: ☐

☐ Quid Pro Quo contribution amount over $75.

Total Cash Contribution Amount Received: $_____
Less Value of Goods or Services Provided: ($_____)
(e.g. Dinners, luncheons, theater tickets, etc.)
Please itemize and attach separate sheet(s) if necessary.

The above information accurately represents the value of the charitable contribution received from Kraft Foods, Inc.

Print Name: Kenneth A. Repp Date: 4/5/96
Signature: [signature] Title: Financial Administrator

Return to: Kraft Foods, Inc.
Corporate Headquarters, Three Lakes Drive, Northfield, IL 60093-2753
Attention: Community Affairs Administrator — NF205

HARVARD SCHOOL OF PUBLIC HEALTH
Department of Health Policy & Management

677 Huntington Avenue, Room 420
Boston, MA 02115

432-4499
Fax: 432-4494

**MEMORANDUM**

To: OFS
From: Dawn Elliott-Linehan
Date: April 4, 1996
Subject: Check receipt

Please deposit the attached check #64-1278 from:

Kraft Foods, Inc.
250 North Street
White Plains, NY
10625

for $20,000.00 in John Graham's account #72-090-3653.

Thank you very much.

cc: Dean Harvey Fineberg
John D. Graham
Mary Esther Otts
Ken Repp

Henderson

HARVARD CENTER FOR RISK ANALYSIS

April 5, 1996

Gary A. Henderson, Ph.D.
Director
Scientific Relations
Kraft Foods, Inc.
250 North Street
White Plains, New York 10625

Dear Gary:

I am writing to acknowledge with thanks Kraft Food Inc.'s gift of $20,000 for the Harvard Center for Risk Analysis. Now in our seventh year, HCRA continues to promote a reasoned public response to health, safety, and environmental risks by addressing the current issues in risk analysis. Kraft's support is crucial to the Center's continued success in achieving our goals, and we certainly appreciate your confidence in our work.

Enclosed please find our 1995 Annual Report. This report highlights HCRA activities and projects during the last year, and use of contributions funding. Please feel free to contact me if I can ever be of your assistance.

Sincerely,

John D. Graham

John D. Graham, Ph.D.
Director and Professor

JDG/meo

Enclosure

HARVARD CENTER FOR RISK ANALYSIS

To: Dr. Gary Henderson
Kraft Foods
Facsimile: (914) 335-6239

From: Mary Esther Otts
Telephone: (617) 432-0394
Facsimile: (617) 432-0190
Total Pages Including Cover (3)

Date: January 17, 1997

Re: Harvard Center for Risk Analysis (HCRA)

Attached please find a copy of Dr. Graham's contribution request letter dated September 20, 1996.

Please let me know if you need additional information regarding this request. Thank you for your time and consideration. I look forward to hearing from you.

HARVARD CENTER FOR RISK ANALYSIS

75

September 20, 1996

Dr. Gary A. Henderson
Director International Scientific Relations
Kraft Foods
250 North Street
White Plains, New York 10625

Dear Gary:

As you know, the Harvard Center for Risk Analysis is gradually establishing a leadership position in the national and international campaign to promote a more reasoned public response to health, safety, and environmental hazards. We appreciate the contributions that Kraft Foods has made to the Center because, without such support, HCRA's programs in communications, science, and training would suffer. The purpose of this letter is to request your continued support in the form of a $20,000 contribution to the Harvard Center for Risk Analysis.

Since we do not always keep you as well informed as we should of our accomplishments, I thought it would be useful to highlight a few of our "wins" during the last year:

--the strong provisions promoting risk analysis in recent Congressional reauthorizations of the Safe Drinking Water Act and the Food Quality Protection Act, provisions that track closely some of the key testimony offered by HCRA faculty;

--quotations of HCRA scientists in over 150 newspaper articles in 1995-96, prime-time television interviews about risk with NBC's Jane Pauley (August 20, 1996) and ABC's John Stoussel (September 9, 1996);

--lectures on the urgent need for risk-based reforms of government policy before a variety of target audiences such as congressional staff, federal judges, and journalists;

--six issues of our newsletter, Risk in Perspective, addressing topics ranging from estrogenic chemicals to domestic violence;

--publication of our new book, Risk versus Risk: Tradeoffs in Health and Environmental Protection (eds., JD Graham, J Wiener), through Harvard University Press, with case studies of pesticide regulation, global climate policy, food safety, energy regulation, pharmaceutical policy, and medical decision making;

--revamped mid-career education offerings in both risk analysis and cost-benefit analysis for professionals in government and industry;

--recruitment of six talented new doctoral students with interests in the risk and decision sciences;

--contributions to the draft revisions to EPA's carcinogen assessment guidelines which, while modest in their ambitions, are an important step toward greater use of science in cancer risk assessment;

--publication of peer-reviewed methodological articles on comparative risk assessment, cost-benefit analysis, and value-of-information analysis; and

--peer-reviewed scientific publications on a wide range of specific risks including global climate change, drinking and driving, firearm-related injury, domestic violence, AIDS, chloroform, and nuclear power.

In the pipeline we also have a variety of exciting products that should be publicly available in 1997. Our newest scholarly book, The Greening of Industry: A Risk-Management Approach, makes the pro-environment case for risk analysis based on historical case studies of lead in gasoline, chlorofluorocarbons, coke production, chlorine-based pulp and paper production, municipal incineration, and dry cleaning. In each case, we demonstrate how risk-based thinking has promoted environmental progress in industry. We also have scientific articles nearing completion on environmental justice in the petroleum and steel industries and public misperception of various hazards and risks that have been publicized in the mass media.

HCRA continues to expand with a diversified base of financial support. Our unrestricted support from corporations includes contributions from 50 Fortune 500 companies and trade associations in the automobile, food, pharmaceutical, petroleum, chemical, consumers' products, metals, and environmental industries. Our restricted grants come from various foundations and government agencies including EPA, DOT, CDC, NIH, NSF and DOE. In order to minimize any real or perceived conflicts of interest related to our funding sources, we have adopted a new, Center-wide, conflict-of-interest policy based on the principles of disclosure and diversity of funding sources, protection of academic freedom, peer review, and restraints on the Center Director's ability to earn outside income from private sources. The policy, to be published in HCRA's forthcoming annual report, mirrors Harvard University's policy in many respects but goes considerably further in several important respects. We also continue to discuss our progress and future agenda with an external advisory committee of leaders from government, industry, academia, and nonprofit organizations.

Our primary agenda, as you know, is to uncover and correct serious mismatches between public concern about risk and scientific evidence of risk. We are eager to hear suggestions from you about future projects or activities that might advance this broad agenda. I am certainly willing to make a visit to White Plains if that would be informative. Thank you in advance for your consideration of this request. My assistant, Mary Esther Otts, will contact you in the weeks ahead to determine if you might desire any additional information to support this request.

Sincerely,

John D. Graham, Ph.D.
Director and Professor

JDG/meo

Enclosures

## HCRA SOURCES OF FINANCIAL SUPPORT

The Harvard Center for Risk Analysis is funded by a combination of industrial, governmental, and foundation funding. Additionally, the Harvard School of Public Health and individual donors contribute to the Center. The Center's Program on the Economic Evaluation of Medical Technology's funding is included in following list of contributors since 1989:

**Restricted grants**
Alfred P. Sloan Foundation
American Crop Protection Association
American Industrial Health Council
Andrew Mellon Foundation
Bradley Foundation
Brookings Institution
California Avocado Commission
Chemical Manufacturers Association
Congressional Research Service
Electric Power Research Institute
International Life Science Institute/Risk Science Institute
Health and Environmental Sciences Group
National Institute of Justice
Pfizer, Inc.
Society for Risk Analysis
U.S. Centers for Disease Control
U.S. Department of Energy
U.S. Department of Health and Human Services
U.S. Department of Transportation.
U.S. Environmental Protection Agency
U.S. National Oceanic Atmospheric Administration
U.S. National Science Foundation

**Unrestricted grants**
3M
Aetna Life & Casualty Company
Alcoa Foundation
American Automobile Manufacturers Association
American Crop Protection Association
American Petroleum Institute
Amoco Corporation
ARCO Chemical Company
ASARCO Inc.
Ashland Inc. Foundation
Association of American Railroads
Astra AB
Astra Merck
Atlantic Richfield Corporation
BASF
Bethlehem Steel Corporation
Boatmen's Trust
BP America Inc.
Cabot Corporation Foundation
Cement Kiln Recycling Coalition
Charles G. Koch Foundation
Chemical Manufacturers Association
Chevron Research & Technology Company
CIBA-GEIGY Corporation
Ciba Geigy Limited
CITGO Petroleum Company
The Coca-Cola Company
Cytec Industries
Dow Chemical Company
DowElanco
Eastman Chemical Company
Eastman Kodak Company
Edison Electric Institute
E.I. DuPont de Nemours & Company
Electric Power Research Institute
Exxon Corporation
Ford Motor Company
Frito-Lay
General Electric Fund
General Motors Corporation
The Geon Company
Georgia-Pacific Corporation
Glaxo-Wellcome, Inc.
The Goodyear Tire & Rubber Company
Grocery Manufacturers of America
Hoechst Celanese Corporation
Hoechst Marion Roussel
Hoffman-LaRôche Inc.
ICI Americas Inc.
Inland Steel Industries
International Paper
The James River Corporation Foundation
Janssen Pharmaceutical
Johnson & Johnson
Kraft Foods
Mead Corporation Foundation
Merck & Company
Mobil Foundation, Inc.
Monsanto Company
National Food Processors Association
National Steel
New England Power Service -- New England Electric System
Nippon Yakin Kogyo
North American Insulation Manufacturers Association
Novartis Corporation
Olin Corporation Charitable Trust
Oxygenated Fuels Association
PepsiCo Inc.
Pfizer
Pharmacia Upjohn
Potlatch Corporation
Praxair, Inc.
Procter & Gamble Company
Reynolds Metals Company Foundation
Rhone-Poulenc, Inc.
Rohm and Haas Company
Schering-Plough Corporation
Shell Oil Company Foundation
Texaco Foundation
Union Carbide Foundation
Unocal
USX Corporation
Westinghouse Electric Corporation
Westvaco
WMX Technologies, Inc.

HARVARD CENTER FOR RISK ANALYSIS

September 11, 1997

Gary A. Henderson, Ph.D.
Director International Scientific Relations
Kraft Foods
555 South Broadway
Terrytown, New York 10591

Dear Dr. Henderson:

As you know, the Harvard Center for Risk Analysis (HCRA) has established a leadership position and the national and international campaigns to promote a more reasoned public response to health, safety, and environmental hazards. We appreciate the contributions that Kraft Foods has made to the Center. The purpose of this letter is to request your continued support in the form of a $25,000 contribution from Kraft Foods for the HCRA.

As a results-oriented unit, we accomplish our mission through research, training, and communications. Here are a few of our contributions in the last year:

--extensive communications with congressional staff and other actors interested passage of the Regulatory Improvement Act of 1997, a comprehensive regulatory reform bill co-authored by Senators Levin and Thompson that promotes the tools of risk assessment, comparative risk assessment, and cost-benefit analysis;

--lectures on the comparative-risk theme before audiences of journalists, opinion leaders, business leaders, government officials in Europe and Asia as well as the USA;

--interviews with print journalists for a wide range of publications including Parade magazine, Washington Post, Wall Street Journal, New York Times, U.S. News and World Report;

--television interviews on risk-related issues before nationwide audiences including the NBC's "Today Show", CBS's "Good Morning America", and CNN's "World News Tonight",

--testimony at congressional and administrative hearings, such as the National Transportation Safety Board's March 1997 hearing on the risks and benefits of automobile airbags;

--production of 8 issues of our newsletter, Risk in Perspective, addressing topics ranging from automobile airbags to breast cancer prevention for an audience of more than 15,000 professionals and opinion leaders in both the public and private sectors;

--publication of our new book, The Greening of Industry (Harvard University Press), which highlights the pro-environment influences of risk analysis in the steel, chemical, waste management, petroleum and pulp and paper industries;

--new mid-career course offerings for professionals interested in cost-benefit analysis and quantitative risk assessment; and

--publication of numerous peer-reviewed scientific articles on a wide range of health problems including cancer, heart disease, trauma,alzheimer's disease.

Although HCRA has a unified intellectual perspective based in risk analysis and decision science, it also has well-defined problem areas that serve as priorities for research and communication. They are environmental health protection, trauma prevention, medical technology assessment, and food safety policy. We are open to suggestions of particular activities that can advance HCRA's contribution to nurturing a more reasoned public approach to these issues.

HCRA has grown steadily since it was founded in 1989. Our unrestricted support from private-sector organizations now includes contributions from 60+ Fortune 500 companies as well as several foundations and trade associations. Restricted grants for project support are received from a variety of foundations and government agencies including EPA, DOT, CDC, HHS, NSF, NOAA, and DOE. The Center also has a well-defined conflict of interest policy aimed at eliminating any real and perceived conflicts of interest associated with the sources of its support and the projects it undertakes. This policy is published regularly in the Center's biennial report. We also continue to discuss our progress and future agenda with our external advisory committee, which meets in Boston each June for a day and a half.

Our primary agenda, as you may know, is to uncover and correct serious mismatches between public concern about risk and scientific evidence of risk. There is tremendous opportunity in this area to save both lives and resources through more cost-effective allocation of time, energy, political will, and resources. We are eager to hear your suggestions about how HCRA can make a more meaningful contribution to these ends.

Thank you in advance for your consideration of this request. I am certainly willing to make a visit to Terrytown if that would be appropriate and informative. My assistant, Ellen Patterson, will be contacting you in the weeks ahead to determine if you might desire any additional information to support this request.

Sincerely,

John D. Graham

John D. Graham, Ph.D.
Director and Professor

JDG/meo
Enclosures

**HARVARD SCHOOL OF PUBLIC HEALTH**
**Department of Health Policy & Management**

677 Huntington Avenue, Room 420 — 432-4499
Boston, MA 02115 — Fax: 432-4494

**MEMORANDUM**

To: OFS
From: Dawn Elliott-Patton
Date: October 8, 1997
Subject: Check receipt

Please deposit the attached check #7375223 from:

Kraft Foods, Inc.
P.O. Box 795093
San Antonio, TX 78279-5093

for $20,000.00 in John Graham's account #72-090-3653.

Thank you very much.

cc: Acting Dean James Ware
John Graham
Mary Esther Otts
Ellen Patterson

01-000-9336124 CUSTOMER SERVICE (210)530-7200 05410100

| 'ER AP BATCH CORP | INV NUMBER | PO NUMBER | INV DT | AMOUNT | DISCOUNT | NET AMOUNT |
|---|---|---|---|---|---|---|
| 9-SSCSS162 | ENVIRONMENTAL HA | | 092697 | 20000.00 | .00 | 20000.00 |
| | TOTALS | | | 20000.00 | .00 | 20000.00 |

HIS MULTI-TONE AREA OF THE DOCUMENT CHANGES COLOR GRADUALLY AND EVENLY FROM DARK TO LIGHT WITH DARKER AREAS BOTH TOP AND BOTTOM

7375223 KRAFT FOODS, INC.

64-1278
611

PAY NATIONSBANK OF GEORGIA, N.A.
ATLANTA, DEKALB COUNTY, GEORGIA

| DATE | CHECK NO. | NET AMOUNT |
|---|---|---|
| 09/29/97 | 05410100 | $*****20,000.00 |

Not Valid After Six Months From Issue Date

TWENTY THOUSAND DOLLARS AND 00 CENTS

TO THE ORDER OF
HARVARD CTR FOR RISK ANALYSIS
718 HUNTINGTON AVE
BOSTON MA 02115

George P Burdell

VOID IF COLORED BACKGROUND IS ABSENT

⑈05410100⑈ ⑆061112788⑆ 011 32 166⑈

THE ORIGINAL DOCUMENT HAS A HELLEFIVE WATERMARK ON THE BACK TO HOLD AT AN ANGLE TO VIEW WHEN CHECKING THE ENDORSEMENT

HARVARD CENTER FOR RISK ANALYSIS

October 20, 1997

Gary A. Henderson, Ph.D.
Director, International Scientific Relations
Kraft Foods, Inc.
555 South Broadway
Terrytown, New York 10591

Dear Dr. Henderson:

This letter is to acknowledge with appreciation Kraft Foods, Inc. gift of $20,000 for the Harvard Center for Risk Analysis. HCRA continues to promote a reasoned public response to health, safety, and environmental risks by addressing the current issues in risk analysis. The support from Kraft Foods Inc. is crucial to the Center's continued success in achieving our goals, and we certainly appreciate your confidence in our work.

Enclosed please find a copy of our 1996-97 Annual Report. I hope you enjoy it and would be glad to have your comments.

Sincerely,

John D. Graham

John D. Graham, Ph.D.
Director and Professor

JDG/meo

Enclosure

bc Mayada Hoque

HARVARD CENTER FOR RISK ANALYSIS

October 20, 1997

Ms. Mayada Logue
Phillip Morris
120 Park Avenue
14th Floor
New York, New York 10017

Dear Ms. Logue:

Thank you for your efforts to expedite Kraft Foods, Inc. gift of $20,000 for the Harvard Center for Risk Analysis. HCRA continues to promote a reasoned public response to health, safety, and environmental risks by addressing the current issues in risk analysis.

We appreciate your support and confidence in our work. Please feel free to contact me if I can ever be of assistance.

Sincerely,

John D. Graham, Ph.D.
Director and Professor

JDG/meo

Enclosure

copy meo file only

EP
Magda Vogel will find new name.
call her (212) 880-5000 after 6/13.
JDC

Harvard Center for Risk Analysis

March 1, 1999

Dr. Gary A. Henderson
Director, International Scientific Relations
Kraft Foods
555 South Broadway
Tarrytown, New York 10591

Dear Dr. Henderson:

As you know, the Harvard Center for Risk Analysis is a mission-oriented unit at the Harvard School of Public Health. Our mission is to promote a more reasoned public response to safety, health, and environmental concerns. The purpose of this letter is to request that Kraft Foods make an unrestricted contribution of $25,000 to the Harvard Center for Risk Analysis (HCRA). These funds will be used to support HCRA's educational, communications, and scientific activities.

HCRA was established in 1989 and has rapidly become recognized as a leader in national and worldwide efforts to bring insights from science and economics into public debates about health, safety, and environmental policy. Our five programmatic priorities are environmental health, automobile safety, medical technology, food safety, and home safety. We have enclosed a copy of HCRA's Biennial Report to provide further explanation of our programs and priorities.

During the last year, HCRA faculty and students have had several notable accomplishments:

--our faculty and students have published over 50 peer-reviewed scientific articles on a range of applied and methodologic topics in top journals such as Journal Of The American Medical Association and Risk Analysis: An International Journal;

--we offered a package of eight risk-related courses to graduate students throughout Harvard University and advised six completed doctoral dissertations on risk-related topics;

--our bimonthly newsletter, Risk in Perspective, was disseminated to 15,000+ opinion leaders in the mass media, government, business, and non-profit organizations;

--our faculty provided congressional testimony to three different U.S. legislative committees on the need to integrate risk analysis into legislative reforms aimed at regulatory improvement (e.g., S. 981);

--our faculty have prepared op-ed pieces that promote or defend elected officials who support a stronger role for science and economics in regulatory decisions (e.g., an op-ed piece in the PORTLAND HERALD about Senator Susan Collins' support of risk analysis and regulatory improvement);

--our intensive short courses on risk analysis and cost-benefit analysis served the training needs of 150 professionals in government and industry;

--our faculty have provided risk-related information to reporters in the electronic media (CNN, ABC-TV, and NPR) as well as the national print media (USA TODAY and Associated Press);

Harvard School of Public Health • 718 Huntington Avenue • Boston, Massachusetts 02115
telephone 617-432-4497 • facsimile 617-432-0190

--we have formed new working groups to provide public comments to U.S. EPA on its implementation of the residual-risk provisions of the Clean Air Act and the negligible-risk provisions of the Food Quality Protection Act; and

--I was the recipient of the 1998 Public Service Award of the Annapolis Center for my contributions in risk communication with the American people.

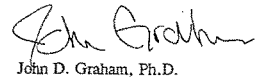
During the next year, we plan to continue these lines of work while we add some exciting new activities. A Spring 1999 conference is being planned on "The Precautionary Principle: Refine It or Replace It?", with applications to issues of global climate change, biotechnology, endocrine disruption, and electric and magnetic fields. We have also begun some careful cost-benefit analyses to address new policies toward fine particulate matter being fashioned under the 1990 Amendments to the Clean Air Act. One of our new faculty members, Dr. Kimberly Thompson, is launching a new comparative risk analysis of hazards to children's health that is designed to stimulate a more rational allocation of resources. And we are expanding the Center's well-known database on lifesaving investments to include information on morbidity benefits and quality of life.

HCRA has received unrestricted contributions from over 60 Fortune 500 companies and several trade associations. Grants for project support have been provided by eight different federal agencies, including the National Science Foundation. Safeguards for the objectivity and quality of the Center's work are embedded in an explicit conflict-of-interest policy that is published in each of the Center's biennial reports. We also meet regularly with an external committee of scientists from academia, government, and industry to evaluate our activities and explore new project ideas.

We understand that there may be specific risk-related issues that are of particular concern to you. I would be happy to meet with you in Tarrytown at your convenience to better understand the nature of your concerns. You should also feel free to contact me or my administrator, Ellen Patterson, if there is any additional information about the Center that may be of interest to you.

Thank you very much in advance for your consideration of this request. We will contact you in several weeks to determine if you have needs for further information.

Sincerely,



John D. Graham, Ph.D.
Director

Harvard Center for Risk Analysis

January 24, 2000

Dr. Gary A. Henderson
Director, International Scientific Relations
Kraft Foods
Postfach 830550
Munich, Germany 81705

Dear Dr. Henderson:

As you know, the Harvard Center for Risk Analysis is a mission-oriented unit at the Harvard School of Public Health. Our mission is to promote a more reasoned public response to safety, health, and environmental concerns. The purpose of this letter is to request that Kraft Foods make an unrestricted contribution of $20,000.00 to the Harvard Center for Risk Analysis (HCRA). These funds will be used to support HCRA's educational, communications, and scientific activities.

HCRA was established in 1989 and has rapidly become recognized as a leader in national and worldwide efforts to bring insights from science and economics into public debates about health, safety, and environmental policy. Our four programmatic priorities are environmental health, automobile safety, medical technology, and food safety. We have enclosed a copy of HCRA's Biennial Report to provide further explanation of our programs and priorities.

A major HCRA priority for the next two years will be a book project entitled Enriching the Precautionary Principle for Public Health and Environmental Protection. This book arises out of concern that extreme demands for precaution are exerting a perverse influence on public policies toward energy production, biotechnology, synthetic chemicals, and pesticides. The book will build on HCRA's 1999 workshop, showing how risk-analytic thinking can produce a wiser formulation of the precautionary principle. Concise excerpts from the book on specific topics will appear in HCRA's Risk In Perspective.

During the last year, HCRA faculty and students have had several notable accomplishments:

--our faculty and students have published over 50 peer-reviewed scientific articles on a range of applied and methodologic topics in top journals such as Journal of The American Medical Association and Risk Analysis: An International Journal;

--we offered a package of eight risk-related courses to graduate students throughout Harvard University and advised six completed doctoral dissertations on risk-related topics;

--our bimonthly newsletter, Risk in Perspective, was disseminated to 15,000+ opinion leaders in the mass media, government, business, and non-profit organizations;

--our faculty provided congressional testimony to three different U.S. legislative committees on the need to integrate risk analysis into legislative reforms aimed at regulatory improvement;

--our intensive short courses on risk analysis and cost-benefit analysis served the training needs of 150 professionals in government and industry;

--our faculty have provided risk-related information to reporters in the electronic media (CNN, ABC-TV,

Harvard School of Public Health • 718 Huntington Avenue • Boston, Massachusetts 02115
telephone 617-432-4497 • facsimile 617-432-0190

and NPR) as well as the national print media (USA TODAY and Associated Press); and

--we recently sponsored a policy workshop in Washington, DC on the "Precautionary Principle" which was attended by 150 professionals from the USA, Canada, Western Europe and Japan.

HCRA has received unrestricted contributions from over 60 Fortune 500 companies and several trade associations. Grants for project support have been provided by eight different federal agencies, including the National Science Foundation. Safeguards for the objectivity and quality of the Center's work are embedded in an explicit conflict-of-interest policy that is published in each of the Center's biennial reports. We also meet regularly with an external committee of scientists from academia, government, and industry to evaluate our activities and explore new project ideas.

We understand that there may be specific risk-related issues that are of particular concern to you. I would be happy to meet with you in Munich at your convenience to better understand the nature of your concerns. You should also feel free to contact me or my administrator, Ellen Patterson, if there is any additional information about the Center that may be of interest to you.

Thank you very much in advance for your consideration of this request. We will contact you in several weeks to determine if you have needs for further information.

Sincerely,

John D. Graham, Ph.D.
Director

## HCRA SOURCES OF FINANCIAL SUPPORT

The Harvard Center for Risk Analysis is funded by a combination of industrial, governmental, and foundation funding. Additionally, the Harvard School of Public Health and individual donors contribute to the Center. The Center's Program on the Economic Evaluation of Medical Technology's funding is included in following list of contributors since 1989:

**Restricted grants**
Alfred P. Sloan Foundation
American Crop Protection Association
American Industrial Health Council
Andrew Mellon Foundation
Bradley Foundation
Brookings Institution
California Avocado Commission
Chemical Manufacturers Association
Chiang Ching-Kuo Foundation for International Scholarly Exchange
Chlorine Chemistry Council
Congressional Research Service
Electric Power Research Institute
Elsa U. Pardee Foundation
International Life Science Institute/Risk Science Institute
Health and Environmental Sciences Group
National Association of Home Builders
National Institute of Justice
Pfizer, Inc.
Society for Risk Analysis
U.S. Centers for Disease Control
U.S. Department of Agriculture
U.S. Department of Energy
U.S. Department of Health and Human Services
U.S. Department of Transportation.
U.S. Environmental Protection Agency
U.S. National Oceanic Atmospheric Administration
U.S. National Science Foundation

**Unrestricted grants**
3M
Aetna Life & Casualty Company
Air Products and Chemicals, Inc.
Alcoa Foundation
American Automobile Manufacturers Association
American Crop Protection Association
American Petroleum Institute
Amoco Corporation
ARCO Chemical Company
ASARCO Inc.
Ashland Inc. Foundation
Association of American Railroads
Astra AB
Atlantic Richfield Corporation
BASF
Bethlehem Steel Corporation
Boatmen's Trust
Boise Cascade Corporation
BP America Inc.
Cabot Corporation Foundation
Carolina Power and Light
Cement Kiln Recycling Coalition
Charles G. Koch Foundation
Chemical Manufacturers Association
Chevron Research & Technology Company
CIBA-GEIGY Corporation
Ciba Geigy Limited
CITGO Petroleum Company
The Coca-Cola Company
Cytec Industries
Dow Chemical Company
DowElanco
DuPont Agricultural Products
Eastman Chemical Company
Eastman Kodak Company
Edison Electric Institute
E.I. DuPont de Nemours & Company
Electric Power Research Institute
Emerson Electric
Exxon Corporation
FBC Chemical Corporation
FMC Corporation
Ford Motor Company
Fort James
Frito-Lay
General Electric Fund
General Motors Corporation
The Geon Company
Georgia-Pacific Corporation
Glaxo-Wellcome, Inc.
The Goodyear Tire & Rubber Company
Grocery Manufacturers of America
Hoechst Celanese Corporation
Hoechst Marion Roussel
Hoffman-LaRoche Inc.
ICI Americas Inc.
Inland Steel Industries
International Paper
The James River Corporation Foundation
Janssen Pharmaceutical
Johnson & Johnson
Kraft Foods
Louisiana Chemical Association
Lyondell Chemical Company
Mead Corporation Foundation
Merck & Company
Millenium Chemical Company
Mobil Foundation, Inc.

Monsanto Company
National Food Processors Association
National Steel
New England Power Service -- New England Electric System
Nippon Yakin Kogyo
North American Insulation Manufacturers Association
Novartis Corporation
Novartis Internationsl
Olin Corporation Charitable Trust
Oxford Oil
Oxygenated Fuels Association
PepsiCo Inc.
The Pittston Company
Pfizer
Pharmacia Upjohn
Potlatch Corporation
Praxair, Inc.
Procter & Gamble Company
Reynolds Metals Company Foundation
Rhone-Poulenc, Inc.
Rohm and Haas Company
Schering-Plough Corporation
Shell Oil Company Foundation
Texaco Foundation
Union Carbide Foundation
Unocal
USX Corporation
Westinghouse Electric Corporation
Westvaco
WMX Technologies, Inc.

January 22, 2000

**Questions Submitted by Senator Daniel K. Akaka**
**for Confirmation of John Graham to be**
**Administrator of the Office Of Information and Regulatory Affairs (OIRA)**

1. Dr. Graham, I'd like to ask one question about the information function of OIRA. As you know, I am interested in the implementation of OMB Directive 15. This Directive provides standards for classifying race and ethnicity for federal statistics and program reporting. In 1993, I began efforts to disaggregate Native Hawaiians from the Asian Pacific Islander category in the Directive. This was based on inaccuracies regarding data collection and statistics for Native Hawaiians. In addition, Native Hawaiians were being classified with populations that had immigrated to the United States. This created a misperception that Native Hawaiians were immigrants rather than the indigenous people of Hawaii.

In 1997, OMB Directive 15 was revised and Native Hawaiians were disaggregated from the Asian Pacific Islander category. A new category was created – Native Hawaiians and Other Pacific Islanders. Federal agencies have until January 1, 2003 to make all existing record keeping or reporting requirements consistent with the Directive. However, these changes in the revised Directive took effect immediately for all new and revised record keeping or reporting requirements.

**QUESTION: Dr. Graham, I want to make sure you are aware of this, especially that agencies must incorporate these changes immediately into all new and revised record keeping and reporting. In addition, I will seek an oversight hearing in the appropriate subcommittee to review compliance with the Directive. Do I have your assurance that if confirmed you will require agencies to comply with the Directive and that you will work with me in this effort?**

ANSWER: In the course of preparing for my confirmation hearing, I was briefed on the statistical policy responsibilities of the OIRA Administrator, including those for government-wide statistical standards and guidelines. In particular, I learned about the review process that resulted in OMB's adoption in 1997 of the Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity. I am aware that one of the principal revisions to the standards is a separate category that was created for classifying data on Native Hawaiians and Other Pacific Islanders. I also know that the provisions of the standards were effective immediately for all new and revised record keeping or reporting requirements and that all existing data collections are to be consistent with the 1997 standards by January 1, 2003. Since adoption of the standard, agency information collections submitted to OMB under the Paperwork Reduction Act have been checked to make sure that questions on race and ethnicity conform to the 1997 standards.

Please be assured that if confirmed I will work with the agencies on their continuing

implementation of the standards.

2. You have explained that the internal peer review protocol used by the Harvard Center for Risk Analysis (HCRA) for the *Risk in Perspective* newsletter is adequate to ensure merit and quality. However, do you see any problem with these newsletters being picked up by the press, policy makers and the public and compared to work presented in scholarly journals, with strict, independent, external peer review systems? You describe *Risk in Perspective* as having a wide general audience. Perhaps HCRA cannot be held responsible for the lack of appreciation by the public and media for the distinction between these.

   **QUESTION: Do you think that the general audience of *Risk in Perspective* would benefit from an explanation of the reasons for peer review and how your protocol differs from other publications? Have your internal peer reviewers ever rejected a report or suggested it not be published in the newsletter?**

   ANSWER: *Risk in Perspective* is targeted at a broad yet educated lay audience with interests in risk issues. The current mailing list for the publication includes over 15,000 people in government, business, non-profit organizations, the mass media, and medicine/public health. I see your point about the need to clarify the nature and purpose of HCRA's peer review process and have suggested to David Ropeik, HCRA's Communications Director, that a future issue of Risk in Perspective highlight the value and limits of its peer review process. I do recall, on several occasions, that the internal peer reviewers stopped publication of a poor quality piece. More often, the review process results in a piece being argued more carefully and clearly. By publishing the names of each reviewer as well as each author, HCRA hopes to encourage reviewers to take their responsibilities seriously.

3. Some reports issues by HCRA go through an external peer review process. For example, your cell phone report had an external, albeit not anonymous, peer review panel. The newsletter is easily obtained off the HCRA website, and has a much wider audience than the full report.

   **QUESTION: How do changes to the full report suggested by the reviewers get integrated into the *Risk in Perspective* newsletter which accompanies a longer report?**

   ANSWER: The *Risk in Perspective* newsletter is typically drafted based on the full report. Thus, changes that have been made to the full report due to reviews should be reflected in the newsletter. However, the space limitations in *Risk in Perspective* are more severe than is the case for the full report. Thus, complex issues tend to be simplified in the newsletter.

4. The Harvard Center for Risk Analysis has an External Advisory Board to oversee the Center's operations. This group is made up of professionals primarily from industry and academia. When you were asked about why there were not more people from labor, environment, public interest and consumer groups on the Board, you mentioned that you had tried to include these groups, and perhaps you had not tried hard enough to do so. However, you then added that having industry well-represented was necessary because of the different culture already ingrained within a school of public health, implying that labor, environment and consumer interests were already well represented and ingrained in the Center.

**QUESTION: Considering the complaints by public interest, consumer, environmental, and labor groups about HCRA's studies and results, could it be that their views are not as ingrained in the Center's culture as you contend?**

ANSWER: I believe the perspectives of public interest, consumer, environmental, and labor groups are reflected in most schools of public health, including the Harvard School of Public Health. At the Center we have reached out to those groups, but we certainly could have done more. From 1989-2000 Alon Rosenthal, J.D., Sc.D. and Adam Finkel, Sc.D were active members of the HCRA Advisory Council. Alon is a graduate of the Harvard School of Public Health who launched a successful environmental advocacy organization in Israel (The Israel Union for Environmental Defense). He is currently based at Arava Institute for Environmental Studies in Israel and is well connected in both the Israeli and U.S. environmental movements. Adam Finkel, also a Harvard graduate, began his career at Resources for the Future and often advised public-interest groups on risk assessment issues. He was, for example, a key expert in the Alar case for the pro-NRDC/CBS side and often opposed me in regulatory reform policy debates. He left RFF several years ago to join OSHA. Inside the Center we have also had significant participation by students and staff who had experience with the activist community. Several doctoral students (e.g., A Cullen and A Smith) were advisors to public-interest groups while our Center hired full-time researchers (K. Walker and J. Hartwell) who had previously worked full-time in the public-interest community. I have also invited activists to speak at several conferences that I organized and their voluntary participation is always welcome. For example, our most recent conference on the "precautionary principle" in Washington, DC drew significant participation from Greenpeace USA.

5. You have made several comments to distinguish between your past role as a university professor, where part of your job was to "stir things up", and that of objective and impartial OIRA Administrator. You also claim that a share of the misunderstanding of your work can be blamed on the media looking for the 30 second story.

**QUESTION: However, how much is due to your statements and interviews in which you highlight controversial conclusions while minimizing important**

**underlying assumptions and limitations? Do you accept some of the responsibility for the confusion surrounding your work and the regulatory process?**

ANSWER: Yes. I do not claim to have a perfect record in explaining the results of my own work to reporters and policy makers. There is a tension between summarizing complex results in a clear manner and disclosing all key assumptions and limitations. I hope to do a better job in the future as I acquire more practical experience in policy communications.

6. Your 2000 study on cell phones uses several factors to determine the benefits to society by cell phone use by drivers. The benefits are simply listed and are not quantified in your report. However, these factors are used to get the net cost per life-year saved of $700,000. Many of the benefits are listed under "community benefits." They include factors such as decreased accident response times and improved knowledge about emergencies for emergency response teams.

   **QUESTION: Is it fair to include emergency responders in this list of benefits? Did you find that emergency responders are as vulnerable to this risk as the rest of society? Do emergency responders use cell phones while on duty? Second, don't they usually work in pairs so that the non-driver will be free to talk on the phone? And finally, are not emergency responders given considerable training for driving under stressful conditions, unlike society at large?**

   Answer: The emergency response benefits described in our report do not refer to the potential use of cell phones by emergency response personnel, although such use is plausible. Instead, these benefits result from the increased prevalence of cell phones in cars belonging to members of the general public. Emergency personnel participating in focus groups conducted by HCRA stated that members of the general public who have cell phones in their cars can and often do provide valuable information to emergency response personnel about accidents, crimes, and other emergencies soon after they occur. The HCRA report's discussion of community benefits (pp. 46-48) provides further detail related to this issue.

7. During your staff interview, you explained that you prefer using benefit-justified cost test, as opposed to the standard benefit-outlay cost test. You believe it allows for non-quantified, intangible benefits and costs to be included in a calculation. For example, your cell-phone study increases the benefits to society by including such intangibles as family cohesion and social good-will. Meanwhile, added costs to society, such as heightened anxiety and stress while driving due to reckless driving habits of others, are not included.

   **QUESTION: How do you assure that such intangibles are applied equally and uniformly, and how do you decide which should be included?**

ANSWER: I agree with your point that any added anxiety and stress due to reckless driving of others should be included as an intangible cost of allowing use of cell phones while driving. The best an analyst can do is make a list of these intangible costs and benefits, perhaps highlighting those that the analyst believes are most significant or important. However, in the final analysis, it is the job of the decision-maker, not the analyst, to decide how much weight to give to quantified versus non-quantified benefits and costs.

8. With respect to the cellular phone study, you present the number of traffic fatalities per vehicle miles traveled and the number of U.S. cellular phone subscribers between the years of 1970 and 1999. You state that the number of fatalities has declined steadily since 1970, even while the number of cellular phone subscribers has increased dramatically since 1986. I'm sure you would agree with me that the number of fatalities has decreased because of many factors, including reduced speed limits, improved safety features on cars, and mandated safety belts. Likewise, the raw number of cellular phone subscribers does not specify if those users actually drive cars.

**QUESTION: What was the study trying to show with this comparison, and was the study implying a relationship between the increase in cell phone subscribers and a decrease in traffic fatalities?**

**ANSWER:** The discussion of the traffic fatality trend data was part of the HCRA report's review of scientific literature. In addition to evaluating the general traffic fatality data, our review also evaluated driver test track/simulator performance studies, case reports, and epidemiological studies that take into account the behavior and characteristics of individual study subjects. With respect to the general trend data, the HCRA report concluded that the concurrent increase in cell phone subscriptions and decrease in driver fatalities do not necessarily imply that the use of cell phones while driving was free of risk. In particular, the HCRA report stated (p. 25):

*Traffic safety researchers do not find much reassurance in the data presented in Figures 2 and 3 because there are many powerful variables (beneficial and adverse) that influence overall fatal crash statistics. As an example, if cellular phones were in fact causing 500 additional fatalities each year in the U.S., the problem – even though large in absolute magnitude – might be masked in the aggregate data by recent reductions in accident fatalities from campaigns against drunk driving and for safety belt use.*

Thus, I agree with your point that many factors (e.g., speed limits and mandated safety features) have decreased the number of fatalities.

QUESTIONS FOR THE RECORD
SUBMITTED BY SENATOR RICHARD J. DURBIN
TO JOHN GRAHAM

May 17, 2001

1. In January 2001, the AEI-Brookings Joint Center for Regulatory Studies released a study, "EPA's Arsenic Rule: The Benefits of the Standard Do Not Justify the Costs".

   (a) Were you a member of the Center's Advisory Board at the time this report was released?

   (b) In your capacity as an Advisory Board member, were you involved in any way with the funding, preparation, design, methodology or review of this report?

   **Answer:** (a) Yes. (b) No.

2. A key finding of the report is that EPA's proposed arsenic standard would result in a net loss of life. It also states that low levels of arsenic may be essential for the human body. If you are not familiar with this report, I would greatly appreciate it if you could review it and answer the following:

   (a) Do you agree with the statement that the arsenic standard would result in a net loss of life?

   (b) Do you agree that arsenic may be essential to human health?

   (c) Do you generally agree with the methodology used in this report?

   (d) As OIRA Administrator, might you advocate the use of similar methodologies in analyzing any new EPA proposed standards for arsenic in drinking water?

   **Answer:** (a) - (d)

   Based on a very quick review of the AEI report, I saw five analytical assumptions that I would want to study further before offering an opinion on the matter. First, AEI's analytic treatment of the carcinogenic potency of arsenic was somewhat unconventional. Second, AEI assumed a 30-year latency period between exposure and cancer, and I do not know whether this is reasonable for arsenic-induced cancer. Third, AEI assigned a 7% real discount rate to future costs and risks, which is at the high end of the rates recently recommended by an expert panel of health economists and decision scientists. Fourth, AEI made a numerical adjustment for unquantified health benefits that is worthy of

additional scrutiny. Finally, the AEI report applies a form of "wealth-health" analysis that raises a host of analytical questions. (On health-wealth analysis, please consult my response to Senator Levin's post-hearing question #1). I do not know whether arsenic is essential to human health.

If I am confirmed as OIRA Administrator, and the EPA arsenic issue comes before OIRA, I can assure you that I will address the manner in a timely, transparent, and rigorous manner taking into account OMB's analytic guidelines, any EPA analytic guidelines, the Presidential Executive Order, the President's policies and priorities, and any statutory constraints that Congress may have placed on this particular rulemaking.

3. Among the findings of the July 2000 HCRA report "Cell Phone Use While Driving: Risks and Benefits", you concluded that the "net cost per life-year saved" for cellular phone restrictions would be $700,000 per life-year saved (Table 5 of the report). How was this figure derived? Please be specific as to the methods, assumptions, calculations, data used, and the sources of data.

**Answer:** The derivation of the $700,000 cost-effectiveness ratio is explained on pp. 54-58 of the HCRA report "Cellular Phone Use While Driving: Risks and Benefits" (July 2000). The references to the key literature are also provided. Section 5 of the report outlines some of this calculation's qualitative limitations.

In brief, the net monetary cost of a ban is the difference between the foregone benefits of the lost calls, and the avoided expenditures associated with cell phone-related accidents. The value of the foregone benefits is the consumer surplus value of cell phone calls made while driving (*i.e.*, the difference between the value individuals place on these calls and the price they must pay for that service) This value of approximately $25 billion per year was taken from an analysis described in a report published by the American Enterprise Institute-Brookings Joint Center for Regulatory Studies (Hahn and Tetlock, 1999). The monetary costs associated with accidents caused by drivers using cell phones ($2 billion per year) was computed by Redelmeier and Weinstein (1999). Hence, the net cost of a ban (subject to the limitations outlined in Section 5 of our report) is $25 billion - $2 billion per year, or $23 billion per year. The number of Quality Adjusted Life Years lost per year (33,000) was also computed by Redelmeier and Weinstein (1999). Dividing the number of Quality Adjusted Life Years saved by banning cell phone use while driving (33,000) into the net monetary value of the lost benefits ($23 billion) yields a cost-effectiveness value of approximately $700,000 per saved Quality Adjusted Life Year.

Post Hearing Questions for John Graham
From Senator Carl Levin
May 18, 2001

1. I have been concerned for some time over the use of what is called "risk-risk" analysis in the context of a health/wealth trade-off. A number of years ago, this committee was involved in reviewing OIRA's work on a rule in which it was argued that since workers who undertake life-threatening jobs get paid more for the risk they face that if the risk is reduced they will be paid less; and since poorer people have fewer vacations and less health care, it's cost-beneficial to keep the work risky so the workers will be wealthier and hence healthier. Do you subscribe to that kind of analysis?

**Answer:** There is a classical economic hypothesis that workers, when faced with life-threatening risks on the job, will demand and be paid a wage premium for the risks they face. Although there is a substantial body of theory and empirical evidence to support this hypothesis, many questions remain. Is this hypothesis valid for all workers or only some workers? Are workers fully aware of the risks that their jobs entail? Even if aware of these risks in an intuitive sense, do workers have sufficient numerical feel for risks to demand an appropriately sized wage premium? Even if fully informed, do workers have sufficient bargaining power to demand an appropriate wage premium from their employer? Do wage premiums exist only for familiar risks, such as accidents, or do they also exist for the more subtle, chronic health risks induced by particular jobs? In my opinion, the answers to these questions are not known with sufficient precision to justify a strictly classical economic position on workplace safety policy.

There is also a large literature indicating that poor people suffer more health problems than wealthy people. However, the causal pathways that produce this association are not well understood.

With respect to the report HCRA issued on organophosphate and carbamate pesticides in 1999, in arguing that a ban of these pesticides would result in a loss of income to the industries and workers that use these pesticides, HCRA was arguing that there would be 10 to 1000 annual premature fatalities from the income losses which should be offset or compared to the premature fatalities from the use of the pesticides. Is that argument a form of health/wealth analysis and do you subscribe to it in the context of this report?

**Answer:** With regard to health-wealth analysis, my own research (with J Evans and YH Lee) suggests that health harms from losses in household income will be significant only if the losses are sustained over a significant period of time (a so-called "permanent" loss in income and associated consumption). In the case of a possible ban on multiple pesticides studied by Gray and Hammitt of HCRA, a critical question becomes how long it will take companies and farmers to develop economical alternatives to the prohibited

products that effectively control pests. If such alternatives can be developed quickly, permanent income losses will be small or negligible. If alternatives are difficult to discover and/or expensive to develop and apply on the farm, then permanent income losses may be significant. I do not know enough about the economics of pesticides and agiculture to make any further observations about the pesticide application.

More generally, I see advantages and disadvantages to bringing health/wealth analysis into the field of regulatory analysis. I have no specific plans to move in this direction if confirmed as OIRA Administrator. I have a stronger interest in the type of risk-tradeoff analysis (unrelated to wealth effects) discussed in J Graham, J Wiener (eds), RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT (Harvard Press, 1995).

2. Do you, personally, or have you, personally, had a financial interest in 1) any company that sponsored a study or report or gave money to HCRA on a restricted basis? 2) any company that gave money to HCRA on an unrestricted basis?

**Answer:** I have never had any investment interests in a company that sponsored a HCRA study on a restricted basis. My personal investments have been mostly in mutual funds during the 1990-2001 period. Since 1988 the only stocks I have held are Microsoft, Lucent Technologies, Araya, Port Financial Corp, and Procter and Gamble. Details on these holdings have been shared with the Committee. Proctor and Gamble is an unrestricted HCRA contributor. I purchased 150 shares of P+G in April of 2,000 and am still holding those shares. P+G has made annual unrestricted contributions to HCRA since 1990 and continues to do so.

I am not sure whether "financial interest" in a company, as you intend it, includes speaking fees and honoraria. During the 1990-1997 period, I received, primarily in the form of speaking fees and honoraria, personal financial compensation from the following companies that also provided unrestricted support to HCRA: Air Products , ALCOA, ARCO, CIBA-Geigy, Dow-Elanco, DuPont, Exxon, General Electric, James River, Mead, Monsanto, and P+G. Since 1997, when HCRA's conflict-of-interest policy took effect, I have not accepted any such personal financial compensation from companies. Under this policy, I decline such income and request that instead donations be made to HCRA's Howard Raiffa Scholarship Fund for students.

Do you know of any report or article that you or HCRA issued that was sponsored by a particular company or collection of companies where that sponsorship was not disclosed? The authors of a letter to the Committee dated May 7, 2001, in opposition to your confirmation claim that you "consistently produced reports" released to the public "that have supported industry positions, frequently without disclosing the sources of [the] funding." Is that true? Do you know to what reports they are referring?

**Answer:** To the best of my knowledge, HCRA has always disclosed the identity of corporate sponsors on reports or articles prepared with restricted corporate sponsorship. The authors of the May 7th article may be referring to the fact that HCRA's unrestricted corporate donors are not disclosed on each report or article that HCRA produces with unrestricted support. This type of disclosure is not required by the University, the School, or the Center's conflict-of-interest policy. HCRA's position is that the identity of HCRA's unrestricted donors is disclosed regularly in our Center's annual report and on HCRA's web site. As a practical matter, please note that HCRA's sources of unrestricted support include the School itself, interest income from the Center's investment accounts, gifts from private individuals, and gifts from numerous companies and trade associations.

Have you ever delayed the release of the results of a study at the request of or out of concern for the sponsor of the study?

**Answer**: No.

Have you ever not published a study at the request of or out of concern for the sponsor of the study or because the outcome of the study was not what you expected or desired?

**Answer**: No.

Have you ever altered a study at the request of a sponsor?

**Answer**: No.

Do you let a sponsor of a restricted grant review a study or an article before it is published?

**Answer**: I do not generally allow pre-publication review by a sponsor. There have been exceptions. I can recall one instance where we allowed an industrial sponsor to review a draft manuscript (prior to peer review) out of a mutual concern that technologies be described accurately in the report. In that case, we maintained complete control over the research process and description of findings. The few comments provided by the sponsor were evaluated and only those that we regarded as valid were used.

Apparently you sent your draft chapter on second-hand smoke to Phillip Morris. Was that unusual for HCRA or you to do that? Did you receive any comments from Phillip Morris? If so, did you take any action with respect to those comments?

**Answer**: In the case of the draft chapter sent to a scientist at Phillip Morris for technical comment, Phillip Morris was not a sponsor of the draft chapter or the larger book project. I do not recall having received any comments from Phillip Morris on the draft chapter. The chapter was ultimately not published in RISK VERSUS RISK (Harvard Press, 1995) because it did not pass a peer review devised in collaboration with selected members of

HCRA's Advisory Committee.

The sharing of the draft chapter with Phillip Morris was not a usual Center practice but it was not a unique event. It is my understanding that, when operating with unrestricted support, a Harvard faculty member has the academic freedom to seek informal comment or peer review from any person or organization that he or she chooses. Speaking for myself, I have always made independent decisions about whether the comments provided by a reviewer are valid and justify a modification to a draft manuscript.

3. I believe strongly in the value of peer review when it comes to risk assessment and even – in some cases – with respect to cost-benefit analysis. You told our staff that but for two instances, HCRA didn't release a report or study that wasn't peer reviewed.

The first one involved air bags. Your center had done a risk assessment of passenger side air bags and concluded that passenger side air bags would cost almost $400,000 for each life saved. You went public with that figure even though the study had not been peer reviewed. Once you did have it peer reviewed the results were significantly different – the cost per life saved being reduced to $61,000. In retrospect, was that a mistake to go public with that first figure without peer review? What's your view on your handling of this report?

The second study that was released without peer review involved pesticide regulations sponsored by the American Farm Bureau. You did a report that found that a complete ban on organophosphates would not be cost effective. You told the staff that you were not involved in that report, but you were the head of the Center and therefore ultimately responsible. Did you know at the time that the report was being released without peer review? If you didn't, when and how did you find out and what was your reaction? Did you take any steps to make sure that didn't happen again?

**Answer:** In retrospect, I should have sought peer review of our draft airbag manuscript from selected members of HCRA's Advisory Committee prior to making oral remarks to reporters and NTSB. I also think I should have consulted a communications specialist on how to deal with the reporter from USA TODAY.

On the pesticides study, I did not learn about the absence of peer review until I consulted colleagues in the process of answering one of Senator Lieberman's pre-hearing questions. I was surprised. I have spoken to each of the authors of the pesticides study about the importance of the peer review policy. Perhaps more importantly, I have suggested to the Center's Director of Communications that he insist on understanding and documenting what peer review has been performed prior to releasing a HCRA study. In this way, he can serve as a reminder to faculty and staff about what is required prior to release. One of the complicating factors in the pesticides study was that it was the sponsor rather than HCRA that did the communications work. At that time, HCRA did not have a communications director and the current director has been informed of the advantages of HCRA taking control of the release process.

4. Since 1981, when President Reagan implemented the first executive order that required OIRA to review all rules, this committee has been very concerned about disclosure of OIRA's role in the rulemaking process. One result of that concern was the so-called Wendy Gramm memo in the mid-80's which established some very important and basic disclosure procedures. Those disclosure procedures were adopted by both the Bush and Clinton Administrations. These disclosure procedures have been standard operating policy, now, for over 15 years. Will you stand by those disclosure procedures if confirmed?

> **Answer:** Yes. I am fully committed to transparency at OIRA and have no specific plans to change the disclosure procedures that have been operating for the last 15 years.

**Addendum**

Senator Levin, in response to your suggestion made at the hearing, I have also listed two references relevant to the hypothesis that dioxin has anti-carcinogenic effects as well as carcinogenic effects. Copies of these papers are attached.

RJ Kociba et al, "Results of a Two-Year Chronic Toxicity and Oncogenicity Study of 2, 3, 7, 8-Tetrachlorodibenzo-p-Dioxin in Rats," Toxicology and Applied Pharmacology vol. 46, 279-303 (1978).

HC Pitot et al, "A Method to Quantitate the Relative Initiating and Promoting Potencies of Hepatocarcinogenic Agents in their Dose-Response Relationships to Altered Hepatic Foci," Carcinogenesis vol. 8 (10), 1491-1499 (1987).

TOXICOLOGY AND APPLIED PHARMACOLOGY 46, 279–303 (1978)

# Results of a Two-Year Chronic Toxicity and Oncogenicity Study of 2,3,7,8-Tetrachlorodibenzo-*p*-Dioxin in Rats

R. J. KOCIBA, D. G. KEYES, J. E. BEYER, R. M. CARREON, C. E. WADE, D. A. DITTENBER, R. P. KALNINS, L. E. FRAUSON, C. N. PARK, S. D. BARNARD, R. A. HUMMEL, AND C. G. HUMISTON

*Toxicology Research Laboratory, Health and Environmental Research, Dow Chemical, U.S.A. Midland, Michigan 48640*

*Received November 1, 1977; accepted February 22, 1978*

Results of a Two-Year Chronic Toxicity and Oncogenicity Study of 2,3,7,8-Tetrachlorodibenzo-*p*-Dioxin in Rats. KOCIBA, R. J., KEYES, D. G., BEYER, J. E., CARREON, R. M., WADE, C. E., DITTENBER, D. A., KALNINS, R. P., FRAUSON, L. E., PARK, C. N., BARNARD, S. D., HUMMEL, R. A., AND HUMISTON, C. G. (1978). *Toxicol. Appl. Pharmacol.* 46, 279–303. Rats were maintained for 2 years on diets supplying 0.1, 0.01, and 0.001 μg of 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD)/kg/day. Analysis of these diets indicated 2200, 210, and 22 parts per trillion (ppt) of TCDD. Ingestion of 0.1 μg/kg/day caused an increased incidence of hepatocellular carcinomas and squamous cell carcinomas of the lung, hard palate/nasal turbinates, or tongue, whereas a reduced incidence of tumors of the pituitary, uterus, mammary glands, pancreas, and adrenal gland was noted. Other indications of toxicity at this dose level included increased mortality, decreased weight gain, slight depression of erythroid parameters, increased urinary excretion of porphyrins and δ-aminolevulinic acid, along with increased serum activities of alkaline phosphatase, γ-glutamyl transferase and glutamic–pyruvic transaminase. Gross and histopathologic changes were noted in the hepatic, lymphoid, respiratory, and vascular tissues. The primary hepatic ultrastructural change at this high dose level was proliferation of the rough endoplasmic reticulum. Terminal liver and fat samples from rats at this high dose level contained 24,000 and 8100 ppt of TCDD, respectively. Rats given 0.01 μg/kg/day for 2 years had a lesser degree of toxicity than that seen at the highest dose level. This included increased urinary excretion of porphyrins in females, liver lesions (including hepatocellular nodules), and lung lesions (including focal alveolar hyperplasia). Terminal liver and fat samples from rats of this dose level contained 5100 and 1700 ppt of TCDD, respectively. Ingestion of 0.001 μg of TCDD/kg/day (~22 ppt in the diet) caused no effects considered to be of any toxicologic significance. At this lower dose level, terminal liver and fat samples each contained 540 ppt of TCDD. These data indicate that continuous doses of TCDD sufficient to induce severe toxicity increased the incidence of some types of tumors, while reducing other types. During the 2-year study in rats, no increase in tumors occurred in those rats receiving sufficient TCDD to induce slight or no manifestations of toxicity.

The compound 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD) is a highly toxic impurity that may be formed under certain conditions during the production of 2,4,5-trichloro phenol. TCDD has been considered one of the causes of chloracne, which has been



0041-008X/78/0462 0279$02.00/
Copyright © 1978 by Academic Press, Inc.
All rights of reproduction in any form reserved.
Printed in Great Britain

associated with the industrial production of 2,4,5-trichlorophenol and other products made from 2,4,5-trichlorophenol.

Most of the earlier toxicologic studies with TCDD were concerned with the assessment of its short-term toxicity and teratogenic potential. Results of these earlier studies have been summarized in a previous publication by Kociba *et al.* (1976). This same publication also reported the results of a subchronic study in which rats were given 1.0, 0.1, 0.01, 0.001, or 0 μg of TCDD/kg 5 days/week for 13 weeks. Doses of 1.0 μg/kg/day caused multiple toxicologic effects, including mortality and morphologic changes in liver, thymus, and reproductive organs. A dose level of 0.1 μg/kg/day caused lesser degrees of toxicity, and rats given 0.01 or 0.001 μg/kg/day had no alterations considered of any toxicologic significance.

More recently, toxicologic studies of TCDD have also been conducted in the monkey. McConnell *et al.* (1978) reported a single oral LD50 in monkeys of <70 μg TCDD/kg. These monkeys died with loss of hair or nails, keratinization of Meibomian glands and hair follicles, and hyperplasia of the epithelium of the renal pelvis, stomach, and bile duct.

Allen *et al.* (1977) reported on a subchronic study in which monkeys consumed a diet containing 500 ppt of TCDD for 9 months. It was calculated that these monkeys ingested 2 to 3 μg TCDD/kg over the course of the 9-month study. Clinically, these monkeys showed changes similar to those described by McConnell *et al.* (1978) as well as hematologic depression and hemorrhages in various tissues. Hypertrophy, hyperplasia, and/or metaplasia were noted in the epithelium of the bile ducts, salivary glands, bronchi, pancreatic ducts, sebaceous glands, skin, gastric lining, and urinary tract.

In regard to long-term or carcinogenic studies conducted in rodents with TCDD, Innes *et al.* (1969) reported no increase in tumors in mice given 2,4,5-Trichlorophenoxyacetic acid contaminated with a level of TCDD sufficient to supply 0.27 μg of TCDD/kg/day. DiGiovanni *et al.* (1977) conducted a study in which TCDD was reported to be only a weak tumor initiator in the two-stage system of mouse skin carcinogenesis with 7,12-dimethylbenz[a]anthracene (DMBA).

Van Miller and Allen (1977) issued a preliminary report on a study of small groups of male rats fed diets containing TCDD for 65 weeks. All 10 rats of each group receiving 1.0, 0.5, or 0.05 ppm of TCDD in the diet died within 4 weeks, with acute toxic effects, including severe liver necrosis, bile duct hyperplasia and edema, atrophy of spleen and thymus, gastrointestinal hemorrhages, and decreased spermatogenesis. Groups of male rats on diets containing 5000 or 1000 ppt experienced increased mortality, decreased weight gain, and liver toxicity. Dietary levels of 500, 50, 5, and 1 ppt of TCDD were also studied. Various neoplasms were found in some rats at all dose levels of 5 ppt and higher, with only the lowest dose level of 1 ppt reportedly free of any neoplasms. These same results on tumorigenesis were included in an updated report by Van Miller *et al.* (1977), which included the data generated through the end of their 95-week study. No tumors were reported in the group given 1 ppt of TCDD or in a total of 50 control rats.

In view of the need for an evaluation of the chronic toxicity and potential for carcinogenicity of TCDD, the study reported herein was conducted. In this study, groups of male and female rats were maintained for 2 years on diets supplying

various dose levels of TCDD, and numerous parameters were evaluated in order to assess the potential chronic toxicity associated with long term ingestion of the material.

## METHODS

*Experimental design.* Male and female Sprague–Dawley rats, Spartan substrain,[1] 6 to 7 weeks old, were randomly placed (two/cage) into suspended wire-bottomed cages for this study. Food[2] and water were available *ad libitum.* Groups of 100 rats (50 males, 50 females) were maintained for up to 2 years on diets supplying 0.1, 0.01, or 0.001 $\mu$g of TCDD/kg/day. The diet of the control group of 172 rats (86 males, 86 females) contained the vehicle.

*Test material.* The TCDD sample used for this 2-year study was prepared by the Dow Chemical Company. Purification of the crude TCDD was followed by gas chromatography and mass spectrometry. The final product had a purity exceeding 99%, as determined by electron-capture gas chromatography. This sample was used to prepare the premixes and test diets according to the following general procedure: Approximately 1 mg of TCDD was weighed on a microbalance and dissolved in 40 ml of reagent-grade acetone. This solution was then added to 1000 g of control feed and mixed for 30 min to prepare a stock premix. A sufficient sample of the stock premix was then mixed with control feed to produce a working premix to be used in preparing the test diets. The stock premix was prepared six times during the course of the study. The test diets were prepared by diluting the working premix with sufficient control feed to provide dose levels of TCDD as required by body weight and food consumption determinations in order to maintain the designated dosages on a microgram per kilogram per day basis. Samples of the working premix and the test diets were analyzed periodically to ascertain that the dietary levels were being maintained as scheduled. The concentration of TCDD in the premix samples was determined using electron-capture gas chromatography and gas chromatography–mass spectrometry. The concentration of TCDD in the test diets was determined by gas chromatography-mass spectrometry after extraction and suitable cleanup.

*Clinical observations.* All rats were palpated on a monthly basis, with a recording of the number of rats bearing palpable masses. Body weights and food consumption of 20 rats/sex/treatment level and controls were routinely recorded for each week of the first 3 months of the study and at approximately monthly intervals thereafter. All remaining rats were weighed monthly throughout the study.

Blood samples for hematological determinations were collected from eight rats/sex/group at 3, 12, and 23 months of treatment. The total erythrocyte count (RBC), total and differential leukocyte counts (WBC), thrombocyte and reticulocyte counts, packed cell volume (PCV), and hemoglobin (Hgb) concentration were determined using automated[3] or manual procedures. Urine samples were collected from seven to eight rats/sex/group at these same time intervals. Urine specific gravity, pH, and the presence

[1] Spartan Research Animals, Haslett, Michigan.
[2] Purina Laboratory Chow, Ralston-Purina Co., St. Louis, Missouri.
[3] Coulter Counter Model ZB 1, Coulter Electronics, Hialeah, Florida.

or absence of sugar, protein, ketones, bilirubin, and occult blood were determined[4] at each of these times, and urinary urobilinogen was also evaluated at Month 23.

Urinary excretion of creatinine, coproporphyrin, uroporphyrin, and δ-amino levulinic acid (δ-ALA) was determined by a consulting laboratory[5] on samples collected from four to five rats/sex/group at Months 3–4, 12, and 23.

Serum samples were collected from seven rats/sex/group by orbital puncture at Month 22 for determination of urea nitrogen (BUN), glutamic pyruvic transaminase (SGPT), bilirubin (total, direct and indirect), cholesterol, and triglycerides. Automated procedures were used for these determinations.[6] Serum samples were similarly collected from seven rats/sex/group at Month 23 for determination of alkaline phosphatase (AP) activity, total protein, albumin and globulin.[6]

At terminal necropsy, serum samples were collected from all survivors or a maximum of 10 rats/sex/group for determination of BUN, SGPT, AP, and total bilirubin.[6] A consulting laboratory[5] also made determinations of serum γ-glutamyl transferase activity (GGT).

All rats dying or culled during the course of the study were subjected to a gross pathologic examination. Representative portions of the major organs and any gross lesion suggestive of a significant pathologic process or tumor formation were collected from each rat and preserved in buffered 10% formalin.

Terminal necropsy examination was conducted at the end of 2 years of treatment (105th week). All rats were deprived of food overnight prior to killing by decapitation. The eyes of all rats were examined by gently pressing a glass slide against the cornea under bright fluorescent illumination. Any observations on the eyes were recorded as part of the gross necropsy observation records. The eyes for a maximum of five rats/sex/group were preserved in Zenker's fixative. Eyes from remaining rats were fixed in formalin fixative.

The weights of the liver, kidney, brain, heart, thymus, spleen, testes, and ovaries/uterus were recorded for a maximum of 10 rats/sex/group. A bone marrow smear was prepared from most rats, and filed for future reference, if indicated. Portions of fat, liver, and kidney from a maximum of five rats/sex/group were frozen for possible TCDD analysis, with subsequent analysis of liver and fat samples from three females/dose level, using gas chromatography–low-resolution mass spectrometry. Portions of esophagus, salivary glands, stomach, small intestine, large intestine, pancreas, liver, kidneys, urinary bladder, prostate, accessory sex glands, epididymis, testes, ovaries, uterus, brain (cerebrum, cerebellum, brain stem), pituitary gland, spinal cord, peripheral (sciatic) nerve, trachea, lungs, spleen, thymus, lymph nodes, heart, aorta, skeletal muscle, mammary tissue (females), adrenal glands, thyroid, parathyroid, tongue, lower jaw, and skull (including nasal turbinates, ear canal), together with any additional gross lesions were preserved in formalin fixative.

Histologic examination of tissues was conducted on paraffin-embedded sections of tissues which were stained with hematoxylin and eosin. All rats from the control and top dose level, regardless of whether they died during the study or were killed at the

[4] Ames Bililabstix or Multistix, Ames Co., Elkhart, Indiana and TS Meter, AO Optical, Buffalo, New York.

[5] Bioscience Laboratories, Van Nuys, California.

[6] Technicon AutoAnalyzer, Technicon Corp., Rye, New York.

termination, were subjected to histologic examination of an extensive list of tissues, intended to include a majority of those tissues listed above as those collected at the time of terminal necropsy. All rats from the two lower dose levels were subjected to histologic examination of those selected tissues identified as possible target organs and all gross lesions suggestive of tumor formation. The actual number of tissues specimens from each group examined histologically is on file and available from the authors. Additional sections of liver from selected females from the terminal necropsy were stained for lipid content using Oil Red O or Sudan IV stains.

Liver tissue collected at the terminal necropsy was examined using an electron microscope[7] to characterize qualitatively the ultrastructure of hepatocytes from three females/group. The liver tissue was fixed in 2.5% phosphate-buffered glutaraldehyde and then postfixed in 1% phosphate-buffered osmium tetroxide, dehydrated through graded ethanol solutions, washed in propylene oxide, infiltrated with Epon 812, and embedded in polyethene capsules. Sections of 1 $\mu$m thickness were stained with toluidine blue and examined using light microscopy. Thin sections were stained with uranyl acetate and lead citrate prior to examination by electron microscopy.

*Statistical evaluation of data.* The significance of differences between control and test values for hematology, urinary and clinical chemistry parameters, body weights, organ weights, and organ/body weight ratios was statistically determined by one-way analyses of variance followed by the Dunnett test (Steel and Torrie, 1960). A significance level of $p < 0.05$ was used. Data on mortality, palpable masses, gross pathology, histopathology, and tumor incidences were analyzed using the Fischer exact probability test, $p < 0.05$, one-sided test (Siegel, 1956). Mortality data were also analyzed using the Mantel–Haenszel Test. Repeated measures analyses across time were not appropriate because of mortality and because the assumptions of the statistical tests were not valid.

Statistical evaluation of gross pathology data collated for the entire study compared the data of each of the treatment groups with the data of the control group of that sex. Statistical evaluation of histopathologic observations and tumor incidences compared the data of the high-dose group with the data of the control group of that sex. The same evaluation was conducted on the lower dose levels in instances in which comparable numbers of tissues were subjected to microscopic examination (apparent target organs).

## RESULTS

### *Dietary Content of TCDD*

Analyses of feed samples indicated the dosage levels of 0.1, 0.01, and 0.001 $\mu$g of TCDD/kg/day equated with approximately 2193, 208, and 22 ppt of TCDD in the diet. Six repeated analyses of the feed samples indicated good agreement between the intended content of TCDD and results of analysis for TCDD content.

### *Clinical observations*

Females given 0.1 $\mu$g/kg/day had statistically increased cumulative mortality during the latter half of the study, whereas those given 0.01 or 0.001 $\mu$g/kg/day had mortality

[7] Carl Zeiss, Inc., New York.

rates comparable to that of the controls. In males, there were some isolated instances of statistical differences between the treated and control groups. However, as the mortality of only the group of males given 0.01 μg/kg/day was significantly different from control using the Mantel–Haenszel test, these deviations in the male rats were considered of questionable toxicologic significance. Mean body weights of males and females given 0.1 μg/kg/day were statistically decreased from control values throughout the major portion of the study, from Month 6 to the end of the 2-year test period. Mean body weights of females given 0.01 μg/kg/day were decreased to a lesser degree during this same time interval. The mean body weights of males given 0.01 or 0.001 μg/kg/day and females given 0.001 μg/kg/day were sometimes lower than controls during the middle of the study, but only occasionally were the differences statistically significant. During the last quarter of the study body weights of these groups were comparable to those of controls.

There were no consistent deviations in food consumption of males or females at any dose. The few sporadic cases in which there was a statistical increase or decrease between the control and treatment groups followed no consistent trend, and were considered of no toxicologic significance. The first palpable mass was noted at Month 5 in a male of the control group. There were no statistically significant differences between the control and treated groups except during Months 15 and 16, when the males given 0.01 μg/kg/day had an increased incidence of palpable masses. This was considered of no toxicologic significance because of its isolated occurrence and lack of dose response. During the last 12 months of the study, females ingesting 0.1 μg/kg/day had a consistent trend toward a decrease in the number of rats with palpable masses. This observation was not noted at lower dosage levels in the females.

*Hematology*

The hematology data collected after 23 months of treatment are listed in Table 1 and are similar to the patterns observed during the study. In rats given 0.1 μg/kg/day, there were statistically significant decreases in the PCV and Hgb values for males after 3 months as well as decreases in the Hgb values for males and decreases in PCV, total RBC, and WBC counts and Hgb values for females after 1 year. At the preterminal examination, this high dose group again had statistically significant decreases in RBC and Hgb values (males) and PCV and Hgb values (females); reticulocyte counts also appeared to be slightly increased. Thrombocyte and WBC differential counts appeared to be unaffected at all dose levels of TCDD. Rats given 0.01 or 0.001 μg/kg/day had no hematologic changes considered related to treatment.

*Urinalyses*

Repeated examination of urinary parameters revealed no consistent alterations that could be attributed to any of the dose levels of TCDD.

*Urinary porphyrins and δ-ALA*

Porphyrin data collected after 23 months of treatment are listed in Table 2 and are representative of the patterns observed during the study. Urinary excretion of coproporphyrin was statistically increased in female rats at a dose level of 0.1 μg/kg/day after each evaluation at 3–4, 12, and 23 months. Coproporphyrin excretion was also

TABLE 1

MEAN HEMATOLOGIC VALUES OF MALE RATS (DAY 681) AND FEMALE RATS (DAY 682) ON DIETS CONTAINING TCDD

| Dose of TCDD (μg/kg/day) | Sex | Number of rats/group | PCV (%) | RBC ($\times 10^6$/mm$^3$) | Hgb (g/100 ml) | Reticulocytes (%) | Thrombocytes ($\times 10^4$/mm$^3$) | WBC ($\times 10^3$/mm$^3$) | WBC differential count (%) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Neut | Lymph | Mono | Eosin | Baso |
| 0 | M | 8 | 46.9 ± 4.7[a] | 7.99 ± 0.64 | 15.6 ± 1.6 | 1.0 | 1.195 ± 0.350 | 14.9 ± 5.4 | 27 | 65 | 7 | 1 | 0 |
| 0.100 | M | 8 | 43.4 ± 4.3 | 7.19 ± 0.65[b] | 13.9 ± 1.5[b] | 2.2 | 1.214 ± 0.358 | 12.1 ± 5.2 | 33 | 62 | 4 | 1 | 0 |
| 0.010 | M | 8 | 47.6 ± 2.8 | 7.65 ± 0.46 | 16.0 ± 0.8 | 1.0 | 1.482 ± 0.342 | 15.8 ± 4.0 | 34 | 60 | 5 | 1 | 0 |
| 0.001 | M | 8 | 47.4 ± 1.8 | 7.73 ± 0.27 | 15.7 ± 0.6 | 0.5 | 1.042 ± 0.143 | 18.7 ± 8.0 | 30 | 65 | 4 | 1 | 0 |
| 0 | F | 8 | 43.6 ± 1.4 | 6.84 ± 0.66 | 14.1 ± 1.1 | 0.8 | 1.046 ± 0.210 | 9.1 ± 1.5 | 34 | 60 | 4 | 2 | 0 |
| 0.100 | F | 8 | 38.9 ± 3.8[b] | 6.38 ± 0.90 | 12.5 ± 1.2[b] | 1.2 | 1.176 ± 0.358 | 7.1 ± 2.1 | 30 | 67 | 2 | 1 | 0 |
| 0.010 | F | 8 | 45.1 ± 1.1 | 7.35 ± 0.32 | 15.1 ± 0.4 | 0.5 | 0.962 ± 0.161 | 9.4 ± 2.2 | 36 | 60 | 3 | 1 | 0 |
| 0.001 | F | 8 | 46.9 ± 4.7 | 7.56 ± 0.69 | 15.7 ± 1.5[b] | 0.5 | 0.857 ± 0.239 | 9.5 ± 1.9 | 23 | 72 | 3 | 2 | 0 |

[a] Mean ± SD.
[b] Statistically significant from control mean using analysis of variance and Dunnett's test, $p < 0.05$.

TABLE 2

URINARY EXCRETION OF CREATININE, COPROPORPHYRIN, UROPORPHYRIN, AND δ-AMINO-LEVULINIC ACID FOR MALE AND FEMALE RATS (DAYS 678–680) ON DIETS CONTAINING TCDD

| Dose TCDD (μg/kg/day) | Sex | Number of rats/group | Total urine vol. 48 hr (ml) | Creatinine (mg/48 hr) | Coproporphyrin (μg/48 hr) | μg Coproporphyrin / mg Creatinine | Uroporphyrin (μg/48 hr) | μg Uroporphyrin / mg Creatinine | δ-amino-levulinic acid (mg/48 hr) | mg δ-ALA / mg Creatinine |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | M | 4 | 51.0 ± 21.6[a] | 27.6 ± 3.2 | 18.0 ± 3.7 | 0.69 ± 0.19 | 5.4 ± 2.2 | 0.200 ± 0.092 | 0.27 ± 0.38 | 0.010 ± 0.015 |
| 0.100 | M | 5 | 63.4 ± 40.5 | 19.6 ± 9.1 | 19.6 ± 11.7 | 1.22 ± 1.08 | 7.3 ± 4.0 | 0.418 ± 0.295 | 0.08 ± 0.02 | 0.005 ± 0.003 |
| 0.010 | M | 5 | 61.4 ± 26.1 | 24.4 ± 5.7 | 16.5 ± 8.0 | 0.64 ± 0.25 | 5.7 ± 2.1 | 0.228 ± 0.056 | 0.26 ± 0.42 | 0.009 ± 0.013 |
| 0.001 | M | 5 | 41.0 ± 6.4 | 30.8 ± 3.2 | 23.8 ± 4.8 | 0.78 ± 0.19 | 5.3 ± 1.6 | 0.174 ± 0.053 | 0.06 ± 0.01 | 0.002 ± 0.001 |
| 0 | F | 5 | 60.0 ± 34.9 | 23.3 ± 6.2 | 9.8 ± 1.3 | 0.43 ± 0.49 | 3.8 ± 1.7 | 0.157 ± 0.050 | 0.07 ± 0.03 | 0.003 ± 0.001 |
| 0.100 | F | 5 | 51.2 ± 22.8 | 18.6 ± 4.3 | 17.4 ± 4.0[b] | 0.98 ± 0.41[b] | 5.7 ± 2.3 | 0.296 ± 0.074[b] | 0.12 ± 0.05 | 0.006 ± 0.002[b] |
| 0.010 | F | 5 | 54.2 ± 20.5 | 19.4 ± 2.3 | 16.4 ± 4.7[b] | 0.83 ± 0.18 | 3.5 ± 1.1 | 0.181 ± 0.053 | 0.08 ± 0.03 | 0.004 ± 0.002 |
| 0.001 | F | 5 | 57.2 ± 20.0 | 20.8 ± 4.7 | 8.6 ± 2.0 | 0.42 ± 0.06 | 3.0 ± 1.1 | 0.143 ± 0.037 | 0.08 ± 0.02 | 0.004 ± 0.001 |

[a] Mean ± SD.
[b] Statistically significant from control mean by analysis of variance and Dunnett's test, $p < 0.05$.

statistically increased in female rats at a dose level of 0.01 μg/kg/day after 3 and 23 months. Urinary excretion of uroporphyrin was statistically increased in females after 3 and 23 months of receiving 0.1 μg/kg/day and after 3 months of receiving 0.01 μg/kg/day. Urinary excretion of δ-ALA was statistically increased in females after 3 and 23 months of receiving 0.1 μg/kg/day. Total urine volume or creatinine excretion was not affected by any of these dose levels in the females. Males had no alterations considered treatment-related in any of these parameters at any of the dose levels of TCDD.

*Clinical Chemistry*

For sake of brevity, only the results obtained at terminal necropsy after 2 years of treatment are presented in Table 3. Analyses of serum samples collected by orbital

TABLE 3

MEAN TERMINAL (2-YEAR) CLINICAL CHEMISTRY VALUES FOR MALE AND FEMALE RATS GIVEN DIETS CONTAINING TCDD

| Dose TCDD (μg/kg/day) | Sex | Number of rats/group | BUN (mg/100 ml) | SGPT (mU/ml) | AP (mU/ml) | Total bilirubin (mg/100 ml) | γ-glutamyl transferase (mU/ml) |
|---|---|---|---|---|---|---|---|
| 0 | M | 10 | 33 ± 34[a] | 49 ± 17 | 87 ± 30 | 0.2 ± 0 | 0 ± 0 |
| 0.100 | M | 5 | 28 ± 11 | 42 ± 6 | 105 ± 17 | 0.2 ± 0 | 1 ± 0 |
| 0.010 | M | 4 | 36 ± 19 | 47 ± 10 | 88 ± 26 | 0.2 ± 0 | 1 ± 0 |
| 0.001 | M | 10 | 20 ± 9 | 43 ± 9 | 86 ± 25 | 0.2 ± 0 | 0 ± 0 |
| 0 | F | 10 | 21 ± 9 | 39 ± 11 | 60 ± 29 | 0.2 ± 0 | 0 ± 0 |
| 0.100 | F | 4 | 20 ± 3 | 54 ± 12[b] | 205 ± 146[b] | 0.2 ± 0 | 14 ± 10[b] |
| 0.010 | F | 10 | 17 ± 3 | 49 ± 7 | 61 ± 20 | 0.3 ± 0.1 | 1 ± 0 |
| 0.001 | F | 10 | 18 ± 5 | 42 ± 5 | 54 ± 28 | 0.4 ± 0.2 | 1 ± 0 |

[a] Mean ± SD.
[b] Statistically significant from control mean using analysis of variance and the Dunnett's test, $p < 0.05$.

puncture at 22 to 23 months of treatment revealed no alterations considered related to treatment in regard to BUN, SGPT, total, direct, or indirect bilirubin, cholesterol, triglycerides, total protein, albumin, and globulin. Serum AP was statistically increased in females given 0.1 μg/kg/day. A statistically significant increase in serum triglycerides noted in males given 0.01 μg/kg/day was considered of no toxicologic significance based on the lack of a dose-response relationship. Analyses of serum samples collected at terminal necropsy after 2 years indicated a statistical increase in SGPT, AP, and GGT activities for females given 0.1 μg/kg/day. Females at the lower dose levels and males at all dose levels were unaffected in these parameters. The BUN and total bilirubin values of either sex were unaffected by any level of treatment with TCDD.

*Gross and Microscopic Observations on Tissues*

Detailed descriptions of all gross and microscopic observations made on all rats killed or dying during the course of the 2-year study are on file and available from the authors. On account of the voluminous nature of the data, the results are summarized below. Tumor and tumor-like lesions are listed in Tables 4 and 5.

TABLE 4

TUMOR INCIDENCE IN MALE RATS MAINTAINED ON DIETS CONTAINING TCDD[a]

| Time intervals during study: | Months 13–24 | | | | Terminal kill | | | | Total | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Dose level in μg/kg/day: | 0 | 0.1 | 0.01 | 0.001 | 0 | 0.1 | 0.01 | 0.001 | 0 | 0.1 | 0.01 | 0.001 |
| Number of rats examined: | 65 | 41 | 46 | 38 | 15 | 5 | 4 | 11 | 85 | 50 | 50 | 50 |
| Rats with tumors/tumor-like lesions: | | | | | | | | | | | | |
| Hepatocellular hyperplastic nodule(s) | 2 | 1 | 2 | 0 | 4 | 1 | 1 | 0 | 6 | 2 | 3 | 0 |
| Hepatocellular carcinoma(s) | 1 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 2 | 1 | 0 | 0 |
| Bile duct adenoma | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| Stratified squamous cell carcinoma of hard palate or nasal turbinates | 0 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4[b] | 0 | 0 |
| Paravertebral or subcutaneous malignant schwannoma | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 |
| Carcinoma of renal tubules pelvis, or bladder | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 2 | 0 | 0 | 1 |
| Adenoma of renal tubules or pelvis | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 |
| Keratinizing squamous cell carcinoma of lung | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| Pulmonary adenoma | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 |
| Pulmonary adenocarcinoma | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| Oligodendroglioma/astrocytoma of brain, or glioma of spinal cord | 2 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 1 |
| Interstitial cell adenoma of testes | 2 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 2 | 0 | 0 | 2 |
| Adenoma of prostate | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| Subcutaneous fibroadenoma/fibroma/lipoma | 8 | 6 | 4 | 1 | 1 | 0 | 1 | 0 | 10 | 6 | 5 | 1[b] |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Benign mammary neoplasms | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| Mammary gland adenocarcinoma | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| Cutaneous papilloma/basal cell tumor | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 |
| Squamous cell carcinoma of integument | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Zymbal gland carcinoma | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| Pituitary adenoma | 19 | 10 | 11 | 5 | 7 | 2 | 0 | 1 | 26 | 13 | 11 | 6 |
| Pituitary adenocarcinoma | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 3 | 0 | 0 | 0 |
| Stratified squamous cell carcinoma of tongue | 0 | 3 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 3[b] | 1 | 1 |
| Fibrosarcoma of tongue | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| Squamous papilloma/polyp of gastric mucosa | 0 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |
| Mucocystadenocarcinoma of small intestine | 1 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 2 |
| Leiomyosarcoma of cecum | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |
| Intraabdominal schwannoma/sarcoma | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 |
| Acinar adenoma of pancreas | 11 | 2 | 4 | 3 | 3 | 0 | 1 | 4 | 14 | 2[b] | 5 | 7 |
| Acinar adenocarcinoma of pancreas | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| Islet adenoma of pancreas | 6 | 3 | 2 | 1 | 6 | 0 | 1 | 2 | 12 | 3 | 3 | 3 |
| Islet adenocarcinoma of pancreas | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| Adenoma of adrenal cortex | 0 | 5 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 5[b] | 2 | 0 |
| Pheochromocytoma of adrenal | 19 | 3 | 10 | 3 | 9 | 1 | 0 | 3 | 28 | 4[b] | 10 | 6 |
| Interfollicular C-cell adenoma of thyroid | 2 | 4 | 0 | 0 | 6 | 0 | 0 | 0 | 8 | 4 | 0 | 0 |
| Interfollicular C-cell adenocarcinoma of thyroid | 2 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 3 | 1 | 0 | 0 |
| Follicular adenoma of thyroid | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 |
| Follicular adenocarcinoma | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 |

TABLE 4—*continued*

| Time intervals during study: | Months 13–24 | | | | Terminal kill | | | | Total | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Dose level in μg/kg/day: | 0 | 0.1 | 0.01 | 0.001 | 0 | 0.1 | 0.01 | 0.001 | 0 | 0.1 | 0.01 | 0.001 |
| Number of rats examined: | 65 | 41 | 46 | 38 | 15 | 5 | 4 | 11 | 85 | 50 | 50 | 50 |
| Malignant lymphoreticular neoplasm | 5 | 0 | 3 | 2 | 0 | 0 | 0 | 1 | 5 | 0 | 3 | 3 |
| Hemangioma of lymph node | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| Fibrosarcoma/osteosarcoma of musculoskeletal system | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| Intraorbital malignant schwannoma | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| Mediastinal fibrosarcoma | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Not available for pathological examination | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |

[a] No tumors occurred during Months 1 through 6. Tumors occurring during Months 7 to 12 included 1 subcutaneous fibroadenoma (control), 1 pituitary adenoma (0.1 μg/kg/day), 1 pituitary adenocarcinoma (control), 1 osteosarcoma (control). These four tumors, which were present in the 10 males dying prior to Month 13, are included in the above total tabulation.

[b] Statistically different from control data when analyzed using the Fischer exact probability test, $p < 0.05$. Appropriate tumor data have been combined for the sake of brevity.

TABLE 5

TUMOR INCIDENCE IN FEMALE RATS MAINTAINED ON DIETS CONTAINING TCDD[a]

| Time intervals during study: | Months 13–24 | | | | Terminal kill | | | | Total | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Dose level in μg/kg/day: | 0 | 0.1 | 0.01 | 0.001 | 0 | 0.1 | 0.01 | 0.001 | 0 | 0.1 | 0.01 | 0.001 |
| Number of rats examined: | 60 | 36 | 34 | 32 | 25 | 4 | 14 | 16 | 86 | 49 | 50 | 50 |
| Rats with tumors/tumor-like lesions: | | | | | | | | | | | | |
| Hepatocellular hyperplastic nodules | 2 | 20 | 8 | 1 | 6 | 3 | 10 | 2 | 8 | 23[b] | 18[b] | 3 |
| Hepatocellular carcinoma(s) | 0 | 10 | 1 | 0 | 1 | 1 | 1 | 0 | 1 | 11[b] | 2 | 0 |
| Bile duct adenoma | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 2 | 0 | 1 |
| Stratified squamous cell carcinoma of hard palate or nasal turbinates | 0 | 4 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 4[b] | 1 | 0 |
| Keratinizing squamous cell carcinoma of lung | 0 | 7 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 7[b] | 0 | 0 |
| Pulmonary adenocarcinoma | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 |
| Astrocytoma of cerebrum | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| Malignant schwannoma of pelvic canal | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| Nephroblastoma of kidney | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 |
| Adenoma of renal tubules | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Carcinoma of renal pelvis | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 |
| Granulosal cell neoplasm of ovary | 0 | 0 | 1 | 1 | 3 | 0 | 0 | 0 | 3 | 0 | 1 | 1 |
| Benign tumor of uterus | 16 | 3 | 7 | 5 | 12 | 2 | 4 | 7 | 28 | 7[b] | 11 | 12 |
| Malignant schwannoma of uterus | 2 | 0 | 3 | 1 | 0 | 0 | 0 | 0 | 2 | 0 | 3 | 1 |
| Adenocarcinoma of uterus | 6 | 4 | 0 | 1 | 0 | 0 | 0 | 0 | 6 | 4 | 0 | 1 |
| Fibroma of cervix/vagina | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 2 | 0 | 1 | 0 |
| Subcutaneous fibroma/fibrolipoma | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 |

TABLE 5—*continued*

| Time intervals during study: | Months 13–24 | | | | Terminal kill | | | | Total | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Dose level in μg/kg/day: | 0 | 0.1 | 0.01 | 0.001 | 0 | 0.1 | 0.01 | 0.001 | 0 | 0.1 | 0.01 | 0.001 |
| Number of rats examined: | 60 | 36 | 34 | 32 | 25 | 4 | 14 | 16 | 86 | 49 | 50 | 50 |
| Subcutaneous fibrosarcoma | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Benign neoplasm of mammary gland | 50 | 22 | 23 | 24 | 23 | 2 | 12 | 11 | 73 | 24[b] | 36 | 35 |
| Carcinoma of mammary gland | 5 | 0 | 1 | 3 | 6 | 0 | 5 | 1 | 8 | 0[b] | 4 | 4 |
| Stratified squamous cell carcinoma of digit | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| Cystadenoma of Zymbal gland | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| Pituitary adenoma | 26 | 12 | 8 | 12 | 17 | 0 | 5 | 6 | 43 | 12[b] | 13 | 18 |
| Pituitary adenocarcinoma | 4 | 2 | 0 | 0 | 2 | 0 | 1 | 0 | 6 | 2 | 1 | 0 |
| Stratified squamous cell carcinoma of tongue | 1 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 2 | 0 | 0 |
| Papilloma of esophagus | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| Squamous papilloma/polyp of gastric mucosa | 0 | 2 | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 2 | 0 | 1 |
| Leiomyosarcoma/sarcoma of small intestine | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 1 | 0 |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Polypoid adenoma of large intestine | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| Acinar adenoma of pancreas | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 1 |
| Islet cell adenoma of pancreas | 1 | 0 | 0 | 1 | 2 | 0 | 1 | 2 | 3 | 0 | 1 | 3 |
| Islet cell adenocarcinoma of pancreas | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 0 | 0 |
| Adenoma of adrenal cortex | 7 | 5 | 1 | 2 | 2 | 0 | 1 | 4 | 9 | 5 | 2 | 6 |
| Pheochromocytoma of adrenal | 4 | 3 | 0 | 1 | 3 | 0 | 1 | 1 | 7 | 3 | 1 | 2 |
| Interfollicular adenoma of thyroid | 9 | 4 | 1 | 1 | 5 | 0 | 1 | 0 | 14 | 4 | 2 | 1 |
| Interfollicular adenocarcinoma of thyroid | 3 | 2 | 0 | 1 | 1 | 0 | 0 | 1 | 4 | 2 | 0 | 2 |
| Follicular adenoma of thyroid | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| Malignant lymphoreticular neoplasm | 1 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 2 | 1 | 1 | 0 |
| Hemangioma of abdominal muscle | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| Not available for pathologic examination | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |

[a] No tumors occurred during Months 1 through 6. Tumors occurring during Months 7 to 12 included two benign tumors of the uterus (0.1 μg/kg/day) and one benign neoplasm of the mammary gland (0.01 μg/kg/day). These three tumors, which were present in the 14 females dying prior to Month 13, are included in the above total tabulation.

[b] Statistically different from control data when analyzed using the Fischer exact probability test, $p < 0.05$. Appropriate tumor data have been combined for the sake of brevity

Gross necropsy examination of the rats of the top dose level indicated the grossl visible target organs to include the liver, vascular system, respiratory system, an lymphoid organs; the general body condition was also consistently affected.

Microscopic examination of tissues from rats dying during the study or killed afte 2 years revealed the following treatment-related affects:

*Liver.* The liver was the organ most consistently affected, and rats given 0.1 or 0.0 μg/kg/day had multiple hepatocellular degenerative, inflammatory, and necroti changes noted upon light microscopy. These hepatic changes, which were mor extensive in females than in males, were characterized by cytomegaly, distortion

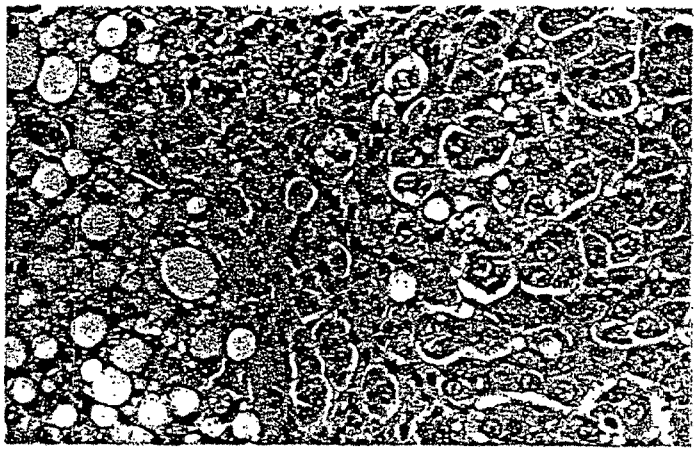


FIG. 1. Lesion classified morphologically as hepatocellular carcinoma in liver of rat given 0.1 μg TCDD/kg/day. Note adjacent fibrosis, inflammation, and fatty infiltration on left. H & E stain. ×200.

lobular pattern, and resultant atrophy of hepatic cords, cytoplasmic vacuolization, fa metamorphosis, altered tinctorial properties with increased basophilia, hepatic necro and inflammation, multinucleated hepatocytes, and foci or areas of hepatocellu alterations. They were accompanied by increased aggregates of pigment, bile d hyperplasia, and some increase in fibrosis and periportal inflammation. During the lat phase of the study and at the terminal necropsy the females given 0.1 μg/kg/day a had hepatocellular proliferative lesions classified morphologically as hepatocellu carcinomas (Fig. 1) and hyperplastic (neoplastic) nodules. There was no evidence metastasis of any liver neoplasms. Female rats given 0.01 μg/kg/day also had increased incidence of these hepatocellular hyperplastic nodules. Upon examinat using light microscopy, livers of female rats given 0.001 μg/kg/day had a statisti increase above the background incidence of foci or larger area of slight hepatocell alteration (swollen hepatocytes). However, in male rats given 0.001 μg/kg/day, th was a statistically significant decrease in the number of livers with an area of hep cellular alteration of this type.

As part of the ultrastructural evaluation of hepatocytes, light microscopy of toluidine blue-stained sections of liver from females given 0.1 μg/kg/day revealed an increased number of individual hepatocytes containing large accumulations of lipid droplets. Ultrastructural evaluation by electron microscopy of liver sections from this high dose

FIG. 2. Hepatocyte from female rat given 0.1 μg of TCDD/kg/day for 2 years. Note disorientation of RER and focal cytoplasmic vacuolization. Uranyl acetate–lead citrate stain. ×3350.

level revealed the most consistent change to be in the rough endoplasmic reticulum (RER), which appeared to be undergoing proliferation with some distortion and fragmentation (Fig. 2). Smooth endoplasmic reticulum (SER) and mitochondrial structures were within the range of variation observed in the control sections. Other changes noted at this high dose level included focal areas of cytoplasmic vacuolization, increased lysosomal activity with residual body formation, and an occasional multinucleated hepatocyte (Fig. 3). Upon ultrastructural examination of hepatocytes from

rats of the 0.01-μg/kg/day dose level, the most notable change was limited to a lesser degree of proliferation and disorientation of the RER and some proliferation of SER (Fig. 4). There was some slight increase in the number of individual hepatocytes with lipid droplet accumulations.

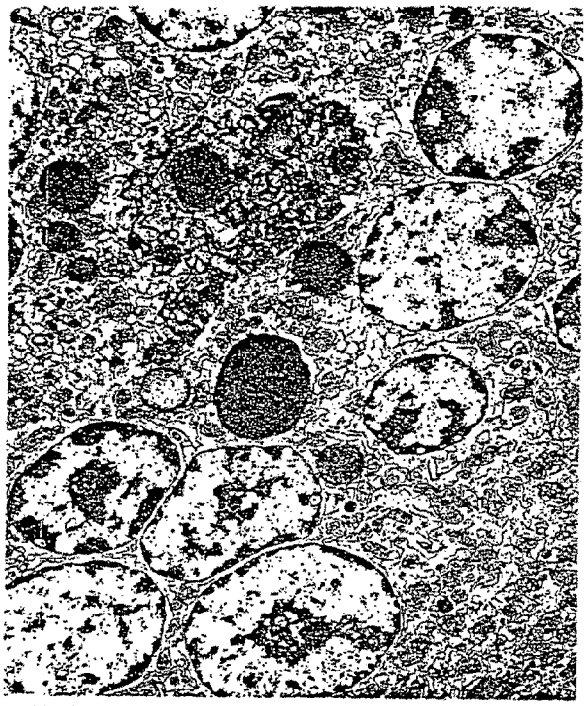


FIG. 3. Multinucleated hepatocyte from female rat given 0.1 μg of TCDD/kg/day for 2 years. Note focal area of cytoplasmic degeneration and distribution of RER. Uranyl acetate–lead citrate stain. ×1620.

The hepatocytes of female rats given 0.001 μg/kg/day were ultrastructurally within the limits of variation seen in the controls (Fig. 5). There was no general increase in the lipid droplet content, but an occasional cell contained increased numbers of lipid droplets.

*Lymphoreticular tissues.* Treatment-related effects, noted only in females of the 0.1-μg/kg/day dose level, included isolated occurrences of thymic atrophy and/or splenic atrophy.

*Respiratory system.* Treatment-related effects were noted in both males and females at the 0.1-μg/kg/day dose level but were much more extensive in the female rats and included an increased incidence of focal alveolar hyperplasia (Fig. 6), aggregates of hematogenous pigment in lung and thoracic lymph nodes, focal

FIG. 4. Hepatocyte from female rat given 0.01 μg of TCDD/kg/day for 2 years. Note proliferation of SER and disorientation of RER. Uranyl acetate–lead citrate stain. ×2070.

accumulation of alveolar macrophages and cholesterol clefts, pulmonary edema, focal interstitial inflammation and fibrosis, keratinizing squamous metaplasia, or squamous cell carcinoma formation (Fig. 7) within the lung. Focal alveolar hyperplasia was also increased in females given 0.01 μg/kg/day. The lower dose level of 0.001 μg/kg/day had no discernible effect on the tissues of the respiratory system.

*Cardiovascular system.* Effects probably related to the ingestion of 0.1 μg/kg/day included an apparent increase in the incidence of hemorrhage in the brain and possibly

spinal cord of females, an increase above the background incidence rate of mesenteric/thoracic periarteritis with accompanying changes, such as thrombosis and hematoma formations in both males and females, and an increase above the background incidence of myocardial degenerative changes (females only). At the 0.01-

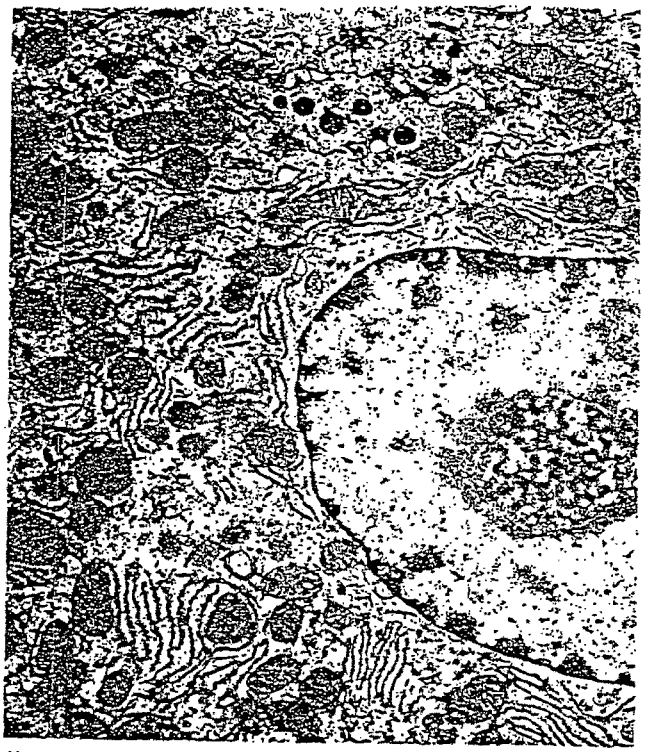


FIG. 5. Hepatocyte from female rat given 0.001 μg of TCDD/kg/day for 2 years. Morphology within normal limits of variation seen in controls. Uranyl acetate–lead citrate stain. ×4100.

μg/kg/day dose level, probable treatment-related lesions were limited to an increase above background incidence of periarteritis and thrombosis of testicular or thoracic/mediastinal vessels of male rats. There were no alterations considered related to treatment with 0.001 μg/kg/day.

*Reproductive system and mammary gland.* Female rats given 0.1 μg/kg/day had a statistically decreased incidence of uterine changes, including endometrial hyperplasia,

cyst formation, and adenomatous polyp formation. This same group of high dose level female rats also had a significantly decreased incidence of subcutaneous mammary tumors. These observations correlated well with a decreased incidence of pituitary

FIG. 6. Focal alveolar hyperplasia near terminal bronchiole within lung of rat given 0.1 μg of TCDD/kg/day. H & E stain. × 100.

FIG. 7. Lesion within lung of rat given 0.1 μg of TCDD/kg/day classified morphologically as squamous cell carcinoma. Note accumulation of keratinized material within lesion. H & E stain. × 100.

adenomas noted in this same high dose level of female rats. There were no discernible effects in female rats given 0.01 or 0.001 μg/kg/day.

The reproductive organs of male rats appeared to be unaffected by these dose levels, with similar degenerative, inflammatory, and proliferative lesions in all treated and control groups.

*Endocrine organs.* Female but not male rats given 0.1 μg/kg/day had a significantly decreased incidence of pituitary changes, including hemangiectasis and adenoma formation. Adrenal changes noted at this high dose level included a decreased incidence of medullary hyperplastic nodule formation (males and females), a decreased incidence of pheochromocytoma formation (males), an increased incidence of cortical necrosis and hemorrhage (females), and an increased incidence of adrenal hematocyst formation (males). A statistical increase in the incidence of adrenal cortical adenomas noted for males given 0.1 μg/kg/day may have been the result of normal biological variation of the incidence of this tumor, which does occur spontaneously in this strain of rat (approximate 10% incidence in the control group of female rats used in this study).

The pancreas of male rats given 0.1 μg/kg/day had a statistical decrease in the incidence of acinar adenoma formation. A statistically increased incidence of fibrosis of atrophic pancreatic tissue noted in the group of females given 0.1 μg/kg/day may or may not have been associated with the increased incidence of periarteritis noted in this group. The thyroid glands of the high dose group of male rats appeared to have a low incidence of various follicular changes that may or may not have been related to treatment; this included isolated cases of follicular cyst or microcyst formation, follicular adenoma, or follicular adenocarcinoma formation. The parathyroid gland was unaffected by treatment, except for a *decrease* in secondary parathyroid hyperplasia as a result of the decrease in severity of chronic renal disease of the males given 0.1 μg/kg/day.

*Gastrointestinal system.* A wide variety of degenerative or inflammatory lesions occurred in all control and treated groups, with no indications of a direct treatment-related effect in the salivary glands, esophagus, stomach, small intestine, or large intestine. However, the group of male rats given 0.1 μg/kg/day had a statistical increase above background incidence of stratified squamous cell carcinomas of the tongue, which were considered to be probably related to treatment. There was also a statistically significant increase in the incidence of squamous cell carcinomas of the hard palate/nasal turbinate region of male and female rats given 0.1 μg/kg/day. Historically, squamous cell carcinomas of the tongue and hard palate/turbinates have occurred at a spontaneous incidence rate of 1 to 3% in this strain of rat. It appears as if treatment with 0.1 μg/kg/day increased the incidence of this type of neoplasm. A secondary effect of treatment was noted in the stomach only of the high dose group of males, in which there was a decrease in the incidence rate of mineralization of the gastric muscularis and mucosa. This was secondary to the decreased incidence and severity of chronic renal disease and uremia in this high dose group of male rats.

*Nervous system.* The only observation considered as probably related to treatment was the increased incidence of focal hemorrhage in the brain (and possibly spinal cord) of female rats given 0.1 μg/kg/day. This was described previously in the description of the cardiovascular system. All groups of rats had the expected spectrum of degenerative, inflammatory, and proliferative lesions considered spontaneous in origin.

*Urinary system.* There appeared to be a *decrease* in the severity of the chronic nephropathy affecting the kidneys of the male rats given 0.1 μg/kg/day. Other degenerative, inflammatory, and proliferative changes occurred in the kidneys or urogenital tract of control or treated groups, with no observations considered related to treatment.

*Musculoskeletal system, eye, and miscellaneous tissues.* Various degenerative, inflammatory, or proliferative lesions occurred in a scattered pattern in all treated and control groups, with no indication of a treatment-related effect. No toxicologic significance was attached to the statistical decrease in the incidence rate of subcutaneous benign tumors noted in males given 0.001 μg/kg/day.

### *rgan Weights*

Statistically significant differences in terminal organ weights considered related to treatment included (1) an increase in liver weight calculated on an absolute basis (males given 0.1 or 0.01 μg/kg/day, females given 0.1 μg/kg/day) and on a relative basis of liver/body ratio (females given 0.1 or 0.01 μg/kg/day) and (2) a decrease in the absolute weight of the thymus of females given 0.1 μg/kg/day. Additional changes in organ weights were considered to be secondary to decreased body weights due to treatment with 0.1 μg/kg/day.

### *TCDD Content of Tissues*

Results of analysis of samples of fat and liver collected at terminal necropsy of female rats after 2 years of treatment indicated that rats given 0.1 μg/kg/day had an average TCDD content of 8100 ppt in the fat and 24,000 ppt in the liver. Rats given 0.01 μg/kg/day had an average TCDD content of 1700 ppt in the fat and 5100 ppt in the liver. Rats given 0.001 μg/kg/day had an average of 540 ppt of TCDD in the fat and also in the liver.

## DISCUSSION

The findings of this chronic toxicity study on TCDD in rats are an extension of the studies of shorter duration reported previously from this laboratory (Kociba *et al.*, 1976). Continuous ingestion of diets containing approximately 2200 ppt of TCDD (0.1 μg of TCDD/kg/day) for 2 years caused multiple toxicologic effects, including increased mortality, decreased body weight gain, slight depression of certain hematologic parameters, increased urinary excretion of porphyrins and δ-ALA, increased serum activities of AP, GGT, and SGPT, and morphological changes primarily of the hepatic, lymphoid, respiratory, and vascular tissues of the body. This high dose level of 0.1 μg/kg/day also caused an increase in the incidence of hepatocellular carcinomas of the liver (females only) and squamous cell carcinomas of the lung, hard palate/nasal turbinates, or tongue. The occurrence of numerous age-related lesions usually encountered in this strain of rat, including tumors of the pituitary, uterus, mammary gland, pancreas, and adrenal gland was reduced at the high dose level. Also reduced was the incidence and severity of chronic renal disease in the aged male rats. Female rats given this high dose level for 2 years had 24,000 ppt present in the liver. This compares with 34,600 ppt of TCDD present in the liver of female rats given this

same dose level for 13 weeks (Kociba *et al.*, 1976) and indicates steady state concer trations were achieved during the early phase of this 2-year study.

Ingestion of the intermediate dose level of 0.01 μg/kg/day (~210 ppt in the die caused a lesser degree of toxicity. The primary effects noted at this dose level include (1) increased urinary excretion of porphyrins (females), (2) liver toxicity, including a increased incidence of hepatocellular nodules, and (3) increased incidence of foc alveolar hyperplasia in the lungs. Terminal liver and fat content of TCDD average 5100, and 1700 ppt, respectively. This compares with 3700 ppt present in the live after 13 weeks of treatment with this dose level (Kociba *et al.*, 1976).

Lifetime ingestion of 0.001 μg/kg/day (~22 ppt in the diet) caused no effect considered to be of any toxicological significance. Light microscopy of livers fro females of this group indicated a statistical increase above the background incidence c swollen hepatocytes; conversely, the livers of the males of the group had a decrease incidence of this observation. When liver tissue was examined using electro microscopy, the hepatocytes from the females were within the limits of variation seen i the controls with an occasional hepatocyte containing increased lipid droplets. Th liver and fat each contained 540 ppt of TCDD at the end of the lifetime ingestion c 0.001 μg/kg/day.

If the results of this lifetime study in rats are compared to the preliminary results c the study in rats by Van Miller *et al.* (1977), it will be noted that both studies repo neoplastic responses in the lung and liver of rats maintained for extended periods c time on high doses of TCDD. In the preliminary report by Van Miller *et al.* (1977 5000 ppt produced both liver and lung neoplasms, while in this study, 2200 pp produced both liver and lung neoplasms.

Thus, there is agreement between the results obtained in both studies at higher do levels of 2200 to 5000 ppt of TCDD in the diet. However, at lower dose levels, there ar differences in the two studies, with Van Miller *et al.* (1977) reporting a diverse spectru of neoplasms in rats given as low as 5 ppt of TCDD, based on a zero incidence c neoplasms in a total of 50 control rats examined in their study. Conversely, in th study, there was no carcinogenic response in rats given 210 or 22 ppt of TCDD for years. DiGiovanni *et al.* (1977) reported TCDD to be only a weak tumor initiator i studies of mouse skin carcinogenesis with DMBA.

In summary, data collected in the study reported herein indicate that doses sufficier to induce severe toxicity increased the incidence of some types of neoplasms in rat while reducing the incidence of other types. No increase in neoplasms occurred in ra receiving sufficient TCDD during the 2-year study to induce slight or no manifestation of toxicity.

## REFERENCES

ALLEN, J. R., BARSOTTI, D. A., VAN MILLER, J. P., ABRAHAMSON, L. J., AND LALICH, J. J (1977). Morphological change in monkeys consuming a diet containing five hundred parts pe trillion of 2,3,7,8 tetrachlorodibenzo-*p*-dioxin. *Food Cosmet. Toxicol.* 15, 401–410.

DIGIOVANNI, J., VIALE, A., BERRY, D. L., SLAGA, T. J., AND JUCHAU, M. R. (1977). Tumo initiating ability of 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD) and Arochlor 1254 in th two-stage system of mouse skin carcinogenesis. *Bull. Environ. Contam. Toxicol.* 18, 552-557.

INNES, J. R. M., ULLAND, B. M., VALERIO, M. G., PETRUCELLI, L., FISHBEIN, L., HART, E. R., PALLOTTA, A. J., BATES, R. R., FALK, H. L., GART, J. J., KLEIN, M., MITCHELL, I., AND PETERS, J. (1969). Bioassay of pesticides and industrial chemicals for tumorigenicity in mice: A preliminary note. *J. Nat. Cancer Inst.* 42, 1101–1114.

KOCIBA, R. J., KEELER, P. A., PARK, C. N., AND GEHRING, P. J. (1976). 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin (TCCD): Results of a 13-week oral toxicity study in rats. *Toxicol. Appl. Pharmacol.* 35, 553–574.

MCCONNELL, E. E., MOORE, J. A., AND DALGARD, D. W. (1978). Toxicity of 2,3,7,8-tetrachlorodibenzo-*p*-dioxin in rhesus monkeys (*Macaca mulatta*) following a single oral dose. *Toxicol. Appl. Pharmacol.* 43, 175–187.

SIEGEL, (1956). *Non-parametric Statistics for the Behavioral Sciences.* McGraw–Hill, New York.

STEEL, R. G., AND TORRIE, H. H. (1960). *Principles and Procedures of Statistics.* McGraw–Hill, New York.

VAN MILLER, J. P., AND ALLEN, J. R. (1977). Chronic toxicity of 2,3,7,8 tetrachlorodibenzo-*p*-dioxin in rats. *Fed. Proc. Fed. Amer. Soc. Exp. Biol.* 36, 396.

VAN MILLER, J. P., LALICH, J. J., AND ALLEN, J. R., (1977). Increased incidence of neoplasms in rats exposed to low levels of 2,3,7,8-tetrachlorodibenzo-*o*-dioxin. *Chemosphere* 9, 537–544.

Carcinogenesis vol.8 no.10 pp.1491–1499, 1987

# A method to quantitate the relative initiating and promoting potencies of hepatocarcinogenic agents in their dose–response relationships to altered hepatic foci

Henry C.Pitot[1,5], Thomas L. Goldsworthy[2], Susan Moran[1], Wendy Kennan[1], Howard P. Glauert[3], Robert R.Maronpot[4] and Harold A.Campbell[1]

[1]Departments of Oncology and Pathology, McArdle Laboratory for Cancer Research, The Medical School, University of Wisconsin, Madison, WI 53706, [2]Chemical Industry Institute of Toxicology, PO Box 12137, Research Triangle Park, NC 27709, [3]Department of Nutrition and Food Sciences, University of Kentucky, Lexington, KY 40506, and [4]National Toxicology Program, National Institute of Environmental Health Sciences, PO Box 12233, Research Triangle Park, NC 27709, USA

[5]To whom reprint requests should be sent

**The relative response to various initiating doses of diethylnitrosamine (DEN) and dimethylbenz[a]anthracene of the induction of numbers and size (vol. % of liver) of altered hepatic foci (AHF) in livers of adult female rats of the Sprague–Dawley and Fischer 344 (F-344) strains was studied by methods of quantitative stereology in the presence and absence of the promoting agent, phenobarbital (PB, 0.05% in the diet). In all cases, a relatively linear response with dose, even at the lowest doses employed, was obtained except for the numbers of AHF at the highest dose of DEN (30 mg/kg), which was not significantly different from that at a dose of 10 mg/kg in F-344 female rats. Similar dose–response data were obtained at various doses of two promoting agents effective in hepatocarcinogenesis, PB and 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD), in livers of F-344 female rats following initiation with DEN (10 mg/kg) 24 h post-70% hepatectomy. The response to these agents exhibited threshold levels below which no increase in number or vol. % of liver of AHF was noted in comparison with that in livers of animals not treated with the promoting agents. At several subthreshold doses of both PB and TCDD an inhibition of AHF formation and growth (measured as vol. % of liver) was observed. Based on quantitative stereologic calculations, parameters for the estimation for the relative potency of chemicals as initiating or promoting agents have been established. These are defined as: initiation index = no. of foci induced × liver$^{-1}$ × [mmol/kg body wt]$^{-1}$ and promotion index = $V_f/V_c$ × mmol$^{-1}$ × weeks$^{-1}$, where $V_f$ is the total volume fraction (%) occupied by AHF in the livers of rats treated with the test agent and $V_c$ is the total volume of AHF in control animals which have only been initiated. These parameters were calculated for a number of agents based on data published in the literature and from those reported herein. Neither parameter varied significantly with the dose of the initiating agent based on the data in this paper. The range of promotion indices extended over more than eight orders of magnitude, whereas that of initiation indices was much less variable. Such parameters may be useful as quantitative estimates of the potency of hepatocarcinogenic agents, such values having potential application to risk estimations.**

*Abbreviations: DEN, diethylnitrosamine; PB, phenobarbital; AHF, altered hepatic foci; DMBA, 7,12-dimethylbenz[a]anthracene; TCDD, 2,3,7,8-tetrachlorodibenzo-*p*-dioxin; GGT$^+$, γ-glutamyl transpeptidase-positive; ATPase$^-$, canalicular adenosine triphosphatase-deficient; G6Pase-, glucose-6-phosphatase-deficient; 3'-Me-DAB, 3'-methyl-4-dimethylaminoazobenzene; DAB, 4-dimethylaminoazobenzene.

© IRL Press Limited, Oxford, England

## Introduction

The multistage nature of carcinogenesis has now been demonstrated in a number of histogenetic systems in several species (1–3). Implicit in such a concept is that carcinogenic agents can act principally or exclusively at one or all of the definable stages in the carcinogenic process. Thus complete and incomplete carcinogens have been defined as agents capable of acting at all stages of carcinogenesis or only at the stage of initiation respectively (3). Promoting agents are considered to affect only the stage of promotion, although they may simulate the action of complete carcinogens through the promotion of spontaneously or fortuitously initiated cells to tumors (3).

A number of methods have been used to determine the relative carcinogenic potencies of chemical agents in rodents (4); however, few have attempted to quantitate the potency of an agent with respect to its action on a specific stage of carcinogenesis (5). Multistage carcinogenesis has been most extensively studied in the mouse epidermis and in rat liver (3,6). Although the former has a much longer history of investigative studies, the liver system offers the advantage, at least for quantitative studies, of the identification and enumeration of the clonal progeny of initiated cells (3,7). This characteristic provides the process of multistage hepatocarcinogenesis in the rat with the potential for quantitating the potencies of agents in their action at each of the stages of hepatocarcinogenesis. A method for determining such parameters is the principal subject of this paper.

## Materials and methods

For all of the experiments described in these studies, adult female rats weighing 150–220 g, of either the inbred Fischer F344/NHsdBR strain or the outbred Hsd:Sprague–Dawley(SD)BR strain (obtained from the Harlan Sprague–Dawley Co., Madison, WI), were used. Female rats were used in the studies reported herein both for consistency and because earlier investigations from this laboratory (H.C.Pitot *et al.*, unpublished observations) and from that of Persino *et al.* (8) have indicated that females respond to these protocols (8,9) more effectively than males. Animals were fed *ad libitum* throughout the experiments described in this paper (Figures 1–4). Initiation was performed by oral gavage of the chemical in corn oil or trioctanoin (l'OH safrole) at the doses indicated in the figures and tables. Diethylnitrosamine (DEN) and phenobarbital (PB) were administered in distilled water at the doses indicated.

The initiating agent was administered in a single bolus 24 h after a 70% partial hepatectomy (9). Two weeks following this procedure, feeding or injection of the promoting agent was begun according to the protocols depicted in the figures. At appropriate times, rats were killed by decapitation, their livers removed, and two representative 3-mm-thick slices taken from each of the three remaining lobes. These tissue samples were frozen on solid $CO_2$ in two montages of three slices each. Another slice from each lobe was fixed in 10% buffered formalin for routine histologic examination by hematoxylin and eosin. In some of the experiments using F-344 animals, separate groups of rats were maintained for a total of 14 months on the promoting agents, at which time the rats were killed, their livers removed, and representative sections removed only for routine histologic examination.

Three serial frozen sections were cut at 10-μm thickness from each frozen montage; this allowed examination of six representative sections, two from each of the remaining lobes. One section was stained histochemically for the enzyme γ-

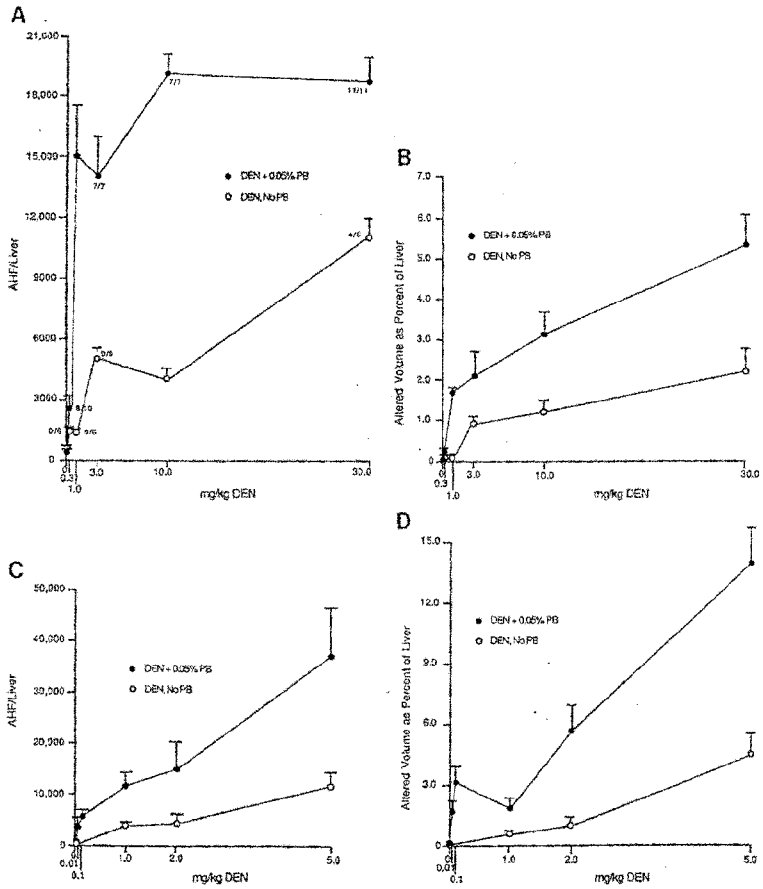



Fig. 1. Dose–response curve relating the number of AHF and the volume percentage of the liver occupied by all AHF to the dose of DEN administered as an initiating agent in the Sprague–Dawley and F-344 female rats after 6 months of promotion with 0.05% PB in NIH-07 diet. (A,B) values for F-344 rats, (C,D) values for Sprague–Dawley rats. The fractional values noted as many of the data points indicate the number of rats with gross tumors (neoplastic nodules and hepatocellular carcinomas) per number of rats in the group after 14 months of promotion.

glutamyltranspeptidase, the second for canalicular ATPase and the third stained for glucose-6-phosphatase activity by methods previously described (8). Scoring, enumeration and quantitative determination of the total area and thus volume of altered hepatic foci (AHF) were determined by techniques previously described from this laboratory (10).

The chemicals employed in the studies described in this paper were obtained from the following sources: PB, free acid, from Sigma Company, St Louis, MO; DEN from the Eastman Kodak Co., Rochester, NY; dimethylbenz[a]anthracene (DMBA) from Fluka Chemicals, Inc., Hauppauge, NY; and 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) from KOR Isotopes, Cambridge, MA.

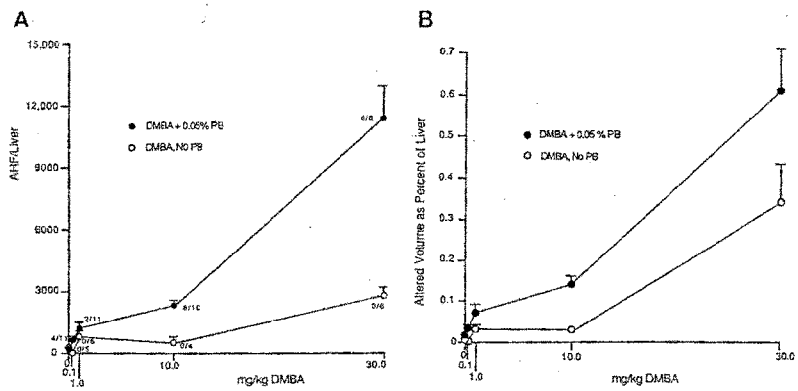



Fig. 2. AHF per liver and volume percentage of AHF in livers of female Fischer 344 rats treated with varying doses of DMBA as described in Materials and methods. See legend of Figure 1 for further details.

## Results

### *Dose–response relationships*

Previous studies from this laboratory have demonstrated a dose–response relationship between the numbers of γ-glutamyl transpeptidase-positive ($GGT^+$) AHF and the dose rate at which the promoting agent was administered (11). This dose response indicated no-effect levels for several low dose rates of the promoting agent PB when it was fed continuously for a period of 7–8 months. In addition, a maximal effect of the administration of higher doses of PB for this period of time was observed. This phenomenon was interpreted, as it has been previously in multistage epidermal carcinogenesis in the mouse (12), as a reflection of the total number of cells initiated by the single dose of DEN that can be scored by this marker. In the studies reported in this paper, these investigations have been extended to another strain of rats, the inbred F-344 strain. In addition, dose responses for the number of AHF and the volume percent of the liver occupied by these lesions as a function of the dose of both a complete carcinogen for the liver, DEN, and an incomplete carcinogen, DMBA. Analogous dose responses for another promoting agent, TCDD, are also included.

Figure 1 shows the number of AHF and their volume percentage induced by varying doses of DEN given as an initiator, with and without PB. Values from both the inbred F-344 and the outbred Sprague–Dawley strains are given for comparison. Only the lower doses of DEN are shown for the latter strain, which appears to be somewhat more sensitive to the effects of the initiating agent, as evidenced by the number of foci induced with DEN. This is also reflected in the volume percentage occupied by these foci in the liver of the outbred strain. The mechanism of such differences between the two strains is not clear at this time. It is of interest, however, that at the highest dose of initiating agent used (30 mg/kg) in the F-344 strain there was no apparent further increase in the number of AHF per liver, although the volume percentage did increase over the 10 mg/kg dose, the next lower dose used in this experiment. This phenomenon may be similar to that which has been previously described by Dyroff *et al.* (13) under somewhat different experimental conditions, in which the initiating agent was given continuously in the drinking water for periods of 6–10 weeks as opposed to a single bolus. One possible explanation for this effect is that the higher dose tends to kill initiated cells (13), and thus a lower number of foci, presumably reflecting clonal growth of initiated cells (14,15), is found. These data are also compatible with those shown earlier by Scherer and Emmelot (16) in following the response to single doses of DEN by enumeration of ATPase– foci in the livers of animals so treated. In that experiment there was a plateau effect above 30 mg DEN/kg, and these authors indicated that at the higher doses tumors eventually appeared, even in the absence of any exogenous promoting agent. In our experiments tumors were seen at the 30 mg/kg dose of DEN given without PB, analogous to the findings of the Dutch workers (Figure 1A).

In view of the fact that DEN is a complete carcinogen for the liver, it became of interest to determine the dose–response effect with an 'incomplete' carcinogen for the liver such as one of the polycyclic hydrocarbons, which are carcinogenic for the bone marrow and mammary gland in the rat but have not been shown to be complete carcinogens in the liver of these animals (17). Figure 2 shows the effects of several doses of DMBA given as an initiating agent (see Materials and methods) followed by promotion with PB, compared with rats receiving DMBA alone. Relatively linear increases in both the number of AHF per liver and their volume percentages are noted in the figure. However, the volume percentage of the lesions occupied following DMBA initiation even in the presence of PB is considerably less than of those initiated by DEN. This effect may be related to a lack of promoting capacity of DMBA in this tissue as might be expected from its action as an 'incomplete carcinogen' in liver.

When one determines the effects of varying doses of PB on the yield and volume percentage of AHF initiated by a single dose of DEN (10 mg/kg), a relationship very similar to that described earlier in female animals of the Sprague–Dawley outbred strain (11) is seen in female animals of the F-344 strain

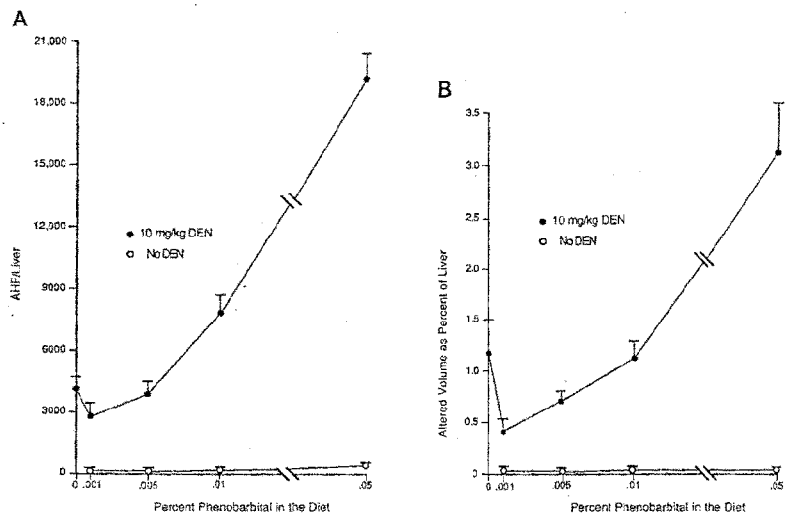



Fig. 3. Difference between the AHF/liver and the volume percentage of AHF in the liver as a function of the percentage of phenobarbital fed in the NIH-07 diet of Fischer 344 female rats for a 6-month period following initiation or not with DEN (10 mg/kg), as described in Materials and methods.

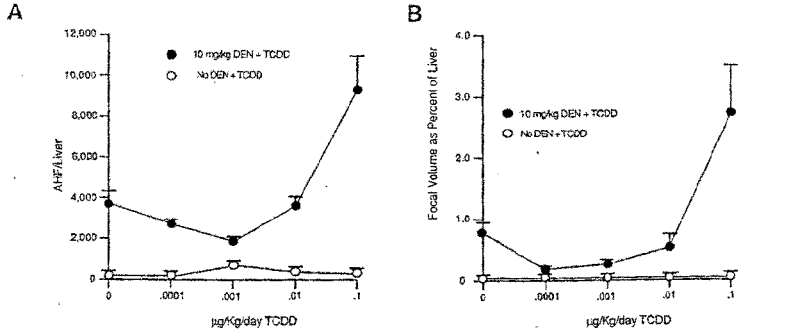



Fig. 4. Difference between the AHF/liver and the volume percentage of AHF in the livers of animals initiated with DEN (10 mg/kg) or not and administered TCDD at the dose levels noted. TCDD was injected intramuscularly in corn oil biweekly at concentrations which resulted in the daily dose shown (17). In this graph, the *x* axis is logarithmic. See legend of Figure 3 for further details.

(Figure 3). The other difference between these two studies is that the dose–response curve determined in the Sprague–Dawley strain used only a single marker, GGT, to score the number and volume percentage of AHF. In this experiment foci scored by any and all three markers—GGT, adenosine triphosphatase (ATPase) and glucose-6-phosphatase (G6Pase)—were analyzed. The shape of this curve is essentially the same as reported previously, including the demonstration of 'no-effect' dose rates of PB

administration. Inasmuch as the earlier study (11) showed a clear maximal effect occurring beyond the 0.05% dose rate of the promoting agent, doses beyond that rate were not carried out in this study. However, it should be noted that both curves seen in Figure 3, as well as the earlier dose response reported for Sprague–Dawley animals (11), exhibit a significantly lower response at the lowest dose rate of phenobarbital both with respect to numbers of foci and their volume percentages compared with animals receiving no PB. This interesting and apparently reproducible finding suggests an actual protective effect, i.e. an inhibition of the appearance of foci and of their growth (volume percentage) by dose rates of PB below the threshold for an increase in AHF.

Figure 4 shows a dose–response relationship of the same parameters when TCDD was used as a promoting agent. Previous studies from this laboratory indicated the effective promoting action of this agent (18) in multistage hepatocarcinogenesis in the rat. As with PB, a 'no-effect' level was seen below 0.1 μg/kg/day of TCDD both with respect to an increase in the number of foci induced and their volume percentages. An apparent 'protective' effect was again seen at the lower doses of this agent as well.

*Relative potency of initiating and promoting agents—the initiation and promotion indices:*

In view of the slightly different effects noted in the two strains of animals, especially with DEN as an initiating agent, it became of interest to ascertain a relative potency for initiation and/or promotion by these and other chemical agents active in one or more stages of multistage hepatocarcinogenesis in the rat. Whereas other workers (5,19) have classified a number of chemicals on the basis of their activity in promoting AHF and nodules after initiation with DEN, with the number of transections/cm$^2$ and area in mm$^2$ of the transections/cm$^2$ of focal lesions as endpoints, we have developed a system based on the quantitative stereologic determination of the values of both number of AHF/liver and volume percentage occupied by AHF. As we have previously pointed out, such a three-dimensional calculation is critical in comparative studies, since it takes into account the differing sizes of the lesions that occur in most model systems (20). On the other hand, the volume occupied by the focal lesions is calculated from the areas of the transections noted on the slides that are analyzed and is a direct function of the area, and thus either area or volume is equally appropriate in the determination of such parameters of potency.

We have based the calculations for determining the potency of a chemical as an initiating and/or promoting agent on the biological characteristics of each of these processes. As has been pointed out by a number of authors (2,3,6,21,22), initiation is a process occurring within a single cell, with this initiated cell conferring its altered state to all of its progeny. In multistage hepatocarcinogenesis there is now ample evidence that each AHF is the clonal progeny of a single cell (14,15) that exhibits essentially all of the characteristics expected of an initiated cell (3,23). Thus, for the purposes of these calculations, we have equated the number of AHF as determined by three independent biochemical parameters—GGT$^+$, ATPase$^-$ and G6Pase$^-$ phenotypes—with the number of initiated cells. In this way one may relate the number of initiated cells to the dose of the initiating agent, since the latter is given only as a single dose in this and many other model systems of hepatocarcinogenesis (24). We have therefore defined the initiation index as follows:

$$\text{Initiation index} = \text{no. of foci induced} \times \text{liver}^{-1} \times [\text{mmol/kg body wt}]^{-1}$$

The number of foci induced are those found in the liver of the animal that has been promoted with a maximally effective dose of promoting agent for at least the time required to express all initiated cells quantifiable by the marker(s) used to score such clones *minus* the number of AHF occurring in animals not receiving the initiating agent but promoted with the same dose of promoting agent. This method thus corrects for levels of spontaneously or fortuitously initiated cells whose formation is independent of the initiating agent administered.

The evaluation of the promoting potency of an agent is based on our knowledge of the nature of the biological effect of promoting agents as determined from experience in those systems *in vivo* in which multistage carcinogenesis is best understood, namely, the mouse epidermis and the rat liver. On the basis of these systems, one may define promotion as that stage in the natural history of neoplastic development which, if existent, is characterized by (1) the reversible expansion of the initiated cell population and (2) the reversible alteration of genetic expression. In this definition, the emphasis is on reversibility, a biological characteristic of promotion in all known model systems of multistage hepatocarcinogenesis in the rat and most, if not all, such systems in the mouse epidermis (25). Numerous studies have demonstrated that promoting agents cause a selective expansion of the cells within AHF in rat liver (7,24,25), and all known promoting agents are known to alter gene expression in normal cells in a reversible manner (3,6,26,27). The phrase 'if existent' is employed in this definition since there are numerous examples in chemical and physical as well as biological carcinogenesis of cancer resulting from direct application of the carcinogenic agent with no demonstrable reversible stages. Presumably under such conditions the stage of initiation is followed immediately by that of progression, the final irreversible stage of multistage carcinogenesis in which malignant neoplasms occur (25,28).

On the basis of such operational knowledge of the characteristics of promoting agents, we have defined the following parameter:

$$\text{Promotion index} = V_f/V_c \times \text{mmol}^{-1} \times \text{weeks}^{-1}$$

where $V_f$ is the total volume fraction (%) occupied by AHF in the liver of animals treated with the test agent and $V_c$ is the total volume of AHF in the control animals, which have only been initiated. The mmol of promoting agent administered per week are determined either directly if a measured amount of the agent is administered per day, week or month, or as that consumed in an average food intake of 20 g/day (29). Since volume occupied by the foci is directly related to cell number, the measurement of effectiveness of a promoting agent is therefore related to its ability to stimulate selectively and/or allow selectively the replication of the promoter-dependent progeny of initiated cells (30,31). The correction for the volume percentage of AHF in animals that have only been initiated allows for the effect of uncontrolled endogenous and/or exogenous promoting agents in the experiment. Unfortunately, such a correction does not take into account any possible synergy between the test agent and uncontrolled promoting activities, such as dietary factors and endogenous hormones. Unlike the initiation index, which is determined after promotion for a period allowing the demonstration of the progeny of all initiated cells, the promotion index, although usually determined after a 6-month treatment with the promoting agent, may be determined at other time intervals during carcinogenesis as well. Of the promotion indices in Table I, only that for TCDD is $>1000$, whereas all but one of the finite initiation indices are $>1000$.

Table I. Relative potencies for initiation and promotion of hepatocarcinogenic agents in the rat

| | Initiation index[a] | Promotion index[a] | Reference |
|---|---|---|---|
| Proflavin | $6.9 \times 10^3$ | – | (32) |
| DMBA | $1.6 \times 10^5$ (F-344)[b] | – | this report |
| DEN | $7.2 \times 10^5$ (F-344) | – | this report |
| | $10.5 \times 10^6$ (S-D)[c] | | this report |
| BHA | – | 0.3 (S-D) | (32) |
| 1'OH-Safrole | $3.1 \times 10^3$ | 950 | (33) |
| TCDD | 0.0 (F-344) | $1.0 \times 10^6$ (F-344) | this report |
| | | $2.8 \times 10^7$ (S-D) | (18) |
| Wy 14,643 | – | 63 | (34) |
| DAB | – | 20 | (35) |
| 3'-Me-DAB | – | 17 | (36) |
| Thiobenzamide | – | 60 | (37) |
| Phenobarbital | 0.0 (F-344) | 6 (F-344) | this report, (32), |
| | | 75 (S-D) | unpublished observations |
| N-2-Fluorenyl-acetamide | – | 927 | (36) |

[a]See text for details of calculations; –, no data available. The animal strain and sex for studies in the literature may be obtained from the references cited or the legends to Figures 1–4.
[b]F-344: Fischer F344/NHsdBR strain rats.
[c]S-D: Hsd:Sprague–Dawley(SD)BR strain rats.

Table II. Initiation indices (II) as a function of dose of initiating agent

| Initiating agent | Dose (mg/kg) | F-344 rats II | S-D rats II |
|---|---|---|---|
| DEN | 0.01 | – | $4.3 \times 10^6$ |
| | 0.1 | – | $6.0 \times 10^6$ |
| | 0.3 | $5.1 \times 10^5$ | – |
| | 1.0 | $1.7 \times 10^6$ | $1.4 \times 10^6$ |
| | 2.0 | – | $0.7 \times 10^6$ |
| | 3.0 | $4.4 \times 10^5$ | – |
| | 5.0 | – | $0.7 \times 10^6$ |
| | 10.0 | $2.2 \times 10^5$ | – |
| DMBA | 0.1 | $3.5 \times 10^5$ | |
| | 1.0 | $1.7 \times 10^5$ | |
| | 10.0 | $0.5 \times 10^5$ | |
| | 30.0 | $0.9 \times 10^5$ | |

The format for the studies resulting in the values in this table is identical with that seen in Figures 1 and 2. See footnotes of Table I for abbreviation key.

Table I shows some representative initiation and promotion indices taken both from studies reported in this paper and from those described earlier in the literature from this and other laboratories. In those values estimated from the literature and not from work in this laboratory some assumptions had to be made, since the format of the experiments was somewhat different from those in the model used in this and other studies (32,34) from this laboratory. In the studies reported by Malvaldi *et al.* (37) on the 'promotive effects' of thiobenzimide, the area of $GGT^+$ foci was used instead of the volume, but, as has been pointed out earlier (20), these two parameters are identical for the purposes of calculating promotion indices. Similarly, the promotion indices for 3'-methyl-4-dimethylaminoazobenzene (3'-Me-DAB) and N-2-fluorenylacetamide were calculated from the area of the $GGT^+$ foci as presented in the work by Tsuda *et al.* (36). In this latter study initiation was accomplished by a single i.p. dose of DEN (200 mg/kg). Two weeks later, rats were fed these agents in the diet for a period of 6 weeks, at which time the area of $GGT^+$ foci was determined. This study described many other compounds tested in a similar manner for which promotion indices could also be calculated by the techniques described in this paper. The promotion index for 4-dimethylaminoazobenzene (DAB) was calculated from the volume percentage of those foci scored as $GGT^+$ in rats initiated by the administration of N-nitrosodiethanolamine in the drinking water (2000 p.p.m.) for 6 weeks followed by a 2-week interval in which no carcinogen was administered, followed by the feeding of DAB in the diet (0.16%). In that study (36) foci were scored either as $GGT^+$ or $ATPase^-$, and the value in the table was that of $GGT^+$ AHF. The promotion index calculated from the $ATPase^-$ foci was 8.0. It is of interest that, where values for initiation and promotion indices were calculated for the same compound in two different strains of rats, the values seen in the Sprague–Dawley animals was always higher than those of the F-344 strain. On the other hand, when initiation indices for DEN and DMBA are calculated over a range of doses (Table II), the values do overlap, although female animals of the Sprague–Dawley strain appear to exhibit higher values than those of the F-344 strain. At doses above 1 mg/kg, the two initiation indices portrayed for each of the rat strains untilized are quite similar, but at lower doses, the initiation indices are somewhat higher, most notably in the 0.1 and 0.01 mg/kg doses administered to the Sprague–Dawley female rats. Such differences may be related to the greater toxicity of higher doses of DEN as suggested by Dyroff *et al.* (13). If such an explanation is correct, then for some highly effective initiating agents, small doses may be the most effective way to measure initiation indices in the absence of cell killing. A similar effect can be seen for the initiation index of DMBA (Table II). The values for initiation indices for these two compounds seen in Table I are the averages of those seen in Table II. Furthermore, as shown in Table III, the promotion index is relatively stable over a wide range of doses of two different initiating agents, DMBA and DEN. The relatively high value seen at the 1.0 mg/kg dose of DEN is unexplained at the moment, but virtually all of the other values are relatively close to one another. Even in studies done in different laboratories with two closely related compounds, DAB and 3'-Me-DAB (Table I), the calculated promotion indices from the available data are quite similar. As yet there are insufficient data to calculate promotion indices as a function of the concentration of the promoting agent administered, since only one or a few points are available on the effective portion of the curve (Figures 3 and 4; ref. 11).

## Discussion

At the present time, the determination of the carcinogenic activity of a chemical is basically a qualitative analysis. At the regulatory level of governmental agencies, no attempt is made to distinguish the action of chemical agents in the various stages of carcinogenesis; rather, all agents are assumed to be complete carcinogens (38,39) if they exhibit any siginificant carcinogenic activity. Studies over the past several decades of multistage carcinogenesis in a number of different tissues in laboratory animals (1–3) have demonstrated that such an assumption, in a significant number of instances, is not warranted. The reversible nature of the stage of tumor promotion, which has been clearly shown by now in the best-studied multistage carcinogenesis models—those of mouse epidermis (6,40) and rat liver (7,30)—demonstrates that no matter what mechanism is involved, the

Table III. The promotion index (PI) of PB in F-344 female rats at various doses of the initiating agents, DMBA and DEN

| Initiating agent | Dose (mg/kg) | PI |
|---|---|---|
| DMBA | 1.0 | 5 |
| | 10 | 10 |
| | 30 | 4 |
| DEN | 1.3 | 4 |
| | 1.0 | 26 |
| | 3.0 | 5 |
| | 10.0 | 6 |
| | 30.0 | 5 |

See legend of Table I and Figure 1 for procedural details.

presence of a no-effect level is inherent in the characteristic of reversibility, and additivity may occur only in a relatively narrow window of the dose–response curve. Since risk estimations in the human always involve quantitative parameters, if animal studies are to be utilized in such determinations, then quantitation of the relative efficiencies of chemicals in animal systems should be very important for quantitative risk estimations across species lines.

Until recently, most methods for the determination of relative carcinogenic potencies of chemical agents related dose of the agent, either total dose or a dose rate, to some time function involving the yield or some fraction thereof of malignant neoplasms. An early proposal by Iball (41) related the carcinogenic potency of a chemical to the percentage of animals developing tumors divided by the latent period in days × 100. By this straightforward analysis potent carcinogens usually induce many tumors in a relatively short time, whereas weak carcinogens induce fewer neoplasms and then only after a prolonged latent period. Barr's review (4) of various calculations used to determine carcinogenic potency refers to many different procedures that have been used in the past, both in experimental circumstances and also from regulatory agencies. Lutz and his associates (42) have developed equations relating the efficacy with which chemicals stimulate DNA synthesis and DNA binding in relation to their carcinogenic potency. These calculations have been applied with some success to the prediction of carcinogenic potency for hepatocarcinogens in experimental situations. Parodi *et al.* (43) related the induction of 'preneoplastic nodules' during hepatocarcinogenesis to the carcinogenic potency of a variety of different compounds, most of which were taken from studies in the literature.

A comparison of the dose–response curves of initiating agents (Figures 1 and 2) with those of promoting agents (Figures 3 and 4) demonstrates in this model system of multistage hepatocarcinogenesis the distinction between the two types of agents in relation to observed 'no effect' or threhold levels. Since it is impossible to prove unequivocally the presence or absence of a threshold under any circumstances involving multiple data points, despite the graphic appearance of the dose–response relationship, the ultimate interpretation of the data will depend on the presumed and/or observed mechanism of the agent in question. Initiation has been shown to be an irreversible phenomenon in those systems in which this stage can be clearly distinguished (3,6). On the other hand, as described earlier both in the liver and the skin systems in which the stage of promotion has been clearly defined and delineated, this stage is reversible. Thus the effect of agents acting exclusively or even predominantly at this stage of carcinogenesis would be expected to exhibit threshold levels, as has been shown for drugs and chemical agents exhibiting reversible effects in a variety of systems (44). The use of the number of focal lesions, each developing clonally from a presumed initiated cell, as a measure of the effectiveness of initiation is quite logical. The relative reproducibility of even the limited amount of data seen in this report would support this approach as a measure of the potency of a compound as an initiating agent in multistage hepatocarcinogenesis in the rat. Promotion indices are apparently more variable than those for initiation (Table I), as might be expected from the known environmental modulation of this stage (2,3). Despite this, promotion indices for the same or related compounds as studied in different laboratories are quite similar. The example cited in Table I is that of DAB and 3′-Me-DAB (35,36). Another example is the similarity of the promotion index for PB as noted in Tables I and III and that of 7.0 as calculated from the data of Tsuda *et al.* (37) in the F-344 strain from that laboratory. Although this report deals only with the enumeration of AHF under the limits of identification used previously by this laboratory (9), recent studies (45) suggest that with different markers it may be possible to identify many more initiated cells. It will be of interest to determine in the future whether the inclusion of such presumably initiated hepatocytes in the calculations will relate to the potency of initiating agents in this system.

The range of initiation and promotion indices noted in Table I is rather extensive. However, while the finite initiation indices range over four orders of magnitude ($10^3-10^7$), the range of promotion indices extends over almost eight orders of magnitude (Table I). It is also of interest that in all cases in which initiation or promotion indices were calculated for the same compound in two different strains of rats, the Sprague–Dawley strain always had a higher value. This finding is supported somewhat by the recent studies of Russell *et al.* (46), who compared initiation by DEN and promotion by PB in the same two strains of animals. Their studies also showed a greater sensitivity to these two compounds in the Sprague–Dawley strain. Further studies are needed to determine exactly how consistent promotion indices are under various experimental conditions of diet, sex, age, etc., since all of these factors have been shown to affect the stage of promotion in multistage carcinogenesis (2,3,21,22). Clearly the dose response affects the promotion index, because no valid index can be calculated below the threshold level of the agent, and calculation of promotion indices after a maximal effect of the promoting agent has been obtained will lead to spuriously low results. Thus, meaningful promotion indices that can be compared from laboratory to laboratory and even from experiment to experiment must be calculated on the relatively linear portion of the dose–response curve. Similarly, initiation indices must be calculated from values on the increasing, relatively linear portion of the dose–response curve (Figure 1A) in order to eliminate possible artifacts due to cell death, toxicity, etc.

Although the potency parameters proposed in this publication are limited to hepatocarcinogenic agents, other systems in which the clonal progeny of initiated cells may be quantitatively determined and in which quantitation of the total promoted cell population is possible are now being developed. Analogous calculations of potency may already be applicable, in part at least, to such tissues as the epidermis (47), pancreas (48), lung (49), thyroid (50,51), brain (52,53) and mammary gland (54,55). Such quantitative calculations, based on a knowledge of the characteristics of these two stages of carcinogenesis, may be helpful in determining quantitative parameters useful in risk assessment in the human being.

## Acknowledgements

The authors wish to express their deepest appreciation to Ms Jane Weeks and Susan Carlson, as well as Mrs Mary Foiz-Erbs, for providing histotechnological expertise necessary for this study and to Mr M.Judkins, Ms A.Jew and Mr K.Moran for expert animal husbandry. The authors would also like to express their appreciation to Mrs Mary Jo Markham and Ms Kristen Luick for their expert technical typing, and to Dr Ilse Riegel for critical editorial comments on the manuscript. This study was supported in part by a contract from the National Toxicology Program of the NIH (ES-82-12) and grants from the National Cancer Institute (CA-07175 and CA-22484).

## References

1. Bohrman,J.S. (1983) Identification and assessment of tumor-promoting and cocarcinogenic agents: state-of-the-art *in vitro* methods. *Crit. Rev. Toxicol.*, 11, 171–177.
2. Slaga,T.J. (1983) Overview of tumor promotion in animals. *Environ. Health Perspect.* 50, 3–14.
3. Pitot,H.C. and Sirica,A.E. (1980) The stages of initiation and promotion in hepatocarcinogenesis. *Biochim. Biophys. Acta*, 605, 191–215.
4. Barr,J.T. (1985) The calculation and use of carcinogenic potency: a review. *Reg. Toxicol. Pharmacol.*, 5, 432–459.
5. Ito,N., Tatematsu,M., Nakanishi,K., Hasegawa,R., Takano,R., Imaida,K. and Ogiso,T. (1980) The effects of various chemicals on the development of hyperplastic liver nodules in hepatectomized rats treated with *N*-nitrosodiethylamine or *N*-2-fluorenylacetamide. *Gann*, 71, 832–842.
6. Boutwell,R.K. (1964) Some biological aspects of skin carcinogenesis. *Prog. Exp. Tumor Res.*, 4, 207–250.
7. Farber,E. and Sarma,D.S.R. (1987) Biology of disease. Hepatocarcinogenesis: a dynamic cellular perspective. *Hep. Carcinogen.*, 56, 4–22.
8. Peraino,C., Staffeldt,E.F., Carnes,B.A., Ludeman,V.A., Blomquist,J.A. and Vesselinovitch,S.D. (1984) Characterization of histochemically detectable altered hepatocyte foci and their relationship to hepatic tumorigenesis in rats treated once with diethylnitrosamine or benzo[a]pyrene within one day after birth. *Cancer Res.*, 44, 3340–3347.
9. Pitot,H.C., Barsness,L., Goldsworthy,T. and Kitagawa,T. (1978) Biochemical characterisation of stages of hepatocarcinogenesis after a single dose of diethylnitrosamine. *Nature*, 271, 456–458.
10. Campbell,H.A., Xu,Y.-D., Hanigan,M.H. and Pitot,H.C. (1986) Application of quantitative stereology to the evaluation of phenotypically heterogeneous enzyme-altered foci in the rat liver. *J. Natl. Cancer Inst.*, 76, 751–757.
11. Goldsworthy,T., Campbell,H.A. and Pitot,H.C. (1984) The natural history and dose–response characteristics of enzyme-altered foci in rat liver following phenobarbitol and diethylnitrosamine administration. *Carcinogenesis*, 5, 67–71.
12. Verma,A.K. and Boutwell,R.K. (1980) Effects of dose and duration of treatment with the tumor-promoting agent, 12-*O*-tetradecanoylphorbol-13-acetate on mouse skin carcinogenesis. *Carcinogenesis*, 1, 271–276.
13. Dyroff,M.C., Richardson,F.C., Popp,J.A., Bedell,M.A. and Swenberg,J.A. (1986) Correlation of $O^4$-ethydeoxythymidine accumulation, hepatic initiation and hepatocellular carcinoma induction in rats continuously administered diethylnitrosamine. *Carcinogenesis*, 7, 241–246.
14. Scherer,E. and Hoffmann,M. (1971) Probable clonal genesis of cellular islands induced in rat liver by diethylnitrosamine. *Eur. J. Cancer*, 7, 369–371.
15. Rabes,H.M., Bücher,Th., Hartmann,A., Linke,I. and Dünnwald,M. (1982) Clonal growth or carcinogen-induced enzyme-deficient preneoplastic cell populations in mouse liver. *Cancer Res.*, 42, 3220–3227.
16. Scherer,E. and Emmelot,P. (1975) Kinetics of induction and growth of precancerous liver-cell foci, and liver tumour formation by diethylnitrosamine in the rat. *Eur. J. Cancer*, 11, 689–696.
17. Hirakawa,T., Ishikawa,T., Nemoto,N., Takayama,S. and Kitagawa,T. (1979) Induction of enzyme-altered islands in rat liver by a single treatment with benzo[a]pyrene after partial hepatectomy. *Gann*, 70, 393–394.
18. Pitot,H.C., Goldsworthy,T., Campbell,H.A. and Poland,A. (1980) Quantitative evaluation of the promotion by 2,3,7,8-tetrachlorodibenzo-*p*-dioxin of hepatocarcinogenesis from diethylnitrosamine. *Cancer Res.*, 40, 3616–3620.
19. Herren,S.L., Pereira,M.A., Britt,A.L. and Khoury,M.K. (1982) Initiation/promotion assay for chemical carcinogens in rat liver. *Toxicol. Lett.*, 12, 143–150.
20. Campbell,H.A., Pitot,H.C., Potter,V.R. and Laishes,B.A. (1982) Application of quantitative stereology to the evaluation of enzyme-altered foci in rat liver. *Cancer Res.*, 42, 465–472.
21. Scribner,J.D. and Süss,R. (1978) Tumor initiation and promotion. *Int. Rev. Exp. Pathol.*, 18, 137–197.
22. Greenebaum,E. and Weinstein,I.B. (1981) Relevance of the concept of tumor promotion to the causation of human cancer. In Fenoglio,C.M. and Wolff,M. (eds), *Progress in Surgical Pathology*, Masson, New York, pp. 27–43.
23. Emmelot,P. and Scherer,E. (1980) The first relevant cell stage in rat liver carcinogenesis. A quantitative approach. *Biochim. Biophys. Acta*, 605, 247–304.
24. Goldsworthy,T., Hanigan,M.H. and Pitot,H.C. (1985) Models of hepatocarcinogenesis in the rat—contrasts and comparisons. *CRC Crit. Rev. Toxicol.*, 17, 61–89.
25. Pitot,H.C., Beer,D.G. and Hendrich,S. (1987) Multistage carcinogenesis of the rat hepatocyte. *Banbury Report 25: Nongenotoxic Mechanisms in Carcinogenesis*, 1–13.
26. Moore,M.A. and Kitagawa,T. (1986) Hepatocarcinogenesis in the rat: the effect of promoters and carcinogens *in vivo* and *in vitro*. *Int. Rev. Cytol.*, 101, 125–173.
27. Diamond,L., O'Brien,T. and Baird,W.M. (1980) Tumor promoters and the mechanism of tumor promotion. *Adv. Cancer Res.*, 32, 1–74.
28. Scholte-Herrmann,R. (1985) Tumor promotion in the liver. *Arch. Toxicol.*, 57, 147–158.
29. Ross,M.H., Lustbader,E.D. and Bras,G. (1983) Dietary practices of early life and age at death of rats with tumors. *J. Natl. Cancer Inst.*, 71, 947–954.
30. Hanigan,M.H. and Pitot,H.C. (1985) Growth of carcinogen-altered rat hepatocytes in the liver of syngeneic recipients promoted with phenobarbital. *Cancer Res.*, 45, 6063–6070.
31. Hendrich,S., Glauert,H.P. and Pitot,H.C. (1986) The phenotypic stability of altered hepatic foci: effects of withdrawal and subsequent readministration of phenobarbital. *Carcinogenesis*, 7, 2041–2045.
32. Goldsworthy,T.L. and Pitot,H.C. (1985) An approach to the development of a short-term whole-animal bioassay to distinguish initiating agents (incomplete carcinogens), promoting agents, complete carcinogens, and noncarcinogens in rat liver. *J. Toxicol. Environ. Health*, 16, 389–402.
33. Boberg,E.W., Liem,A., Miller,E.C. and Miller,J.A. (1987) Inhibition by pentachlorophenol of the initiating and promoting activities of 1'-hydroxysafrole for the formation of enzyme-altered foci and tumors in rat liver. *Carcinogenesis*, 8, 531–539.
34. Glauert,H.P., Beer,D., Rao,M.S., Schwarz,M., Xu,Y-D., Goldsworthy,T.L., Coloma,J. and Pitot,H.C. (1986) Induction of altered hepatic foci in rats by the administration of hypolipidemic peroxisome proliferators alone or following a single dose of diethylnitrosamine. *Cancer Res.*, 46, 4601–4606.
35. Schwarz,M., Pearson,D., Port,R. and Kunz,W. (1984) Promoting effect of 4-dimethylaminoazobenzene on enzyme-altered foci induced in rat liver by *N*-nitrosodiethanolamine. *Carcinogenesis*, 5, 725–730.
36. Tsuda,H., Hasegawa,R., Imaida,K., Masui,T., Moore,M.A. and Ito,N. (1984) Modifying potential of thirty-one chemicals on the short-term development of γ-glutamyl transpeptidase-positive foci in diethylnitrosamine-initiated rat liver. *Gann*, 75, 876–883.
37. Malvaldi,G., Chieli,E. and Saviozzi,M. (1983) Promotive effects of thiobenzamide on liver carcinogenesis. *Gann*, 74, 469–471.
38. Pitot,H.C. (1982) Evaluation of the toxic and carcinogenic risks of environmental chemicals to human beings: scientific, legal, and risk–benefit considerations. In Kahn,S.B. *et al.* (eds), *Concepts in Cancer Medicine*. Grune & Stratton, New York, pp. 101–118.
39. Perera,F.P. (1984) The genotoxic/epigenetic distinction: relevance to cancer policy. *Environ. Res.*, 34, 175–191.
40. Stenbäck,F. (1978) Tumor persistence and regression in skin carcinogenesis. *Z. Krebsforsch.*, 91, 249–259.
41. Iball,J. (1939) The relative potency of carcinogenic compounds. *Am. J. Cancer*, 35, 118–190.
42. Lutz,W.K., Büsser,M-T. and Sagelsdorff,P. (1984) Potency of carcinogens derived from covalent DNA binding and stimulation of DNA synthesis in rat liver. *Toxicol. Pathol.*, 12, 106–111.
43. Parodi,S., Taningher,M. and Santi,L. (1983) Induction of preneoplastic nodules: quantitative predictivity of carcinogenicity. *Anticancer Res.*, 3, 393–400.
44. Aldridge,W.N. (1986) The biological basis and measurement of thresholds. *Ann. Rev. Pharmacol. Toxicol.*, 26, 39–58.
45. Moore,M.A., Nakagawa,K., Satoh,K., Ishikawa,T. and Sato,K. (1987) Single GST-P positive liver cells—putative initiated hepatocytes. *Carcinogenesis*, 8, 483–486.
46. Russell,J.J., Staffeldt,E.F., Wright,B.J., Prapuolenis,A., Carnes,B.A. and Peraino,C. (1987) Effects of rat strain, diet composition, and phenobarbital on hepatic γ-glutamyl transpeptidase histochemistry and on the induction of altered hepatocyte foci and hepatic tumors by diethylnitrosamine. *Cancer Res.*, 47, 1130–1134.
47. Klein-Szanto,A.J.P., Major,S.K. and Slaga,T.J. (1980) Induction of dark keratinocytes by 12-*O*-tetradecanoylphorbol-13-acetate and mezerein as an indicator of tumor promoting efficiency. *Carcinogenesis*, 1, 399–406.
48. Mori,H., Tanaka,T., Takahashi,M. and Williams,G.M. (1983) Exclusion of

cellular iron and reduced γ-glutamyl transpeptidase activity in rat pancreas acinar cell hyperplastic nodules and adenomas induced by azaserine. *Gann*, 74, 497–501.

49. Witschi,H.R. and Morse,C.C. (1983) Enhancement of lung tumor formation in mice by dietary butylated hydroxytoluene: dose–time relationships and cell kinetics. *J. Natl. Cancer Inst.*, 71, 859–866.
50. Ohshima,M. and Ward,J.M. (1986) Dietary iodine deficiency as a tumor promoter and carcinogen in male F344/NCr rats. *Cancer Res.*, 46, 877–883.
51. Hiasa,Y., Kitahori,Y., Ohshima,M., Fujita,T., Yuasa,T., Konishi,N. and Miyashiro,A. (1982) Promoting effects of phenobarbital and barbital on development of thyroid tumors in rats treated with *N*-bis(2-hydroxypropyl)nitrosamine. *Carcinogenesis*, 3, 1187–1190.
52. Yoshino,T., Motoi,M. and Ogawa,K. (1985) Immunohistochemical studies on cellular character of microtumors induced by ethylnitrosourea in the rat brain utilizing anti-leu 7 and anti-glial fibrillary acidic protein antibodies. *Acta Neuropathol.*, 66, 167–169.
53. Naito,M., Naito,Y. and Ito,A. (1982) Effect of phenobarbital on the development of tumors in mice treated neonatally with *N*-ethyl-*N*-nitrosurea. *Gann*, 73, 111–114.
54. Purnell,D.M. (1980) The relationship of terminal duct hyperplasia to mammary carcinoma in 7,12-dimethylbenz[a]anthracene-treated LEW/Mai rats. *Am. J. Pathol.*, 98, 311–324.
55. Dao,T.L. and Chan,P-C. (1983) Hormones and dietary fat as promoters in mammary carcinogenesis. *Environ. Health Perspect.*, 50, 219–225.

*Received on April 10, 1987; accepted on July 14, 1987.*

**Plastics News**

May 7, 2001
Bush's OIRA appointee Graham could lend clout to plastics

Steve Toloken
WASHINGTON -- One of the Bush administration's more obscure political appointments is shaping up to be one of the most important for the plastics industry.

John Graham, who runs a Harvard University center known for sharply questioning whether some environmental regulation is worth the cost, has been tapped to head the Office of Information and Regulatory Affairs, a wing of the Office of Management and Budget.

The job sounds boring and "inside the Beltway." But the office can wield tremendous behind-the-scenes power because it acts as gatekeeper of federal regulations ranging from air quality to ergonomics. It has the power to review them and block those it chooses to.

What worries environmental and public interest groups are Graham's close financial ties to the business community, including plastics and chemical companies. The Harvard Center for Risk Analysis, which Graham founded and directed until Bush nominated him, gets a significant part of its $3 million annual budget from plastics and chemical companies.

The center's donor list reads like a Who's Who of the chemical industry, albeit not updated to reflect recent mergers: the American Chemistry Council, the Chlorine Chemistry Council, Dow Chemical Co., DuPont, Geon Co., Amoco Corp., Exxon Corp., Mobil Corp., Millennium Chemicals Inc., Lyondell Chemical Co., Eastman Chemical Co. and Union Carbide Corp., among others. Earnest Deavenport, Eastman's chairman and chief executive officer, sits on the group's executive council, along with the president of the National Association of Manufacturers.

The center has done special projects for the Washington-based Society of the Plastics Industry Inc., has done work on dioxin issues and is finishing up a two-year, $500,000 study on styrene's health effects for the Styrene Information and Research Center in Arlington, Va.

Graham is very well thought of by industry.

"I think John Graham is one of the brightest and most incisive people in the country on regulatory matters," said Lewis Freeman, former chief federal lobbyist for SPI and now a government affairs consultant.

Freeman said the Bush administration intends to make OIRA more important than it was in the Clinton administration, elevating it to its intended status.

"They have a big stick if the president in office allows them to use it, and if they have someone in that office who knows how to use it," Freeman said.

Graham, whose academic training is in public policy, has said more risk analysis would have avoided problems like the unforeseen health risks from putting the additive MTBE in gasoline to make it cleaner. And he has said that toxic-pollution-control programs cost 146 times more than medical programs, when comparing lives saved.

But critics say Graham sometimes has taken extreme positions that are favorable to his funders, such as telling an Environmental Protection Agency meeting that low levels of dioxin protect against cancer.

"I feel like they lend an intellectual patina to an anti-regulatory agenda," said Laura MacCleery, a lawyer for the consumer group Public Citizen in Washington and author of a lengthy report on Graham.

Harvard Center spokesman David Ropeik said the center's critics have a different view of acceptable risk. Rather than debate, they try to attack him, he said.

"They are trying to impugn our credibility with the stereotype of all corporate money being evil and corrupting," Ropeik said. He noted that the center gets significant funding from government agencies like EPA and the Centers for Disease Control and Prevention.

However, he acknowledged that no environmental group gives money or sits on the group's board. The center's approach "is not one that is going to attract Greenpeace," Ropeik said.

MacCleery said Public Citizen's 130-page report on Graham lays out detailed, substantive objections and questions whether the center inflates industry costs and downplays public benefits of regulations.

In the case of the styrene risk assessment, SIRC paid the Harvard Center for the study but has been at arm's length since then, said Betsy Natz, SIRC executive director.

SIRC had no role in choosing the scientists and officials for the panel, and while the report is done, SIRC will not be told of its conclusions until it is peer-reviewed and published, she said.

SIRC did not establish any parameters or conditions on the study, she said. Ropeik echoed Natz's description of SIRC's role and said the center follows Harvard University rules on scientific independence.

"The idea was to find the most well-respected group we could to do an analysis on styrene," Natz said. "We've been out of the loop, which is the way it should be."

SIRC interviewed one other group about doing the study but chose Harvard because it was "by far the most well-respected," and SIRC wanted an independent review, she said.

## Examples of Graham and Harvard Center Findings Contrary to Interests of Industries that Donated Restricted Funds for a Specific Project

| Project | Graham/Harvard Center Findings | Industrial Donors of Restricted Funds Whose Interests Are Contrary to Harvard Center Findings |
|---|---|---|
| **Cancer Risk of Formaldehyde** | Harvard Center's risk assessment estimated the cancer risk of formaldehyde was twice as high as EPA's estimate. | Formaldehyde Institute<br>Risk Science Institute<br>American Industrial Health Council |
| **Cancer Risk of Chloroform** | Harvard Center's risk estimate was higher than EPA's. | Chemical Manufacturers Association |
| **Panel Review of National Cancer Institute's Agricultural Health Study** | Harvard Center concluded that the study of farmers exposed to agricultural chemicals held a lot of promise, should be expanded, and should be funded more by government and industry. | American Crop Protection Association |
| **Study of Using Diesel vs. Compressed Natural Gas in Transit Buses** | Harvard Center concluded there was no clear winner. | Navistar (diesel engine manufacturer) |

## What John Graham said on Dioxin:

"...it's possible that measures to reduce current average body burdens [of dioxin] further, could actually do more harm for public health than good."

*John Graham's statement to EPA's Science Advisory Board, November 1-2, 2000*

"I think there would be also merit in stating not only that TCDD *[dioxin]* is a carcinogen, but also I would put it in the category of likely anticarcinogen..."

*John Graham's statement to EPA's Science Advisory Board, November 1-2, 2000*

## What others have said:

Dioxin is a "known human carcinogen".

*National Institutes of Health/National Toxicology Program's Ninth Report on Carcinogens, January 19, 2001*

"...exposure to low levels of dioxins over long periods (or high level exposures at sensitive times) might result in reproductive or developmental effects. These could include weakened immune responses and behavior changes in offspring."

*EPA Questions and Answers About Dioxin, July 2000*

May 21, 2001

Honorable Joseph Lieberman
Senate Committee on Governmental Affairs
Washington, D.C. 20510

Dear Senator Lieberman:

At my confirmation hearing last Thursday, you expressed interest in my position on disclosure and transparency issues at the Office of Management and Budget - Office of Information and Regulatory Affairs. I am committed to continuing the progress toward transparency at OMB-OIRA that began with the "memo" written by OIRA Administrator Wendy Gramm in the 1980s and continued through the Bush and Clinton Administrations.

As I have familiarized myself with the various aspects of Executive Order 12866, I can assure you that I have no specific plans to change the transparency and disclosure provisions. Moreover, as I mentioned in my written response to your pre-hearing questions and as we discussed personally, I would like to see OMB-OIRA make greater use of the internet to disseminate information about OIRA's activities to the public.

Senator Lieberman, if confirmed, I promise to work openly and constructively to retain and improve the transparency of decision making within OIRA. I look forward to working with you and your colleagues to achieve this common goal. Please do not hesitate to contact me if you desire any additional information.

Sincerely,

John D. Graham

PHILIP MORRIS
MANAGEMENT CORP.
120 PARK AVENUE, NEW YORK, N.Y. 10017 · TELEPHONE (212) 880-5000

January 22, 1991

Dr. John D. Graham, Director
Center for Risk Analysis
Harvard School of Public Health
677 Huntington Avenue
Boston, MA 02115

Dear John:

Enclosed is a check in the amount of $25,000 payable to the Center for Risk Analysis, Harvard School of Public Health.

Philip Morris Companies Inc. welcomes this opportunity to contribute to your program.

Sincerely,

Mayada Logue

Mayada Logue, Scientist
Corporate Scientific Affairs

Returned 1/31/92

804-274-2921

Enclosure

PHILIP MORRIS MANAGEMENT CORP. 153959
120 PARK AVENUE, NEW YORK, NY 10017-5592 01/21/92 62-20/311

Citibank,Delaware : 1 Penn's Way New Castle, DE 19720

NET AMOUNT
PAY EXACTLY********25,000*DOLLARS AND 00 CENTS *********25,000.00**

TO THE ORDER OF
*HARVARD SCHOOL OF PUBLIC HEALTH
CENTER FOR RISK ANALYSIS
677 HUNTINGTON AVENUE
BOSTON, MA 02115

AUTHORIZED SIGNATURE

⑈153959⑈ ⑆031100209⑆ 388285160⑈

Harvard Center for Risk Analysis

January 31, 1992

[redacted]
Scientist
Corporate Scientific Affairs
Philip Morris Management Corporation
120 Park Avenue
New York, NY 10017

Dear Mayada,

As we discussed, I have enclosed the check Philip Morris recently sent to the Center. I appreciate your understanding of the situation and hope that some arrangement can be made with Kraft. Thank you for your help.

Sincerely,

John D. Graham, Ph.D.
Director
Center for Risk Analysis

Harvard School of Public Health • 677 Huntington Avenue • Boston, MA 02115
tel 617-432-4497 • fax 617-432-2494

Buyers Up • Congress Watch • Critical Mass • Health Research Group • Litigation Group
Joan Claybrook, President

May 22, 2001

The Honorable Fred Thompson
Chairman, Committee on Governmental Affairs
511 Dirksen Senate Office Building
Washington, DC 20510

Dear Mr. Chairman:

At the nomination hearing of John Graham on May 17, emphasis was placed on an April 13, 2001 letter from Michael Finkelstein supporting John Graham's candidacy as Director of OMB's Office of Information and Regulatory Affairs. Mr. Finkelstein, a former NHTSA regulatory official who has for many years been a member of Graham's Center for Risk Analysis advisory board, stated in his April 13 letter the following:

> "The reason that I feel compelled to write is that I discovered that a 1997 letter that I wrote was used by Public Citizen in their recent report criticizing Dr. Graham's nomination as head of OIRA. Frankly, I was very surprised to see Public Citizen use my letter to criticize Dr. Graham."

Mr. Finkelstein's letter of May 13, 1997 to John Graham concerned Graham's oral release to the national media and to an NTSB airbag hearing of findings based on a preliminary analysis of passenger side air bag effectiveness. Graham asserted to the media that he had changed his position from supporting such air bags to opposing them given the results of his unpublished study. Mr. Finkelstein in his April 13, 2001 letter to the Committee explains why he wrote the 1997 letter.

> "With respect to the specific issues surrounding that letter, in March of 1997, the National Transportation Safety Board (NTSB) held a public meeting on the subject of airbag injuries, particularly airbag injuries to children. Dr. Graham was completing an analysis of the cost-effectiveness of airbags and made a presentation of his preliminary findings at that meeting. Given the media interest in the subject and Dr. Graham's prominence as an expert on airbags, he also was interviewed on one of the national morning news shows. (Since the NTSB meeting was open to the public, it was clear that his findings were inevitably going to be covered by the media, whether or not he appeared on that morning's newscast.)

Ralph Nader, Founder
215 Pennsylvania Avenue SE • Washington, D.C. 20003 • (202) 546-4996 • FAX: (202) 547-7392

Printed on Recycled Paper

> I felt that his analysis was flawed, and given the publicity surrounding Dr. Graham's preliminary conclusions, I wrote him a very strong letter raising a number of technical problems that I had with his research. And in fact, during the peer review that his research received prior to its publication many months later, apparently a number of reviewers raised many of the same questions. . . .In fact, given the importance of the subject, Dr. Graham's presentation of his preliminary findings at the NTSB hearing was reasonable."

This April 13, 2001 letter does not convey the full measure of Mr. Finkelstein's concern as laid out in his May 13, 1997 letter. Mr. Finkelstein stated in the May 13, 1997 letter

> "I was quite surprised when I attended the NTSB Public Forum and heard you release the results of your cost-effectiveness analysis before it had been subjected to any meaningful outside review. I was even more surprised when I was told that you had released those same findings on the Today Show that morning. . . . .
>
> I have a number of issues that I will address, but the most critical is the fact that you would release results claiming to address the cost-effectiveness of airbags by seating position when your own sensitivity analysis demonstrates that your findings cannot be supported. Had you selected more appropriate effectiveness estimates for both driver and passenger airbags, the cost of saving an additional year of life would have declined to the point where I expect that the value for passenger airbags would have been well within the range of values that are believed to be generally acceptable.
>
> The conceptual framework for the analysis seems appropriate. However, the application of a suitable methodology does not by itself validate the conclusions of an analysis. And in this case, your own research results should have raised so many questions that at a minimum, you would have delayed the release of your findings until they had been subject to peer review."

Mr. Finkelstein's complete letter of May 13, 1997 has already been submitted for the hearing record. Following these introductory comments, his letter contains a two page critique of all the mistakes in Mr. Graham's study. He concludes his letter with the following:

> "At the NTSB Public Forum, Ms. Judith Stone, the President of Advocates for Highway and Auto Safety, asked you the following question:
>
> > "The study which you are talking about today is still in draft form and has not been published, has not been peer reviewed, may not be cited, and is not available for review by other researchers. Is the public release of your study on national television an accepted practice in your profession?" (Transcript p767-8)
>
> Ms. Stone is a friend of long standing, but a friend with whom I disagree on many issues. And frankly, I found her question almost rude. I was sure that someone of

your standing would not release the findings of your research unless you were quite secure about the validity of those findings.

Having now had a chance to review the study, I owe Ms. Stone an apology. The findings are sufficiently uncertain that they should not have been released, certainly not before subjecting them to outside review.

I believe that debates on important issues need to be conducted in public. I also believe that the issue of airbag-induced injuries is just such an important issue that is now before the public. And I must commend the NTSB for convening a Public Forum that attempted to shed more light on this complex subject. But I do not think that your presentation at the NTSB Public Forum contributed to that goal."

As you can see, for whatever reason, Mr. Finkelstein's harsh critique of Graham on May 13, 1997 for releasing and publicizing an incomplete, misleading and undocumented "study" in 1997 is whitewashed in his April 13, 2001 letter supporting Graham, the nominated public official.

Also worthy of note is the fact that Graham appears to have made misleading comments in response to questions from the committee. He has indicated that he did not make available copies of his preliminary airbag study except to peer reviewers. Mr. Finkelstein was not asked to do a peer review. In fact, Mr. Finkelstein requested a copy of the preliminary study from HCRA and after reviewing it wrote his highly critical letter of May 13, 1997.

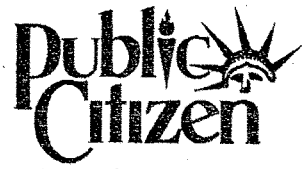
I hope this information clarifies the record of Dr. Graham's highly misleading actions in 1997 with regard to passenger side airbags at a time when they were very controversial and were the subject of pending regulatory action at the U.S. Department of Transportation.

Sincerely,

Joan

Joan Claybrook

enc.



Buyers Up • Congress Watch • Critical Mass • Health Research Group • Litigation Group
Joan Claybrook, President

May 22, 2001

The Honorable Fred Thompson
Chairman
Senate Governmental Affairs Committee
SD-340
Washington, D.C. 20510

Re: May 17, 2001 Hearing before the Senate Governmental Affairs Committee on the Nomination of John D. Graham for Office of Information and Regulatory Affairs Administrator

Dear Mr. Chairman:

An April 25, 2001 "Scholarly Response to Public Citizen" was prepared by "Supporters of John D. Graham, Ph.D.," and has been included in the hearing record. Unfortunately, Public Citizen was not given an opportunity to view this document and other documents in the record until May 17, 2001. However, we wish to briefly make several points in response to this document. We request that this document be included in the hearing record.

1. **All the authors are former employees of John Graham's.** The seven listed authors, who describe themselves as Professors at the Harvard School of Public Health, are all on the faculty of the Harvard Center for Risk Analysis (HCRA), which John Graham founded and, until recently, led (see attached). Only two of the nine members of the HCRA faculty are not listed as authors. We feel this fact should have been disclosed.

2. **HCRA's Conflict-of-Interest Policy Does Not Ensure Objective, Scientific Work.** All the attention paid to HCRA's policies for dealing with *restricted* grants misses the point. It is true that the peer review procedures that often accompany projects directly commissioned by restricted government or industry funding inject some amount of objectivity into the process. (The amount of objectivity depends upon the rigor of the peer review – for example, HCRA's "internal peer review" has been aptly described as an abuse of the term "peer review.")

Ralph Nader, Founder
215 Pennsylvania Avenue SE • Washington, D.C. 20003 • (202) 546-4996 • FAX: (202) 547-7392
Printed on Recycled Paper

However, forty-percent of HCRA's funding comes from *unrestricted* industry money. This funding does not necessarily go towards scholarly or scientific work. Much of it goes to produce short "policy pieces" and media work, intended to influence decision makers, the media and the general public. These "think tank" activities at HCRA are similar to activities undertaken by entities such as the CATO Institute and the Heritage Foundation.

An example of a study that was never subjected to rigorous peer review is a piece Graham co-authored with a graduate student that purported to show that 60,000 additional lives could be saved annually if the nation invested in more "cost-effective" programs [Tengs and Graham, "The Opportunity Costs of Haphazard Social Investments in Life-saving Programs," in Hahn (editor), Risks Costs and Lives Saved: Getting Better Results from Regulation, 1996]. This statistic has been used over and over again by Graham and others to show the need for regulatory "reform" legislation. For example, at a February 15, 1995 hearing before the Senate Governmental Affairs Committee, Graham stated:

> That leads me to the theme of smarter regulation. We could reallocate resources, save more lives, do more for the environment. And here I would like to quote my student, Tammy Tengs', recently graduated from Harvard and now on the Duke Medical School faculty. Her thesis did the following calculation. *She looked at 200 Federal programs covering 20 different Federal agencies.* She said if you could reallocate resources from the expensive ways of saving lives to the inexpensive ways of spending lives, we could save *60,000 lives per year* in this country at no increased cost to the tax-payer, at no increased cost to the private sector. Smarter regulation using risk analysis. [emphasis added]

In addition, on February 2, 1995, Graham testified at a joint hearing before two Subcommittees of the House Committee on Commerce that, "if we reallocated current Federal risk protection dollars from little threats to big threats we could save 600,000 life years per year at no greater cost to government or the private sector."

This year, a scholarly critique of this work was finally produced. In response to criticism made by Professor Lisa Heinzerling, of the Georgetown University Law Center, Graham has now acknowledged that some of the cost-ineffective "programs" he and Tengs considered were never approved by any government agency. In response to written, pre-hearing questions submitted by Senator Lieberman, Graham admitted that if "reallocations were allowed only within REGULATORY programs . . . the efficiency savings are much less than 60,000 lives." [emphasis in original]

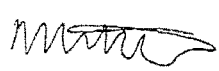
Thus the HCRA study -- never subjected to outside peer review -- that purported to show the need for regulatory "reform," and which has been cited dozens of times by the media and even Members of Congress as evidence that such "reform" is needed, has finally been revealed to be essentially meaningless as an indictment of the current regulatory state.

3. **John Graham's Work Generally Supports the Interests of the Industries that Help Fund It.** The document's authors list ten areas where HCRA has supposedly done work that was against the interest of at least some of its corporate benefactors. Note that the authors do not disagree with our claim that *most* of HCRA's policy recommendations are consistent with the interests of their industry funders. We unfortunately do not have time to examine each of the authors' ten claims in detail, and determine whether HCRA has completed substantive, positive work in each of the subject areas the authors identify, or whether in some cases HCRA's positions supporting regulations nevertheless foster interests of industry. However, we will refute one claim in this section of the document that is obviously misleading.

   The claim made on pages 9-10 of the document (item #6) that Graham supports the need to regulate particulate air pollution does not lend any support to Graham's candidacy, and, indeed, helps make the case against Graham's confirmation. The document claims that Graham's position is that particulate matter "should be regulated under a cost-benefit framework." Since this is a much less protective framework than exists under current law, we cannot see how this refutes Public Citizen's claim that HCRA's work generally favors its industry sponsors. The document also states that Graham thinks the case for stricter ozone rules "is much weaker." This position also favors HCRA's industry sponsors.

Sincerely,

Frank Clemente
Director
Public Citizen Congress Watch



Melissa Luttrell
Legislative Counsel
Public Citizen Congress Watch

# HCRA FACULTY

John D. Graham, Director

John Evans

George M. Gray

Sue Goldie

James Hammitt

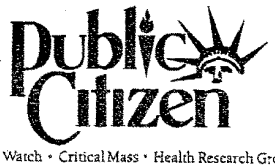
Karen Kuntz

Peter Neumann

Joseph Pliskin

Kimberly Thompson

Milton Weinstein




Buyers Up • Congress Watch • Critical Mass • Health Research Group • Litigation Group
Joan Claybrook, President

May 22, 2001

The Honorable Fred Thompson
Chairman
Senate Governmental Affairs Committee
SD-340
Washington, D.C. 20510

Dear Mr. Chairman:

Public Citizen submits the following statements for the record in response to remarks made by Senator Bennett at the May 17, 2001 hearing before the Senate Governmental Affairs Committee on the nomination of John Graham for the position of Office of Information and Regulatory Affairs Administrator.

**Public Citizen Funding**

In his opening remarks, Senator Bennett asked why Public Citizen does not disclose the sources of its funding. In fact, except for revealing the identities of its individual members, Public Citizen does publicly disclose all its funding sources.

Public Citizen -- unlike the Harvard Center for Risk Analysis, which John Graham founded and, until recently, led -- receives no money from corporations, trade associations, or the government. Public Citizen funding comes from the following sources: its 150,000 members, its publications, litigation fees awarded by courts to Public Citizen, bequests, foundations, and the "Buyers Up" heating oil program. Public Citizen voluntarily posts its IRS Forms 990 on its Internet site (www.citizen.org). In addition, every year Public Citizen voluntarily discloses a list of all foundation supporters and bequests in its annual report, which is published in Public Citizen News.

Public Citizen has received no direct support for its activities in opposition to the Graham nomination.

Ralph Nader, Founder
215 Pennsylvania Avenue SE • Washington, D.C. 20003 • (202) 546-4996 • FAX: (202) 547-7392
Printed on Recycled Paper

**Public Citizen's Reliance on NHTSA Estimates of the Risk of Raising Speed Limits**

Senator Bennett also stated that Public Citizen erroneously claimed that the number of deaths on the highway would greatly increase if Congress eliminated the federal 55 miles-per-hour and 65 miles-per-hour speed limits. The Public Citizen statements to which Senator Bennett referred were based on 1995 National Highway and Traffic Safety Administration (NHTSA) estimates of the number of deaths that could result if the federal speed limits were eliminated.

In fact, according to available data, Congress' 1995 action to repeal the national speed limit *has* cost lives. While Senator Bennett was correct in stating that the number of deaths per miles traveled has decreased since speed limits were raised, he was incorrect in concluding that this statistic tells us anything meaningful about the number of deaths caused by the repeal of the speed limit. Although the deaths caused by increases in speed limits have been statistically offset by gains resulting from increased seatbelt usage, tightened vehicle safety standards, and other improvements, these deaths are real.

Several studies have shown that more deaths are occurring on those roadways where the speed limits were raised as a result of Congress' 1995 action. For example, a 1998 Insurance Institute for Highway Safety study found an increase of 15% in deaths and 17% in the fatality rate on interstate highways and freeways where the speed limit was raised, translating to a total of between 450 and 500 additional deaths nationwide. NHTSA reported to Congress in 1998 that the new speed limit increases had already caused about 350 more deaths. By publicizing the official government estimates of increased deaths that would result if speed limits were raised, we believe Public Citizen and other safety groups positively influenced state decisions to voluntarily retain the 55 mile-per-hour speed limits on some roadways.

Sincerely,

Frank Clemente
Director
Public Citizen Congress Watch

cc: Sen. Joseph Lieberman, Ranking Democrat

**Statement of Joan Claybrook**
**On the Nomination of John Graham to the Office of Information and Regulatory Affairs**
**Office of Management and Budget**
**United States Senate Governmental Affairs Committee**
**Washington, D.C.**
**May 17, 2001**

Mr. Chairman and Members of the Committee:

I am pleased to offer this testimony for the record on the nomination of John Graham to the post of Administrator of the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB). I am President of Public Citizen, a national public interest organization with 150,000 members nationwide that represents consumer interests through lobbying, litigation, regulatory oversight, research and public education. Public Citizen recently authored a 130-page report on nominee John Graham, which details his decade of efforts on behalf of regulated industrial interests, which funded the organization that he headed at the Harvard School of Public Health. We oppose this nomination because of Graham's long record of crusades against health, safety and environmental safeguards. In this role, he would be responsible for overseeing the work of various regulatory agencies charged by law with protecting the public, including laws that he has disagreed with or fought to limit. If appointed, this would truly be a case of the fox guarding the hen-house.

We also wish to express our deep disagreement with Chairman Thompson's decision to prohibit witnesses at the hearing, other than the nominee. This very important and powerful post affects the public's daily life, and this Committee, we believe, should respect its obligation to air opposition points of view. Others who requested to testify and were denied the opportunity include Frank Mirer, of the International Union, United Automobile, Aerospace and Agricultural Implement Workers of America (UAW), Dr. Eric Chivian of Harvard Medical School, Dr. Philip Landrigan of Mount Sinai School of Medicine and Dr. Herbert Needleman, of the University of

Pittsburgh School of Medicine.

**The Potential for Misuse of Review Powers at OIRA**

The development of new regulatory safeguards by federal agencies requires skilled experts, scientists and professionals to conduct extensive studies, research and economic analyses. The federal agencies also conduct a formal notice and comment process, in which stakeholders, including members of the public and representatives of industry, submit written testimony and testify at public hearings. As a result, regulatory agencies sometimes take years to develop new rules.

A series of presidential executive orders has provided that all significant new rules are reviewed by OIRA. In theory, the OIRA director should serve as an honest broker, reviewing regulatory proposals from federal agencies and deferring to agency expertise on most technical and scientific matters. Federal safeguards on industrial chemicals, fuel economy standards, air and water pollution levels, tobacco regulation, implementation of a Patients' Bill of Rights, and virtually every other issue that is critical to human and environmental health fall under the office's purview.

The review power given to OIRA means that its Administrator can serve as a last-minute chokepoint on agency action and has, in the past, enabled anti-regulation political appointees and government economists to intervene in the regulatory process. In addition, under the Paperwork Reduction Act, no government agency can gather information from ten or more entities, a request which often is essential for the research that justifies regulation, without approval from OIRA. Through these mechanisms, OIRA can slow, stall, weaken or stop regulatory proposals and final rules that regulated industry opposes. For example, OIRA has sought to control the agencies' economic analyses so that the costs of a regulation appear greater and the benefits less; ordered

agencies to consider decisions on cost-benefit calculations even when prohibited to do so by Congress, which under the law put safety and public health first; and required agencies to reconsider data it had already disregarded as scientifically unhelpful or flawed.

Under the Reagan and Bush I administrations, OIRA was viewed as a "black hole," and many needed standards were revoked or delayed for long periods, altered to be less protective of the public, or blocked altogether. The office was the home of last resort for regulated industries: whenever an industry did not prevail in the public rulemaking process conducted by agency experts, it came through OIRA's back door to quash a rule. President Bush I created the Council on Competitiveness, the so-called "Quayle Council," headed by Vice President Dan Quayle, to work with OIRA in facilitating industries' anti-regulation objectives. During the Reagan years, Vice President Bush headed the "Task Force on Regulatory Relief," which played a similar role.

There is no doubt that business interests desire the same level of access that they had then to challenge and change regulatory agency decisions. The U.S. Chamber of Commerce told *The Washington Post* in February 2001 that it has drafted a presidential "executive order of its own that it hopes the new administration will use as a template for rewriting its policy on regulation."[1] The draft order lays out the process for "how rules should be reviewed, the role of the Office of Management and Budget, and the economic and scientific criteria that agencies should apply to rule-making."[2] "If you fix [OMB], you rein in all the agencies," Bruce Josten, the Chamber's executive vice president for government affairs, told the *Post*.[3]

Graham's first move at OIRA would likely be to draft a new executive order that could

---

[1] Cindy Skrzycki, "Lining Up to Lobby for Rule Recission," *The Washington Post*, Feb. 6, 2001.

[2] Id.

[3] Id.

immobilize the issuance of new health, safety and environmental safeguards. But Congress has never approved a sweeping regulatory reform bill that would harness every new, significant regulation to a cost-benefit or risk management straitjacket. In legislation and in mandates to the federal agencies, Congress has also repeatedly authorized many statutes, such as the Clean Air Act, which state that public health should be considered paramount when drafting the goals of protective regulation. Under the cover of a re-written executive order, Graham could attempt to undermine these mandates, and accomplish everything that business interests have thus far failed to do through a fair and open democratic process.

Graham is unfit to serve as the Administrator of OIRA, and wield this tremendous power, due to the many conflicts of interest that would plague his service, his history of conducting research that places anti-regulatory policy objectives before academic accuracy and integrity, and his often-stated goal of further enlarging the use of a set of already-suspect economic evaluation tools, tools that contain a bias towards industry and against public health. We are deeply concerned that, in defiance of both express and implicit directions from Congress, an unaccountable OIRA will be able to overturn years of investment by the public, stakeholders, scientific experts and the agencies, and that the OMB will once again become a "black hole" which swallows sorely needed health and safety regulations, turning laws made by Congress into mere paper promises.

**Objection One: Graham Has Deep Ties to Regulated Industries**

Over the past decade, the Harvard Center for Risk Analysis (HCRA) directed by Graham has received unrestricted funding from 100 major industrial corporations and corporate trade associations, including oil, energy, chemical, agribusiness, mining and auto interests, such as Monsanto, National Steel, Kraft Foods (a subsidiary of Philip Morris), Atlantic Richfield, Ford

Motor Company, Dow, 3M, DuPont, Exxon, the Chlorine Chemistry Council, the American Automobile Manufacturers Association, the American Petroleum Institute, the American Crop Protection Association, and the Chemical Manufacturers Association, now called the American Chemistry Council. A fuller list is appended to this testimony. Notably, unrestricted funding is not covered by his Center's conflict of interest policy, so the timing of these donations and the amount of money given to the Center remain a mystery to the public. Corporations also provide restricted funding for use in particular projects, such as the $300,000 from AT&T Wireless Communications that was noted in news reports as the basis for the Center's year 2000 study on the hazards of cellular phones and driving.

High-ranking executives from Oxford Oil, the National Association of Manufacturers, Eastman Chemical, Tenneco Incorporated, CK Witco Corporation, and Novartis Corporation serve on the Center's Executive Board. The Center's Advisory Council includes corporate officers from DuPont and the Grocery Manufacturers Association, and the chief attorney for environmental affairs at Exxon Chemical Americas.

Industry funders, which according to news reports comprise 60 percent of the Center's current annual budget, have seen their interests reflected in the Center's research, in Graham's work, and in his statements to the media and testimony to Congress. As the Public Citizen report, *Safeguards At Risk,* shows,[4] Graham's work at the Harvard Center for Risk Analysis has lent academic legitimacy to regulated industries' opposition to environmental, health and safety standards. Graham has consistently invoked the name of Harvard University and of the Harvard School of Public Health, while failing to mention that a majority of his Center's funding derives

[4] The full text of the report, published March 2001 and entitled *Safeguards At Risk: John Graham and Corporate America's Back Door to the Bush White House*, was submitted to the Senate Governmental Affairs Committee to be printed in the hearing record.

from industry sources. Corporations and industry trade associations have, predictably, been delighted to sponsor an advocate bearing the highly esteemed credentials of Harvard to serve as a mouthpiece for their opposition to potentially costly new rules.

Due to the long history of Graham's service to regulated interests, and his failures to identify relevant financial and other connections to corporate sponsors in his testimony before Congress, there is a special concern about the appearance of conflicts of interest in this case. Graham's record suggests that he may not be as sensitive to issues concerning a real or perceived conflict of interest as he should be as a public servant, and that concrete steps are needed to ensure that his longstanding relationships with regulated interests do not impede his service if he is confirmed. Our conflict of interest laws address perceived, as well as actual, conflicts as part of maintaining governmental integrity.

In addition, it should be made clear that the relationship between OMB and regulated industries is a matter for public scrutiny. There has been, in the past, a grave problem with the staff of OIRA and OMB conducting secret meetings and communications with industry representatives, outside the scope of agency transparency and accountability. Given the intense public interest in the operations of this office, and its enormous power over the regulatory process, Congress must remain vigilant, and, regardless of who occupies this office, must take whatever steps are necessary to maintain OMB's obligation to keep a valid, complete public record of its communications and to remain accountable to the public, Congress and government regulators.

**Objection Two: Graham Research and Advocacy Has Serviced His Industry Funders**

Recently, two separate letters from 74 academics – including 11 colleagues of Graham's from Harvard Medical School and the Harvard School of Public Health, which houses Graham's

Center – wrote to the Governmental Affairs Committee in opposition to the Graham nomination. Both letters raised concerns that Graham's industry-funded research has downplayed hazards faced by the public and triggered conflict-of-interest concerns, one suggesting that his work shows "a remarkable congruency with the interests of regulated industries." Serious questions have been raised about the conflicts involved in the positions advocated by Graham, the research underlying those positions and the links to corporate sponsorship of the Center's and his own research.

**Automobile Air Bags**

In March 1997, the National Highway Traffic Safety Administration was considering an auto industry proposal to amend the safety standards on air bags in order to allow a reduction in inflation power because of problems with particular models of passenger side air bags. Graham announced in news appearances and before the National Transportation Safety Board that a new, unpublished Center report had convinced him that passenger-side air bags were not cost effective enough to justify being mandated. His research, Graham suggested, showed that passenger-side air bags cost $399,000 for each year-of-life saved. After harsh criticism from auto safety advocates, Graham's data and conclusions were revised and peer-reviewed.

This resulted in a dramatic turnaround by Graham, published in the *Journal of the American Medical Association*, which showed that the cost of the same passenger-side air bags had been reduced to $61,000 for each year-of-life saved. Graham's new conclusion was that those air bags were a worthwhile investment by economic standards. Graham's Center has received unrestricted funding from the auto industry, but it is not known in what amount, and unrestricted funding is not covered by Graham's Center's conflict of interest policy.

**Tobacco Industry**

Graham solicited financial contributions from tobacco giant Philip Morris in the early 1990s as the company was fighting an international battle over the regulation of tobacco. Graham also invited Philip Morris officials to review a draft of a chapter on the subject of the Surgeon General's report on smoking. While Graham initially returned a check sent by Philip Morris, later that year money was given to Graham by Kraft Foods, a subsidiary of Philip Morris. According to *The Boston Globe*, the Harvard Center's spokesman, David Ropeik, "said Graham returned the January 1992 Philip Morris donation at the insistence of Harvey Fineberg, then dean of the public health school. The $20,000 check from Kraft General Foods followed that summer, which was noted in a Philip Morris internal memo with the comment 'I hope we can continue to work with and support Dr. Graham's work.' "[5]

**Cell Phones and Driver Distraction**

The Public Citizen report, *Safeguards at Risk*, shows that in July 2000, as many cities and states were considering outlawing the use of cell phones while driving, Graham published a study, funded by $300,000 from AT&T Wireless Communications, assessing the risks to drivers. The Center's self-published study, unsurprisingly, came out against a ban on using cellular phones while driving, concluding that such a ban *would be more costly than air bags* and that there was "not enough reliable information on which to base reasonable policy." The study was publicly criticized by one of its peer reviewers, Dr. Donald Redelmeier, who suggested that the study lacked rigor because it "provides no new data, gives no new expertise and provides no new analysis."[6] Redelmeier also told reporters that the "Harvard researchers left the report open to

---

[5] Anne Barnard, "Nominees Funding At Issue: Critics of Harvard Risk Analyst See Ties to Industry" *The Boston Globe*, Mar. 18, 2001.

[6] Jay Lindsay "Harvard Study Says Risks of Driving With Cell Phones Are Overstated," *Associated Press*, July 24, 2000.

conflict-of-interest questions because they didn't publish it in a scientific journal or take other steps to demonstrate the study's fairness."[7]

The ultimate conclusion of the cell phone study was that it was premature to enact a ban, thereby in effect placing the burden of proof on regulators to show that there is sufficient economic justification to act to protect human life. Because crash data on driver distraction was incomplete, yet the reductions in industry profits from a ban on cell phone use on driving were clear, the Center concluded in its monthly newsletter, *Risk In Perspective*, that nothing should be done to address the risks. In drawing such policy conclusions, the Center thus discarded the practical and policy implications of the common sense approach used by the communities considering legislation to prohibit the use of cell phones while driving. In contrast, a study by the National Highway Traffic Safety Administration on the same issue, while acknowledging that the data were incomplete, had concluded that using a cell phone while driving does increase the risk of a crash from driver distraction.[8]

**Dioxin**

Graham's public communications on risk issues that affect his funders have sometimes been misleading. A National Public Radio (NPR) story on dioxin last year reported that EPA scientists had determined that dioxin causes the average American "an *additional* lifetime risk of cancer as high as one in a hundred."[9] The story also indulged Graham's sleight-of-hand: " 'That

---

[7] "Drivers Not Risking Much on the Horn, Study Says," *The Providence Journal-Bulletin*, July 25, 2000 (emphasis added).

[8] See "Introduction" of study by the National Highway Traffic Safety Administration at <www.nhtsa.dot.gov/people/injury/research/wireless/#exec>.

[9] Noah Adams, "EPA Report on Dioxin is Released and Confirms a Cancer Risk Exists to All Americans," *All Things Considered,* National Public Radio, June 15, 2000.

would put dioxin *on par* with other common risks,' said Graham. 'The average American in their lifetime has about one chance in a hundred of dying in a car crash . . . So this type of risk they're talking about here, if true, would be a significant risk, but it would not be something that would be out of the norm of what people experience in daily life.' "[10]

The catch is that the risks demonstrated by the EPA are cumulative to existing risks, not merely "on par." Although Graham did not say so, these data reveal that members of the public may now have *both* a 1 percent chance of dying in a car crash *and* a 1 percent chance of contracting cancer from dioxin — for a 2 percent fatality rate. The NPR program also failed to mention that Graham has received funding from dioxin interests such as Dow, the Chlorine Chemistry Council, Du Pont, the American Chemistry Council, and a number of others.[11]

Notably, Graham's approach also fails to account for the non-cancer effects of dioxin that were not measured in that particular EPA study, or for the interactive effects that dioxin may have with other chemicals added to the environment. In addition, if, following Graham's advice, we merely compare the *magnitude* of one risk to another — 1 percent to 1 percent — and declare that a one in a hundred risk of dying from a particular hazard is "normal," what would stop the manufacturers of unsafe products and polluters from adding just one more "normal" risk? The more risky the world gets, the lower our benchmark of "normal" will go — into a downward spiral. This is a classic example of the kind of "race to the bottom" that our tradition of strong health and safety regulation is intended to prevent.

Graham's other work on dioxin has also attempted to "normalize" the risks posed by the chemical. Graham served as a consultant on the 1995 Science Advisory Board (SAB) Dioxin

---

[10] Id. (emphasis added).

[11] Listed on the HCRA Web site by its former name, the Chemical Manufacturers Association.

Reassessment Review Committee and until his recent resignation was a member of the current SAB Dioxin Reassessment Review Committee. In 2000, the Environmental Protection Agency (EPA) prepared a draft risk assessment that showed the public faces much higher risks of cancer and non-cancer health harms (infertility, immune system damage and learning disabilities) from dioxin, even at very low levels of exposure, than was previously understood. The EPA's risk assessment was based on more than 100 studies in animals and humans showing that dioxin caused cancer at low doses. More than 90 percent of dioxin exposure comes through the food we eat, and is particularly concentrated in fish, meat and dairy products.

At a meeting of the SAB in November 2000, citing only two limited, outlying studies, Graham claimed that low levels of dioxin may actually protect against cancer, suggesting that the studies showed that dioxin may be an "anti-carcinogen." Based on the transcript of the meeting, it appears that Graham argued that the SAB should ask EPA to revise its risk assessment on dioxin to include the following statement: "It is not clear whether further reductions in background body burdens of TCDD [dioxin] will cause a net reduction in cancer incidence, a net increase in cancer incidence, or have no net change in cancer incidence." If the EPA did adopt Graham's approach, its dioxin risk assessment might fail to provide a basis for federal regulators to ask companies to curtail dioxin emissions.

The *Washington Post* reported that at the November EPA SAB meeting, "[a]bout a third of the 21 panel members were scientists and scholars who have worked as paid consultants to the chemical industry. They included John D. Graham -- long a critic of the notion that dioxin and cancer are linked and founder of the industry-backed Harvard Center for Risk Analysis."[12]

---

[12] "Dioxin Report by EPA on Hold, Industries Oppose Finding of Cancer Link, Urge Delay," *The Washington Post*, April 12, 2001.

According to the Center for Health and Environmental Justice, Graham's Center has received financial support from at least 47 different dioxin producers, including incinerator companies, pulp and paper companies, cement kilns, copper smelters, PVC manufacturers, PCB producers, and the petroleum industry.

Despite the conflict of interest created by Graham's obligation to serve as an objective expert, as a consultant to the SAB, and his real or perceived obligations to HCRA's dozens of dioxin-producing supporters, Graham continued to participate in the SAB process as a vocal proponent for industry's position. Even when two scientists – Frederica Perera and Ellen Silbergeld – recused themselves from the SAB because of their close association with environmental organizations that were pushing for tighter controls of dioxin, Graham still failed to resign.[13]

**Pesticides**

OIRA will play a key role in reviewing any new pesticide regulations that the EPA may promulgate. But in August 1999 Graham's Center issued a biased and fundamentally flawed report[14] on implementation of the unanimously passed Food Quality Protection Act (FQPA). The study was funded by the American Farm Bureau Federation, which opposes restrictions on pesticides. The report, dubbed "The Truth from Harvard" by pesticide lobbyists, has been used to generate congressional support for rolling back FQPA's key public health provisions, which require that manufacturers prove that pesticides are safe for children and infants, yet its

---

[13] "Expert Panel Backs EPA Dioxin Study," *The Charleston Gazette*, October 1, 1995 (Perera, an environmental health sciences professor at the Columbia University School of Public Health, was a board member of the Natural Resources Defense Council. Silbergeld, an epidemiologist at the University of Maryland, was a former staffer for the Environmental Defense Fund).

[14] "Risk/Risk Tradeoffs in Pesticide Regulation: Evaluating the Public Health Effects of a Ban on Organophosphate and Carbamate Pesticides."

methodologies were severely biased and produced results suggesting that such regulation would be very costly for industry.

The report's most prominent flaws are the extreme and unwarranted assumptions that implementation of the FQPA would cause a catastrophic shortage of insecticides available to farmers and that the readily available alternative chemical and non-chemical pest control options would not be used to replace the banned pesticides. The authors assumed for the purposes of the study that EPA would ban all uses of all organophosphate (OP) and carbamate insecticides. This complete ban of more than 50 chemicals is far outside the scope of any action EPA has considered necessary to achieve the goals of the FQPA. The report's authors acknowledge this fact, but then base their analysis on what they concede is a false assumption. Researchers justified their decision on account of its "analytic virtue" (i.e., simplicity). The report's assertion that alternatives are too costly is not based on any analysis of actual costs and is simply not credible.

The truth is that pesticide prices and expenditures in the U.S. are falling across the board as dozens of new products have increased competition. There are many existing, proven alternatives to high risk insecticides. The pest control industry has been developing and introducing new products in response to FQPA's pressure to phase out older, high-risk chemicals. Ironically, the HCRA analysis ignores the effects of market-driven innovation. The study also ignores the progress made by farmers in adopting bio-intensive Integrated Pest Management, or a least-toxic approach.

**Objection Three: Graham Has Made Extensive Use of Faulty Methodologies**

If confirmed, Graham is expected to rely heavily on highly disputed cost-benefit calculations to determine when particular regulations are warranted. But there are numerous

problems with those methods in the regulatory context. The tools that Graham would be very likely to apply at OIRA should be viewed as severely limited in their usefulness to policymakers because cost-benefit analysis systematically short-changes public health and environmental goals and can easily be manipulated on behalf of industry opponents to regulation.

For example, OIRA sometimes uses the industries' own cost estimates, yet studies have shown that the industries' numbers are badly inflated, that companies often find highly cost-effective means of complying with regulations once they are implemented, and that many regulations may even stimulate productivity through the development of sustainable technologies.

The value of any cost-benefit analysis is also limited by the available scientific data — garbage in, garbage out. Because we don't have good numbers for diseases other than cancer, benefits such as a reduction in gastrointestinal or reproductive ailments are usually left out of these types of calculations altogether. Due to a near-exclusive focus on the number of human lives that are saved by a regulation, and the difficulty of deriving a definitive value for so-called "non-tangible" benefits, such as a view of the Grand Canyon, the practice of cost-benefit analysis also often fails to take these factors into account. Yet the focus of much protective environmental legislation is precisely to protect and preserve the value of a healthy ecosystem, or to minimize the effect of human activities upon animal life and habitat. In addition, many believe that translating the value of life into dollar amounts as a basis for societal decision-making is morally questionable, if not reprehensible. At the very least, rendering the impacts on human suffering and lives in monetary terms is out of touch with the public's notions of human value in ways that should matter to democratic decisionmakers.

Graham's agenda, has, over the years, closely tracked the interests, and potential

liabilities, of his corporate benefactors, and he has used various cost-benefit and other analytic techniques to accomplish their goals. For example, Graham has stated in testimony before Congress that virtually any hazard-related agency action should pass through a formal review by the White House. In his 1997 testimony, Graham advocated a sweeping requirement that would have imposed *upon all of the government's risk-related policies* a "peer review" by committees likely to be staffed with industry-friendly "experts" and an onerous, centralized clearance of both the protocols for the risk assessment and the risk assessment's end results through the White House Office of Science and Technology Policy. These red tape burdens would apply even if the agency were merely publicizing information on a hazard that had not been part of any formal rulemaking, such as a pronouncement by the Surgeon General on the risks of smoking.[15] In short, Graham proposed a near stranglehold on the government's ability to communicate public health information.

Graham has also repeatedly suggested that omnibus regulatory rollback legislation should be so sweeping that it over-rides existing agency mandates and *requires* cost-benefit and risk-benefit analysis before any safeguard can be issued.[16] In his over-reaching prescription, the results of a highly technical (and potentially manipulable) economic analysis, often based on severely limited or questionably accurate data, could determine the survival of a rule. In 1997, Graham said that all the agencies' "enabling statutes should be superseded by the general

---

[15] Testimony of John D. Graham before the Senate Committee on Governmental Affairs, Hearing on S. 981, "The Regulatory Improvement Act of 1997," Sept. 12, 1997.

[16] Testimony of John D. Graham, before the Senate Committee on Environment and Public Works, hearing on "Impacts of Regulatory Reform on Environmental Law," Mar. 22, 1995. The Harvard Group On Risk Management, led by Graham, proposed, among other things, authorization of a science advisor to assess and rank all risks addressed by federal agencies, requiring flexibility for industry to comply with rules, and devolvement of regulation to states and localities.

requirement that each rule's identified benefits must justify its identified costs."[17]

Graham has acknowledged that so-called "intangibles," i.e., equity, distributive or ethical goals, may allow a regulation that fails a strict cost-benefit analysis to be enacted by a regulator who is able to show a compelling reason for the rule outside the cost-benefit calculus.[18] But Graham's partial and somewhat begrudging solution fails to explain why regulators must re-justify an action which a congressional mandate, and the democratic process, have already more than fully authorized. Indeed, Graham's history of overlooking the natural limits of his discipline has offended other scholars of regulatory studies, political science, bio-ethics, moral philosophy, public health policy and other social sciences, as recently indicated in two separate letters opposing Graham's nomination that were sent to the Committee. As some of these scholars have argued in their published research and in their letters, allowing cost-benefit analysis the power to overcome agency mandates handed down from Congress is anti-democratic, and is an invitation for abuse by special interests that have a concentrated financial stake in the outcome of regulatory and other federal policy decisions.

A very similar proposal to Graham's, above, in relation to the role of cost-benefit analysis in protective regulation, was soundly rejected by a unanimous Supreme Court in a February 28, 2001 decision. The American Trucking Associations sued the EPA to block new requirements issued under the Clean Air Act.[19] Graham and other anti-regulatory economists, several from the

---

[17] Testimony of John D. Graham before the Senate Governmental Affairs Committee, Hearing on "The Role of Risk Analysis and Benefit-Cost Analysis In Regulatory Reform Legislation (S.291)," Feb. 15, 1995.

[18] Testimony of John D. Graham before the House Government Affairs Committee on Regulatory Revision, Feb. 15, 1995.

[19] American Trucking Associations, Inc., et al,. v. Whitman, Administrator of the EPA, No. 99-1257 (slip. op.) Feb. 27, 2001.

American Enterprise Institute-Brookings Joint Center for Regulatory Studies (AEI-Brookings), submitted a brief to the Court on the side of the trucking industry, arguing that requiring cost-benefit analysis would "improve regulatory decisionmaking."[20] Justice Scalia, writing for the full Court, disagreed, holding that neither the Clean Air Act nor the U.S. Constitution requires that corporate compliance costs be considered when EPA writes a clean air rule.

Graham also often argues that risks should be compared, for policymaking purposes, *with other risks.* In the parlance, this is called comparative risk analysis or risk-benefit analysis. Graham promoted this approach as a media strategy at a Heritage Foundation meeting in 1996, arguing that anti-regulation advocates would appear more environmentally friendly if they couched regulatory rollback arguments in efficiency terms.[21] In order to move an anti-regulatory agenda along more politically acceptable lines, Graham suggested that: "We ought to make the case that if these agencies were smarter and more scientific, we could reallocate resources, save more lives, and do more for the environment at no increased cost to the taxpayer. . . This basic principle of comparative risk, using our resources better, is one that I think we should force some [congressional] votes on — *not linked to congressional review of regulations, not linked to costs and benefits, just that specific issue of comparing risks.*"[22] In other words, because industry interests are not persuasive if they merely oppose all protective regulation, business interests should hone in on regulatory comparisons and suggest that regulators merely have the wrong

---

[20] Brief of Robert E. Litan, Counsel of Record for the AEI-Brookings Joint Center For Regulatory Studies, in the case American Trucking Associations, Inc., et al,. v. Carol M. Browner, Administrator of the EPA, On Writ of Certiorari To the United States Court of Appeals (for Cross Petitioners, the American Trucking Association).

[21] Making Regulatory Reform a Reality, *Heritage Foundation Reports: A Heritage Foundation Symposium; No. 559*, Jan. 31, 1996.

[22] Id. (emphasis added).

priorities.

In fact, Graham has made ample use of this technique in his comments to the media on risk issues. Graham has repeatedly endeavored to deflect attention from toxic chemicals such as pesticides, arguing that instead, regulators should focus upon such uncontroversial, "soft" social interventions as violence prevention and bicycle helmets for children. The news articles that contain such comments often fail to mention that many of the corporate sponsors of Graham's Center have a direct financial interest in the public health and regulatory decisions that are the topic of discussion. A list of Graham's recent comments in this regard, and the corporate sponsors related to the subjects at the center of the article, is appended to this testimony.

In 1996, according to news reports, Graham told political strategists at the Heritage Foundation that environmental regulation should be depicted as an "incredible intervention" in the operation of society.[23] He has also said that support for the regulation of chemicals in our water supply shows the public's affliction with "a syndrome of paranoia and neglect."[24] According to news reports, Graham explained to attendees at a conference at Duke University in 1996 that he believed that "government agencies should be required to depend on expert analyses, rather than public views, in deciding which threats to regulate."[25] Because it is well known in Graham's field of risk management that the public possesses a more cautious attitude about risks than do the so-called "risk experts," a suggestion that agencies should rely on experts alone reveals Graham's disdain for the concerns of the public, and his willingness to arrogantly

---

[23] "Risk-Expert Graham as Political Guru," *Air/Water Pollution Report's Environment Week*, Feb. 2, 1996 (emphasis added).

[24] John D. Graham, "Making Regulatory Reform a Reality," *Heritage Foundation Reports*, Jan. 31, 1996.

[25] "Excessive Reports of Health Risks Examined," *The Patriot Ledger*, Nov. 28, 1996, at 12.

dismiss the significance of risks faced by the public in the workplace, on the highway, and in their daily lives.

Another good example of the bias inherent in both cost-benefit analysis and comparative risk analysis, as they are currently practiced by OIRA, is the devaluing of future generations and the environment which is caused by inappropriately "discounting" the value of the future benefits of regulation. This occurs when the value of goods received in the future are reduced to an estimate of their "present value." If, as Graham has proposed, reviewers give cost-benefit analysis and comparative risk analysis substantially more weight in the regulatory process, this highly technical aspect of the process alone will systematically skew regulatory decisions in favor of regulated industries, and against protecting future generations and the environment.

The practice of "discounting" is perhaps most easily explained by reference to the present and future value of money. In financial terms, it is correct that receiving $1,000 today is worth more than receiving $1,000 in ten years because the $1,000 received today can be invested, and thus would be expected to be worth more ten years from now. It is thus a financial truism that money received in the future is worth less than the same amount of money received today, and this fact requires an adjustment in the estimate of that sum's value in the present.

However, it is not necessarily true that *non-monetary* benefits, such as health, safety, and environmental benefits, are worth less tomorrow than if they were immediate. Discounting the value of future health, safety and environmental benefits, which cannot be invested, at the same rate used to discount money is illogical because such benefits do not become less valuable over time, the way that money does. The practice also makes regulations with long-range benefits appear to be far less beneficial than they actually are. By discounting health, safety and environmental benefits received in the future, we underestimate their true value to society. Such

a system will therefore produce policy decisions that are fundamentally out of step with our support for environmentally sound regulation and with Congress' expressed desire, in legislative mandates to the federal regulatory agencies, to preserve the earth for our children and future generations.

Discounting can have an enormous effect upon whether a rule appears sensible or ridiculous. For example, because there is typically a 30- to 40-year lag time between exposure to a harmful substance such as asbestos and a person's resulting death from cancer, in "discounting" a life saved 40 years from now is calculated as a mere fraction of that person's present value. Moreover, the higher the discount rate that is used, the greater is the bias against protecting future generations and the environment.

Although experts disagree over whether health, safety, and environmental outcomes may properly be discounted, among academic economists who do support discounting such benefits, the consensus is to use the so-called "social rate of time preference," estimated to be a real rate of approximately three percent.[26] However, the agencies are currently advised by an OMB circular to discount all goods at a rate of seven percent, which represents the "opportunity cost of capital," or the rate that money could likely earn if invested. That means that benefits that become evident in thirty years – including lives saved by regulations – are considered to be worth 87 percent less than they would be worth today.

An example of how the choice of discount rate can affect cost-benefit results is a 1996 Housing and Urban Development (HUD) regulation of lead-based paint.[27] This regulation was

---

[26] Richard O. Zerbe, Benefit-Cost Analysis in Theory and Practice 281, 287 (1994).

[27] Comment: Judicial Review of Discount Rates Used in Regulatory Cost Benefit Analysis, 65 U. Chi L. Rev. 1333, 1337 (1998) (citing 61 FR 29170 (1996)).

estimated by the agency to have net benefits of $1,080.2 million when a three percent discount rate was used, even though it showed net benefits of only $39 million at a seven percent rate. As agencies are pressured by OIRA to identify the most "cost-effective" regulatory option, or the option with greatest "net benefits," the discount rate that is used could determine which regulatory option survives.

Although OIRA currently recommends a seven percent discount rate to the executive agencies, in practice the agencies have had some freedom to use lower discount rates to assess benefits in certain cases. It is crucial that the agencies retain this freedom. Forcing agencies to use five or seven percent rates to assess the values of latent harms could actually prevent those harms from ever being regulated. However, because Graham favors greater OMB control and uniformity in agency analyses, he is unlikely to permit agencies to choose lower discount rates.

Even when it is properly applied, cost-benefit analysis is controversial enough, but Graham also has a history of *misapplying* the conclusions of his own cost-benefit analyses. In testimony recently submitted to the Senate Governmental Affairs Committee, Professor Lisa Heinzerling at Georgetown University School of Law completely debunks Graham's most renowned scholarly work — an article that claimed his analysis of life-saving programs, completed with a graduate student, showed that every year 60,000 people die because the nation has chosen less cost-effective programs. Heinzerling establishes in her testimony that many of the cost-ineffective "programs" Graham considered were never implemented by any government body.

Heinzerling also establishes that Graham has perpetuated and encouraged a misinterpretation of his own research data, one that wrongly concludes that Graham's data show that actual federal regulations result in the "statistical murder" of 60,000 Americans every year.

This is a misleading overstatement of the results of his studies, which in fact covered proposed but unimplemented programs, as well as medical interventions, which are not typically part of a federal program at all. As *Safeguards At Risk* further explains, Graham's "statistical murder" hypothesis requires that money saved by regulation be available for other government programs, yet compliance costs "saved" through the de-regulation of the environment or a diminution in health or safety standards lines the pockets of company shareholders, rather than the government's or the public's at large. This bit of misinformation has become legend among opponents of regulation and has been repeated dozens of times by the media, anti-regulation analysts, and even by several Members of Congress. Graham's mischaracterizations of his results in this manner are a serious blemish on his reputation as a scholar.

It is extremely important that someone nominated to a position with oversight of the regulatory process has demonstrated sensitivity to the many difficulties that plague the application of economic analysis in the regulatory setting. As I noted in testimony before Congress that appears in a 1980 Congressional Report on cost-benefit analysis, there are many serious problems faced by regulators in trying to quantify the costs and benefits of regulation:[28]

> We attempt to quantify the life saving potential of our regulations, but imperfect data makes it impossible for us to assess all of the benefits ranging from the saving of lives, reduction of trauma, the maintenance of family relationships, the achievement of employment goals, the reduced cost for state and local governments in emergency medical services, police traffic services, hospital care, rehabilitation, unemployment and welfare, continuing medication, special transportation services, and so on. . . .
>
> Even when we can quantify benefits we are mainly able to do so in terms of fatalities avoided but much less so the reduction in injuries. We are faced with judgmental decisions in comparing the cost with the benefits. How much should consumers or automobile manufacturers spend to save a child's life? Regulatory analysis will never be able answer such a philosophical question.

---

[28] Statement of Joan Claybrook, "Cost-Benefit Analysis: Wonder Tool or Mirage?" Report by the Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce, United States House of Representatives, December 1980.

> Just as important are the effects which can never be quantified, pain, suffering, crushed dreams, guilt. How do we place a value on a victim never being able to walk, what number do we pick to represent the inability to purchase that home the victim otherwise could have afforded, how much should society spend so as to avoid a mother's grief because one of the thousand little children killed in auto accidents each year was hers?
>
> Cost benefit analysis will never be able to reduce these intangible foregone opportunities to a simple numerical ration, and ignoring them in our decisionmaking simply because we cannot quantify them would be an abrogation of our responsibilities under the statutes which govern our program.

**Conclusion**

For more than a decade, John Graham has been at the nexus of a corporate public relations effort intended to undercut the ability of federal agencies to enact new public and environmental safeguards. As Public Citizen's *Safeguards at Risk* report documents, Graham has devoted years to discrediting government regulators and shooting down safety and environmental standards through the use of economic pseudo-science.

Given Graham's past work and close collaboration with regulated industries, his appointment to OIRA would give industry a back door to the White House, enabling the Bush administration to block, delay or diminish new regulatory initiatives under the misleading pretense that they fail on cost-benefit or so-called "sound science" grounds. In ways the public and Congress may never know, the appointment of John Graham to this powerful office within the OMB could dramatically diminish the quality of the air we breathe, the wholesomeness of the food we eat and the safety of the cars we drive.

The members of the Senate Governmental Affairs Committee should not approve the nomination of John Graham to the Office of Information and Regulatory Affairs in the Office of Management and Budget.

Clarfield

96th Congress 2d Session } COMMITTEE PRINT { COMMITTEE PRINT 96-IFC 62

# COST-BENEFIT ANALYSIS: WONDER TOOL OR MIRAGE?

REPORT

together with

MINORITY VIEWS

BY THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES

DECEMBER 1980

U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON : 1980

70-240 O

a strict cost-benefit requirement, it could not compel reductions in the emission of arsenic, if the cost to the firm exceeded $4,450 a year. In cases where benefits did not accrue until after long period of time, the application of large "social discount rates" can reduce the present value of those benefits to relatively negligible figures. Thus, the use of traditional discount factors inherently biases such cost-benefit ratios downward.

Even the propriety of applying rates of discount to most types of benefits is open to serious challenge. This is essentially a question of equity over time. Is the monetary value of preventing severe birth defects 20 years in the future any less than preventing them now? Or consider the case of preventing irreparable harm done to the environment. Is a usable environment worth less to future generations than it is to us in the present?

Even from the cost side, the application of a traditional discount rate may not be desirable. A regulatory action may spur research efforts in the affected industry which result in the development of lower cost substitutes or more efficient production processes. This may be happening in the field of hazardous waste disposal where efforts are underway in a number of industries to find cost-effective ways to recycle waste or use it in the generation of power. In such cases an "enhancement" rate might well be applied to future costs which would offset the total cost of the regulation. Viewed another way, the application of an enhancement rate to the benefit side of the equation may well offset the discount rate and thus the "benefits" of the regulation may increase rather than decrease as time passed.

### E. CONCLUSION

Perhaps Joan Claybrook, Administrator of the National Highway Traffic Safety Administration, best summarized many of the problems faced by regulators in trying to quantify the benefits of a particular proposal when she testified at the Subcommittee's hearings as follows:

> We attempt to quantify the life saving potential of our regulations, but imperfect data makes it impossible for us to assess all of the benefits ranging from the saving of lives, reduction of trauma, the maintenance of family relationships, the achievement of employment goals, the reduced cost for state and local governments in emergency medical services, police traffic services, hospital care, rehabilitation, unemployment and welfare, continuing medication, special transportation services, and so on.
>
> Our crash avoidance standards also pose particular problems. Who would argue that vehicle safety would not be improved if cars could stop from a given speed in 100 feet instead of the present 200 feet? Yet, without detail data on the speeds, breaking distances, tire and roadway traction capabilities and more, of every vehicle involved in every accident, data which obviously does not exist, we are unable to precisely quantify the safety benefits of such actions, but in cases such as these we must pay attention to our common sense and rise above attempts to reduce to the simplest terms—numbers—very complex problems.



> Even when we can quantify benefits we are mainly able to do so in terms of fatalities avoided but much less so the reduction in injuries. We are faced with judgmental decisions in comparing the cost with the benefits. How much should consumers or automobile manufacturers spend to save a child's life? Regulatory analysis will never be able to answer such a philosophical question.
>
> Just as important are the effects which can never be quantified, pain, suffering, crushed dreams, guilt. How do we place a value on a victim never being able to walk, what number do we pick to represent the inability to purchase that home the victim could otherwise have afforded, how much should society spend so as to avoid a mother's grief because one of the thousand little children killed in auto accidents each year was hers?
>
> Cost benefit analysis will never be able to reduce these intangible foregone opportunities to a simple numerical ratio and ignoring them in our decisionmaking simply because we cannot quantify them would be an abrogation of our responsibilities under the statutes which govern our program.[54]

### F. THE QUESTION OF EQUITY: WHO THE NUMBERS SHALL BE

Experts with otherwise diverse viewpoints on the applicability of cost-benefit analysis concur that the most serious theoretical limitation of the tool in any of its forms is that it is incapable of dealing with the question of equity "the fairness implication of the fact that cost and benefits are often borne by different groups of people and firms."[55]

Dr. Weidenbaum, a vocal advocate of the use of cost-benefit and related analyses in decisionmaking, acknowledges that such analyses are only "capable of representing efficiency considerations. . . ."[56] He goes on to suggest that

> the subsequent decisions of elected officials and their appointees might be envisioned as representing society's evaluations of the equity effects of regulatory actions. Economists can provide these decisionmakers with information via benefit-cost analysis and studies of the distribution of the benefits and the costs of regulations, leaving the final decision to society's representatives.[57]

The Subcommittee agrees that the equity considerations involved in regulatory decisions are essentially political in nature. However, Dr. Weidenbaum's view that the current regulatory framework promotes the interest of small groups of politically organized beneficiaries at the expense of the larger consumer interests in society, is totally misguided.

In his testimony, Dr. Weidenbaum articulated this point as follows

> In the final analysis, however, the political factors in regulatory decisionmaking cannot be ignored. Many social regulations involve a transfer of economic resources from a

[54] Testimony of Ms. Claybrook, September 30, 1980, at pp. 40-41 of the transcript.
[55] Testimony of Dr. Nicholas Ashford, Joint Hearings, at p. 71.
[56] Ibid, at p. 849.
[57] Idem.

## A Comparison of Graham's Risk Tradeoffs and the Corporations That Fund the Harvard Center for Risk Analysis

| Source, date, and title of news article | Regulatory subject/s discussed in the article | The regulatory programs that Graham recommends instead | Sources of HCRA funding relevant to the article's subject | Disclosure of any of Graham's funding sources? |
|---|---|---|---|---|
| Dolores Kong, "Scientists Warn Against Panic Over Electromagnetic Field Effect,"*The Boston Globe*, Nov. 13, 1992. | Electromagnetic fields (EMFs) and child leukemia. The article also mentions studies that have suggested a link between EMFs and brain tumors and leukemia from cell phones, electric blankets, television and hair dryers.<br><br>The article discussed new Swedish research indicating that children who live near high-voltage power transmission lines had 4 times the normal risk for leukemia. | Bicycle helmets, poisoning prevention, and immunization<br><br>The article quotes Graham as saying that "the highest priority for our children should be preventing the known risks before we become paralyzed by speculation. So let's get on with bicycle helmets, poisoning prevention, and immunizations." The article also states that "in the spectrum of risk, getting cancer from electromagnetic fields would be slim, even if a connection were proven, say scientists." [This is because childhood cancer is rare in general— an observation which does nothing to counter the prospect of *additional* risks posed by EMFs.] | Carolina Power and Light, Charles G. Koch Foundation, Edison Electric Institute, Electric Power Research Institute, New England Power Service, New England Electric System, Union Carbide Foundation, Westinghouse Electric Corporation, Emerson Electric, General Electric Fund | **No Disclosure** |
| Child Health Alert, Inc., "More Worrisone News About Electromagnetic Fields," *Child Health Alert*, Dec. 1992. | Electromagnetic fields<br><br>According to this article, the Swedish EMF findings "produced anxiety ranging from caution to outright panic among those who care for children." | Preventable accidents, poisonings<br><br>The article states, "Another perspective, and one we've shared for some time, is provided by Dr. John Graham of the Harvard School of Public Health . . . he notes that compared to the number of children who die from preventable accidents and poisonings, leukemia claims far fewer lives," and quotes Graham as above in *The Boston Globe*. | Carolina Power and Light, Charles G. Koch Foundation, Edison Electric Institute, Electric Power Research Institute, New England Power Service, New England Electric System, Union Carbide Foundation, Westinghouse Electric Corporation, Emerson Electric, General Electric Fund | **No Disclosure** |
| J. Madeleine Nash, "Keeping Cool About Risk," *Time*, Sept. 19, 1994. | Dioxin and Alar (a pesticide), radon, asbestos<br><br>**Not mentioned in the article**:<br>The 1994 EPA draft Reassessment had concluded that dioxin was an extraordinarily potent environmental hormone, caused a wide variety of toxic effects, and that background exposures may already be causing health effects. | Vaccinations, bicycle helmets<br><br>The article quotes Graham, "Phantom risks and real risks compete not only for our resources but also for our attention . . . It's a shame when a mother worries about toxic chemicals, and yet her kids are running around unvaccinated and without bicycle helmets." | Dow (the leading producer of dioxin), Chlorine Chemistry Council, CIBA-Geigy, General Electric, DuPont, Georgia-Pacific, Hoescht-Celanese, ICI Americas, Kodak, Monsanto, Olin, BASF, ARCO Chemical Co,, FBC Chemical Corp., 3M<br><br>**See below in chart for a complete list of dioxin producing companies that fund HCRA.** | **No Disclosure**<br>In fact, Graham was actively and directly critical of the EPA's report during his presentations to the EPA's Reassessment Science Advisory Board.[1] And a month prior he had organized a high-profile conference on drinking water and health risks financed by the Chemical Manufacturer's Assoc. and the Chlorine Chemistry Council.[2] |

| Source, date, and title of article | Regulatory subject/s discussed in the article | The regulatory programs that Graham recommends instead | Sources of HCRA funding relevant to the article's subject | Disclosure of any of Graham's funding sources? |
|---|---|---|---|---|
| Patricia Braus, "Everyday Fears,"*American Demographics*, Dec. 1994. | Benzene and agricultural pesticides<br><br>Discusses the general topic of risk, and "misconceptions" about risk, from the perspective that expert risk assessment should guide public policy. | Vaccinations, bicycle helmets, trauma centers<br><br>To quote: "Harvard's John Graham criticizes what he calls excessive regulation of industrial substances such as benzene and certain agricultural pesticides. He believes that more lives would be saved if regulators increased funding for trauma facilities that help victims of traffic accidents and violent crime. He also favors vaccination, expanded use of bicycle helmets, and other preventive actions that benefit those who have the most living to lose — children." | American Petroleum Institute, Amoco Corporation, ARCO, Ashland Inc., Foundation, BASF, BP America, Inc., Chevron Research and Technology Company, CITGO Petroleum Corporation, Exxon, Mobil Foundation, Inc., Oxford Oil, Oxygenated Fuels Association, Shell Oil Company Foundation, Unocal | **No Disclosure** |
| Curt Suplee, "Assessing the Risk in Contract's 'Cost-Benefit' Curb on Regulations," *Washington Post*, Feb. 28, 1995. | Benzene in outdoor air, pesticides, fuel economy standards.<br><br>The article was about the proposed risk assessment "regulatory reform" bill in general. | Community violence reduction, lead paint from old homes, increasing preventive health services — *and airline safety*<br><br>In response to an EPA rule concerning a one in a million *additional* chance of getting cancer from pesticides, Graham argued that "a baby born today, at current mortality rates, incurs a risk of four in a million of being struck and killed on the ground by a crashing airplane." | American Petroleum Institute, Amoco Corporation, ARCO, Ashland Inc., Foundation, BASF, BP America, Inc., Chevron Research and Technology Company, CITGO Petroleum Corporation, Exxon, Mobil Foundation, Inc., Oxford Oil, Oxygenated Fuels Association, Shell Oil Company Foundation, Unocal | **No Disclosure** |
| Emily T. Smith, "Voodoo Regulation?" *Business Week*, Mar. 13, 1995. | Benzene, environmental regulation in general.<br><br>The article discussed whether risk assessment-based regulatory "reform" should be enacted. | Screenings for breast and cervical cancer<br><br>"This country, says Graham, "is paranoid and neglectful about risk at the same time."Graham also said on the regulatory rollback bill:<br>"We need a bill if we want to improve risk assessment . . .it will force the bureaucracy and private sector to improve the process." | American Petroleum Institute, Amoco Corporation, ARCO, Ashland Inc., Foundation, BASF, BP America, Inc., Chevron Research and Technology Company, CITGO Petroleum Corporation, Exxon, Mobil Foundation, Inc., Oxford Oil, Oxygenated Fuels Association, Shell Oil Company Foundation, Unocal | **No Disclosure** |
| "Science Advisory Board Questions Major Parts of EPA Dioxin Report," Air Water Pollution Report, May 22, 1995. | Dioxin.<br><br>The subject was the Science Advisory Board's response to EPA's 1994 draft risk assessment on dioxin. | Graham generally criticized the EPA's findings: "The report overstates the carcinogenic risks that dioxins and related compounds may pose and fails to seriously analyze uncertainties about these chemicals and to show how incremental changes in exposure could affect health, said John Graham." | Philip Morris documents specifically suggested that the EPA's approach to risk assessment in areas other than tobacco and second-hand smoke should be criticized. Graham has received money from Kraft, a Philip Morris subsidiary.<br><br>**HCRA is funded by 48 dioxin producers. See below.** | **No disclosure** |

| Source, date, and title of article | Regulatory subject/s discussed in the article | The regulatory programs that Graham recommends instead | Sources of HCRA funding relevant to the article's subject | Disclosure of any of Graham's funding sources? |
|---|---|---|---|---|
| Stuart Anderson ("policy director" of the Alexis De Tocqueville Institute), "Measuring the Cost of Regulation: How To Save More Lives For the Money," *The San Diego Tribune*, Oct. 1, 1995. | Fuel economy standards | Graham suggests that fuel economy standards have resulted in smaller cars are less safe. | Amoco Corp., American Petroleum Institute, Bethlehem Steel Corp., BP America, Chevron, CITGO Petroleum, Exxon, Ford Motor Co., GM, Mobil, Oxford Oil, Oxygenated Fuels Assoc., Shell Oil, Texaco, Union Carbide, Unocal, Automobile Manufacturers Assoc. | **No disclosure** |
| David Lore, "Determining Toxic Risks is Costly Voodoo, Lawyer Says," *The Columbus Dispatch*, Nov. 24, 1995. | Toxin control rules (chemicals) | Health care and injury prevention<br><br>Graham says, "The failure to compare the costs of toxin control rules to rules on health care and injury prevention and to allocate resources based on those comparisons is resulting in 'statistical murder.'" | Dow, DuPont, American Chemistry Council., Millenium Chemical Co., Monsanto, Atlantic Richfield Corp., ARCO Chemical Co., FBC Chemical Corp., Eastman Chemical Co., Louisiana Chemical Co., Air Products and Chemicals, Inc. Chlorine Chemistry Council, Rohm and Haas Co., and many others. | **No disclosure** |
| Scott Allen, "US Accepts $129 M for Cleanup of Love Canal; Some Say Set a Wrong Course," *The Boston Globe*, Dec. 22, 1995. | Superfund cleanup of Love Canal paid for by Occidental Chemical Corp.<br><br>20,000 tons of chemicals were dumped into Love Canal in Niagara Falls, NY from 1942 to 1953. | Violence prevention and pregnancy prevention.<br><br>"'Does it really make sense to spend, say $50 million on speculative risks when you don't have the resources to provide violence prevention or pregnancy prevention in the schools?' asks John Graham . . . Graham said his review of more than 100 Superfund cases found 'a basic reluctance to apply basic principles of cost-benefit analysis.'" | Graham generally attacked the Superfund program, which affects many funders. Specifically, according to its Web site, Occidental's partners in its petrochemicals operations are Lyondell Chemical Co. and Millenium Chemicals. Both are donors to HCRA. | **No disclosure** |
| Rick Weiss & Gary Lee, "Pollution's Effect on Human Hormones," *The Washington Post*, Mar. 31, 1996. | Endocrine disruptors, DDT, PCBs, DDE, pesticides, dioxin (also mentions electromagnetic fields and global warming)<br><br>The article described reactions to the publication of *Our Stolen Future*, a book on endocrine disruptors, which detailed the evidence that they may cause reproductive problems, childhood hyperactivity and a decline in global intelligence. | "'True or not, the idea that chemicals are wreaking havoc with our reproductive systems has all the elements needed to provoke a public panic,'said John Graham."<br>A quote from Graham also ended the article: "'We are just beginning to understand why we are so paranoid about some risks and tragically neglectful of others,' [Graham] said. 'But in the final analysis, it often comes down to, Who do we trust? *And that makes risk management very difficult these days, because people aren't inclined to trust anyone.*'" | **American Crop Protection Association, American Chemistry Council (formerly the Chemical Manufacturers Association), Chlorine Chemistry Council**, Dow (the leading producer of dioxin), CIBA-Geigy, General Electric, DuPont, Georgia-Pacific, Hoescht-Celanese, ICI Americas, Kodak, Monsanto, Olin, Kraft Foods, Frito-Lay, PepsiCo Inc., Coca-cola, DowElanco, Grocery Manufacturers of America, International Paper, National Food Processors Association | **No disclosure**<br>The article also described the chemical industry's proactive plans to "counterattack against the issue of endocrine disruptors" in anticipation of the book's publication: "Among those in the huddle were the **Chemical Manufacturers Association, the Chlorine Chemistry Council . . . and the American Crop Protection Association.**" |

| Source, date, and title of article | Regulatory subject/s discussed in the article | The regulatory programs that Graham recommends instead | Sources of HCRA funding relevant to the article's subject | Disclosure of any of Graham's funding sources? |
|---|---|---|---|---|
| John Graham, "There's a Deadly Confusion About Health Risks,"*The Houston Chronicle*, Nov. 29, 1996. | Electro-magnetic fields (EMFs), silicone breast implants, Superfund and abandoned industrial waste sites, cancer | Bicycle helmets, injury prevention (accidental crashes and falls), lead in peeling paint [removal is mostly the responsibility of individual landowners], firearm violence, encouraging regular physical exercise | On EMFs only: Edison Electric Institute, General Electric, Electric Power Research Institute, Emerson Electric, New England Power Service, England Electric System | **No disclosure--**<br><br>Note that Graham is the author |
| Steve Schenck, "The Chemical Flood," *Alt HealthWatch*, Oct. 1996. | Endocrine disruptors, including dioxin, and cosmetics, DDT, PCBs, Bisphenol-A (used in canned foods and dental sealants), Phthalates (plastics), estrogen pills, hormone replacement therapy | Said Graham, "'We are just beginning to understand why we are so paranoid about some risks and tragically neglectful of others,' [Graham] said. 'But in the final analysis, it often comes down to, Who do we trust? And that makes risk management very difficult these days, because people aren't inclined to trust anyone.'" | Dioxin-Producing Companies:[3]<br>Air Products and Chemicals Inc., Eastman Kodak Company, WMX Technologies Inc., Fort James International Paper, The James River Corporation Foundation, Mead Corporation, Potlatch Corporation, Westvaco Corporation, Boise Cascade, Georgia Pacific, Asarco Inc., Bethlehem Steel, Inland Steel, National Steel Nippon Yakin Kogyo, Alcoa Foundation, Reynolds Metals Company Foundation, Cement Kiln Recycling Coalition, American Crop Protection Association, Arco Chemical Corporation, Ashland Inc. Foundation, BASF, Cabot Corporation Foundation, Chemical Manufacturers Association, (aka American Chemistry Council), Chlorine Chemistry Council, CIBA-GEIGY, Cytec Industries, Dow Chemical Corporation/Union Carbide, DowElanco (Dow AgroSciences), DuPont Agricultural Products, FBC Chemical Corporation, FMC Corporation, Hoechst AG, ICI Americas, Louisiana Chemical Association, Lyondell Chemical, Olin Corporation, 3M, Praxair Inc., The Geon Company, Rohm & Haas Company, Petroleum Industry, American Petroleum Institute, Amoco, BP America Inc., Charles G. Koch Foundation, Chevron Corporation CITGO Petroleum, ExxonMobil, Oxford Oil, Oxygenated Fuels Association, Shell Oil Foundation, Texaco Foundation, Unocal Corporation, Edison Electric Institute, General Electric Foundation, Monsanto Company, New England Power Service, Westinghouse Electric Corporation | **No Disclosure** |

| Source, date, and title of article | Regulatory subject/s discussed in the article | The regulatory programs that Graham recommends instead | Sources of HCRA funding relevant to the article's subject | Disclosure of any of Graham's funding sources? |
|---|---|---|---|---|
| Hilary Shenfield, "The Environment Often Seems Far More Hazardous To Your Health Than It Really Is," *Chicago Daily Herald*, Mar. 15, 1999. | The topic was our irrational "fears" — mentions our fears of toxins and chemicals in general, toxic waste, creosote (a coal-byproduct), pesticides, EMFs, power lines, tap water, cell phones, Alar, benzene, EDB, asbestos, amalgam dental fillings | Graham said, "We should strive to spend our *mental health budget* on prevention of the big killers and not be distracted by the syndrome of the month."<br><br>The American Council on Science and Health also weighed in: "'We have a limited capacity for dealing with health scares,' said Jeff Steier, associate director of ACSH. 'So we have to prioritize.'" | Pesticides, power lines, benzene and EMFs are elsewhere in the table.<br><br>Creosote from coal: 3M, American Petroleum Institute, BASF, Amoco, BP America, Koch Foundation, CITGO Petroleum, Exxonmobil, Unocal, Shell Oil | **No disclosure of HCRA or ACSH sources**<br>This article makes repeated use of especially suspect conclusions. One example suggests that asbestos should not be feared (i.e., regulated) because its removal can sometimes stir up greater level of the toxin. |
| Noah Adams, "EPA Report on Dioxin is Released and Confirms a Cancer Risk Exists to All Americans," *All Things Considered, National Public Radio*, June 15, 2000. | Dioxin.<br><br>EPA scientists found dioxin could cause the average American "an *additional* lifetime risk of cancer as high as one in a hundred." | The story continued, "That would put dioxin *on par* with other common risks," said Graham. 'The average American in their lifetime has about one chance in a hundred of dying in a car crash. . . So this type of risk they're talking about here, if true, would be a significant risk, but it would not be something that would be out of the norm of what people experience in daily life.'" | Dow (the leading producer of dioxin), Chlorine Chemistry Council, CIBA-Geigy, General Electric, DuPont, Georgia-Pacific, Hoescht-Celanese, ICI Americas, Kodak, Monsanto, Olin Corp., American Crop Protection Association, American Chemistry Council.<br>**HCRA is funded by 48 dioxin producers.** | **No disclosure**<br>And the risks are cumulative (not merely "on par"). Although Graham did not say so, according to these data, we now know that we have *both* a 1 % chance of dying in a car crash *and* a 1 % chance of contracting cancer from dioxin. |

1. "Science Advisory Board Questions Major Parts of EPA Dioxin Report," *Air/Water Pollution Report,* May 22, 1995. Graham was reported as saying that "[t]he report overstates the carcinogenic risks that dioxins and related compounds may pose and fails to seriously analyze uncertainties about these chemical sand to show how incremental changes in exposure could affect health."

2. A report on dioxin posted on the Greenpeace Web site describes Graham's participation in the EPA process on the dioxin reassessment. See <www.enviroweb.org/issues/dioxin/dow_brand_dioxin.txt>.

3. Dioxin producers were identified by the Center for Health and Environmental Justice.

## Appendix B
## LIST OF HARVARD CENTER FOR RISK ANALYSIS FUNDING SOURCES

The Harvard Center for Risk Analysis receives financial support from a vast number of private corporations and trade associations, as well as a few government agencies and conservative advocacy groups. According to information provided over the phone by staff at HCRA and the Center's Conflict of Interest policy, these lists are "cumulative," showing all HCRA donors, past and future. There is no mention of the amount of the donation, or list of companies that support the Center on a regular basis. Therefore, the presence of an entity on this list could represent a single donation or a tradition of ongoing support. These organizations provide funding to the HCRA either in the form of restricted or unrestricted grants. The information on products and companies below is from the named corporation's official Web site, unless otherwise specified. Information on dioxin producers is from a partial list created by the Center for Health, Environment and Justice. Unrestricted grants are sorted by industry. Funders may be listed in more than one category.

### Unrestricted Grants: List of Donors

**Agribusiness**

- American Crop Protection Association *(Dioxin Producer)*
- Dow Chemical Company *(Dioxin Producer)*
- DowElanco (Dioxin Producer)
- DuPont Agricultural Products *(Dioxin Producer)*
- E.I. DuPont de Nemours & Company
- Hoeschst Marion Roussel *(Dioxin Producer)*
- Monsanto Company *(Dioxin Producer)*
- Novartis Corporation
- Novartis International
- Pharmacia

**Chemicals**

- Air Products and Chemicals, Inc. *(Dioxin Producer)*
- 3M *(Dioxin Producer)*
- ARCO (Atlantic Richfield Company) Chemical Company *(Dioxin Producer)*
- BASF *(Dioxin Producer)*
- BP America Inc. *(Dioxin Producer)*
- Cabot Corporation Foundation *(Dioxin Producer)*
- Chemical Manufacturing Association (now the American Chemistry Council) *(Dioxin Producer)*

- CIBA-GEIGY Corporation *(Dioxin Producer)*
- Cytec Industries *(Dioxin Producer)*
- Dow Chemical Company *(Dioxin Producer)*
- Eastman Chemical Company
- E.I. DuPont de Nemours & Company
- Exxon Corporation *(Dioxin Producer)*
- FBC Chemical Corporation *(Dioxin Producer)*
- The Geon Corporation *(Dioxin Producer)*
- Hoeschst Celanese Corpration
- Hoeschst Marion Roussel
- Hoffman-LaRoche Inc.
- ICI Americas Inc. *(Dioxin Producer)*
- Louisiana Chemical Association *(Dioxin Producer)*
- Lyondell Chemical Company *(Dioxin Producer)*
- Millennium Chemical Company
- Mobil Foundation, Inc. *(Dioxin Producer)*
- Olin Company Charitable Trust *(Dioxin Producer)*
- Praxair, Inc. *(Dioxin Producer)*
- Rohm and Haas Company *(Dioxin Producer)*
- Union Carbide Foundation ($10,000 to HCRA) *(Dioxin Producer)*

**Consumer Products**

- Eastman Kodak Company *(Dioxin Producer)*
- Procter & Gamble Company
- Reynolds Metals Company Foundation *(Dioxin Producer)*
- Rohm and Haas Company *(Dioxin Producer)*

**Financial Services and Insurance Companies**

- Aetna Life & Casualty Company
- Boatmen's Trust

**Food**

- E.I. DuPont de Nemours & Company
- The Coca-Cola Company
- Frito-Lay
- Grocery Manufacturers of America
- Kraft Foods
- National Food Processors Association
- PepsiCo Inc.
- Procter & Gamble Company

**Heavy Industrial**

- Alcoa Foundation *(Dioxin Producer)*
- American Automobile Manufacturers Association
- Astra AB
- Bethlehem Steel Corporation *(Dioxin Producer)*
- Cement Kiln Recycling Coalition *(Dioxin Producer)*
- Emerson Electric
- Ford Motor Company
- General Electric Fund
- Inland Steel Industries *(Dioxin Producer)*
- National Steel *(Dioxin Producer)*
- Nippon Yakin Kogyo *(Dioxin Producer)*
- North American Insulation Manufacturers Association
- Westinghouse Electric Corporation *(Dioxin Producer)*

**Mining**

- Alcoa Foundation *(Dioxin Producer)*
- ASARCO
- Reynolds Metals Company Foundation *(Dioxin Producer)*

**Oil & Gas**

- American Petroleum Institute *(Dioxin Producer)*

  *From the API Web Site:* The API's "most pressing issues today revolve around public perceptions and government policies toward the industry." The API "strives to reduce the financial impact of government oversight on industry operations." Under a section entitled "FIGHTING UNNECESSARY REGULATION," API celebrates three victories over the EPA:

  1) API "saved" the industry $9 billion, most of it in the upstream sector, by demonstrating why the US EPA should exempt most oil and gas production facilities and service stations from unnecessary risk management regulations.
  2) At API's urging, the EPA changed gasoline detergent certification rules, "saving" the industry $2.5 billion in needless upgrades to terminal equipment.
  3) API won a federal court decision overturning EPA's attempts to require the use of ethanol in reformulated gasoline, "saving" the industry almost $1 billion annually.

- ARCO (Atlantic Richfield Company) Chemical Company *(Dioxin Producer)*
- Ashland Inc. Foundation
- BASF *(Dioxin Producer)*
- BP America Inc. *(Dioxin Producer)*
- Charles G. Koch Foundation *(Dioxin Producer)*
- Chevron Research & Technology Company *(Dioxin Producer)*
- CITGO Petroleum Company *(Dioxin Producer)*
- Exxon Corporation *(Dioxin Producer)*
- Mobil Foundation, Inc. *(Dioxin Producer)*
- Oxford Oil *(Dioxin Producer)*
- Oxygenated Fuels Association *(Dioxin Producer)*
- Shell Oil Company Foundation ($15,000 to HCRA) *(Dioxin Producer)*
- Texaco Foundation *(Dioxin Producer)*
- Unocal *(Dioxin Producer)*

**Paper and Lumber**

- Boise Cascade Corporation *(Dioxin Producer)*
- Fort-James *(Dioxin Producer)*
- Georgia-Pacific Corporation *(Dioxin Producer)*
- International Paper *(Dioxin Producer)*
- The James River Corporation Foundation *(Dioxin Producer)*

- Mead Corporation Foundation *(Dioxin Producer)*
- Potlatch Corporation *(Dioxin Producer)*
- Westvaco *(Dioxin Producer)*

**Power Utilities**

- Carolina Power and Light
- Edison Electric Instititute
- Electric Power Research Institute *(Dioxin Producer)*
- New England Power Service *(Dioxin Producer)*
- New England Electric Service

**Pharmaceuticals**

- E.I. DuPont de Nemours & Company *(Dioxin Producer)*
- Glaxo-Wellcome, Inc.
- Hoffman-LaRoche Inc.
- Janssen Pharmaceutical
- Johnson & Johnson
- Merck & Company
- Monsanto Company
- Novartis Corporation
- Novartis International
- Pfizer
- Pharmacia
- Procter & Gamble Company
- Schering-Plough Corporation

**Transportation**

- American Automobile Manufacturers Association
- Association of American Railroads
- Ford Motor Company
- General Motors Corporation
- The Goodyear Tire & Rubber Company
- USX Corporation

**Waste Management**

- WMX Technologies, Inc. *(Dioxin Producer)*

**Restricted Grants: List of Donors**

- Alfred P. Sloan Foundation
- American Crop Protection Association

  The ACPA, which was formed in 1933, is a nonprofit trade organization representing the major manufacturers, formulators and distributors of crop protection, pest control, and biotechnology products.
- American Industrial Health Council
  The American Industrial Health Council assesses the regulation of risks associated with human health effects and ecological effects.
- Andrew Mellon Foundation
- Bradley Foundation
  The Lynde and Harry Bradley Foundation are devoted to the support of limited government and an open economic market.
- Brookings Institution
- California Avocado Commission
- Chemical Manufacturers Association

  The CMA is now called the American Chemistry Council (ACC). "The ACC is the voice of the U.S. Chemical Industry."
- Chiang Ching-Kuo Foundation for International Scholarly Exchange
- Chlorine Chemistry Council
- "The Chlorine Chemistry Council was established in 1993 to participate in the public policy debate surrounding chlorine chemistry." "It facilitates comparative risk and risk benefit analyses through the collection, development, and use of scientific data on health and environmental issues surrounding chlorine chemistry. CCC believes that public policy, regulatory actions and industry stewardship regarding chlorine chemistry should be based on sound science and focus on comparative risk assessment."
- Congressional Research Service
- Electric Power Research Institute
- Elsa U. Pardee Foundation
- International Life Science Institute/Risk Science Institute
- Health and Environmental Sciences Group
- National Association of Home Builders
- Pfizer, Inc.
- Society for Risk Analysis (corporate-funded — *see* list of Graham's affiliations).

**Government Funding**

- National Institute of Justice
- U.S. Centers for Disease Control
- U.S. Department of Agriculture
- U.S. Department of Energy
- U.S. Department of Health and Human Services
- U.S. Department of Transportation
- U.S Environmental Protection Agency
- U.S. National Oceanic Atmospheric Administration
- U.S. National Science Foundation

**Testimony of Professor Lisa Heinzerling**
**Concerning the Nomination of John D. Graham to be Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget**

## I. Introduction

My name is Lisa Heinzerling. I am a Professor of Law at the Georgetown University Law Center. I am a graduate of the University of Chicago Law School, where I served as editor-in-chief of the University of Chicago Law Review. After law school I clerked for Judge Richard Posner on the U.S. Court of Appeals for the Seventh Circuit and then for Justice William Brennan on the U.S. Supreme Court. I was an Assistant Attorney General in the Environmental Protection Division of the Massachusetts Attorney General's Office for several years before coming to Georgetown. I have also taught at the Harvard and Yale law schools. My expertise is in environmental and administrative law. My published articles in the field of risk regulation include, among others, *Environmentalists and Pragmatists,* 113 HARV. L. REV. 1421 (2000) (book review); *The Rights of Statistical People*, 24 HARV. ENVIR. L. REV. 189 (2000); *Discounting Life*, 108 YALE L.J. 1911 (1999); *Discounting Our Future*, 34 WYO. LAND & WATER L. REV. 39 (1999); *Regulatory Costs of Mythic Proportions*, 107 YALE L.J. 1981 (1998); and *Political Science*, 62 U. CHI. L. REV. 449 (1995) (reviewing Stephen Breyer, *Breaking the Vicious Circle*).

John Graham's work has had a large influence on debates over health, safety, and environmental regulation. In particular, Dr. Graham's claims regarding the costs of federal regulation and the life-saving potential of a rearrangement of our regulatory priorities have been widely circulated and widely accepted by other scholars, elected representatives, and the interested public. These claims are, however, exceedingly problematic, for three basic reasons: they misrepresent the output of the current regulatory system; ignore many of the benefits of federal regulation; and rest on controversial moral judgments about whose life is worth saving.

In this testimony, I first describe Graham's research on regulatory costs and on the implications of these costs for life-saving results. I then describe how Dr. Graham himself has perpetuated and encouraged a misinterpretation of his own data, one that wrongly concludes that these data show that federal regulations result in the "statistical murder" (to borrow Graham's phrase) of 60,000 Americans every year. I also explain how Dr. Graham's research ignores many benefits of regulation, particularly environmental regulation, and how this research slights our collective future. I conclude by suggesting that Dr. Graham's misuse of his own data in the service of an anti-regulatory agenda makes him an unsatisfactory choice to lead the Office of Information and Regulatory Affairs.

## II. Graham's Research on Life-Saving Costs: "Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness"

In research supervised by Dr. Graham, graduate student Tammy O. Tengs and several co-authors analyzed the costs of 587 life-saving measures.[1] These measures fall into three broad categories: fatal injury reduction, toxin control, and medicine. The specific measures included under the heading of fatal injury reduction encompass such things as airplane safety, automobile safety, and fire prevention. The category of toxin control includes measures to control arsenic, asbestos, benzene, radiation, and other hazardous substances. Finally, the category of medicine includes a wide variety of preventive and curative measures ranging from vaccinations to advice about quitting smoking.[2] Graham and Tengs' reported criterion for the inclusion of a life-saving intervention in this study was the availability of quantitative data on the intervention's costs and benefits.[3]

In evaluating this study and in evaluating Dr. Graham's subsequent uses of it, it is important to understand several basic features of the study. These include the study's inclusion of many life-saving measures that have never been undertaken; the inclusion of both regulatory and non-regulatory life-saving measures; the duplication of measures on the list; the use of life-years saved as the sole metric by which to judge these measures; and the use of the technique of discounting future life-saving. I discuss each of these features of Graham's methodology in turn.

*The Inclusion of Unimplemented Life-Saving Measures*. The "Five-Hundred Life-Saving Interventions" study includes many life-saving measures that have never been undertaken by anyone. As Graham and his co-authors acknowledge, their study includes life-saving measures "that are fully implemented, those that are only partially implemented, and *those that are implemented not at all*."[4]

---

[1]Tammy O. Tengs, Miriam E. Adams, Joseph S. Pliskin, Dana Gelb Safran, Joanna E. Siegel, Milton C. Weinstein, and John D. Graham, *Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness*, 15 RISK ANALYSIS 369 (1995) (hereinafter *Five-Hundred Life-Saving Interventions*).

[2]For a list of the interventions analyzed in this study, see *id.* at 373-384.

[3]Tengs, *et al.*, *Five-Hundred Life-Saving Interventions*, at 370. Numerous scholars have observed that quantitative estimates of the benefits of health and environmental regulation, in particular, are frequently too low. *See, e.g.*, Thomas O. McGarity, *A Cost-Benefit State*, 50 ADMIN. L. REV. 7, 27-29 (1998).

[4]*Id.* at 372 (emphasis added).

In fact, a very large number of the toxin controls studied by Graham and Tengs were never implemented by any agency, frequently for the very reason that their costs were thought to exceed their benefits. An equally large number of these controls were never even proposed by any agency. Indeed, although nine of the ten most expensive life-saving interventions in the entire study involved toxin control, *not one* of those nine interventions was ever implemented by a regulatory agency.[5] The most expensive intervention on Graham and Tengs' list - the control of chloroform from paper mills, purportedly costing $99 billion per year of life saved - was never even proposed.[6]

*The Inclusion of Both Regulatory and Non-Regulatory Life-Saving Measures.* This study also includes both regulatory and non-regulatory life-saving measures. Many of these measures would be undertaken, if at all, by individuals acting in their private capacities, such as doctors advising patients about quitting smoking[7] or 35-year-old men undertaking an exercise regimen.[8] Many other measures would entail government intervention. Indeed, the category of toxin control consists almost entirely of measures that might be (but in many cases have not been) undertaken by the government.

There is, of course, nothing inherently wrong with including both regulatory and non-regulatory life-saving programs in such a study. As will become clear, however, one must be careful to attribute life-saving costs to their appropriate source, and not to blame the regulatory system for any costs and misallocations found in the private sector.

*The Duplication of Life-Saving Measures on Graham and Tengs' List.* Graham and

---

[5]*See* Tammy O. Tengs, *Optimizing Societal Investments in the Prevention of Premature Death*, A Thesis Submitted to the Faculty of the Harvard School of Public Health in Partial Fulfillment of the Requirements for the Degree of Doctor of Science in the field of Health Policy and Management, at p. 25, Table 8 (Boston, Mass., June, 1994) (hereinafter Tengs, *Optimizing Societal Investments*)(showing "Ten Most Expensive Interventions"). In order to determine which regulatory interventions on Graham and Tengs' list were implemented (or even proposed) by the relevant regulatory agency, one must consult the original studies providing the costs and effectiveness data on which Graham and Tengs relied. For references to these studies, see Tengs, *et al., Five-Hundred Life-Saving Interventions*, at 385-390.

[6]Ralph A. Luken, *Toxic Pollutants, in* EFFICIENCY IN ENVIRONMENTAL REGULATION: A BENEFIT-COST ANALYSIS OF ALTERNATIVE APPROACHES, AT 249 (Kluwer Academic Publishers 1990) (referring to chapter as study of "potential regulations") (hereinafter Luken, *Toxic Pollutants*).

[7]Tengs, *et al., Five-Hundred Life-Saving Interventions*, at 384, Appendix A.

[8]*Id.* at p. 380, Appendix A.

Tengs' study does not in fact look at 587 *different* interventions. In numerous cases, Graham and Tengs examined the very same life-saving measure, but from the perspective of different analysts. These analysts obviously had very different views about the costs and effectiveness of the very same life-saving measures. For example, Graham and Tengs report two estimates of the cost per life-year saved of a ban on urea-formaldehyde form insulation in homes; one estimate puts the cost at $11,000 per life-year saved, and another at $220,000 per life-year saved.[9] To take another example, Graham and Tengs also offer two estimates of the costs of controlling arsenic emissions at glass plants; one estimate is $2.3 million per life-year saved, the other is $51 million per life-year saved.[10] Graham and Tengs provide no guidance as to how one might choose between these strikingly different perspectives on the costs of the very same life-saving measures. They also do not face up to the strange consequence of their duplication of life-saving measures: one might conclude that we could save a large amount of money in arsenic control simply by adopting the views of the $2 million analyst rather than the $51 million analyst!

*Life-Years Saved as the Measure of Effectiveness.* In estimating the costs of these 587 life-saving measures, Graham and his research team used two significant and controversial analytical techniques. First, they defined the only relevant regulatory benefit to be the saving of *years* of life, or *life-years*.[11] Put simply, this means that, in the view of Graham and his co-authors, a measure that saves the lives of the elderly is not as good as one saving the lives of the middle-aged, and likewise, a measure saving the lives of the middle-aged is not as good as one saving the lives of the young. It also means that benefits like the prevention of nonfatal illnesses and the protection of ecosystems are not taken into account in Graham and his co-authors' analysis.

*Discounting Future Life-Saving Benefits.* Second, in calculating the benefits of life-saving measures, Graham and his co-authors employed an analytical technique known as "discounting." Specifically, they reduced all future life-saving benefits by 5 percent per year. Equations available in appendices to their study seem to indicate that Graham and his co-authors performed this calculation in the following way. Suppose, for example, that a particular measure would save the life of a 35-year-old, thus saving 42 life-years if one assumes that this person's life expectancy is 77 years. Graham and his co-authors discounted all of the years of life saved by such an intervention by 5 percent per year, *from the year in which the year of life would otherwise have been lived.* This means that Graham

---

[9] *Id.* at p. 377, Appendix A.

[10] *Id.* at p. 375, Appendix A.

[11] *Id.* at 370.

and his co-authors would have discounted the last year saved by the hypothetical intervention over a period of 42 years. As a result, the last year of life saved would be reduced in their analysis to one-eighth (1/8) of a year. This large reduction in future benefits is the inexorable result of discounting, a process akin to compound interest in reverse.

*Conclusions of the Study*. After applying these analytical techniques, Graham, Tengs, and their co-authors found that the costs per year of life saved varied widely across interventions and often reached very high levels. Graham and Tengs also found that toxin control was the most costly, in general, of the categories of life-saving interventions they considered. Specifically, they found that the costs of toxin control ranged from equal to or less than zero (meaning that some interventions saved more money than they cost) to as high as $99 billion for every year of life saved. As noted, however, many of the toxin controls considered by Graham and Tengs were never implemented, and many were never even proposed by a regulatory agency.

### III. Graham's Research on Opportunity Costs: "The Opportunity Costs of Haphazard Social Investments in Life-Saving"

In a study building upon their "Five-Hundred Life-Saving Interventions" study, Graham and Tengs set out "to assess the opportunity costs of our present pattern of social investment in life-saving."[12] In other words, what, they purported to ask, do we give up in addressing life-threatening risks the way we now do?

This second study considered a subset of the 587 interventions included in the "Five-Hundred Life-Saving Interventions" study. Because, this time around, Graham and Tengs required that data on costs and effectiveness be national in scope, the number of interventions included in the second study dropped from 587 to 185.[13] Ninety of these interventions (almost half of all those included in the study) were toxin control measures that were under the jurisdiction of the Environmental Protection Agency (or would have been, if they had ever been proposed).[14]

---

[12]Tammy O. Tengs and John D. Graham, *The Opportunity Costs of Haphazard Social Investments in Life-Saving*, in RISKS, COSTS, AND LIVES SAVED: GETTING BETTER RESULTS FROM REGULATION, at 168 (Robert W. Hahn, ed., Oxford University Press and AEI Press 1996) (hereinafter Tengs & Graham, *Opportunity Costs*).

[13]*Id.* at 169.

[14]I obtained a complete list of the interventions considered in this study from Tammy Tengs. This list indicates that ninety of the interventions were environmental measures. *See also* Tengs,

*Inclusion of Unimplemented Measures.* Of the ninety environmental measures included in the second study (representing almost half of all the measures considered), only eleven were ever implemented by the relevant agency, EPA. In other words, **seventy-nine** of the environmental measures included in this study were **never implemented**. Most of these were rejected (or never even proposed) by EPA itself.[15] Twenty-one of the environmental measures were part of EPA's nationwide ban on asbestos products, which was overturned in a single, controversial judicial decision.[16]

In this study, Graham and Tengs assert that they considered the extent to which the interventions they discuss have been implemented. They write:

> For each intervention, we supplemented cost-effectiveness data with two measures of the degree to which that intervention was implemented. For the subset of interventions where a "go/no-go" decision was made (for example, laws, regulations, or uniform building codes), we collected binary data on the implementation decision ($B_{ijk}$). Because some degree of implementation can exist even in the presence of a "no-go" decision or can be absent even with a "go" decision, however, we also collected data on "percent implementation" ($P_{ijk}$). We defined that measure as the percent of people in the target population who received the life-saving intervention as of 1992.[17]

Graham and Tengs then explain that, to gather information on "percent implementation," they consulted two independent experts. In estimating how many women over age twenty receive annual cervical cancer screening, for example, they consulted two experts in cervical

---

*Optimizing Societal Investments*, at 150, Appendix Q (indicating that ninety interventions based on "EPA Regulation" were considered in the dissertation which formed the basis of Tengs and Graham's "Opportunity Costs" study).

[15]For example, ten of the ninety environmental measures included in the study are bans on certain asbestos products. As the study on which Graham and Tengs relied for their data on the costs and effectiveness of these measures clearly states, however, these products were not in fact banned by EPA. *See* George L. Van Houtven and Maureen L. Cropper, *When Is a Life Too Costly to Save?*, Policy Research Working Paper 1260, Environment, Infrastructure, and Agriculture Division, Policy Research Department, World Bank, at (unnumbered) p. 23, Table 1 (March 1994).

[16]*See Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991) (overturning EPA's nationwide ban on asbestos products in part because the court disagreed with the agency's cost-benefit analysis).

[17]Tengs & Graham, *Opportunity Costs*, at 169-170.

cancer.[18]

Unfortunately, however, Graham and Tengs do not give any information as to which measures they considered implemented, which unimplemented, and which partially implemented. From the quoted passage above, it appears that as to government regulations, they assumed that the regulations were either fully implemented or not implemented at all (they assumed, in their words, a "go/no-go" decision). However, careful review of their study and related research indicates that, as to at least some and perhaps many of the unimplemented toxin controls, they wrongly treated such interventions as having been undertaken.

In order to show the "percent implementation" they assumed for the interventions in their study, Graham and Tengs provided a chart containing black squares that represent the interventions. These squares are plotted on the chart as a function of both their percent implementation and their cost per year of life saved. Although the chart is somewhat hard to read, the chart seems to indicate that Graham and Tengs assumed "zero percent implementation" for only about ten or so of the 185 life-saving interventions they considered.[19]

However, as noted, of the ninety EPA measures considered by Graham and Tengs, only eleven were ever implemented by EPA; seventy-nine were never implemented, and many of these were never even proposed. If Graham and Tengs had considered this virtually complete lack of implementation of the environmental measures included in their study, their chart showing the "percent implementation" of the interventions in their study would have included seventy-nine environmental regulations alone. Yet, as just discussed, that chart shows only about ten or so "zero percent implementation" interventions.[20] Thus, despite what they say, it appears that Graham and Tengs did not taken into account the non-implemented status of most of the toxin controls in their analysis.

Given Graham and Tengs' very limited description of the precise assumptions underlying their analysis, it is impossible to know how many of the unimplemented environmental measures in Graham and Tengs' study were treated, wrongly, by the authors

---

[18] *Id.* at 170.

[19] *Id.* at 173, Figure 8-1.

[20] *Id.*

as having been implemented.[21] At least based on the chart showing the "percent implementation" assumed for different measures, it appears that a large percentage of the seventy-nine unimplemented environmental measures were mistakenly treated by Graham and Tengs as having been implemented. Moreover, based on information provided in related research, it is clear that Graham and Tengs assumed that EPA's nationwide ban on asbestos was fully implemented - which, as noted above, it was not.[22]

Is it possible that Graham and Tengs assumed that, even absent government regulation, firms were undertaking the environmentally protective measures discussed in their study, and that therefore the study accurately reflects life-saving costs even if those costs cannot be attributed to regulation? In that case, however, it would be extremely important to make clear that the costs were private costs borne voluntarily by firms, not regulatory costs. In addition, it is highly unlikely that a firm would voluntarily undertake toxin controls that cost as much money as Graham says they cost. Most economists would argue that a firm would undertake such controls only if they could save money by doing so, yet the cost figures cited by Graham hardly show money-saving potential. Furthermore, one of the signature features of environmental problems is that the person or firm that invests in solving them cannot capture all or even most of the benefits of doing so, as environmental problems involve "public goods" enjoyed by all. The implication of this "public goods" analysis is that profit-maximizing firms will not undertake large-scale environmentally protective measures on their own initiative. All in all, without a good deal of empirical information about voluntary toxin control undertaken by firms (information not apparent in any of Graham's research discussed here), it would be unreasonable to assume that such voluntary behavior occurs and that it costs what Graham says toxin control costs. In sum, it seems highly unlikely (because it would be so implausible) that Graham and Tengs would have assumed that firms were undertaking the toxin controls they identify on their own initiative.

*Inclusion of Regulatory and Non-regulatory Measures.* The "Opportunity Costs" study again included both regulatory and non-regulatory measures. This time around, however, the vast majority were (or would have been, if they had ever been undertaken) regulatory measures. Only fifteen of the life-saving measures included in this study were

---

[21]For sake of completeness, I note that I have tried to obtain more information about these studies' assumptions about the extent of implementation of the relevant interventions by contacting both Dr. Graham and Dr. Tengs. Thus far I have not received a response to these inquiries.

[22]*See* Tammy O. Tengs, *Dying Too Soon: How Cost-Effectiveness Analysis Can Save Lives*, National Center for Policy Analysis Report No. 204, at p. 6, Table II (May 1997) (showing assumption of "100%" implementation of invalidated asbestos rule).

medical interventions. Yet the majority of the life-saving benefits found by Graham and Tengs came from the medical category.[23] Again, although there is nothing wrong in principle with studying both regulatory and non-regulatory measures, one must be careful to avoid attributing the costs and misallocations of private decisions to governmental actors. As I shall explain in Part IV, this is precisely what has happened with respect to Graham's research.

*Duplication of Life-Saving Measures.* In this study, too, many life-saving measures appear more than once even though only one such measure would ever be undertaken or even proposed. Arsenic emission controls at glass plants appear twice on the list; arsenic emission controls at primary copper smelters appear three times; benzene emission controls at chemical manufacturing process vents appear twice; benzene controls at bulk gasoline plants, and at bulk gasoline terminals, both appear twice, benzene controls at elemental phosphorous plants appear a stunning five times; radionuclide controls at coal-fired industrial, and utility, boilers appear thrice and twice, respectively.[24] I can conceive of no explanation for these duplications. Moreover, given the limited description of this study provided by Graham and Tengs, it is impossible to determine what role these duplications played in Graham and Tengs' results. The most that can be said is that *if* Graham and Tengs assumed that resources could be saved simply by choosing one expert's views over another, this would be a large mistake.

*Limited Set of Life-Saving Measures.* As I will explain in Part IV of this testimony, many people, including Graham himself, have used the "Opportunity Costs" study to launch a large-scale attack on environmentally protective programs. Not only does this attack ignore the fact that the vast majority of the environmental measures included in this study were never implemented; it also ignores the extremely limited scope of Graham and Tengs' analysis insofar as it applies to environmental measures. Although ninety of the 185 measures in the "Opportunity Costs" study were environmental measures - thus, superficially, suggesting a rather comprehensive look at environmental regulation - fifty (over one-half) of these measures were (or would have been, if they had ever been adopted) implemented under just one provision of one environmental statute - section 112 of the Clean Air Act, dealing with hazardous air pollutants. Moreover, Graham and Tengs' analysis applies to measures undertaken (or, mostly, *not* undertaken) under an earlier version

---

[23]Tengs, *Optimizing Societal Investments*, at pp. 144-146, Appendices K-M (showing life-saving benefits across categories of medicine, fatal injury reduction, and toxin control).

[24]Again, I obtained a complete list of the life-saving measures included in the "Opportunity Costs" study from Tammy Tengs.

of section 112 *which no longer exists*.[25] Fully twenty-one of the environmental measures were part of EPA's nationwide ban on asbestos, undertaken under section 6(a) of the Toxic Substances Control Act.[26] That ban was overturned in court ten years ago,[27] and since then EPA has not banned a single substance under section 6. To sum up, then, out of ninety environmental measures considered by Graham and Tengs, **eighty-one** were undertaken (or not undertaken) under statutory provisions that are either formally or effectively defunct, and have been so for at least a decade. Therefore, to the extent one attempts to develop a critique of environmental protection based on this study, one's critique will be directed at the past rather than the present.

*Life-Years and Discounting*. In this second study, Graham and Tengs again used the analytical techniques they had used in the first study: they measured the effectiveness of interventions solely according to how many years of human life they saved, and they discounted future years of life by 5 percent per year.[28]

*Conclusions of the Study*. Graham and Tengs' conclusions are now famous: they found that if resources were directed to the most cost-effective of the interventions they considered, we could save 60,200 more lives every year with the same amount of money, or, alternatively, we could save $31.1 billion and save the same number of lives.[29]

Again, however, careful attention to the study's precise findings is necessary in order to understand the study's implications. The vast majority of lives saved through Graham and Tengs' proposed reallocation of life-saving resources occurred in the categories of fatal injury reduction and medicine; over half of the life-saving potential was found in the medical category alone.[30] Only about five percent of the life-saving benefits found by

---

[25]Section 112, 42 U.S.C. 7412, was completely revised in the 1990 Amendments to the Clean Air Act.

[26]15 U.S.C. 2605(a).

[27]*Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

[28]Tengs & Graham, *Opportunity Costs*, at 169.

[29]*Id.* at 172-173.

[30]Tengs, *Optimizing Societal Investments*, at pp. 144-146, Appendices K-M (showing life-years saved in separate categories of fatal injury reduction, medicine, and toxin control).

Graham and Tengs came from the category of toxin control.[31] Even more strikingly, less than two percent of the total life-saving benefits found by Graham and Tengs could be obtained by reallocating EPA's regulatory resources.[32]

According to Graham's own logic, then, one would have expected him, after this study, to have concentrated his efforts on reforming, *first*, health-care expenditures (in particular, one would expect him to be in the vanguard of efforts to limit tobacco use), *second*, expenditures on fatal injury reduction, and, *only as a distant third*, toxin controls. Moreover, one would have expected EPA's operations to be of relatively little concern to Dr. Graham, given the quite small contribution even a major overhaul of this agency's priorities could make to overall life-saving results, according to his research. This is not, however, how Dr. Graham has allocated his own resources. Indeed, as I next explain, he has used his research on life-saving costs in arguing for a major restructuring of our regulatory system. And he has reserved a special disfavor for environmentally protective programs.

### IV. How Graham's Research Has Been Misused

Many observers have misinterpreted Graham's research. Most prominently, they have cited the "Opportunity Costs" study as if it shows that *government regulation* results in the "statistical murder" (to use Graham's phrase) of 60,000 Americans every year. This misinterpretation appears frequently in the academic, political, and popular literature on risk regulation. This Committee, for example, has been told more than once that Graham's research shows that a rearrangement of *regulatory* priorities would save 60,000 lives per year.[33] The misrepresentations of Graham's data began, in fact, simultaneously with their initial publication: in the introduction to the book in which the "Opportunity Costs" study appears, Robert Hahn claims that the study by Graham and Tengs "compiles new data on hundreds of *regulatory interventions* and estimates their costs and life-saving benefits." This study, Hahn continues, "assesses the opportunity costs of the current activity and determines an 'optimal portfolio' of *regulatory activity* that could save more lives at less cost."[34] The ink was not even dry on Graham and Teng's study, in other words, before it

---

[31] *Id.*, at p. 146, Appendix M.

[32] *Id.*, at 150, Appendix Q.

[33] *See, e.g.*, Joint Testimony, Robert W. Hahn and Robert E. Litan, The American Enterprise Institute and The Brookings Institution, Before the Senate Committee on Governmental Affairs (Feb. 24, 1998) (testifying on S. 981, the Regulatory Improvement Act of 1998).

[34] Robert W. Hahn, Introduction, in RISKS, COSTS, AND LIVES SAVED, at 3 (Oxford University and AEI Press 1996) (emphasis added).

was being misused as an indictment of government regulation.

Of course it is possible that Graham himself is not aware of others' misrepresentations of his research. Thus, in this section I explain how *Graham himself* has misrepresented the implications of his own research. These misrepresentations fall into two general categories. First, Graham has marketed his research as if it revealed government regulation to be the primary culprit in the misallocation of life-saving resources. Second, he has misstated the regulatory costs found by his studies.

*Attributing Resource Misallocations to Regulation.* In congressional testimony, Dr. Graham has used the research just described as a basis for calling the present allocation of life-saving resources "statistical murder."[35] Dr. Graham has told this Committee that his research demonstrates that federal regulation is in serious need of reform. In testifying in favor of "regulatory reform" bills several years ago, Dr. Graham stated:

> For the past fifteen years, I have studied the decision making of federal agencies responsible for protecting public health, safety, and the environment. These agencies include, for example, the Consumer Product Safety Commission, the Environmental Protection Agency, the Food and Drug Administration, the National Highway Traffic Safety Administration, the Occupational Safety and Health Administration, and the Nuclear Regulatory Commission. Although each of these agencies serve[s] a vital public function, I have found that the decisions of these agencies are not always based on a good understanding of science, engineering, and economics. As a result, *our regulatory system* is far less effective and efficient than it could and should be. One of my previous doctoral students at [the Harvard Center for Risk Analysis], Professor Tammy Tengs of the University of California at Irvine, found in her doctoral dissertation that lifesaving investments in the United States are often inefficient. Based on a sample of 200 policies, she estimated that a reallocation of lifesaving resources to cost-effective programs could save 60,000 more lives per year than we are currently saving, at no increased cost to taxpayers or the private sector! In short, a *smarter regulatory system* can provide the public with more protection against hazards at less cost than we are achieving today.[36]

---

[35]Risk Assessment and Cost Benefit Analysis: Hearings Before the Comm. on Science, United States House of Representatives, 104th Cong., 1st Sess. 1124 (1995) (written testimony of John D. Graham).

[36]Testimony of John D. Graham, Ph.D., Director, Center for Risk Analysis, Harvard School of Public Health, Before the Committee on Governmental Affairs, United States Senate (April 21, 1999) (testimony on S. 746, the Regulatory Improvement Act of 1999); *see also* Risk Assessment

Similarly, last summer, Dr. Graham joined a group of economists in signing onto a brief filed in the United States Supreme Court in a case challenging the constitutionality of the federal Clean Air Act. In that brief, Dr. Graham and his co-signatories urged the Court to interpret the Clean Air Act to require cost-benefit analysis of national air quality standards. They premised their argument on the perceived failings of current health, safety, and environmental regulation. As they put it:

> Both the *direct benefits and costs of environmental, health, and safety regulations* are substantial–estimated to be several hundred billion dollars annually. If *these resources* were better allocated with the objective of reducing human health risk, scholars have predicted that tens of thousands more lives could be saved each year.[37]

In his academic work, moreover, Graham has used the research conducted with Dr. Tengs to launch a large-scale attack on regulatory programs that protect health, safety, and the environment. Calling the "public's general reaction to health, safety, and environmental dangers" a "syndrome of paranoia and neglect," Graham has chosen to focus his disapproval on regulatory agencies rather than, say, the medical professionals whose apparent failure to offer smoking cessation advice to their patients results in a good deal of lost opportunity for life-saving.[38] For example, he has contended that the data he has compiled with Dr. Tengs "call for reconsideration of the toxin-control budgets of agencies such as EPA and OSHA."[39]

Thus, in testimony, Supreme Court briefing, and academic writing, Graham himself has misused his "Opportunity Costs" study. He has suggested that this study supports the conclusion that the current regulatory system squanders the opportunity to save tens of thousands of additional lives every year. This conclusion does not follow from Graham's

---

and Cost/Benefit Analysis for New Regulations: Joint Hearings Before the Subcomm. on Commerce, Trade, and Hazardous Materials and the Subcomm. on Health and Environment of the Comm. on Commerce, 104th Cong., 1st Sess. 307 (1995) (written testimony of John D. Graham) (identical quotation).

[37]Brief *Amici Curiae* of AEI-Brookings Joint Center for Regulatory Studies, *et al.*, in *American Trucking Ass'ns. v. Whitman*, No. 99-1426, at 1-2 (U.S. Supreme Court 2000) (citing Tengs & Graham, *Opportunity Costs*) (emphasis added).

[38]John D. Graham, *Making Sense of Risk: An Agenda for Congress*, in RISKS, COSTS, AND LIVES SAVED, at 183-207 (Robert W. Hahn, ed., Oxford University and AEI Press 1996).

[39]John D. Graham, *Comparing Opportunities to Reduce Health Risks: Toxin Control, Medicine and Injury Prevention*, National Center for Policy Analysis Report No. 192 (June 1995), available at http://www.ncpa.org/studies/s192/s192.html.

research. As noted, most of the life-saving potential found in Graham's research comes from reallocating expenditures in the field of medicine, not from reallocating resources used by, say, the Environmental Protection Agency or the Occupational Safety and Health Administration. It is a myth that federal regulation "statistically murders" 60,000 Americans every year, yet not only has John Graham apparently done nothing to correct the widespread impression that his own research supports this claim; he has also actively promoted this misinterpretation of his own data.

*Inaccurate Statements About Regulatory Costs.* As I have said, there is nothing inherently wrong with including both regulatory and non-regulatory programs in studies such as those done by Graham. There is also nothing inherently wrong with including in such studies programs that have not been implemented; indeed, part of the point of such research is to examine how things might change if we changed our priorities. Yet there *is* something wrong with treating unimplemented programs *as if they were implemented.* Graham has misused his own research in this fashion as well.

For example, as noted above, the most expensive intervention in the "Five-Hundred Life-Saving Interventions" study - the control of chloroform from paper mills, weighing in at $99 billion per year of life saved - was never even proposed.[40] Yet Graham has cited this measure as an "EPA standard for chloroform emissions" and has stated that it "imposes over $99 billion in costs for each year of life added."[41] But the "standard" was never proposed, and hence the costs never "impose[d]."

In addition, in treating unimplemented environmental measures as if they were implemented, Graham and Tengs' "Opportunity Costs" study greatly inflates the apparent costs of environmental regulation. Again, it is impossible to determine the magnitude of this inflation based on the public record, but given the available evidence as described in Part III of this testimony, it appears to be very large.

*Summary of Misuses of Graham's Research.* In short, Dr. Graham has misused his own research. For example, in signing onto the economists' brief in this Term's Clean Air Act case in the Supreme Court, he endorsed the conclusion that "tens of thousands of lives" could be saved if resources now spent on regulation were redirected.[42] He has also used his

---

[40]Luken, *Toxic Pollutants*, at 249.

[41]John D. Graham, *How to Save 60,000 Lives*, Electric Edison Institute (1995).

[42]Brief *Amici Curiae* of AEI-Brookings Joint Center for Regulatory Studies, *et al.*, in *American Trucking Ass'ns. v. Whitman*, No. 99-1426, at 1-2 (U.S. Supreme Court 2000).

research to critique the regulatory system in testimony given to this Committee. Yet Graham's own research does not simply look at regulation. Indeed, the majority of the lives saved through Graham and Tengs' rearrangement of priorities were saved in the field of medicine, not in regulatory fields such as environmental law.[43] To suggest, as Dr. Graham has, that the figure of 60,000 additional lives saved comes from a rearrangement of *regulatory* priorities is deeply misleading.

Dr. Graham has also misrepresented the actual costs of regulation by referring to measures never even proposed by the government as government "standards." In addition, the "Opportunity Costs" study explicitly states that it takes implementation status into account in assessing costs and effectiveness. However, as I have described, it clearly does not do this with respect to many of the environmental measures considered in the study. How large this error is, and how large an effect it had on Dr. Graham's overall conclusions, is impossible to determine based on available information.

One last point bears mentioning here. Although Graham and Tengs devote considerable energy to arguing, in general terms, that we should reallocate our life-saving resources, they actually provide no concrete examples in their "Opportunity Costs" study of what we should be doing instead of what we are now doing. Only by studying Tengs's unpublished PhD. dissertation, written under Graham's supervision, can one learn which life-saving interventions these researchers favor. I will limit my observations here to toxin control.

As it turns out, most of the toxin controls that Graham and Tengs found to be cost-effective have already been implemented. A handful of apparently cost-effective interventions regarding asbestos and benzene were not implemented, but these rules together would have saved a total of only twenty-four (24) lives - nowhere close to the 60,000 lives cited in the Graham and Tengs study. The only large life-saving opportunity in the area of toxin control that is identified by Graham and Tengs is radon remediation in homes, as encouraged by government funding of low cost loans, tax write-offs, or other financial incentives.[44] In effect, then, what Graham is really arguing for is a wholesale shift of EPA's responsibilities from the regulation of pollution of the air, water, and land through mandatory controls on polluters to the encouragement of residential radon remediation - which typically involves simply caulking basements - through loans and tax incentives.

---

[43]Tengs, *Optimizing Societal Investments*, at pp. 144-146, Appendices K-M (showing life-years saved in the categories of medicine, fatal injury reduction, and toxin control).

[44]*See* Kenneth L. Mossman & Marissa A. Sollitto, *Regulatory Control of Indoor Rn*, 60 HEALTH PHYS. 169 (1991).

Nowhere does Graham face up to the shrinking, indeed trivialization, of environmental law that his proposals would entail.

## V. How Graham's Research Ignores Many Benefits of Health, Safety, and Environmental Protection

An important limitation of Graham's studies is that they assume that the only benefit of environmental protection is to prevent fatal illnesses in humans. Thus these studies ignore many significant benefits of environmental programs. Most obviously, their fixation on fatal illnesses ignores nonfatal harms to human health. Most lethal substances also cause nonfatal health effects. Toxic chemicals can, for example, cause respiratory, neurological, reproductive, hematological, and other health-impairing disorders. Not all of these disorders are fatal, yet they are nevertheless unpleasant and costly byproducts of toxic pollution. In addition, environmental toxins can cause harms to ecosystems, harms which simply do not show up in Graham's limited analysis.

Graham's analysis not only excludes the many benefits of health, safety, and environmental regulation that do not involve life-saving; it also excludes life-saving benefits themselves if these cannot be quantified. This often means that, in the context of toxin control, any life-saving benefits other than the prevention of cancer are ignored because cancer prevention is often the only life-saving benefit that can be quantified.[45]

To be sure, Graham acknowledges that his analysis does not capture all of the benefits of life-saving programs. But it is worth keeping in mind that his focus on quantified life-years saved ignores some of the most important benefits of the programs in question.

## VI. Whose Life Is Worth Saving?

The final problem with Graham's studies on regulatory costs involves the studies' assumptions about whose life is worth saving. Graham's studies do not assume that all human lives endangered by human action are equally valuable. On the contrary, these studies assume that it is better to save the lives of the young than the lives of the old, and they operationalize this assumption by focusing on the number of life-years, and not the number of lives, saved by an intervention. Graham also assumes that lives saved in the

---

[45]One reason why it is easier to quantify risk of cancer than other risks to human health is that there exists a clear end point; the subject under study - either a human or a laboratory animal - either does or does not develop a tumor. With respect to other kinds of effects on human health, however, such as impairments of cognitive development and reproductive capacity, the relevant end point is not so obvious.

future are worth less than lives saved today, and he operationalizes this assumption by applying a 5 percent discount rate to future life-saving. Both of these analytical devices have a large negative effect on assessments of environmental programs in particular, and both are very controversial.

Absent these assumptions, the cost-benefit ratios of the life-saving measures evaluated by Graham and Tengs, especially those involving toxin control, would have been very different. As noted, typically the only quantifiable benefit of toxic substances control is the prevention of cancer. Since cancer is a disease primarily of old age, and since it has a long latency period, the practices of looking at life-years saved and of discounting future benefits produce results that systematically disfavor toxin control.

Discounting, in particular, can have a profound effect on the perceived present-day benefits of actions whose purpose is to prevent future harm. If discounted over a long enough period, even the benefits of preventing catastrophes become trivial. Graham's 5 percent discount rate, for example, means that the death of one billion people 500 years from now is less important than the death of one person today. The logic of discounting also means that saving the lives of your children in the future is worth less than saving your own life in the present. Discounting also systematically downgrades the importance of actions taken to prevent long-latency diseases and long-term ecological harm. Yet these long-term aspirations are among the major aims of the kinds of programs that have fared so poorly in analyses of costs per life saved, especially environmental programs.

It is not difficult to grasp the issues inherent in the question whether to evaluate life-saving programs according to the life-years, or according to the lives, they save. The question turns, essentially, on whether one views older people as equally worthy of protecting from the hazards of, say, air pollution as younger people. It seems to me that our society's norms of equality argue strongly against offering less protection to people based simply on age.

Discounting is more complicated. In discounting, one reduces a benefit one expects to receive in the future by a fixed rate that is designed to capture, in essence, the costs of waiting for the benefit. In the financial context, discounting future sums of money reflects the fact that money received in the future is worth less than money received today because if one receives money today, one can invest it and produce even more money for the future. One might also be impatient to receive the money now. In the life-saving context, discounting is a far more problematic and controversial concept than it is in the financial context. The controversy over the discounting of life-saving benefits is complex, but there are three basic reasons why discounting is problematic in this setting.

First, lives do not compound the way money does. You cannot put a life - or a life-year, for that matter - in the bank and earn money on it. Although one could argue that lives do indeed "compound" through human births, no serious scholar in the literature on discounting advances this as an argument in favor of discounting future life-saving.

Second, it is inaccurate to suggest that a human life, or life-year, lost in the future is somehow not a "whole" life or life-year. If a person dies 30 years from now due to cancer caused by exposure to arsenic, a whole life is lost. Yet at a discount rate of 5 percent, analysts like Graham would deem a regulation saving that person's life to have saved less than one-quarter of a life. But human lives do not come in fractions.

Finally, although many people who advocate discounting purport to do so on the basis of people's preferences, it would surprise me to learn that most members of the public agree with the idea, implicit in discounting at a 5 percent rate, that lives saved in the future are essentially trivial compared with lives saved today. Indeed, one could make a very plausible argument that the existence and widespread popularity of dozens of federal statutes ensuring a high level of environmental protection belie the claim, implicit in discounting, that the future matters relatively little to the ordinary person. Closer to home, most parents, I think, are at least as concerned about their children's future, and as anxious to make it good, as they are concerned about their own present well-being. Discounting ignores - indeed, it discourages - this fundamental human impulse.

## VII. Conclusion

Perhaps the most famous empirical claim in John Graham's research - indeed, one of the most famous claims in all of the literature on risk regulation - is that we could save 60,000 more lives per year if we reallocated our life-saving resources. Graham's empirical research has frequently been misinterpreted as supporting a claim that we are "statistically murdering" approximately 60,000 Americans every year through foolish government regulations. At least some of the life-saving potential Graham has found, however, is based on elimination of government regulations that were never implemented. Most of this life-saving potential, moreover, has nothing to do with government regulations, but instead comes from a rearranging of priorities in non-regulatory situations such as the advice doctors give to patients about quitting smoking.

John Graham has, from all appearances, done nothing to correct the widespread misinterpretation of his own research. Indeed, Graham has frequently encouraged this misinterpretation - by telling the Supreme Court that 60,000 lives could be saved if resources

now spent on regulation were spent more wisely;[46] by publishing articles that refer to unimplemented, indeed unproposed, environmental measures as if they were implemented;[47] and by testifying that bills that would have substantially changed environmentally protective programs in this country were a good idea because without such reform we could be rightly accused of "statistical murder."[48] These are not someone else's misrepresentations of Graham's data; they are Graham's misrepresentations.

The Administrator of the Office of Information and Regulatory Affairs is charged with overseeing a vast array of proposed health, safety, and environmental regulations. The person given this responsibility should not come to the job with a preconceived, cynical notion that whatever a regulatory agency puts before him or her must be a bad idea. Nor should he or she bring to the job any tendency to make the regulatory system look worse than it deserves. Because I believe that John Graham's written record fails him on both these counts, I believe he is an unsatisfactory choice to lead this office.

---

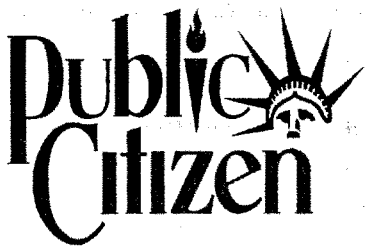
[46]Brief *Amici Curiae* of AEI-Brookings Joint Center for Regulatory Studies, *et al.*, in *American Trucking Ass'ns. v. Whitman*, No. 99-1426, at 1-2 (U.S. Supreme Court 2000) (citing Tengs & Graham, *Opportunity Costs*).

[47]John D. Graham, *How to Save 60,000 Lives*, Electric Edison Institute (1995).

[48]Risk Assessment and Cost Benefit Analysis: Hearings Before the Comm. on Science, United States House of Representatives, 104th Cong., 1st Sess. 1124 (1995) (written testimony of John D. Graham).

# Safeguards At Risk:

## John Graham and Corporate America's Back Door to the Bush White House




March 2001

**Acknowledgments**

This report was researched and written by Laura MacCleery, with research assistance from Paul Schmitt, Debbie Quint, Daniel Becker, and Ed Ricci. Editorial assistance and direction were provided by Joan Claybrook, Booth Gunter, Angela Bradbery, Melissa Luttrell and David Vladeck. Reproduction of the report was managed by Johnette Washington.

**About Public Citizen**

Public Citizen is a non-profit, 150,000-member organization based in Washington, D.C. that represents consumer interests through lobbying, litigation, regulatory oversight, research and public education. Since its founding by Ralph Nader in 1971, Public Citizen has fought for consumer rights in the marketplace, safe and secure health care, health and safety standards, fair trade, clean and safe energy sources, and corporate and government accountability. Public Citizen is active in every public forum: Congress, the courts, governmental agencies and the media.

**Public Citizen**
**1600 20th St. N.W.**
**Washington, D.C. 20009**
**(202) 588-1000**

**March 2001**

**©2001 Public Citizen. All rights reserved.**
**ISBN No. 1-58231-022-X**

# TABLE OF CONTENTS


**EXECUTIVE SUMMARY** ..... 1
Health, Safety and Environmental Regulations Are At Risk 3

**PART ONE: WHO IS JOHN GRAHAM?** ..... 9
Graham's Credentials 10
I. The Money: Graham's "Sound Science" Is Brought To You By . . . 11
List of Harvard Center for Risk Analysis Funders 12
Graham Is At The Center of An Anti-Regulation, Corporate-Funded Network 13
II. The Objective: Corporate Regulatory Control Through OMB 14
Graham's Role in the Push for Regulatory Rollback 14
Graham's Risk Tradeoffs Are Political Cover for An Anti-Regulation Agenda 16
III. Graham's Methods are Deeply Flawed And Antithetical to Environmental and Public Health Safeguards 18
At OMB, Graham Would Imbalance the Regulatory Process 18
Expanding the Role of Risk Analysis and Cost-Benefit Analysis Undermines Public Health 19
Graham's Policy Recommendations Block a More Protective Approach to Public Health 24
IV. Graham's Problematic History of Non-Disclosure 26
A Comparison of Graham's Risk Tradeoffs and the Corporations That Fund HCRA 28
Following the Money: Graham's Affiliations with Other Organizations 33

**PART TWO: CASE STUDIES: GRAHAM GOES TO BAT FOR INDUSTRY** ..... 39
Case Study #1: Graham Joins the Campaign to Defend Second-Hand Smoke 39
Case Study #2: Graham Weighs In On the Safety of Cell Phones 48
Letter from Tom and Ray Magliozzi, Hosts of Car Talk from National Public Radio 53
Case Study #3: Graham Opines on Passenger-Side Air Bags 56

**PART THREE: A CORPORATE AGENDA** ..... 69
Science Sellout #1: The Counterfeit Science of Graham's Risk Analysis 70
Science Sellout #2: Flack Science: Manipulating the Media Pays Off 74
Science Sellout #3: Selling Half the Story 78
Science Sellout #4: Misleading Risk Communication: The Difference Between Falling and Being Pushed 81
Science Sellout #5: Concocting "Science" for Corporate Counter-Spin 85
Science Sellout #6: The Misuse of Scientific Uncertainty 90
*No Comment I:* Consumers Union Letter to EPA And USDA About HCRA 92
*No Comment II:* Natural Resources Defense Council Letter About HCRA 95

**PART FOUR: APPENDIX** ..... 99
Appendix A: In His Own Words 99
Appendix B: Full List of HCRA Funding Sources 102
Appendix C: Graham's Record on the EPA's Dioxin Science Advisory Board 109
Appendix D: Risk Assessment and Risk Management 110
Appendix E: The Misuse of Comparative Risk "Analysis" 113
*How a Social Science Becomes Swiss Cheese* 115
Endnotes 116

# EXECUTIVE SUMMARY

News reports published the week of March 5, 2001 indicate that John Graham, founding director of the Harvard Center for Risk Analysis (HCRA), was nominated by President Bush for a position as the new regulatory czar in the White House Office and Management and Budget (OMB). Most Americans have never heard of John Graham, but if the U.S. Senate approves, he will be in a position to wield enormous power, and to undercut public health, safety and environmental protections for years to come.

Graham would head the Office of Information and Regulatory Affairs (OIRA), which vets any significant or controversial regulation before it can be implemented. Over the past decade, Graham has been a prominent figure in the fight to halt or delay the issuance of protective safeguards by federal regulatory agencies, working with and receiving funds for his activities from dozens of major corporations. At OMB, he would be able to impose his will on the agencies, perhaps even on behalf of his former industry supporters, by blocking the development of standards and eviscerating the government's regulatory framework.

There are three major problems with Graham's potential rise to power within OMB. First, Graham is certain to favor the regulated industries that have handsomely supported his Center. Graham has amply demonstrated his willingness to ignore, or gloss over, his own conflicts of interest. This report shows that Graham's Center has accepted money from chemical companies, auto manufacturers, energy and oil interests, and other industries hostile to regulation.[1] Yet, invoking the prestige of Harvard University, he has consistently testified before Congress and been widely quoted by the media as though he is a neutral academic "expert," with no disclosure of the sources of his Center's funding in the article or testimony.[2]

As discussed in *Part One: Who Is John Graham?*, Graham's research has been used to lend a "scientific" veneer to corporate efforts to roll back safety and environmental standards, and to push for a top-down reorganization of the government's basic regulatory scheme. Graham's Center is funded by more than 100 large corporations and trade associations, including such known environmental offenders as Dow, 3M, DuPont, Monsanto and Exxon, in addition to the Chlorine Chemistry Council, the American Automobile Manufacturers Association, the American Petroleum Institute, and the Chemical Manufacturers Association, now called the American Chemistry Council.[3] High-ranking corporate officers from Oxford Oil, the National Association of Manufacturers, Eastman Chemical, Tenneco Inc., CK Witco Corp., and Novartis Corp. sit on the Center's Executive Board.[4] The HCRA Advisory Council includes executives from DuPont and the Grocery Manufacturers Association, and the chief attorney for environmental affairs at Exxon Chemical Americas.[5]

Second, Graham's methodology appears to be informed more by the wishes of his corporate backers than by anything recognizable as "science." Although he often calls himself a "scientist," Graham's field of risk analysis is a discipline within the field of public policy, and he does not in fact hold any degrees in the hard science disciplines that often form the basis for regulatory policy.[6] As this report demonstrates, Graham's research conclusions are frequently marred by his inflation of industry costs and underestimations of the public benefits of safeguards. The practice of cost-benefit analysis also omits or downplays ethical and moral factors such as justice, consent and equity, and inappropriately discounts the value of human life and the environment.

Graham's Center, acting under the auspices of the Harvard School of Public Health, churns out research in support of industries that have a keen financial interest in seeing health and environmental safeguards dismantled or delayed. In *Part II*, we examine three case studies of his work and show that:

- Graham solicited financial contributions from tobacco giant Philip Morris in the early 1990s and invited the company's public relations officials to review a draft chapter of Graham's book on the subject of second-hand smoke. Internal company memos show that Big Tobacco relied on Graham as part of its strategy to generally discredit the Environmental Protection Agency (EPA) and to undermine an EPA risk assessment of the cancer-causing effects of second-hand smoke.

- In July 2000, as many cities and states were considering outlawing the use of cell phones while driving, Graham published a study (funded by AT&T Wireless Communications for $300,000) assessing the risks. The study came out against a ban on using cellular phones while driving, concluding that such a ban *would be more costly than air bags* and that there was "not enough reliable information on which to base reasonable policy." As Tom and Ray Magliozzi, hosts of Car Talk from National Public Radio put it in response to a similar study by Robert Hahn, Graham's intellectual and political ally at the American Enterprise Institute-Brookings Joint Center for Regulatory Studies, "This seems to us to be a clear case of cost/benefit analysis run amok."[7]

- Graham has wildly distorted the facts when advocating industry positions in the media. For example, amid fierce controversy over defectively designed air bags in 1997, he wrongly told the Associated Press that "most" of the 38 children killed by air bags had been decapitated. The same year, he appeared on ABC's Good Morning America to report that a Harvard Center for Risk Analysis study had found that the "cost" of passenger side air bags was $399,000 for each year of life saved. After harsh criticism, the study was peer reviewed. When it was finally published in the *Journal of the American Medical Association*, Graham had flip-flopped — revising that estimate down to $61,000 per life year saved, and concluding that air bags were, in fact, a worthwhile and life-saving investment.

The third reason Graham is unfit to serve at OMB is because of his long-standing strategic and research services to an entire network of anti-regulatory corporate interests, who would expect to call upon his sympathy. *Part III: Science for Sale*, explains six of Graham's public relations techniques, showing how an anti-regulation political strategy is packaged as "necessary" information about human health and the environment.

For example, Graham was a member of the EPA Science Advisory Board that reviewed the agency's risk assessment on dioxin, an industrial contaminant, in 1994 and 2000.[8] In June 2000, the EPA announced a draft of its study, which showed that exposure to the level of dioxin currently in our environment causes an increase in the average American's lifetime cancer risk to as high as 1 in 100. The EPA's reassessment also found that dioxin, even at very low levels of exposure, is linked to infertility, immune system damage and learning disabilities.[9]

But rather than acknowledging that dioxin poses an *additional* threat to human health, in his comments to the media Graham misleadingly downplayed the risk by comparing the EPA's findings to other types of risks, such as the risk of dying in a car crash.[10] When compared with these risks, Graham suggested, the risk posed by dioxin appears "normal."

The National Public Radio report containing Graham's comments failed to mention his position on the Science Advisory Board and failed to disclose that his Center is supported by money from 48 different dioxin producers, including incinerator companies, pulp and paper companies, cement kilns, copper smelters, PVC manufacturers, PCB producers and the petroleum industry.[11]

Graham's tight connections to the chemical industry have also influenced his legislative work. Graham spoke at a panel discussion held around 1994 at the Chemical Industry Institute of Toxicology (CIIT) alongside executives from Eastman Kodak, the American Industrial Health Council, Air Products and Chemicals, E.I. DuPont de Nemours, and the Chemical Manufacturers Association (now called the American Chemistry Council).[12]

The topic was a Congressional bill that would have imposed rigid cost-benefit criteria on federal regulatory agencies in order to deter the development of new public health, safety and environmental protections. Graham commented on the relationship between the rollback "reform" bill and the chlorine's industry's support for institutions such as CIIT: "Those of us advocating reform could not be as effective as we have been in advocating the role of science in risk assessment if we did not have the underlying data and methodologies that were created here at CIIT," he said.[13] All of the trade associations and companies listed above are also funders of Graham's Center.[14]

Graham has been a critical player in a decade-long, multi-industry campaign to discredit federal agencies and to block the regulatory process, and his use of the Harvard name helped to legitimize these attempts to rewrite the rules on public health and environmental issues. As this report shows, debates over the safety of pesticides, injury prevention, pollution, second-hand smoke, toxic chemicals and contamination of our food and water have all been victims of these efforts.[15] If Graham goes to the OMB, he could serve as the back-door conduit for a new corporate assault on public and environmental health.

**Health, Safety and Environmental Regulations Are At Risk**

Under a standing Executive Order, a primary function of the Office of Information and Regulatory Affairs is to "review" cost-benefit calculations produced by federal agencies before new standards and rules can be issued. In theory, the OIRA director should serve as an honest broker, reviewing regulatory proposals from federal agencies and deferring to agency expertise on most technical and scientific matters.

However, the OMB's "review" process has been used in the past to block the issuance of key health and safety standards.[16] During the Reagan-Bush I years, political appointees within OMB, in conjunction with councils run by Vice President Bush and Vice President Quayle, were given broad discretion to review and block new standards created by federal agencies, often at the direct request of chemical companies, auto manufacturers and other regulated interests.

It is clear that Corporate America is expecting the same treatment from Bush II. The U.S. Chamber of Commerce told *The Washington Post* in February 2001 that it has drafted a presidential "executive order of its own that it hopes the new administration will use as a template for rewriting its policy on regulation."[17] The draft order lays out the process for "how rules should be reviewed, the role of the Office of Management and Budget, and the economic and scientific criteria that agencies should apply to rule-making."[18] "If you fix [OMB], you rein in all the agencies," said Bruce Josten, the Chamber's executive vice president for government affairs.[19]

The "fix" may be in. In 1996, Graham told political strategists at the Heritage Foundation that "environmental regulation should be depicted *as an incredible intervention in the operation of society.*"[20] He has said that support for the regulation of chemicals in our water supply shows the public's affliction with "a syndrome of paranoia and neglect."[21] According to news reports, Graham also explained to attendees at a conference at Duke University in 1996 that he believed that "government agencies should be required to depend on expert analyses, rather than public views, in deciding which threats to regulate."[22]

Graham's record on public health issues is clear. For the past decade, Graham has vigorously promoted a set of economic tools called "risk analysis" in regulatory decision-making,[23] and has pushed for omnibus legislation that would rank all activities by the federal agencies according to their cost to businesses and impose onerous, industry-favoring additional requirements on every new regulation.[24] In 1999, Graham supported S.746, which would have invited litigation over an agency's implementation of cost-benefit rules, and thus further hold up the process of establishing safeguards.

Important regulations are at risk. Graham recently joined a group of economists who argued to the Supreme Court that EPA action under the Clean Air Act did not pass muster on cost-benefit grounds.[25] Their argument was found meritless by a unanimous Court, but at OMB Graham could impose the same requirements the Court struck down, behind closed doors and out of public view. In 1997, Graham announced that passenger air bags were not cost-effective, and in 1999 he supported the passage of a "reform" bill that likely would have prevented any air bag regulation from being developed, if the law had been in place at the time a rule was considered.[26] According to government records, the air bags rule alone has saved 6,733 lives to date.[27]

If Graham is approved by the U.S. Senate for OIRA Director, he will be in the catbird seat; overseeing the entire executive regulatory process. Only the independent regulatory agencies, which are considered an arm of the Congress, will be outside his direct regulatory reach. No significant safety, health, environmental or any other proposed or final rules can be issued without approval through this office in the OMB. Nor, under the Paperwork Reduction Act, can any government agency gather information from ten or more entities, a move which often is essential for the research that justifies regulation, without approval from OIRA.

Through these mechanisms, OIRA can slow, stall, weaken or stop regulatory proposals and final rules that the regulated industry opposes. Graham's first move at OIRA would likely be to draft a new executive order that could immobilize the issuance of new health, safety and environmental safeguards. Graham's prescriptions on the application of risk analysis have been sweeping; it appears that there is little agency action that would remain beyond his purview.[28] And Graham's "comparative risk" approach could easily drown the agencies in a sea of red tape. In short, Graham would become the new master of "paralysis by analysis."

Graham's philosophy, well demonstrated by his years of advocacy for industry interests, is that federal agencies must wait to impose rules until near-perfect estimates of the precise causes and effects of the hazards to be regulated are known. But regulators often know that a substance or product is dangerous long before they can measure the exact magnitude of the harm, extent of the exposure, or exact mechanism by which a substance acts on the human body or environment. Collecting this secondary information can take years — years during which the public will continue to be exposed.

At the same time that OIRA under Graham's direction could impose endless analytical requirements on government agencies, another office within the OMB undoubtedly will be cutting the already paltry agency budgets, essentially making it impossible for them to keep up with the public needs for industry oversight and law enforcement. The combination is a sure recipe for public health and environmental disasters.

Given his public statements on the subject and his efforts over the past decade, Graham would likely quash any safety or health rule that his numbers indicate is not the most economically "efficient" option. As were Vice President Dan Quayle's "Council on Competitiveness" and Vice President Bush's "Task Force on Regulatory Relief," the OMB would once again become a black hole into which our national safeguards disappear. For all of the reasons documented by this report, Graham should not be approved by the U.S. Senate to head the Office of Information and Regulatory Affairs in the Office of Management and Budget.

# PART ONE

## WHO IS JOHN GRAHAM?

**Introduction**

Patricia Pena didn't know what hit her. Just three days after she left her job to become a full-time mother, her car was broadsided at an intersection and her only child, a 3-year-old girl, was killed. The police investigation revealed that the driver who hit her car was dialing a number on his cellular phone when the crash occurred. Pena has since become a national advocate for banning the use of cellular phones while driving, traveling to Washington, D.C., to speak with legislators and writing about her story in *USA Today*.[29]

Opposing her are the wealthy cellular communications industry and a well-coordinated network of corporate lobbyists, conservative public policy think tanks and industry-funded academics. One of these academics is John D. Graham, whose Harvard Center for Risk Analysis (HCRA) accepted $300,000 from AT&T Wireless Communications to do research on driver distraction and cell phones. Graham's study concluded that a ban on cell phones while driving was too "costly" to be worthwhile.

Graham's cell phone cost-benefit analysis misapplied basic statistical methods and weighed projections of the public's injuries and fatalities against lost industry profits and other consequences of a ban.[30] This approach to matters of public health and safety is typical of his work, this report shows. Now, Graham has been nominated to be the regulatory gatekeeper of the Bush administration in the Office of Management and Budget (OMB) regulatory affairs office, with the power to undermine standards set by federal agencies under congressional mandates.

Graham's appointment to the Office of Regulatory Affairs within OMB represents a serious threat to public health and environmental protections. Graham worships at the altar of economic analysis, proposing that all government regulatory actions conform to a methodologically suspect system of decision-making. Although it is marketed as "sound science," in fact his approach is perfectly aligned with the financial interests of regulated industries, such as chemicals, oil and gas, agribusiness and industrial metals. More than a hundred major companies have provided direct, unrestricted funding for his Center over the past decade (*see* p. 12).

Acting as a political strategist for these companies, Graham has advocated that the government give economic factors (like the cost to industry of complying with new regulations) the virtual trump card in any decision involving the enactment of new safeguards.[31] His paradigm for regulatory decision-making is anti-consumer, anti-environment, and hostile to preventive measures in public health. As a practical matter, Graham's regulatory proposals will also make it far more difficult for the federal agencies to act to protect public health and safety.

**Graham's Credentials**

Graham is currently the director of the Harvard Center for Risk Analysis (HCRA), which is connected to Harvard University as a separate sub-unit of the Harvard School of Public Health. The Center offers some twelve courses in a field called "decision analysis" to Harvard students but does not itself grant degrees. In addition to the student courses, the Center also offers, at a fee, short courses and multi-day seminars that grant "continuing executive education" credits to corporate officers. Graham teaches several of the courses, which train business executives to, among other things, "identify subgroups of lay people who are likely to be particularly outraged or tolerant about a potential risk."[32]

The Center also publishes a monthly newsletter called *Risk in Perspective*.[33] One recent issue suggested that "speculative [and] minor" risks to children include pesticides and Bisphenol-A and phthalates (toxic chemicals found in plastics and some children's toys), without acknowledging that funders of HCRA make these products. Another issue of the newsletter from April 1999 was titled, "*Toxic Pollution from Power Plants: Large Emissions, Little Risk.*"

Although Graham himself has sometimes been called a "scientist," and he often uses the honorific "Dr." to the press while invoking the name of Harvard's School of Public Health, he has earned no degrees in medicine, public health or the hard sciences.[34] The subjects of his degrees are omitted from his resume on the HCRA Web site, but Graham has previously told Congress that both his undergraduate and master's degrees are in public policy.[35] We called Wake Forest University, where Graham earned his bachelor's degree, and were told by staff in the alumni office that there is no undergraduate program in public policy and that, according to their records, Graham earned his B.A. in economics.[36] Graham's doctorate from Carnegie Mellon is in a subset of public policy called "decision analysis."

For the uninitiated, the name of Graham's Center for Risk Analysis might be a bit misleading. "Risk Analysis" is a broad, umbrella term that includes at least two sub-disciplines: "risk assessment" and "risk management." *Risk assessments* survey hazards from human exposure to a substance (or an activity) and the effects upon human health or the environment, and often involve original research in an area of the hard sciences, such as biology, chemistry, toxicology, etc. Risk assessment also uses estimates and theoretical models, because the scientific data are often lacking.

Risk assessment asks an objective question: "How risky is this situation?" However, the results of risk assessments are hardly "objective." As Mark Shere, a conservative lawyer who represents industrial clients in pollution cases, noted, "A typical risk assessment consists of about 50 separate assumptions and extrapolations, each of which may skew the analysis by a factor of 10 or more . . . . these assumptions and extrapolations can alter the final numeric estimate of risk by a multiple of billions, and this result is again, unverifiable."[37]

*Risk management*, on the other hand, is a field of public policy that uses the results of risk assessments, as well as information about social and political values and data and statistical modeling tools, to come up with recommendations about risk policy. Risk management is a normative inquiry, asking "What should we *do* about the risk?" Graham also frequently invokes concepts that rightly belong under the rubric of "cost-benefit analysis" or "risk-benefit analysis." These phrases refer to two closely related sets of public policy tools that weigh either projected *costs* or *risks* against the projected *benefits* of some activity or rule.

Most — if not all — of Graham's work falls into the risk management category, meaning that it is informed by public policy as well as by data from the underlying hard science discipline. Many risk managers do have degrees in biology, or chemistry, etc., and the federal regulatory agencies employ them to make policy recommendations based on the science they know. Crafting regulations that protect health, safety and the environment is normally viewed as a highly specialized endeavor.

## I. THE MONEY: GRAHAM'S "SOUND SCIENCE" IS BROUGHT TO YOU BY . . .

Graham's Center is funded by more than 100 large corporations and trade associations, including such known environmental offenders as Dow, 3M, DuPont, Monsanto and Exxon, in addition to the Chlorine Chemistry Council, the American Automobile Manufacturers Association, the American Petroleum Institute, and the Chemical Manufacturers Association, now called the American Chemistry Council.[38]

High-ranking corporate officers from Oxford Oil, the National Association of Manufacturers, Eastman Chemical, Tenneco Inc., CK Witco Corp., and Novartis Corp. sit on the Center's Executive Board.[39] C. Boyden Gray serves on the Center's executive board and regularly joins strategic huddles at the corporate-backed Heritage Foundation.[40] Gray is a prominent lobbyist for chemical, steel and energy interests[41] and was former White House counsel for Bush I, and a transition adviser to Bush II. The HCRA Advisory Council includes executives from DuPont, the Grocery Manufacturers Association and the Chief Attorney for Environmental Affairs at Exxon Chemical Americas.[42] Gray also served as "Group Chair" of the "Harvard Group on Risk Management Reform," a 15-member group which headed a 1995 effort for regulatory rollback.[43]

Documents made public by the state attorneys general tobacco litigation in 1997 to 1998 show that in the mid-1990s, Graham personally solicited large donations in support of his Center from Philip Morris and its subsidiary, Kraft, in sums from $25,000 to $50,000 — while criticizing the EPA's conclusion that second hand smoke causes lung cancer.[44] Graham has also repeatedly spoken out against fuel economy standards, often without acknowledging that his Center receives large donations from many oil and gas companies, including Mobil, BP America, Chevron, Unocal and Amoco, and motor vehicle manufacturers such as Ford, General Motors and Goodyear.

**Harvard Center for Risk Analysis (HCRA) Funders**

*As Posted on the HCRA Web site, March 6, 2001*

| Unrestricted | Unrestricted | Restricted |
|---|---|---|
| 3M | The Goodyear Tire & Rubber Company | Alfred P. Sloan Foundation |
| Aetna Life & Casualty Company | Grocery Manufacturers of America | American Crop Protection Association |
| Air Products and Chemicals, Inc. | Hoechst Celanese Corporation | American Industrial Health Council |
| Alcoa Foundation | Hoechst Marion Roussel | Andrew Mellon Foundation |
| American Automobile Manufacturers Association | Hoffman-LaRoche Inc. | Bradley Foundation |
| American Crop Protection Association | ICI Americas Inc. | Brookings Institution |
| American Petroleum Institute | Inland Steel Industries | California Avocado Commission |
| Amoco Corporation | International Paper | Chemical Manufacturers Association |
| ARCO Chemical Company | The James River Corporation Foundation | Chiang Ching-Kuo Foundation for International Scholarly Exchange |
| ASARCO Inc. | Janssen Pharmaceutical | Chlorine Chemistry Council |
| Ashland Inc. Foundation | Johnson & Johnson | Congressional Research Service |
| Association of American Railroads | Kraft Foods | Electric Power Research Institute |
| Astra AB | Louisiana Chemical Association | Elsa U. Pardee Foundation |
| Atlantic Richfield Corporation | Lyondell Chemical Company | International Life Science Institute/Risk Science Institute |
| BASF | Mead Corporation Foundation | Health and Environmental Sciences Group |
| Bethlehem Steel Corporation | Merck & Company | National Association of Home Builders |
| Boatmen's Trust | Millenium Chemical Company | National Institute of Justice |
| Boise Cascade Corporation | Mobil Foundation, Inc. | Pfizer, Inc. |
| BP America Inc. | Monsanto Company | Society for Risk Analysis |
| Cabot Corporation Foundation | National Food Processors Association | U.S. Centers for Disease Control |
| Carolina Power and Light | National Steel | U.S. Department of Agriculture |
| Cement Kiln Recycling Coalition | New England Power Service — New England Electric System | U.S. Department of Energy |
| Charles G. Koch Foundation | Nippon Yakin Kogyo | U.S. Department of Health and Human Services |
| Chemical Manufacturers Association | North American Insulation Manufacturers Association | U.S. Department of Transportation. |
| Chevron Research & Technology Company | Novartis Corporation | U.S. Environmental Protection Agency |
| CIBA-GEIGY Corporation | Novartis International | U.S. National Oceanic Atmospheric Administration |
| Ciba Geigy Limited | Olin Corporation Charitable Trust | U.S. National Science Foundation |
| CITGO Petroleum Company | Oxford Oil | |
| The Coca-Cola Company | Oxygenated Fuels Association | |
| Cytec Industries | PepsiCo Inc. | |
| Dow Chemical Company | The Pittston Company | |
| DowElanco | Pfizer | |
| DuPont Agricultural Products | Pharmacia Upjohn | |
| Eastman Chemical Company | Potlatch Corporation | |
| Eastman Kodak Company | Praxair, Inc. | |
| Edison Electric Institute | Procter & Gamble Company | |
| E.I. DuPont de Nemours & Company | Reynolds Metals Company Foundation | |
| Electric Power Research Institute | Rhone-Poulenc, Inc. | |
| Emerson Electric | Rohm and Haas Company | |
| Exxon Corporation | Schering-Plough Corporation | |
| FBC Chemical Corporation | Shell Oil Company Foundation | |
| FMC Corporation | Texaco Foundation | |
| Ford Motor Company | Union Carbide Foundation | |
| Fort James | Unocal | |
| Frito-Lay | USX Corporation | |
| General Electric Fund | Westinghouse Electric Corporation | |
| General Motors Corporation | Westvaco | |
| The Geon Company | WMX Technologies, Inc. | |
| Georgia-Pacific Corporation | | |
| Glaxo-Wellcome, Inc. | | |

HCRA's conflict of interest policy (published on its Web site) primarily concerns protocols for research and does not appear to extend to media work. In reference to the disclosure of funding it provides only that "[a]ll sources of financial support for the Center's activities are disclosed publicly on this site, in our annual report, and *on every publication of HCRA scientific research*."[45] But as to scientific research, the HCRA policy imposes only spotty coverage: While it does contain specifications for "restricted grants," no mention is made of the much larger category of funds received by the Center that are "unrestricted." The funding list also does not reveal when funding was received by the Center, the amount of the funding, or how often a donor has given money.

**Graham Is At the Center of An Anti-Regulation, Corporate-Funded Network**

After a decade of criticizing the EPA and other agencies for being overly cautious in calculating risks, industry forces decided in the 1980s to co-opt the regulatory language of risk assessment, and to re-write the rules of the game from within. As this report shows in Parts Two and Three, large corporations established and funded pseudo-science front groups, fake grassroots organizations and anti-regulatory think tanks; spread wildly distorted anecdotes about runaway regulators and costly bureaucracies; and, under the misleading language of "sound science," plotted counterattacks to government-funded studies on issues such as second-hand smoke and styrene. Their goal was to generally discredit the enterprise of protective regulation. They sought to exploit any breach in the public's confidence about the wisdom of federal agencies by instituting the rule of risk "experts" — whose calculations they could control by rigging the technical rules of the game and whose decisions would trump the democratic development of health and safety protections.

Graham is a bridge figure in this network. He has a place on highly technical university-based committees and on the boards of international "professional" societies, while regularly advising political strategists at the Heritage Foundation[46] and serving on the board of the American Enterprise Institute-Brookings Joint Center on Regulatory Affairs. In this way, Graham helps to coordinate strategic and tactical decisions of the moment; by promoting the concept that government regulation has been based on "junk science," or emphasizing cost-benefit tradeoffs in order to obscure his allies' opposition to regulation across the board.[47]

Through Graham's behind-the-scenes participation in the regulatory debates on the part of Philip Morris, and his assistance to the media campaigns of counter-spin front groups like the American Council on Science and Health, Graham lent his Harvard credentials to the cause and helped to legitimize industry's attack on public health, safety and environmental objectives.[48] Besides regularly marketing his anti-regulatory paradigm to the "paranoid yet neglectful" public,[49] and working on regulatory rollback bills with lawmakers on Capitol Hill,[50] Graham also gets directly involved with the regulatory process by serving on Science Advisory Boards involved with particular risk assessments, as he did with the EPA's work on dioxin. A more complete summary of his organizational affiliations and a brief description of their involvement in the regulatory debate is found at the end of this chapter.

The astonishing growth and media savvy of this corporate-funded "regulation defense" has been chronicled in several books and articles.[51] In *Toxic Sludge Is Good For You*, co-authors John Stauber and Sheldon Rampton describe how the National Agricultural Chemical Association, now called the American Crop Protection Association (ACPA), created a multi-layered buffer of pseudo-science front groups and public relations offensives to offset the anticipated negative publicity from publication in 1962 of Rachel Carson's environmental classic, *Silent Spring*.

Their techniques have been refined and now serve as the model for other counter-assaults, as detailed in Part Three, Sellout #5: *Concocting "Science" For Corporate Counter-Spin*. The same corporate trade group that refined those tactics, the ACPA, supports Graham's operation at Harvard. More importantly, Graham has been extensively cited in the media coverage of chemical policy issues,[52] and his comments routinely downplay the health risks posed by chemicals. He was also cited in several articles about the publication of a book on dioxin and other hormone disrupting chemicals, *Our Stolen Future,* by Theo Colborn, Dianne Dumanoski and John Peterson Myers. His funding by ACPA was undisclosed in the coverage.

## II. THE OBJECTIVE: CORPORATE REGULATORY CONTROL THROUGH OMB

### Graham's Role in the Push for Regulatory Rollback

The same companies that provide funding for Graham's Center have been the chief promoters of a wholesale revision of the federal regulatory process, along lines more favorable to their interests.[53] Unsurprisingly, Graham was a major participant in these efforts. For example, Graham was regularly communicating with Big Tobacco during the early 1990s push for regulatory rollback as well as its precursor, Bush I's 1992 draft Executive Order (*see* Part Two, Case Study #1).[54]

Then again in late 1994, Graham became a prominent figure in the Washington establishment debate over the merits of so-called regulatory "reform." Under the Contract With America, Republicans had pledged to subject most new regulation on the part of a dozen federal agencies — and especially the EPA — to an obstacle course of hurdles like risk-benefit analysis and cost-benefit analysis, along terms drafted by business interests.[55] There were several bills floated on the topic, but only fragments of the rollback initiative were eventually signed into law.

In the fall of 1994, Graham was commissioned by the conservative American Enterprise Institute to, according to his own later testimony before the Senate, "write a blueprint for regulatory reform legislation. This blueprint influenced the regulatory legislation that passed the House of Representatives in March of 1995."[56] (The bill failed to pass the Senate.) Graham's claim is probably an exaggeration, but it is true that he had a distinct media presence in the debate over regulatory rollback.[57] Graham told an audience at the Heritage Foundation in 1996, "*I don't think there's any more passionate advocate of regulatory reform than myself.*"[58]

An article in the *National Journal* in 1995 described Graham's promotion to the Chamber of Commerce of a sweeping, inter-agency requirement: [59]

> John D. Graham . . . predicted that the risk assessment legislation will be the first installment in a 10-year overhaul of federal health, safety and environmental policies. During that time, he said, Congress should rank all the risks with which the federal departments and agencies must deal and shift resources to focus on the most dangerous ones.

As OIRA Administrator, Graham would be perfectly positioned to implement an anti-regulatory agenda. A bill from the last Congress, S. 746, the "Regulatory Improvement Act of 1999,"[6] clearly aligns with recommendations from Graham's 1996 chapter in a book on cost-benefit analysis called an "Agenda for Congress."[61] In testimony before the Senate, Graham offered his "enthusiastic support for the measure."[62]

S. 746 would have harnessed every agency to the same rigid risk assessment and cost-benefit formulas, subjected new rules to mandatory "peer review" by committees that likely would have a strong pro-industry bias, permitted the OMB to nix a rule without any written explanation, and, in a "judicial review" clause, invited industry litigation over whether the agency had properly done its job under the new requirements.[63] According to a Public Citizen report, *The Unintended Consequences of the S. 746 Regulatory Obstacle Course*, the 1999 rollback bill would have threatened, eliminated or considerably delayed critical regulatory programs like nursing home safety, disability rights, factory farm pollution controls, youth smoking prevention and food safety, just to name a few.[64]

Since the advent of Bush II, the Chamber of Commerce has proposed a new draft executive order that would give far greater power to the OMB. Under the order, OMB could insist that federal agencies weigh "compliance costs" (which are often comprised mainly of foregone profits) much more heavily, direct the agencies to give preference to "flexibility" and "market-based" approaches, and require that the projected benefits of a regulation outweigh the "costs," without looking at factors like justice, or social goals other than "efficiency."

Regardless of the many, unresolved moral and methodological questions, Graham and his industry allies want to do more with tools like cost-benefit analysis. They want the ability to use "economics," rigged their way, to block agency implementation of legislation that is unpopular with business, under the guise of "maximizing efficiency" and "prioritizing" all regulation within the OMB. Under some of their proposals, the cost-efficiency of any new regulation must be compared to — and appear justified against — every other possible program to regulate that risk.[65]

Graham believes that virtually any hazard-related agency action should pass through a formal review by the White House. In 1997, Graham advocated a sweeping requirement that would have imposed *upon all risk-related determinations* a "peer review" by committees likely to be staffed with industry-friendly "experts" and centralized clearance through the White House Office of Science and Technology Policy. These red tape burdens would apply even if the agency was merely publicizing information on a hazard that had not been not part of any formal rulemaking, such as a pronouncement by the Surgeon General on the risks of smoking.[66] In short, Graham proposes a near stranglehold on the government's ability to communicate public health information.

Graham has also repeatedly suggested that congressional regulatory rollback legislation should be so sweeping that it over-rides every existing agency mandate and *requires* an exhaustive cost-benefit and risk-benefit analysis before any safeguard can be finalized.[67] In his over-reaching prescription, the results of the economic analysis would determine the survival of a rule. In 1997, Graham told Congress that when a reviewer's cost-benefit calculus collides with the agency's Congressional mandate, the democratic process must give way. Graham said that all the agencies' "enabling statutes *should be superseded by the general requirement* that each rule's identified benefits must justify its identified costs."[68]

A very similar proposal related to the role of cost-benefit analysis in protective regulation was soundly rejected by a unanimous Supreme Court in a February 28, 2001 decision. The American Trucking Associations sued the EPA to block new requirements issued under the Clear Air Act.[69] Graham and other anti-regulatory "economists" from the American Enterprise Institute-Brookings Joint Center for Regulatory Studies (AEI-Brookings) submitted a brief to the Court on the side of the trucking industry, arguing that requiring cost-benefit analysis would "improve regulatory decisionmaking."[70]

Justice Scalia, writing for the full Court, held that *neither the Clean Air Act nor the U.S. Constitution requires that corporate compliance costs be considered when EPA writes a rule to protect health and the environment*. Even Bush II's new head of the EPA, Christine Todd Whitman, supported the Supreme Court's decision, calling it "*a solid endorsement of EPA's efforts to protect the health of millions of Americans from the dangers of air pollution*."[71]

**Graham's Risk Tradeoffs Are Political Cover For An Anti-Regulation Agenda**

A 1995 article in *The Boston Globe* described the Superfund cleanup of chemical contamination of Love Canal, New York.[72] After the EPA filed a lawsuit over the cleanup, Occidental Chemical Corporation and the government reached an agreement that Occidental would reimburse taxpayers for $129 million of the costs.

Thanks to EPA's efforts, Occidental — which inherited the legal liability for 20,000 tons of chemicals that were dumped in Niagara Falls, N.Y., over the course of nine years — and *not* taxpayers were footing the bill. Yet Graham was quoted in the article as saying, "Does it really make sense to spend, say, $50 million on speculative risks *when you don't have the resources to provide violence prevention or pregnancy prevention in the schools?*"[73] Graham failed to mention — or the reporter failed to report — that two of his Center's funders, Millenium Chemical and Lyondell Chemical, are Occidental's petrochemical business partners.[74] Graham's comments are also misleading because reducing costs to industry does not free up money for government programs that address other risks, as Graham implies. Instead, the money goes back into shareholders' pockets.

Graham often argues that risks should be compared, for policymaking purposes, *with other risks*. In the parlance, this is called comparative risk analysis or risk-benefit analysis. Graham promoted this approach as a media strategy at a Heritage Foundation meeting in 1996, arguing that conservatives would appear more environmentally friendly if they couched regulatory rollback arguments in efficiency terms.[75] Graham had just returned from a weekend conference held by the National Wildlife Federation, an environmental organization, and was full of spin ideas for his conservative colleagues.[76]

In order to move the anti-regulatory agenda along more politically acceptable lines, Graham suggested to the strategists at Heritage that: "We ought to make the case that if these agencies were smarter and more scientific, we could reallocate resources, save more lives, and do more for the environment at no increased cost to the taxpayer. . . This basic principle of comparative risk, using our resources better, is one that I think we should force some [congressional] votes on — *not linked to congressional review of regulations, not linked to costs and benefits, just that specific issue of comparing risks*."[77] In other words, because industry interests are not persuasive if they merely oppose all protective regulation, conservatives should hone in on regulatory "errors" and argue that regulators have the wrong *priorities*.

Comparing risks in a vacuum is still one of Graham's major rhetorical techniques. A National Public Radio (NPR) story on dioxin last year reported that EPA scientists had determined that dioxin causes the average American "an *additional* lifetime risk of cancer as high as one in a hundred."[78] The story also indulged Graham's sleight-of-hand: "That would put dioxin *on par* with other common risks," said Graham. 'The average American in their lifetime has about one chance in a hundred of dying in a car crash . . . So this type of risk they're talking about here, if true, would be a significant risk, but it would not be something that would be out of the norm of what people experience in daily life.' "[79]

The catch? The risks demonstrated by the EPA are cumulative to existing risks, not merely "on par." Although Graham did not say so, these data reveal that we now have *both* a 1 percent chance of dying in a car crash *and* a 1 percent chance of contracting cancer from dioxin — for a 2 percent overall fatality rate. The NPR program also failed to mention that Graham has received funding from dioxin interests such as Dow, the Chlorine Chemistry Council, Du Pont, and the American Chemistry Council.[80]

Notably, Graham's approach also fails to account for the non-cancer effects of dioxin that were not measured in that particular EPA study, or for the interactive effects that dioxin may have with other chemicals added to the environment. In addition, if, following Graham's advice, we merely compare the *magnitude* of one risk to another— 1% to 1% — and declare that a one in a hundred risk of dying from a particular hazard is "normal," what would stop the manufacturers of unsafe products and polluters from adding just one more "normal" risk? The more risky the world gets, the lower our benchmark of "normal" will go — into a downward spiral. This is a classic example of the kind of "race to the bottom" that our tradition of strong health and safety regulation is intended to prevent.

The Senate regulatory rollback bill of 1995 would have required that federal agencies also run through this rather spurious exercise in comparing species of risk — by mandating that agencies must publicly compare a risk they wish to regulate with commonly known risks.[81] But comparing risks to other risks like that is dicey. It matters whether a risk is assumed voluntarily or is forced upon an unwilling person. For example, while we choose to drive a car, we do not choose to be exposed to dioxin contamination in the environment. And the fairness of a person's exposure to the risk matters as well. (For more explanation of this flaw in Graham's risk comparisons, *see* Part Three, Sellout #4.)

## III. Graham's Methods Are Deeply Flawed and Antithetical To Environmental and Public Health Safeguards

**At OMB, Graham Would Imbalance the Regulatory Process**

Graham has repeatedly supported regulatory rollback proposals that would add cumbersome and dilatory steps to what is already a carefully scrutinized process.[82] When Congress enacts protective legislation (such as the Food Quality Protection Act and the National Traffic and Motor Vehicle Safety Act), it delegates to particular federal agencies the responsibility for implementing the legislation's goals. These agencies have the hard science, technical expertise and authority to develop regulations that will accomplish congressional objectives.

After a congressional mandate and before any regulatory proposal is issued, all of the stakeholders — the public, regulated businesses, health experts and advocacy groups — have the opportunity to express their positions through the agencies' notice and comment process. When a final rule is published, agencies must publicly explain and justify their decisions based upon years, and sometimes decades, of study and experience. Final regulations can be appealed within agencies or to the courts, or both, and can be attacked legislatively, as was the recent ergonomics regulation.

Before proposing any new rule, federal agencies look at the likely costs, as well as the benefits, of implementing the regulation. Most agencies also undertake some form of formal cost-benefit analysis for any regulation judged to be "economically significant."[83]

**Expanding the Role of Cost-Benefit Analysis and Risk Analysis Undermines Public Health**

Graham has often suggested that virtually *any* misallocation of the government's risk-reduction resources is, in his words, "statistical murder" — that is, if we choose to put seat belts on school buses instead of to deliver vaccinations we are guilty of murdering children.[84] That is an astonishing overstatement of the ability of economic tools to come up with objective, politically neutral answers.[85]

First, even the agencies' current, limited use of risk and cost-benefit analysis suffers from widespread and persistent difficulties, such as the unreliability of the cost data submitted by the regulated industries, the inadequacy of benefit data (and lack of funding to get better data). Second, there is a basic methodological and political problem in that the costs of regulatory programs typically occur up front, and are concentrated within industries, while benefits accrue over time and are often diffuse.[86] Rather than accounting for these difficulties — and for the risk of political capture by regulated industries — Graham has repeatedly supported legislative proposals that would concentrate "review" power within OMB or other White House offices[87] and give far greater weight to industry compliance costs.[88] Both of these proposals would greatly magnify the serious distortions discussed above.

While Graham is certainly not unaware of the problems in his methodology, his legislative prescriptions are so sweeping that he may as well be. Specific critiques of cost-benefit methodology and its negative implications for public health decision-making include the following:

- **Economic "efficiency" is not the only goal of health and safety regulation.** Relying on an OMB cost-benefit analysis to decide the level of public protection is inappropriate and undemocratic. Cost-benefit analysis is usually confined to producing estimates of economic "efficiency," within the serious limitations of whatever data are available. Because it is an economic tool, it takes little or no account of factors such as fairness and equality, or the value of more intangible resources, such as a pristine environment. The catch is that while Graham and his business friends would like economic considerations to be foremost in the equation, most government agencies are charged by Congress with accomplishing goals that, by their nature, will not maximize "efficiency." For example, requiring compliance with the Americans with Disabilities Act may be economically "inefficient" in the short-term. But it is critical for the access of millions of Americans to basic services such as education, employment and mobility, which can provide a boost to the economy as well as to our goal of living independently in an open, free society. Likewise, establishing safe workplaces can be economically inefficient in the short-term, but employers and society in general reap greater long-term benefits from healthier workers.

- **There are persistent problems in calculating the costs of regulation**. The real "costs" of acting — or of failing to act — are unclear and can be highly controversial.[89] Industries who resist regulation are well known for vastly overestimating the costs of compliance as technology improvements or as "foregone profits" while fighting the regulation, and then finding much more cost-effective ways of complying once the rule is actually in place.[90] While complying with some regulations may be costly for industry, not all costs are passed on to consumers. Some costs may be one-time compliance costs, or the government's regulatory program may even stimulate the economy by creating an incentive for cleaner technologies.[91] In some cases, the gains from regulation-induced technology make operations so efficient that regulation has no cost at all.[92]

- **There are also problems in calculating the benefits of regulation.** We have very limited information about the health effects of many potential hazards, and scientists frequently disagree on the meaning of the data that are available. An EPA official explains: "For the vast majority of chemicals, we simply have very little data on low exposures and non-cancer effects."[93] These "non-cancer" effects include such important health considerations as neurological impacts, fertility problems, birth defects and gastrointestinal ailments.[94] For some substances, such as saccharin, assessments of carcinogenic potency differ by more than 1 billion.[95] As an article in *Business Week* put it: "The inescapable conclusion: Science is decades away from being able to pinpoint the hazards of the thousands of chemicals that permeate our environment."[96]

- **Limited scientific information will yield poor results and require political and ethical judgment.** The value of risk decision-making is limited by the types and quality of the information that researchers use as an input— garbage in, garbage out.[97] In areas where researchers have incomplete information, the costs of gathering better information may be considerable, even prohibitive.[98] In the meantime, delaying action may carry its own risks. At that point, our shared values should inform our public policies, because, as any scientist will tell you, we will need to make a judgment call, informed— but not controlled— by the numbers we have available at the time.[99]

- **Like the underlying science, the risk assessment *process* is also plagued by uncertainties which require policy judgment.** Despite Graham's confident presentation to the media,[100] the risk assessment process can only very rarely produce a single answer. According to an EPA report, "depending on the data selected, scientific assumptions, policy calls and perspectives, different experts or organizations may describe risk differently . . . The risk assessment process has an enormous capacity to expand and contract in line with the available data, science policies, and problems."[101] In fact, the risk assessment process involves many separate levels of uncertainty, and researchers must make or use specific *policy* assumptions at virtually every step — any of which may be disputed.[102]

- **Risks— and their potential harm— are understated in a typical risk assessment.** Risk assessments frequently examine the impact of chemicals such as pesticides in isolation, rather than looking for the cumulative or interactive effect of that substance with other materials in the environment. Additionally, assessments typically measure the effect of a chemical upon the average person, which may not accurately predict its impact upon vulnerable populations such as children or the elderly.[103] When the EPA attempted to solve these problems by using protective assumptions in its risk calculations, business and corporate think tanks attacked the government's efforts as "junk science."[104]

- **Practitioners of risk *assessment* find there is *no consensus* for its proper use in policy making for risk *management*.** The hard sciences are characterized — perhaps even defined— by the methodological consensus that practitioners share: To be a scientist is to use well-recognized and agreed-upon set of research tools. The field of "risk analysis" is too new to have generated this kind of agreement.[105] The National Academy of Sciences' National Research Council, an academic and scientific body which answers to Congress, was appointed to evaluate risk assessment methods and concluded that "among agency decision makers, the courts, Congress, and analysts, there is *no consensus regarding the use of a specific set of analytical techniques for a specific purpose*"[106] — that is to say, there is no consensus on the proper use of the results of risk *assessments* in risk *management*.

- **Every value must be represented in monetary terms, or cannot be calculated.** In order to compare costs and benefits, any risk management scheme employing cost-benefit analysis will require that every social value be given a dollar price. Such calculations have a hard time measuring, for example, the value of plants, animals, unspoiled places, scenic views and our natural amenities such as clean air and water. As Gilbert Omenn, dean of the University of Washington School of Public Health has pointed out, "[t]his makes reliable estimates of the risk of ecosystem damage from global warming, ozone depletion, or ocean pollution hard to quantify."[107] The public and decision makers often choose to value and protect those things regardless of any calculation. But if the end result of a risk management decision is to override a valued piece of protective legislation, pseudo-science "experts" can take over this democratic process. To his credit, Graham has occasionally acknowledged the importance of these so-called "intangibles;"[108] allowing for the possibility that a bill which fails on strict cost-benefit grounds may still be enacted by a regulator who is able to show a compelling reason for the rule outside the cost-benefit calculus. But Graham's partial and somewhat begrudging solution fails to explain why regulators must re-justify an action which a Congressional mandate, and the democratic process, has already more than fully authorized.

- **Risk management involves combining many incompatible factors and values.** Besides the results of risk assessments, decision makers consider information from the fields of *economics, political science, law and other indicators of our social values and concerns, such as directions encoded in statutes written by Congress*.[109] Because of complexities in the data, "best estimates" of various studies are often impossible. A Senate Bill from 1995 that was similar to an idea that Graham has suggested[110] required researchers to combine all of the different risk assessment studies, from potentially different scientific disciplines, into one definitive number that could be used in an overarching risk formulation. Graham also encouraged these "working scientists" to formulate a "central" or "best" estimate by "going beyond the available hard data and *offering speculative forecasts* of what is most likely to prove to be true when the uncertainty about chemical carcinogenesis is resolved."[111] But even if we had that kind of crystal ball, Graham's approach of averaging risk estimates from different fields of the hard sciences just wouldn't work.

As toxicologist Ellen Silbergeld testified before the Senate in 1995:[112]

> Calculating a "central estimate" of risk is like "averaging the winning percentage of all Los Angeles sports teams — basketball, football, hockey, and baseball— *to derive a central estimate of likely success for an athlete playing in that city.*

- **Where risk management involves cost-benefit analysis, it can leave ethical and democratic values far behind.** A common convention in cost-benefit analysis is to cost out the value of a human life *in monetary terms*. To make matters worse, it is also accepted practice to then "discount" the value of a life by the number of years that it will take before the regulation benefits the individual. For example, because there is typically a 30- to 40- year lag time between exposure to a harmful substance such as asbestos, and a person's death from cancer, a life saved 40 years from now is calculated as a mere fraction of that person's present value. This custom is anti-democratic, because it is fundamentally out of step with our support for environmentally sound regulation, and our desire to preserve the earth for our children and future generations.[113]

> *The idea that a harm prevented in the future is* ***worth less*** *than a harm prevented today turns the ethical and practical rationale for protective health and environmental regulation on its head.*

- **The basic morality of converting the risks to human beings into monetary values is hotly disputed within political and academic circles.**[114] As Professor Douglas Maclean observed, assigning an exchange price to such benefits of regulation as human health, safety and the environment "is to treat them as commodities when they really have a *different kind of value — a sacred value perhaps* — and should be treated as such."[115] The point is that statistical numbers in the aggregate fail to respect individual rights and the freedom to live free of harm. If the public knew that the federal agencies would be required under Graham to do a "bean-count" that measures corporate profits against public suffering prior to issuing regulations — citizens such as Patricia Pena would likely be outraged.

- **Graham has been criticized for his arrogant and misleading presentation of risk issues.** Risk *communication* has suffered greatly from the one-sided presentation of risk analysis as an "objective" and "scientific" tool. As Law Professor Thomas McGarity, from the University of Texas at Austin, wrote in a direct reference to Graham's work:[116]

> Many professional risk assessors are inclined *arrogantly to dismiss the fears of ordinary people who are actually exposed to risk and to blame the news media and environmental groups for stirring up public anxiety.*

A coalition of environmentalists from Environmental Working Group and the National Campaign for Pesticide Policy Reform wrote to *Dateline* following an appearance by Graham:[117]

> The express intent of the Harvard Center for Risk Analysis (HCRA) is to conduct research and advocacy on behalf of an unproven regulatory model. *Often mistaken for science itself, comparative risk analysis is in fact a policy tool, commonly used today as one of many tools at regulators' disposal* . . . . [HCRA] would make comparative risk analysis the paramount method, even though the practice has been widely questioned . . . [and uses] speculative comparisons of costs and hard-to-measure benefits.

Our legislative and regulatory processes wisely incorporate many values, as well as ethical an moral concerns, that have little or nothing to do with cost-efficiency. And our experience shows tha democratic institutions *should* respond to the developing concerns of the public, regardless of th prevailing fads in economic analysis or the arrogance of industry-funded "experts" — or the government' legitimacy to make decisions on behalf of the public could be threatened. Enlarging the role of ris "experts" would merely exacerbate current difficulties regarding public access to the regulatory proces As Jay Wexler, a Law Professor at Duke University, noted:[118]

> Our current risk management system is not democratic. Despite a few examples to the contrary, laypeople are generally excluded from the risk assessment process, and their opinions are generally ignored by risk managers. The process is enveloped in secrecy, and nonexperts provide little input into the many crucial decisions made every day by administrative decisionmakers. This lack of popular access to the process severely undermines both the efficacy and the legitimacy of the regulatory system.

In addition to being undemocratic, using economic analysis to vote regulations up or down woul create another layer of unnecessary bureaucracy, would add very little useful information to the proces and could threaten much-needed health, safety and environmental protections.

**Graham's Policy Recommendations Block A More Protective Approach to Public Health**

One casualty of Graham's notion that we should rank all risks and put a premium on cost-efficiency is that his emphasis forecloses more just and sound approaches to science and health policy debates. *There is a solution to the bottomlessness and compounded uncertainty of a risk-to-risk comparison.* Rather than asking — "what is a 'normal' level of acceptable risk?" — some groups of environmentalists and policymakers apply a more protective policy, used in Europe, that is called the "precautionary principle."

The precautionary principle suggests a paradigm shift in regulation to a "safety first" approach, and away from the cost-benefit straitjacket. Research in risk perception has persistently demonstrated that the public is far more concerned with prevention (and preventative action) than are the so-called "experts."[119] The precautionary principle follows the public's intuition, stating that: "*When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.*"[120]

This age-old wisdom is also captured in the adage: *an ounce of prevention is worth a pound of cure.*[121]

The precautionary principle is grounded in the following ethical and political concepts:

- People have a duty to take anticipatory action to prevent harm.
- The burden of proof lies with the proponents of a technology, not with the public.
- Before using a new technology, process, or chemical, or starting a new activity, people have an obligation to examine a full range of alternatives, and an obligation to address the certainty or uncertainty associated with understanding the threats of harm from a proposed activity or substance.
- Decisions applying the precautionary principle must be open, informed, and democratic and must include affected parties.

This approach is 180 degrees away from Graham's approach, yet its philosophy is the underpinning of many of the regulatory statutes that Graham seeks to undermine, such as the U.S. pre-market testing of pharmaceuticals. Because of the threat that precautionary thinking poses to industries' power over regulatory policy, Graham has already hatched a plan to hijack the principle. According to the HCRA Web site: "In the next two years, Center Director John Graham is planning to write a new, scholarly book that will *redefine the precautionary principle with insights from disciplines of decision analysis, risk analysis and cost-benefit analysis.* This refined version of the precautionary principle will be compared, in the context of real-world case studies, to the more simplistic versions of the principle now being advocated in policy debates."[122]

The workshop on the precautionary principle that was held by HCRA in June 1999 was supported in part by grants from the American Chemistry Council, the Chlorine Chemistry Council, and the Koch Foundation, a fund backed by Koch Industries, the nation's largest privately held energy and oil company.[123] Just as industry has managed, through manipulation of terms like "sound science," to co-opt risk assessment and cost-benefit analysis, Graham evidently hopes to co-opt the language of the precautionary principle while at the same time gutting its animating concepts.

Once again, however, Graham is speaking mainly for corporate self-interest. In contrast, Republicans such as Bush's new head of EPA, Christine Todd Whitman, have publicly urged the further application of the precautionary principle in environmental policy: [124]

> We must acknowledge that uncertainty is inherent in managing natural resources, recognize it is usually easier to prevent environmental damage than to repair it later, and *shift the burden of proof away from those advocating protection toward those proposing an action that may be harmful.*

## IV. Graham's Problematic History of Non-Disclosure

Graham is a leading spokesman to the media on regulatory issues, yet he consistently downplays the risks of that are the subject of the discussion. As he recommended to attendees at a Heritage Foundation seminar in 1996, Graham frequently disputes the need for a particular regulation indirectly — by claiming that *X* is not the *best* possible use of our resources.[125] He asks, in essence, why should we be concerned with toxic chemicals from a Superfund cleanup site when we could pay for cancer screening tests instead?[126]

When Graham appears in print or on television, there is frequently no disclosure of the fact that much of his Center's funding is derived from industry sources. More specifically, it is also unmentioned that the regulation that is being discussed could directly impact the companies that financially support his Center.[127]

There are three distinct problems with Graham's statements to the media along these lines. The first is that his (or the reporter's) failure to disclose the funding relevant to the subject of the article is very misleading, given Graham's consistent depiction as a Harvard-based academic presumed to be a neutral "expert" on risk-related issues. The second problem is that many of the tradeoffs Graham discusses are false dichotomies— of course we can, and do, choose to worry about both poisoning prevention and poisoning from petrochemicals in our water or air (*see* Part Three, Science Sellout #4).

The third problem is that risk management would have a hard time doing what Graham promises it can. As Law Professor Thomas McGarity put it, the notion that risk-benefit or cost-benefit analysis is "ready for prime time" is just wrong on the facts:[128]

> It is simply wrong to suggest, . . . as do regulatory reformers, that a consensus exists that thousands of lives or billion of dollars could easily be saved if Congress and the agencies merely made more effective use of cost-benefit analysis in setting priorities.

The following chart depicts some of the phony risk tradeoffs that Graham has promoted over the past decade and shows whether Graham's pertinent funders were disclosed in the coverage.[129] This list addresses specific, potential conflicts of interest. However, we note that to the extent that Graham's comments are about "risk" or "fear" in general, they serve the anti-regulatory purposes of most of his funders.

Public Citizen called HCRA to inquire about the timeliness of the Center's posted list of funders, and the person at HCRA who answered the phone stated that the list on the HCRA Web site was a "cumulative" list of all funders of HCRA, both past and present.[130] Thus, we are unable to define whether Graham's funding from a particular source was contemporaneous with his comments. Also we found at least one source that was unlisted: it is well-documented that HCRA accepted $300,000 in the year 2000 from AT&T Wireless Communications for the cell phone study discussed in Part Two, Case Study #2, yet it is not listed on the HCRA Web site as providers of either restricted or unrestricted funds.

## A Comparison of Graham's Risk Tradeoffs and the Corporations That Fund the Harvard Center for Risk Analysis

| Source, date, and title of news article | Regulatory subject/s discussed in the article | The regulatory programs that Graham recommends instead | Sources of HCRA funding relevant to the article's subject | Disclosure of any of Graham's funding sources? |
|---|---|---|---|---|
| Dolores Kong, "Scientists Warn Against Panic Over Electromagnetic Field Effect," *The Boston Globe*, Nov. 13, 1992. | Electromagnetic fields (EMFs) and child leukemia. The article also mentions studies that have suggested a link between EMFs and brain tumors and leukemia from cell phones, electric blankets, television and hair dryers.<br><br>The article discussed new Swedish research indicating that children who live near high-voltage power transmission lines had 4 times the normal risk for leukemia. | Bicycle helmets, poisoning prevention, and immunization<br><br>The article quotes Graham as saying that "the highest priority for our children should be preventing the known risks before we become paralyzed by speculation. So let's get on with bicycle helmets, poisoning prevention, and immunizations." The article also states that "in the spectrum of risk, getting cancer from electromagnetic fields would be slim, even if a connection were proven, say scientists." [This is because childhood cancer is rare in general— an observation which does nothing to counter the prospect of *additional* risks posed by EMFs.] | Carolina Power and Light, Charles G. Koch Foundation, Edison Electric Institute, Electric Power Research Institute, New England Power Service, New England Electric System, Union Carbide Foundation, Westinghouse Electric Corporation, Emerson Electric, General Electric Fund | **No Disclosure** |
| Child Health Alert, Inc., "More Worrisome News About Electromagnetic Fields," *Child Health Alert*, Dec. 1992. | Electromagnetic fields<br><br>According to this article, the Swedish EMF findings "produced anxiety ranging from caution to outright panic among those who care for children." | Preventable accidents, poisonings<br><br>The article states, "Another perspective, and one we've shared for some time, is provided by Dr. John Graham of the Harvard School of Public Health . . . he notes that compared to the number of children who die from preventable accidents and poisonings, leukemia claims far fewer lives," and quotes Graham as above in *The Boston Globe*. | Carolina Power and Light, Charles G. Koch Foundation, Edison Electric Institute, Electric Power Research Institute, New England Power Service, New England Electric System, Union Carbide Foundation, Westinghouse Electric Corporation, Emerson Electric, General Electric Fund | **No Disclosure** |
| J. Madeleine Nash, "Keeping Cool About Risk," *Time*, Sept. 19, 1994. | Dioxin and Alar (a pesticide), radon, asbestos<br><br>**Not mentioned in the article:**<br>The 1994 EPA draft Reassessment had concluded that dioxin was an extraordinarily potent environmental hormone, caused a wide variety of toxic effects, and that background exposures may already be causing health effects. | Vaccinations, bicycle helmets<br><br>The article quotes Graham, "Phantom risks and real risks compete not only for our resources but also for our attention . . . It's a shame when a mother worries about toxic chemicals, and yet her kids are running around unvaccinated and without bicycle helmets." | Dow (the leading producer of dioxin), Chlorine Chemistry Council, CIBA-Geigy, General Electric, DuPont, Georgia-Pacific, Hoescht-Celanese, ICI Americas, Kodak, Monsanto, Olin, BASF, ARCO Chemical Co., FBC Chemical Corp., 3M<br><br>**See below in chart for a complete list of dioxin producing companies that fund HCRA.** | **No Disclosure**<br>In fact, Graham was actively and directly critical of the EPA's report during his presentations to the EPA's Reassessment Science Advisory Board.[12] And a month prior he had organized a high-profile conference on drinking water and health risks financed by the Chemical Manufacturer's Assoc. and the Chlorine Chemistry Council.[132] |

| Source, date, and title of article | Regulatory subject/s discussed in the article | The regulatory programs that Graham recommends instead | Sources of HCRA funding relevant to the article's subject | Disclosure of any of Graham's funding sources? |
|---|---|---|---|---|
| Patricia Braus, "Everyday Fears,"*American Demographics*, Dec. 1994. | Benzene and agricultural pesticides<br><br>Discusses the general topic of risk, and "misconceptions" about risk, from the perspective that expert risk assessment should guide public policy. | Vaccinations, bicycle helmets, trauma centers<br><br>To quote: "Harvard's John Graham criticizes what he calls excessive regulation of industrial substances such as benzene and certain agricultural pesticides. He believes that more lives would be saved if regulators increased funding for trauma facilities that help victims of traffic accidents and violent crime. He also favors vaccination, expanded use of bicycle helmets, and other preventive actions that benefit those who have the most living to lose — children." | American Petroleum Institute, Amoco Corporation, ARCO, Ashland Inc., Foundation, BASF, BP America, Inc., Chevron Research and Technology Company, CITGO Petroleum Corporation, Exxon, Mobil Foundation, Inc., Oxford Oil, Oxygenated Fuels Association, Shell Oil Company Foundation, Unocal | **No Disclosure** |
| Curt Suplee, "Assessing the Risk in Contract's 'Cost-Benefit' Curb on Regulations," *Washington Post*, Feb. 28, 1995. | Benzene in outdoor air, pesticides, fuel economy standards.<br><br>The article was about the proposed risk assessment "regulatory reform" bill in general. | Community violence reduction, lead paint from old homes, increasing preventive health services — *and airline safety*<br><br>In response to an EPA rule concerning a one in a million *additional* chance of getting cancer from pesticides, Graham argued that "a baby born today, at current mortality rates, incurs a risk of four in a million of being struck and killed on the ground by a crashing airplane." | American Petroleum Institute, Amoco Corporation, ARCO, Ashland Inc., Foundation, BASF, BP America, Inc., Chevron Research and Technology Company, CITGO Petroleum Corporation, Exxon, Mobil Foundation, Inc., Oxford Oil, Oxygenated Fuels Association, Shell Oil Company Foundation, Unocal | **No Disclosure** |
| Emily T. Smith, "Voodoo Regulation?" *Business Week*, Mar. 13, 1995. | Benzene, environmental regulation in general.<br><br>The article discussed whether risk assessment-based regulatory "reform" should be enacted. | Screenings for breast and cervical cancer<br><br>"This country, says Graham, "is paranoid and neglectful about risk at the same time."Graham also said on the regulatory rollback bill: "We need a bill if we want to improve risk assessment . . .it will force the bureaucracy and private sector to improve the process." | American Petroleum Institute, Amoco Corporation, ARCO, Ashland Inc., Foundation, BASF, BP America, Inc., Chevron Research and Technology Company, CITGO Petroleum Corporation, Exxon, Mobil Foundation, Inc., Oxford Oil, Oxygenated Fuels Association, Shell Oil Company Foundation, Unocal | **No Disclosure** |
| "Science Advisory Board Questions Major Parts of EPA Dioxin Report," Air Water Pollution Report, May 22, 1995. | Dioxin.<br><br>The subject was the Science Advisory Board's response to EPA's 1994 draft risk assessment on dioxin. | Graham generally criticized the EPA's findings: "The report overstates the carcinogenic risks that dioxins and related compounds may pose and fails to seriously analyze uncertainties about these chemicals and to show how incremental changes in exposure could affect health, said John Graham." | Philip Morris documents specifically suggested that the EPA's approach to risk assessment in areas other than tobacco should be criticized.<br><br>**HCRA is funded by 48 dioxin producers. See below.** | **No disclosure** |

| Source, date, and title of article | Regulatory subject/s discussed in the article | The regulatory programs that Graham recommends instead | Sources of HCRA funding relevant to the article's subject | Disclosure of any of Graham's funding sources? |
|---|---|---|---|---|
| Stuart Anderson ("policy director" of the Alexis De Tocqueville Institute), "Measuring the cost of regulation: How to save More Lives for the Money," *The San Diego Tribune*, Oct. 1, 1995. | Fuel economy standards | Graham suggests that fuel economy standards have resulted in smaller cars which cause 3,900 additional traffic fatalities and 20,000 serious injuries. | Amoco Corp., American Petroleum Institute, Bethlehem Steel Corp., BP America, Chevron, CITGO Petroleum, Exxon, Ford Motor Co., GM, Mobil, Oxford Oil, Oxygenated Fuels Assoc., Shell Oil, Texaco, Union Carbide, Unocal, Automobile Manufacturers Assoc. | **No disclosure** |
| David Lore, "Determining Toxic Risks is Costly Voodoo, Lawyer Says," *The Columbus Dispatch*, Nov. 24, 1995. | Toxin control rules (chemicals) | Health care and injury prevention<br><br>Graham says, "The failure to compare the costs of toxin control rules to rules on health care and injury prevention and to allocate resources based on those comparisons is resulting in 'statistical murder.'" | Dow, DuPont, American Chemistry Council., Millenium Chemical Co., Monsanto, Atlantic Richfield Corp., ARCO Chemical Co., FBC Chemical Corp., Eastman Chemical Co., Louisiana Chemical Co., Air Products and Chemicals, Inc. Chlorine Chemistry Council, Rohm and Haas Co., and many others | **No disclosure** |
| Scott Allen, "US Accepts $129 M for Cleanup of Love Canal; Some Say Set a Wrong Course," *The Boston Globe*, Dec. 22, 1995. | Superfund cleanup of Love Canal paid for by Occidental Chemical Corp.<br><br>20,000 tons of chemicals were dumped into Love Canal in Niagara Falls, NY from 1942 to 1953. | Violence prevention and pregnancy prevention.<br><br>"'Does it really make sense to spend, say $50 million on speculative risks when you don't have the resources to provide violence prevention or pregnancy prevention in the schools?' asks John Graham . . . Graham said his review of more than 100 Superfund cases found 'a basic reluctance to apply basic principles of cost-benefit analysis.'" | Graham generally attacked the Superfund program, which affects many funders. Specifically, according to its Web site, Occidental's partners in its petrochemicals operations are Lyondell Chemical Co. and Millenium Chemicals. Both are donors to HCRA. | No disclosure |
| Rick Weiss & Gary Lee, "Pollution's Effect on Human Hormones," *The Washington Post*, Mar. 31, 1996. | Endocrine disruptors, DDT, PCBs, DDE, pesticides, dioxin (also mentions electromagnetic fields and global warming)<br><br>The article described reactions to the publication of *Our Stolen Future*, a book on endocrine disruptors, which detailed the evidence that they may cause reproductive problems, childhood hyperactivity and a decline in global intelligence. | "'True or not, the idea that chemicals are wreaking havoc with our reproductive systems has all the elements needed to provoke a public panic,' said John Graham." A quote from Graham also ended the article: "'We are just beginning to understand why we are so paranoid about some risks and tragically neglectful of others,' [Graham] said. 'But in the final analysis, it often comes down to, Who do we trust? *And that makes risk management very difficult these days, because people aren't inclined to trust anyone.*'" | **American Crop Protection Association, American Chemistry Council (formerly the Chemical Manufacturers Association), Chlorine Chemistry Council,** Dow (the leading producer of dioxin), CIBA-Geigy, General Electric, DuPont, Georgia-Pacific, Hoescht-Celanese, ICI Americas, Kodak, Monsanto, Olin, Kraft Foods, Frito-Lay, PepsiCo Inc., Coca-cola, DowElanco, Grocery Manufacturers of America, International Paper, National Food Processors Association | **No disclosure**<br>The article also described the chemical industry's proactive plans to "counterattack against the issue of endocrine disruptors" in anticipation of the book's publication: "Among those in the huddle were the **Chemical Manufacturers Association, the Chlorine Chemistry Council . . . and the American Crop Protection Association.**" |

| Source, date, and title of article | Regulatory subject/s discussed in the article | The regulatory programs that Graham recommends instead | Sources of HCRA funding relevant to the article's subject | Disclosure of any of Graham's funding sources? |
|---|---|---|---|---|
| John Graham, "There's a Deadly Confusion About Health Risks,"*The Houston Chronicle*, Nov. 29, 1996. | Electro-magnetic fields (EMFs), silicone breast implants, Superfund and abandoned industrial waste sites, cancer | Bicycle helmets, injury prevention (accidental crashes and falls), lead in peeling paint [removal is mostly the responsibility of individual landowners], firearm violence, encouraging regular physical exercise | On EMFs only: Edison Electric Institute, General Electric, Electric Power Research Institute, Emerson Electric, New England Power Service, England Electric System | **No disclosure--**<br><br>Note that Graham is the author |
| Steve Schenck, "The Chemical Flood," *Alt HealthWatch*, Oct. 1996. | Endocrine disruptors, including dioxin, and cosmetics, DDT, PCBs, Bisphenol-A (used in canned foods and dental sealants), Phthalates (plastics), estrogen pills, hormone replacement therapy | Said Graham, "'We are just beginning to understand why we are so paranoid about some risks and tragically neglectful of others,' [Graham] said. 'But in the final analysis, it often comes down to, Who do we trust? And that makes risk management very difficult these days, because people aren't inclined to trust anyone.'" | Dioxin-Producing Companies:[133]<br>Air Products and Chemicals Inc., Eastman Kodak Company, WMX Technologies Inc., Fort James International Paper, The James River Corporation Foundation, Mead Corporation, Potlatch Corporation, Westvaco Corporation, Boise Cascade, Georgia Pacific, Asarco Inc., Bethlehem Steel, Inland Steel, National Steel Nippon Yakin Kogyo, Alcoa Foundation, Reynolds Metals Company Foundation, Cement Kiln Recycling Coalition, American Crop Protection Association, Arco Chemical Corporation, Ashland Inc. Foundation, BASF, Cabot Corporation Foundation, Chemical Manufacturers Association, (aka American Chemistry Council), Chlorine Chemistry Council, CIBA-GEIGY, Cytec Industries, Dow Chemical Corporation/Union Carbide, DowElanco (Dow AgroSciences), DuPont Agricultural Products, FBC Chemical Corporation, FMC Corporation, Hoechst AG, ICI Americas, Louisiana Chemical Association, Lyondell Chemical, Olin Corporation, 3M, Praxair Inc., The Geon Company, Rohm & Haas Company, Petroleum Industry, American Petroleum Institute, Amoco, BP America Inc., Charles G. Koch Foundation, Chevron Corporation CITGO Petroleum, ExxonMobil, Oxford Oil, Oxygenated Fuels Association, Shell Oil Foundation, Texaco Foundation, Unocal Corporation, Edison Electric Institute, Electric Power Research Institute, General Electric Foundation, Monsanto Company, New England Power Service, Westinghouse Electric Corporation | **No Disclosure** |

| Source, date, and title of article | Regulatory subject/s discussed in the article | The regulatory programs that Graham recommends instead | Sources of HCRA funding relevant to the article's subject | Disclosure of any of Graham's funding sources? |
|---|---|---|---|---|
| Hilary Shenfield, "The Environment Often Seems Far More Hazardous To Your Health Than It Really Is," *Chicago Daily Herald*, Mar. 15, 1999. | The topic was our irrational "fears" — mentions our fears of toxins and chemicals in general, toxic waste, creosote (a coal-byproduct), pesticides, EMFs, power lines, tap water, cell phones, Alar, benzene, EDB, asbestos, amalgam dental fillings | Graham said, "We should strive to spend our *mental health budget* on prevention of the big killers and not be distracted by the syndrome of the month."<br><br>ACSH also weighed in: "'We have a limited capacity for dealing with health scares,' said Jeff Steier, associate director of ACSH. 'So we have to prioritize.'" | Pesticides, power lines, benzene and EMFs are elsewhere in the table.<br><br>Creosote from coal: 3M, American Petroleum Institute, BASF, Amoco, BP America, Koch Foundation, CITGO Petroleum, Exxonmobil, Unocal, Shell Oil | **No disclosure of HCRA or ACSH sources**<br>This article makes repeated use of especially suspect conclusions. One example suggests that asbestos should not be feared (i.e., regulated) because its removal can sometimes stir up greater level of the toxin. |
| Noah Adams, "EPA Report on Dioxin is Released and Confirms a Cancer Risk Exists to All Americans," *All Things Considered, National Public Radio*, June 15, 2000. | Dioxin.<br><br>EPA scientists found dioxin could cause the average American "an *additional* lifetime risk of cancer as high as one in a hundred." | The story continued, "That would put dioxin *on par* with other common risks," said Graham. 'The average American in their lifetime has about one chance in a hundred of dying in a car crash. . .So this type of risk they're talking about here, if true, would be a significant risk, but it would not be something that would be out of the norm of what people experience in daily life.'" | Dow (the leading producer of dioxin), Chlorine Chemistry Council, CIBA-Geigy, General Electric, DuPont, Georgia-Pacific, Hoeschr-Celanese, ICI Americas, Kodak, Monsanto, Olin Corp., American Crop Protection Association, American Chemistry Council. **HCRA is funded by 48 dioxin producers.** | **No disclosure**<br>And the risks are cumulative (not merely "on par"). Although Graham did not say so, according to these data, we now know that we have *both* a 1 % chance of dying in a car crash *and* a 1 % chance of contracting cancer from dioxin. |

## FOLLOWING THE MONEY: GRAHAM'S AFFILIATIONS WITH OTHER ORGANIZATIONS

There is an interlocking network of "think tanks," pseudo-science industry front groups and university-based institutions that provide the intellectual and public relations underpinning to the corporate anti-regulation campaign. Graham has played a critical role in this network and is one of its most consistent public voices.

Industry's funneling of tax-exempt dollars into this system of organizations was at least partially outlined in a report by Sally Covington of the Center for Responsive Philanthropy in 1997 entitled *Moving A Public Policy Agenda: The Strategic Philanthropy of Conservative Foundations*. As early as 1981, journalist Karen Rothmeyer described the hydra-headed nature of these groups and the overwhelming influence of their corporate funders in setting the terms of the debate in an article called "Citizen Scaife" published in the *Columbia Journalism Review*.[134]

Below is a list of Graham's affiliations. Graham's corporate funders also financially support many other organizations that use Graham's studies in their public policy work. Moreover, the companies promote his research and analysis on their Web sites and in public relations materials. It is worth noting that many of these organizations are the same companies that support HCRA.

Information is taken from the organizations' 990 tax forms and their official Web sites, unless otherwise noted.

**The American Council on Science and Health (ACSH)**

Graham serves on the ACSH Board of Scientific and Policy Advisors and is extensively quoted in the group's campaigns. ACSH defines itself as a "consumer education institution concerned with issues related to food, nutrition, chemicals, pharmaceuticals, lifestyle, health and the environment" and cites its mission as promoting sound science and the free enterprise system.[135]

ACSH Media updates from 1997 to the present include the following titles:

- Why the National Toxicology Program Cancer List Does More Harm Than Good
- The Fuzzy Science Behind Clean-Air Rules
- Eat Beef, America
- Evidence Lacking That PCB Levels Harm Health
- At Christmas Dinner, Let Us Be Thankful for Pesticides and Safe Food

Funding for ACSH from 1986-1999 was provided by donations from:[136] American Cyanamid, American Meat Institute, BP Amoco, Anheuser-Busch, Archer Daniels Midland, Boise Cascade, Burger King, Chevron, Ciba-Geigy, Coca-Cola, Coors, Dow Chemical, DuPont, Exxon, Ford Motor Co., General Mills, General Motors, Kraft General Foods, National Agricultural Chemicals Association, Nestle, Monsanto, Pepsi-Cola, Shell Oil, Sugar Association, Texaco Foundation, Union Carbide Corp., Uniroyal Chemical, USX Corp., ConAgra Foundation Inc., Abbottt Laboratories, Achelis Foundation, Bristol-Myers Squibb Foundation, GE Fund, Kirby Foundation, Inc., The Robert Wood Johnson Foundation, Rollin M. Gerstacker Foundation, Crystal Trust, Kellogg's Corporate Citizenship Fund, Klingenstein Fund Inc., National Starch and Chemical Foundation, Olin Foundation, Procter & Gamble Fund, Samuels Foundation, Starr Foundation, Leavey Foundation, Sarah Scaife Foundation, and the David Koch Charitable Foundation.

**The Advancement of Sound Science Coalition (TASSC)**

Graham served on the policy advisory board of TASSC and was extensively quoted in the group's media efforts.[137] The group operated from 1993 to 1998. TASSC argued that federal and local environmental public policy is based on "junk science." The group was funded by start-up money from Philip Morris and run by the public relations firm APCO & Associates, a Washington, D.C., public relations firm that generates positive corporate spin by founding front groups and fake grassroots organizations.[138] TASSC was involved in Philip Morris's international public relations effort through a European sister organization, as documented by Elisa Ong in *The Lancet*.[139]

From 1993 to 1996, according the group's press release, TASSC engineered counter-spins on nutrition issues raised by the Center for Science in the Public Interest and a pesticide study by Environmental Working Group, and defended the genetically engineered Flavr Savr tomato as well as the use of bovine growth hormones.[140]

TASSC eventually grew to over 400 corporate "members" including: 3M, Amoco, Chevron, Dow Chemical, Exxon, General Motors, Occidental Petroleum, Santa FE Pacific Gold Corp., Louisiana Chemical Assoc., National Pest Control Association, Lawrence Livermore National Laboratory, Lorillard Tobacco, W.R. Grace & Co. and Procter & Gamble.[141]

**Public Health Policy Advisory Board (PHPAB)**

Graham serves as a "distinguished fellow" on the PHPAB. According to the group's tax forms, in 1997, he received $8,333 in compensation for his service and another $30,000 in 1998. PHPAB is funded primarily by industry sources such as the American Chemistry Council (formerly the Chemical Manufacturers Association), Chlorine Chemistry Council, and Procter & Gamble as well as grants from a few government agencies.[142]

**Biological Effects of Low Level Exposures (BELLE)**

Graham is a member of the advisory committee of Biological Effects of Low Level Exposures (BELLE), a group that claims to evaluate the existing scientific literature on the biological effects of low doses of chemicals and radioactivity. In particular, the group emphasizes "paradoxical dose-response relationships," in which, it is argued, increasing the concentrations of a toxin do not produce a proportional increase in biological harm. In 1998, Exxon provided $75,000 for BELLE activities.

**Society for Risk Analysis (SRA)**

Graham served as elected president of the SRA from 1995-1996. Following his term as president, he became a "Fellow of the Society." The Society for Risk Analysis posted an Internet list of corporate "sustaining members" that includes Amoco, the Chemical Manufacturing Association, Chevron, DuPont, Exxon, Procter & Gamble and the "Sapphire Group," an organization composed of chemical, cosmetic, food and health care interests.[143]

**National Council on Radiation Protection and Measurements (NCRP)**

Graham is a year 2000 "Council Member" of NCRP, which seeks to formulate and widely disseminate information, guidance and recommendations on radiation protection and measurements which represent the consensus of leading scientific thinking." NCRP's current corporate sponsors include 3M, Commonwealth Edison, Consolidated Edison, Duke Power, Florida Power Corporation, ICN Biomedicals, Inc., Landauer, Inc., New York Power Authority, Nuclear Energy Institute, Nycomed Amersham Corporation, and Southern California Edison Corporation. Past sponsors include Motorola Foundation, Inc.

**American Enterprise Institute (AEI)-Brookings Joint Center for Regulatory Studies**

Graham is a member of the Center's Advisory Board.[144] Established by the American Enterprise Institute in conjunction with the Brookings Institute, the AEI-Brookings Joint Center for Regulatory Studies' primary purpose is to "provide objective analysis of existing regulatory programs as well as new regulatory initiatives." Donors to AEI and the Joint Center include many corporate-backed foundations, including the Olin Foundation, Charles Stewart Mott Foundation, Sarah Scaife Foundation, Castle Rock Foundation, Bradley Foundation, Carthage Foundation, Earhart Foundation, Smith Richardson Foundation, and the Phillip M. McKenna Foundation.[145] A partial list of corporate sponsors from 1998 Brookings annual report includes Alcoa, Archer Daniels Midland, AT&T, Exxon, KPMG Peat, Ford, Chase Manhattan, Toyota, Johnson & Johnson, E.I. du Pont de Nemours, Microsoft, Texaco, Pfizer, CIGNA Corp., Mobil, Coca Cola and Boeing.

**Ketchum Communications**

Graham serves on Ketchum's advisory board of consultants in legal media relations.[146] Ketchum is "a public relations and marketing agency which specializes in corporate and product positioning." Case studies on the company's Web site include work for BP Amoco, British Telecom, Nokia, Dow Chemical, Esso, ITT Industries, and American Dairy Brands.

**Wharton School of Business Risk Management and Decision Processes Center, University of Pennsylvania**

Graham is on the Advisory Committee for the Center. Corporate "Associates" of the Wharton Risk Management Center include: American Re-Insurance Co., Dow Chemical, Du Pont, Elf Atochem North America, ECS, INc., ICI Americas, Inc., Institute for Business and Home Safety, Price Waterhouse, Rohm and Haas Co., State Farm Fire and Casualty Co., Sun Co., Inc., Union Carbide, Zurich Insurance Co., and Air Products and Chemicals.

## Case Study #1:
### *Graham Joins the Campaign to Defend Second-Hand Smoke*

**Where there's smoke. . .**

Thousands of internal business documents belonging to Philip Morris were made public as part of the tobacco litigation settlement agreements and are available over the Internet.[147] Public Citizen's research shows that in the 1990s, Philip Morris was extremely concerned about the effect of scientific findings that "environmental tobacco smoke" (ETS), also known as second-hand smoke, was dangerous to the non-smoking public. Philip Morris realized that non-smokers would be angered by the news that their health was being endangered by smokers, and that the imposition of bans on smoking in public areas and workplaces would reduce the use of their products and be a legal and public relations disaster for the industry.

Hundreds of Philip Morris strategy documents reflect a highly coordinated effort to fund more industry-friendly "science," to "create and exploit" contacts at the Office of Management and Budget (OMB) and OSHA, and to influence the ETS debate and regulatory efforts at every conceivable level.[148] Philip Morris established an internal task force to manage these efforts, calling it the "Corporate Affairs Scientific Department."[149]

**Philip Morris and the Push for Risk Assessment: "We are right! We shall fight!"**

A Philip Morris document on ETS strategy from this period listed these items:[150]

**Objectives**

- Protect the franchise.
- Discredit the EPA report on ETS specifically and the EPA generally.
- Demonstrate the scientific weaknesses of the EPA conclusions in consequential terms.
- Put the risk in perspective.

**Recommendations**

- Establish the strongest possible input into OSHA deliberations.
- Point to EPA excesses and mistakes unrelated to tobacco.
- Demonstrate EPA "corruption."
- Re-evaluate the risk assessment process.
- Assess scientists' availability for public service. The D-Day precedent of making scientists available should be continued and expanded, with scientists playing not only a reactive role, but a pro-active one as well. This is our best bet for credibility.
- Discuss additional scientific recruitment/inoculation. Explore a broader base of potential scientific allies, some of whom would speak to the issue of ETS, others who would address science, scientific methodologies, the science at EPA, and risk assessments in a broader sense. This is where we start to put the science of EPA into perspective.

The memo also noted that a possible avenue of defense for Philip Morris was litigation: *"Sue the Bastards! . . . In [litigation] is defined the substance and the symbolism of our principal message: We are right! We shall fight!"*[151]

One overriding purpose of Philip Morris's efforts on risk assessment was to interfere in any way possible with the anticipated results of an ongoing EPA test of the carcinogenicity of ETS for nonsmokers. Philip Morris predicted unfavorable results from EPA's tests, and was busy trying to prevent or change the verdict of the tests by changing in mid-stream the risk assessment rules that would have to be used by the agency. As one memo on ways to influence EPA's determination stated, " the key question is — which approach is most likely to prevent classification of ETS as a class A carcinogen?"[152]

**Risk Assessment and the Bush I Executive Order**

As an integral part of this campaign, in 1992 Philip Morris was tracking political developments with regard to a sweeping "risk assessment" executive order that was awaiting signature by then-President Bush.[153] The executive order would have imposed a requirement on all government agencies to decide the validity and priority of regulatory proposals in terms of rigid risk estimates and would have mandated clearance of all regulations through a centralized office, in violation of many agencies' direct authorization from Congress to act to protect the public health and safety.

Philip Morris was working closely with governmental officials on the precise terms of the executive order. Corporate documents reflect ongoing conversations between Philip Morris and Thorne Auchter, who was a former Administrator of OSHA and was appointed in 1992 to the President's Risk Assessment and Management Commission and has been affiliated with the anti-regulation group, the Institute for Regulatory Policy (IRP).[154] According to *PR Watch*, Philip Morris had given Jim Tozzi, of Multinational Business Services, $880,00 to establish IRP, a non-profit "think tank "which would work with both Philip Morris and APCO & Associates.[155]

Philip Morris documents reflect a *monthly* donation to IRP of $25,000 in 1993, and record gifts of $40,000 per month for Multinational Business Services (MBS), an organization headed by Auchter's close associate Jim Tozzi, who was working on "the need for scientific standards" in the areas of ETS, radon in water, chlorinated water and electro-magnetic fields.[156] According to *PR Watch*, "Junk Man" Steven Milloy also worked with Tozzi at MBS.[157]

While still at IRP, Auchter wrote to Philip Morris officials on the letterhead of his "Coalition for Uniform Risk Evaluation (CURE)" to discuss a White House meeting that he had attended regarding the 1991 draft of the executive order. Auchter's 1991 memo contains his handwritten notes addressed to Philip Morris officials, in which he points out an inconsistency in the text of the draft executive order and suggests that the highlighted language might enable Philip Morris to re-open the EPA's pending risk assessment on ETS.[158]

**Graham's Associations with Thorne Auchter, Philip Morris and Regulatory "Reform"**

Mayada Logue, a Philip Morris official assigned to risk assessment/ETS issues from the company's "Worldwide Regulatory Affairs" group, reported on her monthly activities for February 1992. Philip Morris officials were evidently very interested in risk assessment. She provided the details of several ongoing studies of ETS and cancer risks, and indicated her concern that one study might demonstrate that ETS does incur serious health problems.[159]

Logue also wrote that a comprehensive "Risk Assessment Project" notebook "describing the activities of approximately 40 groups involved in risk assessment" had been completed, and mentioned that she had gone to a lunch meeting with John Graham. At their meeting, Graham had provided Logue with "specifics" about two meetings that he recently had. One of Graham's meetings was with "Thorne Auchter concerning the Executive Order and the other [was] with [C.] Boyden Gray, President Bush's General Council."

Both Auchter and Gray were very involved with the early and mid-90s regulatory "reform" efforts. Gray held a position on Reagan's regulatory "relief" commission and as White House Counsel for Bush I.[160] Gray now serves on HCRA's Executive Council, and he is an adviser on the transition of Bush II.

Logue's memorandum continued:[161]

> John Graham is writing a book about the unintended risks we take when attempting to avoid other risks. There will be a chapter on smoking in the book. He said that most of the information in that chapter is from the Surgeon General's Report and asked if we would review it for accuracy. Bob Pages has agreed to review it.

Pages was an employee of Philip Morris in the company's "Scientific Affairs" division. One may wonder why a corporate executive from Philip Morris was asked by Graham to review his research on ETS.

**Graham to Philip Morris:** ***Please Send Cash***

It appears that Graham first became involved with Philip Morris in October 1991. On October 18 of that year, he called Logue to set up a meeting in Washington, and the meeting was duly scheduled. On October 21, Graham solicited donations from Philip Morris to HCRA.[162] Graham's letter noted that the Center had "major projects underway in carcinogen classification, risk assessment, public health priorities, and the use (and misuse) of risk numbers in environmental legislation."

Graham went on:[163]

> The Center has been launched primarily with gifts from the following corporations: the Amoco Company, Bethlehem Steel Corporation, British Petroleum, Chevron Corporation, The Coca Cola Company, Dow Chemical Company, Eastman Kodak Company, Exxon Corporation, General Electric Corporation, General Motors, Inland Steel Industries, Merck and Company, Mobil Oil Corporation, the Monsanto Company, Pepsico Incorporated, Rohm and Haas Company, Texaco, Union Carbide Corporation, and Westinghouse Corporation.

Stating that the "Center is now looking to a broader base of industrial sources to supply critical funding for the years ahead," Graham asked for a meeting with the Vice President of Government Affairs at Philip Morris and the sum of $25,000:[164]

> in financial support in 1992 and 1993 that can help the Center expand its public policy activities. *It is important for me to learn more about the risk-related challenges that you face.*

In an internal memorandum, Bob Pages supported the idea of getting acquainted with Graham and learning about the Center based upon this last sentence from Graham's letter, writing to Steve Parrish, General Counsel for Philip Morris, that:[165]

> Why not take him up on the offer? Sure, he's after $ to help support his Center, but whether or not PM [Philip Morris] decides to contribute it's more important to meet him and perhaps get 'looped in' better with his activities. From all that Mayada [Logue] has learned, [Graham] is a key player in all this risk analysis stuff that's currently going on in the government.

Subsequent documents show that Graham was probably successful in his bid. Philip Morris drafted a check in the amount of $25,000.[166] Strangely, the company later, evidently at Graham's request, placed a stop payment on that check.[167] But in August 1992 Graham received $20,000 to be spent over two years from Philip Morris's subsidiary, Kraft General Foods. The letter from Kraft's Vice President of Scientific Relations, Enrique Guardia, stated that the money was intended "to support the work of the Center, in general, *and your contributions to the food safety debate (Pesticides)*. I would like to meet from time to time to discuss topics of mutual interest."[168]

**Thinking Big**

Kraft executive Guardia also responded in another letter to a funding proposal from Graham, in which Graham announced the launch of an "effort to increase food industry support for work on food safety legislation."[169] Graham's letter evidently had asked Guardia for the names of other potential corporate donors for the new project and had named the sum to be solicited from the food sector as $25 million. This amount of money was so grossly high that Guardia demurred: "You know fund raising better than I, *but your request of $25 M strikes me as excessive in a year like 1992.* Ask yourself whether you would not be better off asking for $10 M."[170]

**Graham Writes to the Bush White House**

What did Philip Morris get for its money and bit of assistance locating additional funding sources for Graham? One item contained in the Philip Morris files is a letter on HCRA letterhead from Graham to Jonathan Wiener in June 1992. At the time, Wiener was the policy counsel of the Bush I White House Office of Science and Technology Policy and the senior staff economist for environmental and regulatory issues at the White House Council of Economic Advisors. Wiener was also working on Bush I's draft executive order on economic analysis and later would assist Clinton in crafting his Executive Order on Regulatory Review.[171]

The subject line of Graham's letter to Wiener read: "The Release of Risk Assessment as a Regulatory or Policy Action: The Case of ETS."[172] In the letter, Graham suggested that the EPA's recent risk assessment process on ETS should have been part of a formal rulemaking. Despite having very recently solicited money from Philip Morris, Graham wrote to Wiener: "since I am not an expert on ETS, I don't know whether EPA's report is based on good science . . . If one is trying to make a case against smoking, the EPA risk assessment is certainly good ammunition."[173]

Graham's letter to Wiener continued:[174]

> In light of this example, think more broadly about future EPA risk assessments of electromagnetic fields, video display monitors, styrene, formaldehyde, carbon dioxide emissions, and so forth. As matters stand now, the White House and the nation are very vulnerable to EPA (or other agency) risk assessments that are not based on sound science or do not adequately convey the degree of uncertainty in the science. . . A small, yet well-qualified group of risk assessors in the White House could make an enormous difference on these issues, particularly if they established credibility among agency risk assessors.

Graham's letter did not disclose his relationship with Philip Morris, which was relevant to his framing of the EPA's work on ETS. Nor did Graham's letter mention the considerable funding that Graham has received from: 1) power companies and utilities, which closely monitor the debate over the safety of electromagnetic fields, 2) many chemical conglomerates, including DuPont, the American Chemistry Council and Dow, which makes styrene, and 3) numerous auto makers and energy and oil concerns with a direct stake in the fight over carbon dioxide emissions.[175]

**Philip Morris Writes the Handbook for "Good Epidemiological Practices"**

Elisa Ong, in an article in *The Lancet*, a leading British medical journal, further detailed Philip Morris's efforts to promote so-called "sound science" through the development of industry-favorable guidelines, marketed under the guise of analytical rigor.[176]

Following the lead of the Chemical Manufacturers Association, (now called the American Chemistry Council) which also funds Graham's HCRA, Philip Morris's World Regulatory Affairs division considered the usefulness of publishing its own guidelines for "Good Epidemiology Practices." As Logue's close associate, Thomas Borelli, commented, Philip Morris thought it would a "good offensive strategy" for Philip Morris-affiliated scientists to undertake the revision of "standard epidemiological practice,"[177] so Philip Morris issued new guidelines for endorsement by a "sound science coalition" and planned seminars with carefully screened groups of epidemiologists.[178]

A document entitled "The Need for Good Epidemiology Practices (GEPs) in Studies Used by Regulatory Agencies" was presented at an OSHA public meeting in November 1994 by Thorne Auchter, who at that stage was working for IRP.[179] The Auchter "GEP" report included highly specific and technical recommendations for a re-working of OSHA's epidemiological standards, including a determined emphasis on the role of so-called "negative studies." (*See* Part Three, Sellout #6). It is not clear whether the document reflects the Chemical Manufacturers Association guidelines, Philip Morris's, both in combination, or neither of the companies' blueprints, but a copy of the Auchter submission was found among the Philip Morris files.

Notes on a revised agenda from an August 1993 meeting that included Logue and other members of Philip Morris's "Worldwide Regulatory Affairs" group reflected their brainstorming about further avenues to discredit the European study. Scrawled writing indicates that those at the meeting had plans for Graham's participation: *"Need a war of words European v. USA Studies, etc. — J. Graham Ast. Symposium."*[180]

**The Verdict**

The EPA's risk assessment of environmental tobacco smoke was published in 1993. It estimated that secondhand smoke causes some 150,000 to 300,000 cases per year of lower respiratory tract infections such as bronchitis and pneumonia in children up to 18 months of age, resulting in 7,5000 to 15,000 hospitalizations, plus somewhere between 400,000 and 1 million cases of asthma.

The EPA also decided, for the first time, that secondhand smoke should be labeled a "Class A carcinogen" — a government term which means that ETS is not merely suspected but *known* to cause lung cancer. The impact of secondhand smoke is small compared to the effect of direct smoking in cancer terms, but EPA estimated that some 3,000 lung cancer deaths per year among U.S. nonsmokers should be attributed to secondhand cigarette smoke.

**Graham's Other Work on ETS**

Graham's work was also connected with the ETS debates in the U.S. and with the counter-spin of the EPA's results on ETS. Graham was quoted in a 1994 report by the Alexis de Tocqueville Institute (ADT) that was found in the Philip Morris files, an anti-regulation group.[181]

The ADT report was entitled "Science, Economics and Environmental Policy: A Critical Examination." The report quotes Graham's criticisms of the EPA and his promotion of "good science": "But as Dr. John Graham, of the Harvard Center on Risk Analysis notes 'While it may seem obvious that EPA should use good science, students of the Agency have documented that the Agency's leadership, when preoccupied with public fears and legal pressures, has sometimes allowed good science to be neglected.' "[182]

The report's "case study" of EPA "abuses" targeted the agency's decisions on ETS, accusing the agency of poor science and biased results:

> Unfortunately, in [the EPA's] zeal to abolish smoking, science has been sacrificed. . . In short, the EPA study relied on methodologies different from those which have been historically used in such analyses. *Scientific standards were seriously violated in order to produce a report to ban smoking in public settings.*

**Other contacts between Graham and Philip Morris/Kraft**

- Mayada Logue, of Philip Morris' regulatory affairs bureau, received promotional materials from a 1992 conference featuring Graham and Duke University's Kip Viscusi, as well as Aaron Wildavsky, who is mentioned in Part Three in connection with a campaign on the issue of Alar, a pesticide. The conference was called "Making Sense of Safety." The cover quotes Wildavsky as saying, "There can be no guarantee that the dangers people seek to avoid are the ones that will harm them the most." Heritage Foundation documents credit Wildavsky with development of the idea that risks should be compared to other risks as a political strategy that masks a general anti-regulatory agenda.[183]
- On Aug. 31, 1992, Logue wrote that "the meeting between myself . . . and Graham was beneficial in that the Harvard Center for Risk Analysis has launched an effort to address issues in food safety legislation. I am pleased with this development and hope that we can continue to work with and support Dr. Graham's work on issues that involve Risk Analysis."[184]
- Logue also records that in February 1992, Philip Morris had sent a check to the Center for Risk Analysis for an unspecified amount, and that Philip Morris would be asking for Graham's assistance on a project for a Philip Morris official on "Weak Relative Risk."[185]
- In May 1992 Logue met with Graham and Guardia "concerning the Center for Risk Analysis" and attended a Harvard School of Public Health Symposium on Occupational Health Risk Assessment. In June 1992, another meeting with Graham and a Philip Morris official was planned.[186]
- Logue had meetings with Graham in February 1993, and attended the Winter Toxicology Forum Meeting in Washington, D.C., "where Dr. John Graham presented a novel approach to risk assessment."[187]

**More Recent Graham/Philip Morris Activity**

Graham's projects eventually went global. In June 1998, Graham and two others from the Society for Risk Analysis wrote to Thomas Borelli of Philip Morris on HCRA letterhead to solicit $50,000 of a total funding schedule of $250,000 for an international symposium in Brussels.

The Society for Risk Analysis posted an Internet list of corporate "sustaining members" that includes Amoco, the Chemical Manufacturers Association, Chevron, DuPont, Exxon, Procter & Gamble and the Sapphire Group, which is made up of chemical, cosmetic, food and health care interests.[188]

The objectives of the conference were to set the stage for a first World Congress on Risk Analysis by helping:

> 1) to articulate the state of the field of risk analysis, including a review of what is happening worldwide and where the field should be going, and 2) to build and catalyze the international community of scientists, practitioners and decision makers who are dedicated to risk-based decision making and related processes of risk assessment, management and communication."[189]

Graham's letter continued:[190]

> the fields of application to be addressed at the symposium will be broad: *food and product safety, chemical risk management, global climate change, natural hazards management, medical technology assessment, insurance, energy development, and injury prevention.* We are open to suggestions of specific issues that you would like to see addressed at this rather unique gathering of international leaders in the field of risk analysis. We are also open to suggestions of possible participants who you believe would make a significant contribution.

As in his other fund-raising letters, Graham closed by saying that someone would call soon to follow up.[191] Philip Morris is not on the HCRA Web site list of funders. Kraft Foods is named as a contributor of "unrestricted" funds.[192]

## Case Study #2:

### *GRAHAM WEIGHS IN ON THE SAFETY OF CELL PHONES*

**Driver Concentration Is the Problem . . .**

In a recent *Dallas Morning News* article about the causes of recent traffic deaths in Texas, Graham emphasized his faith in the driving ability of ordinary citizens, indicating that "virtually everyone, except people who have significant health problems, is capable of being a safe, competent driver."[193] Graham implied that unnecessary traffic deaths could be prevented by increasing the level of driver concentration — saying that "the problem we have is maintaining people's level of attention."[194]

**. . .But Driver Distraction Is Not the Problem.**

Despite this statement, Graham has come down against eliminating one possible source of driver distraction: the use of a cellular phone while driving.

One week after the National Highway Traffic Safety Administration (NHTSA) held a public hearing on driver distraction and recommended that drivers pull over before using cell phones,[195] the Harvard Center for Risk Analysis, using Graham's name, self-published a report funded with $300,000 from AT&T Wireless Communications which assessed the risks of using a cell phone while driving.[196]

The report, released in July 2000, was very timely. Communities and states all over the country were in the midst of considering whether to enact bans on the use of cell phones while driving. Just prior to the study, the township of Marlboro, New Jersey, banned drivers from using cell phones, and Brooklyn, Ohio, had passed the country's first such law in March of 1999.[197] While twenty-two states had considered bans, none had been passed at the time of the report's release.[198] As in the battle over environmental tobacco smoke described above, industries that anticipate that new laws and public attitudes may discourage the use of their products take these threats very seriously indeed.

The HCRA report surveyed existing data and concluded that because the level of risk to drivers was not *clearly* indicated, further regulation in this area was unwarranted. HCRA's report stated that "*although there is evidence* that using a cellular phone while driving poses risks to both the driver and others, it may be premature to enact substantial restrictions at this time. We simply do not have enough reliable information on which to base reasonable policy."[199]

The report also made use of a "collateral benefits" theory of risk tradeoffs. According to the report, the benefits of cell phone use while driving may actually outweigh the potential dangers of using them. The report attributed gains to users such as "peace of mind," "expanding productive time," and "strengthening social networking."[200] The obvious problem is that these benefits are difficult to quantify so as to weigh them against the risk to human life from driver distraction. And to the extent that the benefit of "peace of mind" derives from having a phone in the car for emergencies, a ban on using a phone while driving could be crafted to preserve this benefit entirely.

The HCRA study drew the main power of its conclusion that the risks of driving and cell phones had not been adequately demonstrated using *general* data that showed that while "cellular phone use has grown 17-fold between 1990-1998, U.S. traffic fatalities have continued a steady decline."[201] These data did not include any specific information on cellular phone use *while driving*, nor did the study analyze crash records to ascertain whether cellular phone use was a cause of the crash, as NHTSA has done.[202]

HCRA's comparison of gross figures on cell phone use with gross crash data does not account for recent innovations in air bags and increased use of seat belts that were likely major contributors to recent declines in fatalities. Yet these data form the basis of the study's position against banning the use of cell phones while driving.

**Comparing Apples and Oranges**

The central problem in Graham's study actually relates to the evidence presented in support of his conclusion that the risks are undemonstrated. In a media interview about the study, Graham applied a misleading risk tradeoff: "Based on the information to date, the risks [of driving while talking on a cell phone] look fairly small *compared to risks people face in daily life*."[203] But the central question is whether the activity creates an *additional* or unnecessary risk, not whether it comprises just yet another risk that we should learn to live with.

This simple problem plagues each part of his analysis. According to Graham's study, driving while using a cell phone *causes fatalities of 6.4 deaths per million drivers annually.*[204] But instead of comparing this figure with drivers under similar conditions who do not use cell phones, the study spuriously compares this data to cases involving extreme risk factors, such as driving with a blood alcohol concentration of .10, which causes annual fatalities of 30.9 per million drivers, and driving without wearing a lap and shoulder belt, which causes 49.3 annual fatalities per million drivers.[205] This choice of methodology shows a basic lack of commitment to elementary standards of research. As Charles Osgood said on *The Osgood File* when reporting on the study, these categories of data are "apples and oranges."[206]

It is true that, when compared with these few circumstances, driving while talking on a cellular phone may appear relatively safe— but the study fails to compare driving with a cell phone to the risks of *driving without a cell phone under normal conditions*. In addition, these comparisons are wrong because the risks could be cumulative — for example, drivers may be at risk from *both* talking on a cell phone *and* being intoxicated while driving.

Therefore, regulation banning the use of cell phones while driving might help to eliminate an *additional* risk on the road, as many communities appear to believe. Fundamentally, comparisons like the ones in the Graham study are flawed because comparing the riskiness of some activity *to some other risk* makes little sense if we can choose to live with no additional risk at all.

**My Study vs. Your Study**

As the media framed it upon its release, the HCRA study "contradicted the finding by another study done in 1997." That other research, published after full peer review in the *New England Journal of Medicine*, avoided such ridiculous comparisons, and had concluded *that the risk of car crashes is four times greater when a driver uses a cell phone.*[207]

Dr. Donald Redelmeier was one of the authors of the *New England Journal of Medicine* study. In an attempt to approximate something like peer review, which is the accepted practice in the sciences to assure the validity of a study, Graham asked 12 independent specialists to "peer review" Graham's study, Redelmeier among them. After reviewing it, Redelmeier publicly disapproved. But the study was published and amply advertised regardless, thus demonstrating the toothlessness of Graham's "independent peer review" process.

Redelmeier publicly criticized Graham's assessment of cell phone risk, suggesting that the HCRA report lacked rigor because it "provides no new data, gives no new expertise and provides no new analysis."[208] Redelmeier also told reporters that the "*Harvard researchers left the report open to conflict-of-interest questions because they didn't publish it in a scientific journal or take other steps to demonstrate the study's fairness.*"[209]

**Other Problems With the Data**

The policy conclusions in Graham's study appear to assume that cell phone use while driving will not increase in the future.[210] This factor is taken account into a recent NHTSA study of the issue, which noted that "with a growth rate of about 40 percent per year, it is estimated that by the year 2000 there will likely be about 80 million cellular telephone users in the United States."[211] For comparison, that NHTSA study concluded that *using a cell phone while driving does increase the risk of a crash.*[212]

**From a Dubious Risk "Assessment" To Even More Suspect Public Policy**

The report's policy evaluation of bans on cell phone use while driving is even more questionable than the risk "assessment" piece. The report suggests that such restrictions are "inefficient," because the net cost per life-year of the regulation is alleged to be significantly greater than the use of lap/shoulder belts, daytime running lights, and even greater than the use of air bags. The HCRA study asserts that it would cost approximately $700,000 per life year-saved to restrict cell phone usage while driving, compared to $24,000 for front-crash air bags for drivers, and less than $0 for lap and shoulder belts.[213]

These conclusions are highly suspect, as a relatively expensive but life-saving safety system such as an air bag requires a financial outlay for development and implementation of new technology. Passing a ban on cell phone use while driving requires no such initial resources.

Moreover, HCRA assumes that regulation must be *cost-effective* in order to be warranted. But the proposition that using a cellular phones while driving is distracting and potentially dangerous is common sense. It relates to a common experience — driving — and requires little technical expertise to evaluate as a hazard in comparison to, say, varying levels of toxic chemicals.

Without saying so explicitly, the HCRA study assumes that *regulators* alone must carry the burden of proof on the cost-effectiveness of their recommendations: It requires that a ban be justified on cost efficiency grounds (based on the limited information that we have available) before we can act. In so doing, it leaves common sense, the rights of other drivers and pedestrians not to be injured or killed by a distracted driver, and the precautionary logic and experience of individual communities, far behind. As the eminently logical Tom and Ray Magliozzi, hosts of Car Talk from National Public Radio, put it in response to a similar study by Robert Hahn, Graham's ally at the American Enterprise Institute-Brookings Joint Center for Regulatory Studies, "This seems to us to be a clear case of cost/benefit analysis run amok."

The timing of the study in relation to the NHTSA recommendation about limiting cell phone use while driving was surely no accident — and the study's conclusion concerned the *political wisdom* of enacting a ban. This assumption that risk "experts" should quash good sense by finding regulation is unjustified *unless the harm of an activity has already been demonstrated* blatantly favors business interests and the status quo, given the political context of the study.

Often, incomplete information on risks means that *the benefits of preventive regulation can appear very small, when in fact they could actually be enormous.* Unless we are very careful about adjusting cost-benefit equations to account for our uncertainties, it will always turn out that regulation which prevents a future risk is not cost-efficient.[214] Until there are demonstrated risks, such as bodies on the highway, cost-benefit analysis can tell us that protecting safety (or health, or the environment) is just not worth a dime.

And because up-front prevention often must occur in the absence of complete information, using a cost-benefit approach to evaluate health policy at the outset will doom us to forever locking the barn door after the horses are gone. The recklessness of these conclusions — and the study's lack of a protective attitude towards human life — is stunning.

## LETTER FROM TOM AND RAY MAGLIOZZI, HOSTS OF CAR TALK FROM NATIONAL PUBLIC RADIO, TO THE NEW YORK TIMES ABOUT AEI-BROOKINGS' ROBERT HAHN'S STUDY ON COST BENEFIT ANALYSIS AND CELLULAR PHONES[215]

**********

18 November 1999

Letters to the Editor, The New York Times

229 West 43d Street

New York, NY 10036

Re: "Driving and Talking Do Mix" (New York Times, November 12, 1999)

To the Editor:

As proponents of "Drive Now, Talk Later," we must take issue with the op-ed piece by Robert Hahn. This seems to us to be a clear case of cost/benefit analysis run amok.

Just what is this guy thinking? First, he refers to accident reports — which for the most part do not even record the use or nonuse of cellular phones. Then he cites his own estimates of the mere "10,000 people (who will be) in serious accidents and the minuscule number of "100 people who will die" due to cell phone use.

And the benefits associated with these accidents and deaths? First is the ability to summon help on a lonely highway. Are we a little short of logic here? Just how would a ban on cell phone use while driving prevent one from using the phone from the breakdown lane? The almost invaluable benefit is the convenience of reminding your spouse of your daughter's school play. But not if you happen to be Patricia Pena. Her two-and-a-half-year-old daughter, Morgan Lee, was killed by one of Robert Hahn's new breed of highly productive citizens. What price has Mr. Hahn plugged into his nice, clean economic model to account for the misery and tears that such outright selfishness has wrought?

Mr. Hahn, you're just not that important that you need to talk and drive, and endanger the lives of innocent people on the roads. And next time you consider writing an op-ed piece, please remember the admonishment of Ted Williams to one of his not-too-bright teammates: "If you don't think too good, then don't think too much."

Tom and Ray Magliozzi, Co-hosts

Car Talk, on National Public Radio

**Update from the Web Site of Tom and Ray Magliozzi**
**Co-hosts, Car Talk, on National Public Radio**
**About the Cell Phone Issue**

A couple of interesting developments that you might be interested in.

1. That Great Newspaper and arbiter of what's "fit to print" — the "New York Times" — opted to print a guest op-ed column on November 12 ("Driving and Talking Do Mix") by some guy named Robert Hahn from the American Enterprise Institute.

We wanted to reprint it so you could read it yourself, but the NYT wants $250 for permission to reprint. Instead, we'll paraphrase. Mr. Hahn says that it's silly to ban the use of cell phones while driving. In fact, according to his personal estimates, cell phones will cause only 10,000 serious accidents this year, leading to (a mere) 100 fatalities.

Then this moron (in our opinion) goes on to explain to us that he has done a cost/benefit analysis, and in his opinion 100 deaths and 10,000 serious accidents is a small price to pay for the enormous benefits we derive from using the cell phone.

Here are a couple of his benefits:

#1. The ability to call for help when your car breaks down. (Right away one has to wonder if this guy is playing with a full deck. If your car breaks down, you'd hardly be using the cell phone AND driving. Duh, Mr. Hahn.)

And this one is a beauty. The 10,000 serious accidents and 100 fatalities are a small price to pay (says Mr. Hahn) for "the ability to remind your spouse that your daughter's school play starts in 20 minutes." At this point you know that he is DEFINITELY not playing with a full deck.

Naturally we immediately penned a letter to the editor, who apparently did not consider it to be "fit to print." (Admittedly, the letter was a little short on tact and diplomacy. We didn't think such moronic thinking deserved tact and diplomacy.)

Fortunately the NYT did print a couple of letters that did address the issues. One said, "Does he really consider a cell phone call from a car to "remind your spouse that your daughter's school play starts in 20 minutes" more important than even one life? Since when do small conveniences rank above human life?"

#2. A few weeks ago, we at Car Talk Plaza were approached by NBC News. They had heard our ranting and seen the feature here on the site, so they wanted to do an interview with Tom and Ray on the cell phone issue. We generally eschew the media whenever possible. But this seemed like an opportunity to help a good cause, so we agreed to do it. Everything was arranged; a date, time and location for the taping were set up.

But...a few days before the event, we were informed that "the producer in New York had decided not to do it."

#2 part 2. We were approached by CBS with a similar request.

Again, mysteriously, the "producer in New York decided not to do it."

Now, it's certainly possible that there's a simple explanation for these two incidents. The most likely--even we admit it--is that the producer had never seen or heard of us before. I mean, that would certainly explain it. If you were a producer of a major network show and...well, you get the idea.

On the other hand, there's a distinct possibility that the news that's fit to print and the news that's fit to put on the air are very much influenced by big bucks. Let's face it: there's a lot of money involved in the cell phone industry--and lots of it goes to advertising.

Just a thought.

—Tom Magliozzi

## Case Study #3

### *GRAHAM OPINES ON PASSENGER-SIDE AIR BAGS*

**Graham Flips Over On Air bags**

As Good Morning America commented, it was big news when Graham went before the National Transportation Safety Board (NTSB) on March 17, 1997, and announced that he was changing his tune on the safety benefits of passenger-side air bags.[216]

Graham's early research on air bags in the 1980s was cited in a footnote to a 1983 Supreme Court case and cited by the Secretary of Transportation, Elizabeth Dole, in support of a passive restraint mandate.[217] And in December 1996, Graham told *The Boston Globe* that public fear over the dangers of air bags was exaggerated and could produce a harmful over-reaction: "People are getting the idea that drivers are getting killed, and they're getting a lot of specifics wrong . . . . *I have the sense that the benefit side of air bags isn't being shown in as compelling a fashion as the risks have been.*"[218]

But in March 1997, Graham dramatically renounced his earlier position, telling a stunned group of safety advocates and government regulators that a new, as-yet-unpublished study done by his Center had convinced him that passenger air bags were not cost-effective enough to justify the requirement, when compared to the cost-efficiency of driver-side air bags or seatbelts.

That same day, prior to testifying at the NTSB hearing, HCRA released a consumer survey on public attitudes about air bags, called *The Airbag's Teflon Image: A National Survey of Knowledge and Attitudes*. The morning of the NTSB hearing, Graham went on ABC's Good Morning America to talk about both the survey and the unpublished HCRA study.

Good Morning America anchor Charles Gibson introduced the segment: "Today, the researcher whose analysis helped get air bags into cars 20 years ago is coming forward to say that they don't save enough lives to justify their risk or their cost." Reporter Steve Filmer further dramatized Graham's turn-around: "We can't overstate what a big deal this headline is. Dr. Graham's research set policy on air bags over the past 10 years. What have you found in your research now? Why have you changed your mind?"

Graham stated that the news from his research on the cost-effectiveness of passenger-side air bags was "sobering" and that they "kill three times as many children *as they save*." Yet in other articles, including one that ran in the *Atlanta Journal and Constitution*, Graham said, in an apparent contradiction, that "there are *no* documented cases of a child being saved by an air bag."

The Associated Press (AP) also put out a story on March 17, in which Graham claimed that "most" of the 38 children killed by air bags had been decapitated.[219] The comment was picked up by several newspapers — in articles giving a prominent position to HCRA survey findings that America was misinformed on air bags[220]— but Graham's statement was actually a frightening exaggeration that later had to be corrected by AP. According to the National Highway Traffic Safety Administration (NHTSA), *three* of the 38 children killed by air bags had met with such a terrible death.[221]

**Bad Science in Graham's First Study on Air Bags' Cost-Effectiveness**

On Good Morning America, and later at the NTSB meeting, Graham reported that a HCRA study had demonstrated that the relative cost of passenger-side air bags was, he suggested, an unreasonably high $399,000 for each year of life saved, whereas driver-side air bags cost a more reasonable, but still high, $70,000 per life-year saved.

The announcement came at a critical time. NHTSA was preparing to issue a proposed rule permitting vehicle owners to depower air bags, which would be subject to review for cost-effectiveness by the Office of Management and Budget (OMB) before its public release.[222] Graham knew that his remarks would likely be controversial given the pending rulemaking and because air bags have for the past three decades remained a highly contentious area of debate between public safety advocates and the motor vehicle manufacturers.

Speaking before the NTSB, Graham qualified his findings significantly more than he did on Good Morning America. For example, he told the NTSB that the high cost of passenger-side air bags could be a result of differences in occupancy rates between the driver and passenger side. While all cars, and thus all crashes, must have a driver, passenger-side occupancy rates are much lower. Thus, passenger side air bags are utilized far less frequently than those on the driver's side.

In fact, passengers accounted for 189 of the lives saved by air bags in crashes considered in Graham's study, compared to around 1,600 drivers whose lives were saved by air bags between 1989 and March 1997.[223] That makes the size of the statistical sample for passenger-side crashes very low, which in turn makes it likely that the study's conclusions would be affected by any small change in other factors.

Before the NTSB, Graham also acknowledged that the passenger numbers were high because of the number of child fatalities attributed to air bags. Children sit only on the passenger's side and the air bags' effectiveness was measured by the number of life-years saved (the loss of a child's life is represented by a negative 75 years of life expectancy, whereas an adult driver loses, on average, 35 years of life expectancy per fatality). Therefore, the information on childhood fatalities and injuries greatly impacted Graham's conclusions.

Graham failed to release the study that he announced in March until May 1997, despite the loud outcry from consumer advocates for his presentation of a study to the media that was incomplete. When it was finally made available, the flaws in his research were obvious to concerned safety experts and engineers.

It turned out that the data Graham chose to use in his study were not internally consistent. Michael Finkelstein, a transportation safety expert who had headed NHTSA's motor vehicle safety office for years and whose clients include air bag manufacturers, pointed out in a letter to Graham and federal regulators that Graham's study had not been peer-reviewed, and that his data choices would be unlikely to survive that process.[224] According to Finkelstein, there were grave problems with both the information on benefits and Graham's research on costs.

Because risk management frequently combines the outcome of several different studies, it is critical to make logical choices and to keep the numbers coherent. Graham had, it appears, combined information from two different studies, picking inconsistently from each. Finkelstein wrote that, after reviewing the two studies which had served as the basis for Graham's conclusions about fatalities and air bag effectiveness: "*Your choices with respect to airbag effectiveness estimates were hard to understand.*"

As Graham's conclusions on passenger-side air bags were very vulnerable to changes in the data, his choice to use a particular number changes the study's outcome. Finkelstein wrote that, unlike the data on the driver's side air bag effectiveness, "the cost-effectiveness of passenger air bags is extraordinarily sensitive to small shifts. Thus, if you had used the 13.5 percent effectiveness estimate from [one of the two studies], rather than the 11 percent estimate that you did use, that by itself would have cut the cost [of a life-year saved] in half."

Finkelstein also found "questionable" the data Graham had used on cost, which dated from 1992. Finkelstein observed that more recent data should have been used because:

> The cost of most technology declines as the technology matures. . . . Using a government tear-down study of 1992 technology to estimate the cost of air bags in 1997 would be the same as using the cost of a 1992 laptop computer to estimate the cost of current technology. *I think that, at a minimum, your cost estimate overstates current costs by a factor of two.*

An overstatement of that magnitude, needless to say, would have a considerable impact upon the study's ability to accurately measure air bag technology's cost-effectiveness.

Furthermore, Finkelstein wrote, his own calculations using Graham's numbers had revealed that the conclusions did not stand up to scrutiny (this kind of testing for validity, or "robustness," is called "sensitivity analysis"):

> After conducting a sensitivity analysis, I found it hard to believe that you still released your findings to the media. . . . Sensitivity analysis is used to reinforce a finding by demonstrating that an outcome is robust, *i.e.*, that the conclusion is not very sensitive to potential changes in the variables upon which the result rests. And for the driver air bag analysis, that is in fact confirmed. *But for passenger air bags, the sensitivity analysis should have produced a conclusion that the findings are just not robust enough to release.*

At the least, according to Finkelstein, because of the shakiness of the data, Graham should have *waited* to go public out of a sense of scientific responsibility:

> Your own research results should have raised so many questions that, at a minimum, you would have delayed the release of your findings until they had been subject to peer review.

Consumer advocates and safety groups were also upset by Graham's presentation of poorly analyzed data at the NTSB hearing. In particular, they were critical of Graham's omission of any comparison of the advantages and disadvantages of differing air bags systems (top-mounted, dual inflation, etc.), as this dramatically impacts the number of fatalities and injuries, particularly those concerning children and small adults, who are more vulnerable to injury than a statistically "typical" adult male. This was critical for a valid study of air bag effectiveness, the groups argued, because some types of air bag systems, such as those installed in Hondas, had not killed any children.

This fact, ignored by Graham, revealed that safer air bag systems were actually within the reach of any manufacturer who chose to install them. The key issue on air bag safety was in fact the poor design of many passenger air bag systems, which varies by vehicle make and model. Sorting the data according to that information would have yielded far more specific and useful results on effectiveness, cost and risk than did Graham's study, which lumped together all types of passenger air bags and all types of passengers.

Additionally, the groups, including the Center for Auto Safety, the National Safety Council, and Public Citizen, noted that Graham's results "were based on preliminary research which should have been available for review by experts before being released via national television."[225] Clarence Ditlow, Executive Director of the Center for Auto Safety, commented that:

> *For someone who claims to be a respected scientist, John Graham makes a mockery of the scientific process by going for sensationalized and misleading headlines which would be refuted by a peer review of his paper.*

**Flopping Back: Graham's Revised Study on Air Bags' Cost-Effectiveness**

Ditlow's instincts about the impact of a peer review on Graham's study would turn out to be prophetic. In fact, Graham's conclusions did not survive scientific treatment, and when the same study was finally published in the prestigious *Journal of the American Medical Association* (*JAMA*) in November 1997, following a peer review, both the numbers *and* the study's ultimate policy conclusion had experienced a miraculous transformation.

The new numbers were far lower than the ones released the day of the NTSB hearing. The *JAMA* study authored by Graham concluded that driver-side air bags cost $24,000 for each life-year saved, rather than the $70,000 originally stated.[226] And the estimate for passenger-side air bags, which originally had been set at just under $400,000, *was reduced to only $61,000* — well within the range of affordability sometimes used to measure the costs of health and medical interventions.

The new numbers required a U-turn in the study's conclusion as well. This time around, the press release, sent out on Harvard School of Public Health letterhead, was titled: *"Study Shows Air bags a Worthwhile Investment: Risk to Children Must be Addressed."*[227]

Despite these improvements, the *JAMA* study still had several serious deficiencies. For example, the method of cost-benefit analysis used in the *JAMA* study assumed that all the costs and benefits should be weighed against each other, regardless of any consideration about *who* pays a cost and *who* benefits.[228] This approach puts industry first and our safety goals a distant second — because it assumes that the benefit of saving a human life can and should be measured against the cost to the auto makers of coming up with better safeguards. Current costs, and technological capacity, are input as the given. A better approach would be to project what improvements in safety are within the reach of the industry, and to measure the kind of investment needed to get us there.

Researchers also assumed that fairness plays little or no part in the results, because they assumed that any cost on the part of the companies could be measured against the "benefits" to the public in the form of reduced death and injury. That is like saying that money out of General Motors' pocket is the same as the medical bills, personal loss, and grief felt by a driver of a GM car that is involved in a crash. This assumption ignores important policy questions, such as whether the public *would* pay more for safer air bags if we were educated about the options, whether it is ethical to balance corporate profits against public suffering, and whether some compromise of profits should be required in order to preserve human life.

In addition, the *JAMA* version of the study, like its predecessor, failed to distinguish between different models of air bags and types of air bag release systems — a failing which threatens the validity of the results because, for example, top-mounted, vertically deploying air bags hit the windshield before impacting with occupants and had not caused *any* fatalities at the time the study was completed.[229]

Instead of analyzing the causes of the problems with specific air bags, which could have put the burden on industry to fix the problem, Graham's official spin on the *JAMA* study emphasized a typical motor vehicle industry "line" that the solution for air bag injuries is to *fix the public* by passing a law that would prohibit parents from putting young children in the front seat.[230]

Although Graham has been quick to point out risk tradeoffs in the past, he missed the opportunity as to this issue. A law putting all children in the back seat runs the risk that weak front seatbacks may collapse in a rear-end crash and send adults rocketing backwards, injuring or potentially even killing their children. This ongoing hazard was the subject of a February 2001 *60 Minutes II* report.

In the political context of the day, the suggestion that a law should require children to be seated in back was often used to deflect any further regulation of air bags. Advanced air bag rules could have required automobile manufacturers to design and install more sophisticated, and potentially more costly, air bag systems. In addition, a law prohibiting children from sitting in the front seat could be used as a liability shield, depending upon how the law was drafted. Under such a law, auto companies would likely argue that the primary responsibility for a child's injury rests with the parent, rather than with the air bag system or the motor vehicle manufacturer.

In contrast, another study published in the same issue of *JAMA* by Dr. Elisa Braver and her team emphasized technological solutions and concluded that, to reduce at least some of the risks to children, "modifications in air bag technology [are] needed. Making air bag inflators deploy with less force should reduce, but not eliminate, the risks to children *and can be readily developed by car manufacturers in the near future*. . . . In the longer term, more sophisticated air bags are being developed that will detect occupant characteristics and crash severity and then tailor deployment characteristics to maximize protection for all occupants regardless of their sizes or seating positions."[231] That study concluded that passenger side air bags effectively reduced deaths by 18 percent in frontal crashes and by 11 percent in all crashes.

However, in at least one notable aspect Graham's *JAMA* study was a vast improvement over his earlier comments. Whereas in March Graham had breezily told reporters that passenger air bags were not "cost-effective,"[232] the *JAMA* study correctly stated that:[233]

> *No consensus currently exists about what levels of expenditures are cost-effective, and consequently it is difficult to make absolute statements about whether an intervention is a worthwhile safety investment.*

**Graham's Failure to Correct His Earlier Conclusions**

Public Citizen's investigation failed to uncover any attempt by Graham to correct the March 1997 news coverage of his charges about the allegedly dismal cost-effectiveness of passenger air bags. Instead, Graham seized the opportunity presented by release of the *JAMA* study to promote a new angle which emphasized a misleading air bag risk "tradeoff" between adults and children.

*The Boston Herald* reported Graham's new twist: "Passenger-side bags are saving the lives of adults but for every 10 saved, there is one child killed, according to today's studies . . . . 'That kind of ratio is not very impressive,' said John Graham of the Harvard School of Public Health . . . '*If we had a mandatory vaccine program in the country that would require children to be placed at risk so adults could be saved, it would be unacceptable*,' he said."[234]

Of course, the ratio between the number of adults saved and number of children killed is far from immutable. To use his analogy, we could adjust Graham's "vaccine" to very rarely injure fewer people, including children, by mandating the use of advanced air bag inflation and sensing technology, or we could refuse to administer the air bag "vaccine" to children altogether, which would be the equivalent of moving them into the backseat or technologically suppressing them for smaller occupants. As so frequently happens in Graham's work, his comments to the media cover up far more information than they reveal.

Although the HCRA Web site lists Ford Motor Company, General Motors, and the Goodyear Tire & Rubber Company as providers of unrestricted funds, these potentially relevant sources of funding were not mentioned in the articles describing either Graham's performance before the NTSB, on Good Morning America, or in the media coverage of the *JAMA* study. We note that, according to *JAMA*, funding for the study itself was provided by the Centers for Disease Control and Prevention to the Harvard Injury Control Center at the Harvard School of Public Health, and not to HCRA directly.

**Survey Says: The Expert Knows Best**

There were also serious problems with the survey results that Graham had announced in March 1997. The survey was called *The Airbag's Teflon Image* and a March 13 HCRA press release summarized its conclusion that a "Survey of Americans Shows Air bags are Misunderstood." The report's press release contended that Americans' widespread support for air bags was founded upon bad information:

> Despite recent news reports that highlight the danger for young children of passenger side air bags, Americans overwhelmingly favor the use of air bags. *However, their support is based on a variety of misperceptions about their use and safety.* The findings come from a survey reported today by the Harvard School of Public Health.

The survey was full of rather complicated questions. For example, to test public knowledge on child seats, the survey asked: "True or False: *Air bags are not a danger to an infant in the front seat if the infant is restrained in an approved, rear-facing child restraint device.*" Despite the potentially confusing use of the word "approved," nearly 70 percent of the survey's respondents answered "False," which is the correct response.

The survey did manage to trip up the public in some areas — but in some of them, the survey was part of the problem. Its so-called "findings" could have easily contributed to, rather than alleviated, the public's misunderstanding of air bag safety issues.

For example, the press release on Graham's survey emphasized that Americans had gotten the following question wrong: "True or False: A majority of the lives that have been saved by air bags have been among people who were not wearing seatbelts." The answer, according to the survey, was "true." But the question's "majority" was tricky. According to the extremely rough calculations used for the survey, the survey tested the public's knowledge of a 59 percent margin — a bare majority, and hardly a good indicator of public awareness about air bag safety.

In a repeat of the poor scholarship applied in the cellular phone study, *see* Case Study #2, HCRA came up with the 59 percent figure number by comparing the *total number* of belted and unbelted crashes with NHTSA's general data on the effectiveness of air bags — without examining the type of crash, *whether there was an air bag in the vehicle* and the type of air bag, or the placement of the occupant. Obviously, many older cars lack air bags, so this extrapolation is, to say the least, highly suspect.

And their numbers don't match up with the more in-depth analysis published in *JAMA* by Dr. Braver and her team. That study concluded that "the risk of frontal crash death for right front passengers in cars with driver and passenger air bags was reduced 14 percent among those reported to be using belts and 23 percent among belt nonusers." The data in that study shows that the number of fatalities that were probably prevented by the presence of a passenger air bag during a frontal crash was similar for both belted and unbelted occupants.[235]

So why was a test on this kind of sloppily worked out detail promoted as evidence of American ignorance on air bag issues? In addition to the media-ripe timing of the survey's release, it appears that the survey's conclusions were a great fit with the political strategy of the motor vehicle industry.

According to safety experts such as Joan Claybrook, President of Public Citizen and former Administrator of NHTSA, the motor vehicle industry was, at that time, waging a campaign to deflect attention from the need for more advanced air bag systems by focusing on the public's knowledge of safety issues involving air bags. A survey such as Graham's would thus have perfectly dovetailed with the industry's interest in preventing the development of additional, safety-motivated air bag requirements.

Information that allegedly shows public ignorance about risk is also politically useful as general evidence in support of rule by "experts." The implication, of course, is that whenever the public disagrees with the "experts," it is the needs of the public that must take a back seat.

Graham has used this technique again more recently. In 1999, he announced the results of a survey on risk perception that he helped design in an article in *American Health Line*. His study concluded, unsurprisingly, that the public considerably overestimates health risks, such as disease, and hazards, as well as accidents and injury. The public's overestimation of risk is dangerous, said Graham, because it "can trigger *unreasonable* demands for expensive policies which are not cost-effective."[236]

In fact, it is well known that the public generally has a more precautionary attitude toward risk than do most risk experts.[237] Some risk assessment and risk management specialists are very attentive to the importance of this divide between the experts and the public, and argue that any government action or policy must take meaningful account of these kinds of differences as a matter of both practical and moral legitimacy.[238]

Ellen Silbergeld, a toxicologist with the Natural Resources Defense Council, has emphasized that questions on the magnitude of a controversial risk have no "right" answer, saying that "*We don't want to turn our democracy over to a priesthood of people who have Ph.D.'s.*"[239] Against the backdrop of this critical discussion within his own field, Graham's repeatedly pejorative characterization of our public "fears" as irrational and uninformed suggests his message has a premeditated purpose.

**The Real Agenda: Graham's Air Bag Testimony in Support of Regulatory Rollback**

In May 1999 Congress was considering the enactment of Senate Bill 746, the so-called "Regulatory Improvement Act of 1999." The bill was a dream for industry because it would have laid out a nearly impossible regulatory obstacle course for most of the federal agencies to jump through *before* they could finish a rule. Among other things, the regulatory rollback bill required the agencies' rulemaking to:[240]

- Include a uniform, formal risk assessment before acting to protect human health or safety, according to detailed specifications in the law that were developed for evaluation of chemicals but are inappropriate for other health and safety problems;
- Wait for full submission of the industry's data — with no time limits on submissions, this was an invitation for corporate abuse;
- After a complicated cost-benefit analysis, ensure that the chosen regulatory program was the most cost-effective for industry of all the possible options, or prove why the rule should be adopted anyway;
- Pass muster with a secret, and likely industry-funded cadre of peer review "scientists" — under the law, government scientists were barred on conflict of interest grounds, but industry "experts" were given free rein;
- Escape the "black hole" of OMB — the law would have allowed the OMB to avoid putting in writing why it failed to approve a proposed rule; and
- Survive an invitation in the law for "judicial review" that could have allowed courts to overturn an agency rule based on a disagreement over risk assessment or cost-benefit analysis *methods*.

Predictably, Graham came out in support of the rollback initiative, and used the example of NHTSA's air bag regulations as a poster child for rulemaking gone wrong.[241] Graham told Congress that the law's requirement for risk assessments would probably have torpedoed NHTSA's earlier air bag regulation, and that its "peer review" requirement would have produced a better rule.

But NHTSA had undertaken extensive research prior to issuing its air bag rule, including a complete risk assessment, and also had looked to the body of outside research, such as the economic analysis performed by Graham himself.[242] As he told reporters in 1997, in the 1980s Graham had "argued that . . . air bags were a good idea on cost-benefit grounds."[243]

Speaking before the Senate, Graham called attention to the number of children killed by air bags but failed to mention the 2,620 lives that air bags had saved between 1987 and 1997.[244] But contrary to his argument, nothing in S. 746 would have made air bags safer for children. In fact, in some areas, S.746 would ensure that NHTSA could only have implemented far more dangerous regulations.

For example, the 1999 rollback bill required agencies to give a preference to "flexible regulatory options," such as "outcome-oriented performance-based standards." The standards that NHTSA issued on air bags measured air bag performance protecting occupants in certain crash tests, and did not make specific design requirements, just as S.746 recommended. S.746 would have done nothing to save children on that front.

The bill would also have forced NHTSA to give far more consideration, even determinative weight, to the industry's costs in complying with the rule. This section of S.746 would have prevented NHTSA from issuing a more protective standard with better results for children, because more sophisticated systems would surely have driven up the compliance costs for manufacturers.

In the 1980s, NHTSA already contracted with many outside groups in formulating its air bag requirements, and looked to the results of outside research, including Graham's, in writing the standard. But due to the lack conflict of interest provisions for industry-paid experts, the "peer review" requirement of S.746 would merely have ensured that the reviewing panels were staffed with industry-friendly experts, who would likely have resisted the development of any rule at all.

Contrary to Graham's claims, the preventable tragedy of child deaths from air bags was not a perverse result of bad regulation. It was a direct consequence of choices by automobile manufacturers to install less protective, cheaper air bag systems.[245] The evidence shows that the choices made by the manufacturers were ruled by cost-cutting incentives despite their knowledge that such air bag systems could be dangerous to children and smaller occupants and knowledge of far safer designs, including dual inflation and top-mounted, vertically deploying air bags.[246]

Air bags have saved well over 6,000 lives thus far.[247] Although Graham called the bill a victory for safety, the regulatory "flexibility" and other rollback provisions of S.746 would have done nothing to improve the situation for children, and could easily have been used to halt or block the issuance of the standard and the further development of this life-saving technology.

# PART THREE

## A CORPORATE AGENDA TAKES OVER THE PUBLIC HEALTH, SAFETY AND ENVIRONMENTAL DEBATES

After a decade of criticizing the EPA and other agencies for being overly cautious in calculating risks, industry forces decided in the 1980s to co-opt the regulatory language of risk and cost-benefit analysis and to re-write the rules of the game. Chemical companies and their allies in the pseudo-science community even developed elaborate advance plans to counter-spin the publication of a single book, *Our Stolen Future*, by Theo Colborn, Dianne Dumanoski and John Peterson Myers, which describes the disastrous effects of endocrine disrupters upon human reproductive health and intelligence.

Their goal was to generally discredit the enterprise of protective regulation. They sought to exploit any breach in the public's confidence about the wisdom of our federal agencies by instituting rule by risk "experts" — whose calculations they could control by rigging the technical rules of the game and whose decisions would trump the democratic development of health and safety protections.

Graham has been an integral part of this campaign. Throughout his behind-the-scenes participation in the regulatory debates on the part of Philip Morris, and his work with corporate counter-spin front groups like the American Council on Science and Health, Graham lent his Harvard credentials to the cause and helped to legitimize the industry attack on public health, safety and environmental objectives.

Below are six of the science sellouts used by Graham in contacts with the media:

**Science Sellout #1:** *The Counterfeit Science of Graham's Risk Analysis*

**Science Sellout #2:** *Flack Science: Manipulating the Media Pays Off*

**Science Sellout#3:** *Selling Half the Story*

**Science Sellout #4:** *Misleading Risk Communication: The Difference Between Falling and Being Pushed*

**Science Sellout #5:** *Concocting "Science" for Corporate Counter-Spin*

**Science Sellout #6:** *The Misuse of Scientific Uncertainty*

## Science Sellout #1

### THE COUNTERFEIT SCIENCE OF GRAHAM'S RISK ANALYSIS

We give scientists considerable credibility because of the supposed stringency of their tools for acquiring knowledge, and we expect and trust that they will speak clearly about the limitations of the information they convey to the public. While Graham has been described as a "scientist" numerous times,[248] his approach to his field is profoundly unscientific.

As we suggest below, by failing to make critical disclosures about the limits of his supposed "science" and the sources of funding for his Center, Graham has positioned himself as primarily a political actor — but he is a political strategist who uses Harvard's prestigious name and operates under the cover of a false objectivity.

One 1996 article discussed a Graham strategy session with colleagues at the Heritage Foundation, a conservative think tank.[249] Entitled "*Risk-Expert Graham as Political Guru: GOP Must Change Reg-Reform Pitch*," the article began:[250]

> Harvard University risk-analysis expert John Graham moved from policy development to political strategist last week, telling a seminar that the stalled Republican regulatory-reform effort needs to reframe its arguments to appeal to public opinion and change the way people think about environmental issues . . . *Graham said "environmental regulations should be depicted as an 'incredible intervention' in the operation of society*. . . [Graham also said that] In order to sway public opinion to their side, conservatives' focus should be on comparative risk assessment: reallocating resources to address the biggest environmental risks."

This passage shows Graham's hostility to environmental regulation across the board, and how that hostility is deliberately obscured by a public focus on comparative risk tradeoffs. Graham has provided political mentoring and research support for anti-regulatory conservatives at the industry-funded Heritage Foundation more than once, and lent his name to media campaigns on anti-regulatory topics dozens, if not hundreds, of times.[251]

Graham has also, it appears, absorbed lessons from other strategists. Many of Graham's media "tricks" were wholly encapsulated by two 1996 "talking points" reports, one of which was called *How To Talk About Risk: How Well-Intentioned Regulations Can Kill*, written by Heritage Foundation analyst John Shanahan, who citing Graham, recommends that conservatives emphasize the themes of prioritizing risks, the failure of "liberal" environmental policies and the idea that "badly designed policies can kill."[252]

In all of Graham's dealings with the media that were assembled by Public Citizen, he has never been quoted pointing out any of the limitations of his risk assessment tools.[253] Nor does Graham typically term his policy recommendations in the context of *real* political trade-offs and institutions. In fact, he frequently suggests the opposite — that our societal failure to apply sweeping risk management and cost-benefit principles across every level of political decision results in perverse resource allocations and is equivalent to "statistical murder."[254]

Graham fails to indicate the highly contested nature of his assumptions and the considerable opposition that he faces even within his own field,[255] or to qualify his suggestions in any manner appropriate to the limitations of his research.[256] The real risk here is that someone who merely presents results without discussing the assumptions underlying his or her research may produce a very distorted picture.

The hard sciences are characterized — perhaps even defined — by the methodological consensus that practitioners share: To be a scientist is to use a well-recognized and agreed-upon set of research tools. However, Graham's field of "risk analysis" is too new to have generated this kind of agreement.[257] The National Academy of Sciences' National Research Council, an academic and scientific body that answers to Congress, was appointed to evaluate risk assessment methods and concluded that "among agency decision makers, the courts, Congress, and analysts, there is *no consensus regarding the use of a specific set of analytical techniques for a specific purpose*" — that is to say, there is no consensus on the proper use of the results of risk assessments in risk management.[258]

The still-developing nature of his field no doubt contributes to Graham's demonstrated ability to be loose with his tools and facts. Indeed, as Linda-Jo Schierow explained in a year 2000 Congressional Research Service brief to Congress, "[p]rofessional risk analysts do not agree on how key terms should be defined."[259]

Scientific knowledge is mostly accomplished in incremental, baby steps — and most scientists are therefore concerned with answering the next logical question, rather than with cutting off the pursuit of further knowledge. In contrast, Graham's statements to the media often imply that no additional work on the subject of, for example, pesticides, is necessary and that, in fact, we've been wasting our money bothering with all the research thus far.[260]

The misinformation that results from a partial or self-serving treatment of public health information is critical for the industry's strategy of rule by economic "experts." This is a serious matter of ethics in public policy, in risk communication and in the social sciences generally. As Law Professor Tom McGarity has noted, omissions related to risk assessment in the public health debates obscure problems with the data and the uncertainty of policy conclusions:[261]

> Given the huge uncertainties involved in risk assessment and the extent to which policy fills the factual gaps, the confident portrayal of risks as point estimates in terms of deaths-per-year or dollars-per-death-avoided *do not so much inform decisionmakers and the public as mislead them. . . .*

Graham's attitude is also dangerous because many of the problems addressed in his work are extraordinarily complex. For example, Graham has repeatedly criticized the government's standards for the fuel economy of motor vehicles on "safety" grounds. Yet the collateral benefits of pollution controls is one of the most compelling cases for a risk tradeoff argument, as it is clear that vehicle emissions make a large contribution to air pollution, which has a significant role in global warming.

Global warming is precisely the sort of problem that specific risk assessments (which form the basis of risk management decisions) have trouble addressing, due to the complicated interaction of enormous and subtle factors such as ocean temperature and atmospheric alterations. Solutions to challenges like global warming are often dependent on the continuing development of better monitoring systems and pollution data, but the consequences of inaction while we study the issue could be devastating for the planet as a whole. Acting in accordance with the precautionary principle, in this context, could save us. Graham's "wait and see" approach will not.

As in this example, the value of a risk assessment, or of decisions in risk management, is limited by the types and quality of the information that researchers use as an input — garbage in, garbage out.[262] In areas where researchers have incomplete information, the costs of gathering better information may be considerable, even prohibitive.[263] In the meantime, delaying action may carry its own risks. At that point, our shared values should inform our public policies, because, as any scientist will tell you, we will need to make a judgment call, informed — but not controlled — by the numbers we have available at the time.[264]

Despite Graham's repeated expressions of confidence,[265] the risk assessment process can only very rarely produce a single answer. According to an EPA report on the subject, "depending on the data selected, scientific assumptions, policy calls and perspectives, different experts or organizations may describe risk differently . . . *The risk assessment process has an enormous capacity to expand and contract in line with the available data, science policies, and problems.*"[266] In fact, the risk assessment process involves many separate levels of uncertainty, and researchers must make or use specific *policy* assumptions at virtually every step — each of which may be disputed.[267]

Even if Graham were in fact a "scientist," some risk managers have repudiated the determinative role to which Graham aspires. For example, Kristin S. Shrader-Frechette wrote in the journal *Risk* that:[268]

> Because risks do not affect merely current health and safety, but also human autonomy, consent, distributive equity, equal opportunity, future generations, civil liberties, social stability and so on, scientific experts ought not be the sole assessors. Assessments of multi-attribute risks should be the products of social, ethical, cultural and legal rationality— not merely the projects of a bounded scientific rationality.

## Science Sellout #2

### FLACK SCIENCE:

### *MANIPULATING THE MEDIA PAYS OFF*

If Graham and the other proponents of sweeping regulatory rollback legislation were not as successful as they hoped in 1995, it was not for lack of trying. Alongside conservative think tanks like the Heritage Foundation,[269] third-party "experts" with dubious credentials sought to establish public support for the rollback efforts, among them a corporate front group called the American Council on Science and Health (ACSH). ACSH is still very much in business, and in fact is listed by *USA Today* as one of the most-cited sources in the country.[270] Like Graham's Center, much of the budget for ACSH comes from large corporate donors.[271]

Graham serves on the ACSH board, and in 1994 and 1997 his work and public statements were an integral part of their "Facts, not Fear" campaign to support industry's anti-regulatory efforts on Capitol Hill.[272] In many of the articles covering the ACSH spin, Graham was quoted extensively. Graham also served on the board of The Advancement of Sound Science Coalition (TASSC), a fake grassroots anti-regulatory group founded by APCO & Associates that ran an identical, multi-pronged "Facts, not Fear" campaign.[273]

An article by Sheldon Rampton and John Stauber entitled "The Junkyard Dogs of Science" described the *modus operandi* of third-party pseudo-science groups like ACSH:[274]

> Although ACSH styles itself as a 'scientific' organization, it does very little independent primary research. Instead, it specializes in generating media advisories that criticize or praise scientists depending on their philosophical position. It has mastered the modern sound-bite, issuing a regular stream of news releases with catchy, quotable phrases responding to hot-button environmental issues.

As just one example of Graham and ACSH's handiwork, at the height of the regulatory rollback battles in 1994, ACSH bragged about the success of its "Facts, not Fear" campaign and successful placement of "the ACSH message" in an ABC News special program that failed to mention ACSH's name, saying that "our behind the scenes work and insight were the program's foundation."

ACSH boasted that it had literally put its words in the mouth of ABC reporter John Stossel,[275] who "*after spending lots of time conferring with ACSH and other public health professionals about the true risks to health in America today*,"[276] ran a two-part, prime time, national program suggesting that public fears about chemical and pollution-related threats to health were vastly overblown.

True to their claims, Stossel's piece was called *Are We Scaring Ourselves to Death?* and opened with the following announcer voiceover:[277]

> Fear— it's one our most powerful and complex emotions. Some of us master it and take big risks. It's helped to build America into exploring new frontiers. But others seem almost paralyzed by fear. We're afraid of the air we breathe, the water we drink, the food we eat.

The hour-long special was comprehensive, suggesting that the public was overly fearful about everything from pesticides and cellular phones to crime. Attacking the need for the EPA's Superfund cleanup program, both the ACSH article[278] and the ABC television special included statements of opinion by Graham. The article said:

> Dr. John Graham . . . confirmed that pursuing hypothetical risks is causing 'statistical murder.' For every million we spend to clean up a 'Superfund' site, we could be giving more cancer screening tests, making prenatal care more widely available, funding non-smoking campaigns and testing AIDS drugs.

The program quoted Graham as saying that "[t]he evidence on pesticide residues on food as a health problem is virtually nonexistent. It's speculation."[279] While the chemical industry could not have said it better itself, ABC never mentioned that funding for Graham's Center is provided by more than fifty agribusiness and chemical conglomerates.[280] The corporate-backed ACSH got stealth treatment as well. As they told supporters in their press release, "*Although our name and efforts were sanitized from the ABC program*, the message that ACSH has been reaffirming for over 15 years reached millions of viewers."[281]

**Double Feature**

In 1996, Graham and the anti-regulation forces repeated the feat on Dateline, in a story focused on the cancer risks of cellular phones. Dateline reporter Robert Bazell stated on the show that "the scare over cellular telephones shouldn't surprise us. Many of us have been confused for years about what causes cancer and convinced that our environment is loaded with agents that are killing us. Trouble is, experts say, that just isn't so."[282]

The program included lengthy comments from Graham, who called himself a scientist, and it failed to mention his potential conflicts of interest. A group of environmentalists pointed out this problem directly to Dateline, complaining in a letter that:[283]

> The report was riddled with factual and interpretive errors, and important omissions. . . . You failed to tell viewers that Dr. Graham's HCRA receives a large portion of its funding directly from chemical and other industrial companies with an enormous financial interest in minimizing public concerns over chemical and pesticide risks — funding sources that even HCRA itself acknowledges openly. The omission is especially ironic given Dr. Graham's allegations during the segment about other scientists' biased or ulterior motivations. You also let stand Dr. Graham's highly misleading reference to 'us scientists,' when in fact his doctorate is in public policy, not science. . . .

The letter also flagged a few of the errors in the report:

| NBC Dateline: | Environmentalists respond: |
|---|---|
| There is no cancer epidemic in the U.S. | According to the National Cancer Institute, cancer of the kidney has increased 116%, liver cancer increased 88%, brain cancer increased 74%, and thyroid cancer increased 102% since 1950. These cancers have been shown in lab tests to be specifically prone to tumor development following exposure to carcinogenic chemicals. |
| Aging is a 'cause' of cancer. | In fact, a greater percentage of children are developing cancer than ever before. Childhood incidences of leukemia and brain cancer have grown by a third since 1973. Cancer kills more kids under 14 than any other disease. |
| Graham claims that our understanding of unsafe chemicals is often based on studies that expose animals to unusually high dosages. | According to a recent review by the National Toxicology Program, 94% of all chemicals that cause cancer at high doses are known to cause cancer in low doses as well. In most instances, the cancers simply take longer to develop. |

When asked, a Dateline public relations staff member told *Pesticide and Toxic Chemical News* that officials would "let the series speak for itself."[284]

**Deja Vu All over Again: Public Health Information in the Hall of Mirrors**

Replication of the ACSH message was achieved by a similar campaign launched under the same "Facts, not Fears" title by the Washington, D.C.-based group TASSC. A press release from the group's third anniversary lauded its efforts to help "the public separate sound scientific data from narrow special interest agendas by launching a national "Facts, not Fear" campaign to set the record straight when certain groups seek to accomplish political goals by distorting or ignoring solid scientific data."

As the TASSC brag sheet made clear, Graham served on the group's Advisory Board,[285] which was founded in 1993 by APCO & Associates, a D.C. public relations firm, in 1993 with money from Philip Morris.[286] TASSC closed up shop in 1998, but was just one of the many front groups for industries hostile to regulation established by APCO in Washington.[287] Public Citizen has previously reported on APCO's systematic creation of fake grassroots (or "astroturf") groups that do political battle on behalf of business for limits on tort liability, an approach that was extremely successful in Texas under then-governor George W. Bush.[288]

APCO advertising material promoted the firm's backdoor approach:[289]

> "You won't read about APCO on the front page of the newspaper talking about our work, but that doesn't mean that our work is not making the front page. Our coalitions speak for themselves and the results speak volumes."
>
> Other promotional literature stated that the firm uses "*campaign tactics to create an environment in support of client's legislative and regulatory goals.* Our staff has written the direct mail, managed the telephone lines [and] crafted the television commercials."

In 1996, TASSC and its organizer Steven Milloy[290] announced a fight to combat "unfounded scares," in which it conducted polls, concocted awards to generate media, and wrote a "series of opinion articles that [were] published in newspapers around the country."[291] As part of the "Facts not Fear" campaign, TASSC gave a "Vindication of Science" Award to silicone breast implants and a "Potential Exaggerated Scare of 1996 Award" to electromagnetic fields.[292]

## Science Sellout #3:

### SELLING HALF THE STORY

In an attempt to repeat the media whitewash documented in Sellout #2, a pamphlet called "*Facts, not Fears: A Review of the 20 Greatest Unfounded Health Scares of Recent Times*" was sent in 1997 directly to journalists all over the country by the ultraconservative American Council on Science and Health (ACSH). As mentioned above, Graham enjoys a prominent position on the ACSH board and actively participates in its media campaigns.

The ACSH brochure consisted of approximately a page and a half of "research" devoted to each of 20 unfounded "scares," which, according to the group, included the chemical contamination of Love Canal, the Alar pesticide "crisis," the dioxin spill at Times Beach and the removal of asbestos from the public schools.[293]

The propaganda sent out by ACSH *looked* real based on the sheer number of footnotes, but a closer investigation reveals that most cite to books written by Elizabeth Whelan, the director of ACSH. The mailing garnered amazing amounts of media coverage — and yet it was absolutely riddled with factual errors, half-truths, faulty logic and drastic overstatements.[294]

For example, Jane Brody in the New York Times in 1997,[295] and Hilary Shenfield in 1999 in the Chicago Daily Herald,[296] faithfully repeated ACSH's observation in the pamphlet that Unfounded Scare #17, the Alar "crisis," was an overblown, fear-crazed response driven by an irrational public.[297]

Graham was quoted in at least three articles containing the ACSH spin on Alar and gave his endorsement to the notion of the fear-driven public.[298] For example, in a *Time* magazine article called "Keeping Cool About Risk" that mentioned Alar, Graham said: "Phantom risks and real risks compete not only for our resources but also for our attention . . . It's a shame when a mother worries about toxic chemicals, and yet her kids are running around unvaccinated and without bicycle helmets."[299]

Use of the events surrounding Alar as a lesson in anti-regulatory politics was pioneered by anti-regulatory researcher Aaron Wildavsky, in his book, "But Is It True? A Citizen's Guide to Environmental Health and Safety Standards." As OSHA risk assessor Adam Finkel has clarified, that book's various assertions about Alar are "untrue, irrelevant, or at best half-true."[300] Much of the same information on Alar from Wildavsky's book was repeated verbatim in the ACSH brochure, despite the criticism Wildavsky received after the book was published.

For example, citing only to Whelan's book, *Toxic Terror*, the 1998 third edition of ACSH's brochure states:

> Back on the apple farm the effects of Alar's loss are still being felt. Farmers from Ohio to New York are reporting decimation of their crops, and ironically, a need to use additional pesticides to enable the trees to hold their fruit.

In fact, apple sales after Alar recovered nicely. As Finkel wrote in *Who's Really Crying Wolf?*, the truth about the Alar story was far from the way Wildavsky had recounted it. Two of the book's more significant "half-truths" about Alar are below:[301]

| Assertions about Alar from Wildavsky's book | Adam Finkel responds: |
|---|---|
| "It is likely that no child has been harmed by drinking apple juice with trace elements of an Alar metabolite." | A child who drank only four glasses of apple juice each day containing a typical level of UDMH contamination would have eaten nearly 1/100th the amount that caused half of all mice to develop cancer — hardly a 'trace.' |
| Apple growers in just one state lost at least $125 million after the 1989 'Alar scare.' | By 1991, consumer demand for apples and industry revenues had doubled over 1989 levels, for a net gain of nearly $1 billion in constant dollars. |

The ACSH's coverage of Alar was particularly misguided when it came to the risks that the pesticide poses to children. The Natural Resources Defense Council, which first blew the whistle on Alar, explains that "more than half of the lifetime risk of developing cancer from exposure to carcinogenic pesticide use on fruit is typically incurred by the time a child reaches age six." And while apples account for around 2.5 percent of the average diet of North Americans, they are nearly 13 percent of the diet of children.[302]

Seven out of twenty-two of the footnotes in the Alar section cite to Whelan's own books. Yet at least one journalist, Paul Harvey, described the ACSH pamphlet as "meticulously researched."[303] And ABC reporter John Stossel, whose anti-regulatory work is discussed in Sellout #1, was still trotting out the Alar example during talks last year as indicative of government regulation gone amuck.[304] Notably, Graham also features the Alar example in an upcoming HCRA "executive education" course on risk perception and risk communication.[305]

The brochure by ACSH claims:

As the public followed the Alar story, it learned of the basis for the government's risk estimates — and it began to see how poorly such tests actually predicted human cancer risks. More generally, many consumers started to grow skeptical of the countless health scares popping up almost daily in the media.

If only it was not so.

## Science Sellout #4:

### MISLEADING RISK COMMUNICATION:

### *THE DIFFERENCE BETWEEN FALLING AND BEING PUSHED*

Graham has said that "the difficulty we face in our culture is that we don't have highly reliable, trustworthy sources of information about what are the biggest risks in life. So many people are confused; they're bombarded with information."[306] Another article, on the risks posed by electromagnetic fields, quotes Graham as saying that "the highest priority for our children should be preventing the known risks before we become paralyzed by speculation. So let's get on with bicycle helmets, poisoning prevention, and immunizations."[307]

Graham frequently has called attention to what he labels a "syndrome of paranoia and neglect" that afflicts the public's response to risk.[308] Graham and his allies frequently suggest that we simply fear too much — that we pay too much attention to some risks while ignoring others. Graham goes pretty far with this — literally calling the misallocation of our "risk" resources "statistical murder."[309] While there is a kernel of truth in the observation that we may pay considerable attention to certain kinds of health risks and under-react to others, Graham exploits that kernel.[310]

In the real world, of course, we are fully capable of both choosing to wear a bicycle helmet *and* worrying about that messy Superfund site next door. Studies in a field of research called *risk perception* have turned up interesting results.

The public knows, for example, that it is cheaper to avoid some risks at the outset than to deal with them later, and that if we allow companies to make a toxic mess, chances are we might all have to pay to clean it up.[311] Studies show that the public expects the government and industry to cover some risks, *i.e.*, toxic chemicals, while individuals should take care of others, such as those which involve matters of personal choice.[312] And risks that are assumed voluntarily are morally distinct from those imposed upon us against our will. As environmentalist Mark Sagoff put it: "*There is an ethical difference between falling and being pushed — even if the risks and benefits are the same.*"[313]

Research also shows that the public most wants the government to act when it is helpless about preventing risks and needs good information about exposure and possible health consequences.[314] This makes sense because the government has the resources to collect the information and the obligation to share it with the public. That kind of protection, in a fundamental sense, is what government is for.

Additionally, if the public did not cause the risk and did not benefit from it, we in the public rightly expect not to be harmed at all. This is reflected in research that shows that we expect the distribution of costs for the cleanup to be fair.[315] If a company has polluted, we expect that company to clean it up, because it profited when it made the mess.[316]

We also expect the government to encourage and enforce safe behavior by individual people and corporations, because it makes financial sense to concentrate our efforts in that way.[317] And where we may not be certain of the safety of some chemical or activity, but the possible health consequences are awful, we expect the government to step in until we know that the situation is safe.[318]

**Falling Versus Being Pushed:**
***Factors That Influence Our Feelings About Risk***

- **Catastrophic potential:** We believe that some risks are worth extra money to avoid because the possible consequences are awful.
- **Fairness:** It is important to know who benefits from the risk-creating activity and who is exposed to the risk. Risk research shows that the public believes that even small risks should not be borne by those who have not benefited from the risky activity.
- **Control:** It matters who is in charge of controlling the exposure or hazard, and whether the public trusts that organization or individual.
- **Voluntariness:** Our sense of the reasonableness of a risk also depends upon whether exposure to it occurs without the public's knowledge or consent.

As one researcher on risk perception notes, "knowledge and ignorance exist for both laypeople and experts."[319] When being asked to think about a risk/risk tradeoff, it is critical to ask what kinds of risk we are being asked to compare and how justified we are in thinking: *those risks refer to different things.*[320]

When we understand the importance of factors like control, fairness and voluntariness, pesticides and bicycle helmets might as well be penguins and bathtubs. This shows us that ordinary citizens — and the regulators in the government — are actually much more sophisticated and discerning than Graham's analysis. In fact, we can and do worry about toxic chemicals and preventing injuries at the same time, and still can sleep at night.[321]

**Bicycle Helmets All Around**

According to the Web site of Graham's Harvard Center for Risk Analysis (HCRA), the general population has a 1 in 385 chance of dying of heart disease, a 1 in 519 chance of dying of cancer, a 1 in 65,116 chance of death by drowning, and, coming in last on HCRA's list, a 1 in 369,881 chance of dying in a bicycle accident.[322]

Despite these slim odds, Graham has often suggested that purchasing bicycle helmets for children would be the best expenditure of our limited risk resources.[323] To find out the extent of Graham's support for reducing risks by asking children to wear bicycle helmets *instead of* worrying their parents about pesticides, we looked at the record of his participation in the congressional debates over these issues.

From 1993 to 1996, regulatory rollback efforts on Capitol Hill were gathering steam. Graham testified to least four committee meetings on rollback proposals, and his statements on the issues found their way into several of the key floor debates.[324] The bills generally addressed the concentration of regulatory review power in the OMB and would mandate priorities on a cost-efficiency basis. Graham devoted the September 1993 issue of the HCRA newsletter to an EPA regulatory rollback bill that was under consideration by Congress, and, following a discussion, that newsletter was added to the Congressional Record on September 13, 1993.

On November 11, 1993, Graham testified at a meeting of the Senate Committee on Energy and Natural Resources "on the use of risk management and cost-benefit analysis in setting environmental policy priorities."[325] Graham also testified at a joint hearing on pesticides on September 21, 1993.

Other issues were also moving on the Hill. Nine days after the regulatory rollback hearing, on November 20, 1993, the Senate passed the Child Safety Protection Act, the second section of which was known as the Children's Bicycle Helmet Safety Act of 1994.

The Act provides funding for the promotion of bicycle helmets to children and authorizes the Consumer Product Safety Commission (CPSC) to create consumer standards for the helmets. Based upon a search of the Congressional Record, Graham was not involved with any of the hearings or floor debate on the Children's Bicycle Helmet Safety Act.[326]

The Child Safety Protection Act was signed into law by President Clinton on June 16, 1994. But in an article published in *Time* magazine in September 1994, Graham failed to mention this great leap forward for risk reduction, saying instead only that: "Phantom risks and real risks compete not only for our resources but also for our attention . . . *It's a shame when a mother worries about toxic chemicals, and yet her kids are running around unvaccinated and without bicycle helmets.*"[327]

We decided to ignore the distributional questions — parents, and not the government, usually purchase bicycle helmets — and looked into whether we could figure out how valuable bicycle helmets are, and how many helmets, as a society, we would need by collecting data about the number of children that currently have bicycles but ride them without a helmet on.[328] We found that this kind of information can be hard to come by.

An audit by the General Accounting Office (GAO) in 1997 showed, in fact, that the kind of risk management that Graham has promoted for all these years, and presumably, that he relied upon for his recommendations about the use of bicycle helmets, has thus far proved nearly impossible for the Consumer Product Safety Commission itself to do.[329] The CPSC has jurisdiction over bicycle helmets, children's toys and poisoning prevention (another Graham favorite), as well as many other areas.

But a GAO study called "Consumer Product Safety Commission — Better Data Needed to Help Identify and Analyze Potential Hazards," concluded that, due to the lack of good data on the hazards to consumers, the CPSC is actually unable, as an agency, to do very meaningful risk assessment or cost-benefit analysis:

> CPSC's data are often insufficient to support a thorough application of . . . both risk assessment and cost-benefit analysis. . . . *CPSC's imprecise and incomplete death and injury data make risk assessment and cost-benefit analysis at best less reliable and at worst impossible to do.*

Lest it be thought that the GAO's evaluation methods were incomplete, it should be noted that Graham was himself consulted about the appropriate methods for GAO investigators to use in their study.[330]

## Science Sellout #5:
### CONCOCTING "SCIENCE" FOR CORPORATE COUNTER-SPIN

Billions of pounds of styrene are produced each year to make products such as rubber, plastic, insulation, fiberglass, pipes, automobile parts, food containers and carpet backing.[331] The public is routinely exposed to low levels of styrene in consumer products, cigarettes, and our water and air.[332]

Studies have shown that someone who breathes high levels of styrene for even a short period of time is likely to experience nervous system effects such as depression, concentration problems, muscle weakness, fatigue and nausea. Other research involving workers has shown that breathing styrene over a longer time may cause leukemia.[333] Based on this research and our other experience with the chemical, government agencies have determined that styrene is dangerous in high doses and has regulated it accordingly.[334]

But just in case the public was concerned that these regulations might be a little too strict for our own good, Dow Chemical and the Harvard Center are looking into it.

Dow's official Web page whitewashes what we know about the health effects of styrene and mentions that the company has funded a study by HCRA, timed to be released alongside the EPA's upcoming risk assessment:[335]

> For many years, Dow and the global styrene industry have supported extended and continuing research on styrene . . . even though most government studies conclude that if exposure guidelines are followed, the substance does not pose a danger to human health. . . .One such effort is a cooperative effort between the U.S. Environmental Protection Agency (EPA) and the Styrene Information and Research Center (SIRC) to fully review all the scientific data, and to develop a hazard assessment for all potential health effects. . . .
>
> Additionally, the Harvard Center for Risk Analysis is conducting a full risk assessment of styrene, which will look at all potential health effects and exposures. This risk assessment will better determine whether or not existing regulations adequately protect public health. The Harvard review was made possible with the assistance of a grant from SIRC. We will study carefully both the EPA styrene recommendations and the Harvard risk assessment, both due for publication by mid-2000.

The EPA's study has not yet been released; unsurprisingly, neither has HCRA's.

It is typical for industry to proactively combat the anticipated findings of government regulators by funding their own research, the release of which is timed to coincide with the publicity given to government findings on health risks. The corporations know that in their search for balance, journalists are likely to cover both studies in the same article.

What the public hears is the mixed message that while some government scientists are saying, "cancer," other scientists are saying, "no cancer." The net effect is that the studies' conflicting results muddy the waters, canceling out some of the negative information and associations for the companies whose profits — and public relations — are on the line.

Industry will go to surprising lengths for this effect. There have likely been such efforts on behalf of the cell phone industry (see Case Study #2), and there was a similar, all-out assault on a World Health Organization (WHO) study of the carcinogenic effects of second-hand smoke.

Elisa Ong described the major onslaught planned and carried out by Philip Morris and big tobacco to blunt the impact of the long-awaited WHO study (by a group called the International Agency for Research on Cancer, or IARC), with a kind of awe:[336]

> The massive effort launched across the tobacco industry against one scientific study is remarkable. Whereas over ten years the IARC study is estimated to have cost 1.5 to 3 million, PM alone budgeted at least $2 million for "IARC" plans for just one year (1994) and proposed $4 million for studies to help discredit IARC's work. *The elaborate plans were developed by PM's top management, implemented by an elite task force, and designed to coordinate the international tobacco industry. The complex plan relied on third-party vehicles that did not reveal the extent of the industry's efforts to shape the scientific, communications, and government relations issues of secondhand smoke on a worldwide basis.*

As Case Study #1 details, Graham was involved in the domestic effort on behalf of Philip Morris during this period. He was also on the board of the APCO's & Associates, Philip Morris-founded group TASSC, which, as Ong documents, put together a European "TASSC" sister group for the IARC study media miseducation campaign in Europe.[337]

**Stealing the Future**

A related practice is the full-on counter-spin of the anticipated publication of an environmentally friendly book or major article. Having seen the consciousness-raising that can result from a single book in the cases of Ralph Nader's *Unsafe at Any Speed*, and Rachel Carson's *Silent Spring*, industries awaiting a new, potentially informative book can afford to take no chances.

The publication of the book *Our Stolen Future: Are We Threatening Our Fertility, Intelligence, and Survival? A Scientific Detective Story* by Theo Colborn, Dianne Dumanoski and John Peterson Myers, which addressed the potential health effects of dioxin and other hormone-disrupting chemicals and contained a foreword written by then-Vice President Gore, threatened to be another potential watershed in public education over health hazards. The book documented such chemical-induced health effects as widespread reproductive problems, childhood hyperactivity and a decline in global intelligence.

So the flack army went to war. A timely *Washington Post* article by Rick Weiss and Gary Lee focused mostly on the counter-spin. Entitled "Pollution's Effect on Human Hormones: When Fear Exceeds Evidence," the article gave a prominent position to comments from Graham:[338]

> " 'True or not, the idea that chemicals are wreaking havoc with our reproductive systems has all the elements needed to provoke a public panic,' said John Graham."
>
> Graham had the last word in the article: " 'We are just beginning to understand why we are so paranoid about some risks and tragically neglectful of others,' [Graham] said. 'But in the final analysis, it often comes down to, who do we trust? *And that makes risk management very difficult these days, because people aren't inclined to trust anyone.*'"

Shifting attention away from a potential health threat to the public's irrational response is a time-honored tactic. Scary things show that the public can be scared, the *Post* editorialized: "Like similar controversies over global warming and the health effects of electromagnetic fields, concerns over endocrine disrupters *show how easily people can be persuaded to worry about a potential health threat when scientific evidence is incomplete.*"[339]

Following a partial description of the book's findings, the *Post* also reported on the turf battle:[340]

> That kind of talk has set off alarms in the chemical industry. Almost immediately after the book was released, the Chemical Manufacturers Association sent journalists *a 23-page sheaf of paper citing scientific studies that contradict the findings mentioned in the book.* The Competitive Enterprise Institute, a conservative Washington-based think tank, held a briefing to attack the book. And the American Council on Science and Health, a new York-based group funded by food and chemical interests including the National Agricultural Chemicals Association, *distributed a 13-page point-by-point rebuttal of the book's claims.*

In anticipation of the book's release, the chemical industry had concocted elaborate plans to "counterattack against the issue of endocrine disruptors. . . . Among those in the huddle were the Chemical Manufacturers Association [now called the American Chemistry Council], the Chlorine Chemistry Council . . . and the American Crop Protection Association." All three are HCRA funders, as are Dow, Du Pont and many other chemical and agribusiness conglomerates, but Graham's conflicts of interest were not disclosed in the *Post*.

The chemical industry's other flack scientists jumped on the bandwagon as well. *PR Newswire* reported that in 1996 "TASSC established a scientific 'truth squad' in response to unfounded environmental doomsday predictions in the book 'Our Stolen Future.' "[341]

The TASSC press release described the set-up:[342]

> It is often difficult for the public and the news media to get at the scientific facts. To help, TASSC brought together 10 scientists to produce a fact sheet, "What Scientists Are Saying," in reference to the book "Our Stolen Future." *TASSC was concerned that news media coverage of the book would prompt an unnecessary public health scare.* The statements provided by toxicologists, endocrinologists and others attracted significant media interests.

Steven Milloy, the former president of TASSC, directs a "junkscience.com" Web site that still contains a mockumentary of the 60 Minutes coverage of the book, complete with pejorative cartoons of the 60 Minutes staff under the heading "Our Swollen Future."[343]

The American Council on Science and Health (ACSH), another Graham-affiliated group, summed up the success of the counter-spin effort in an aside to their write-up of the Alar issue, commending the many "balanced journalists" who had, thanks to the efforts of ACSH and other front groups, given equal air time to the environmentalist message of *Our Stolen Future* and to the industry's flack science assault.[344]

Of course, the replication of the message is the point. The way a corporate "fun-house hall of mirrors" is used to pre-determine the political atmosphere in support of a particular agenda was first captured in 1981 by Karen Rothmeyer in an article for *Columbia Journalism Review*:[345]

> Layer upon layer of seminars, studies, conferences, and interviews, [can] do much to push along if not create, the issues, which then become the national agenda of debate . . . . *By multiplying the authorities to whom the media are prepared to give a friendly hearing, [corporate dollars] have helped to create an illusion of diversity where none exists.* The result could be an increasing number of one-sided debates in which the challengers are far outnumbered, if indeed they are heard from at all.

## Science Sellout #6:

### THE MISUSE OF SCIENTIFIC UNCERTAINTY

Graham has attempted to institutionalize an emphasis on studies that return inconclusive results, which he called "negative studies." According to a memorandum written by a member of Philip Morris' regulatory monitoring team in 1992, at a conference on Occupational Health and Safety Risk Assessment, Graham recommended that a panel be created that would be required to "review" all of the "negative," as well as the positive, epidemiological findings on a particular issue *before* a risk assessment could begin to be conducted by OSHA.[346]

While this may sound reasonable at first, merely adding up the studies that produced results suggesting "no correlation" and allocating research resources accordingly may cut off the inquiry far too soon. For example, cigarette research required 100 years before a link between cigarette smoke and lung cancer was established, while asbestos research took 80 years to make the link to cancer.[347]

And Graham's insistence upon calling inconclusive results a "negative" study is itself misleading. People are generally aware that a poll that asks 50 people a question will not produce results that are as significant — or "powerful" — as a poll that asks 400 hundred people the same question.

In the same way, the meaning of a research project can be determined by many factors, including the number of people or animals included in the study and the relative commonness of the disease being studied. A study with very little "statistical power" should not be labeled a "negative" study *just because it failed to detect a correlation that it had very little power to find.*

In those cases, it is always possible that a more powerful study would detect a cause-effect relationship between a person's exposure to a harmful substance and a particular disease or symptom. Because the power of the study always matters, counting the number of inconclusive studies provides little or no useful information — and it is very misleading to suggest that studies can be just added up to conclude that a substance is safe. Graham's "review" process may add needless delay, confuse the issues, and, depending upon whether such a review was used to shut down the inquiry, place undue emphasis upon low-power studies that are inconclusive, rather than "negative."

Suspicion of Graham's suggestion may be justified by past experience on such issues. Even when a study is not negative, industry has sometimes seized upon inconclusive results to suggest that we are risk-free. Elisa Ong reported in *The Lancet*, the leading British medical journal, that a major study by the World Health Organization (WHO) demonstrating that second-hand smoke increases cancer risks by 16 percent was frequently mischaracterized in the media as not showing *any* increase in risk, due to a multimillion-dollar, decade-long spin campaign that was conducted by Philip Morris and its tobacco industry allies in anticipation of the WHO results.[348]

How did the study's real results get blurred? The industry hired guns interviewed by the media on the issue repeatedly suggested that *inconclusive* numbers meant that the study showed *no risk.*

Graham was affiliated with the organization that helped to carry out this smear campaign by Philip Morris.[349] More importantly, however, this example shows the technique that allows companies to seize upon the findings of a single study to proclaim that a product is safe for all time and all uses

In contrast, a recent article about a Danish research project that showed no link between cellular phones and cancer properly contextualized the study's inconclusive finding. Despite a flack science attempt to spin the results — a Washington, D.C., science group disseminated an "editorial" with the Danish study "derid[ing] the 'fear merchants' who say links to cancer exist" — the *Washington Post* was careful to clearly explain what the Danish study did, and did not, mean.[350]

First, the article specifically noted the limitations of the study by saying that it "did not address whether users [of cell phones] might be susceptible to other diseases." Second, the study noted that there was a major distinction between characterizing the results as conclusive evidence that cell phones are now "safe" and saying, correctly, that the study suggests that "there is increasing evidence against the hypothesis that use of cellular telephones causes cancer."[351]

This is a critical distinction for the clarity of communication with the public. George Carlo, who has tangled with Graham over his cellular phone research,[352] explained in the article that "[t]he idea that there is 'increasing evidence' against health risks is 'a lot different than implying to consumers that there is *no* risk.'"[353]

508

***No Comment I:***

**CONSUMERS UNION LETTER TO EPA AND USDA**

**ABOUT A HCRA PESTICIDE STUDY[354]**

**********

April 19, 2000

The Honorable Dan Glickman
Secretary
United States Department of Agriculture
14th Street and Independence Avenue, SW
Washington, DC 20250

The Honorable Carol M. Browner
Administrator
Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Dear Secretary Glickman and Administrator Browner:

We are writing to express our concerns about a recent study by the Harvard Center for Risk Analysis (HCRA) concerning purported economic effects of pesticide regulation. The study, Risk/Risk Tradeoffs in Pesticide Regulation: Evaluating the Public Health Effects of a Ban on Organophosphate and Carbamate Pesticides, is biased and fundamentally flawed, and reaches conclusions that are not remotely credible. Nevertheless, this study, and the prestigious name of Harvard, are being used to frighten the public about potential consequences of implementing the Food Quality Protection Act (FQPA), and to generate support in Congress for rolling back the FQPA's key public-health provisions.

The HCRA study was paid for by the American Farm Bureau Federation (AFBF), which has waged a vociferous campaign to undercut the FQPA. The study rests upon admittedly unrealistic assumptions and a remarkably shallow analysis, yet reaches blatantly inflammatory conclusions. For example, the study asserts that FQPA implementation could result in up to 1,000 premature deaths per year due to decreased food consumption, an incredible claim. Nevertheless, assertions that the FQPA will kill the very children it aims to protect have been cited as "The Truth from Harvard" in partisan editorials in the agricultural and pesticide industry trade press. The HCRA study is also cited in a letter from several members of Congress to Administrator Browner that warns of unintended adverse public-health effects of FQPA implementation.

We urge you, Administrator Browner, to firmly resist political pressure based on this severely flawed study. We also understand that USDA has been asked to meet with the authors of the study, to hear a presentation of its findings. Secretary Glickman, we hope you will take great care to ensure that USDA does nothing to enhance the credibility of this partisan and unsound research. We urge that any meeting between the authors of the Harvard study and USDA staff be structured so that USDA experts on pesticide risk analysis have "equal time" to point out the mistakes and flawed assumptions of the study.

The most prominent flaws of the Harvard study are: (1) the authors assume that implementation of the FQPA would result in a catastrophic loss of insecticides available to farmers for control of crop pests, and (2) they ignore the availability of alternative chemical and non-chemical pest control options, which would replace FQPA-curtailed uses of high-risk chemicals and largely offset economic impacts of restrictions on the highest-risk insecticides.

**(1) Unrealistic Assumptions About Loss of Insecticides**

The authors assume that EPA will ban all uses of all organophosphate (OP) and carbamate insecticides. This scenario, a complete ban of more than 50 chemicals, has never been even a remote possibility; it is far outside the scope of any action EPA has ever considered necessary to attain the FQPA's goals. The study's authors acknowledge this fact, then base their analysis on what they concede is a false assumption. They justify their decision on account of its "analytic virtue" (i.e., simplicity).

Of the 35 economically important OP and carbamate insecticides used in food production, only about 15 leave detectable residues in foods, based on several years of data from the USDA Pesticide Data Program. Well over half of the 600+ current uses of OPs and carbamates pose minimal risks of dietary exposure and are likely to survive EPA's review. Consumers Union's analyses of residue and toxicity data have repeatedly shown that only about 100 of those 600+ uses account for more than 99 percent of dietary risk. (See for example, D*o You Know What You're Eating? An Analysis of U.S. Government Data on Pesticide Residues in Foods*, by Consumers Union, January 1999. This and other analyses of the PDP data are on CU's FQPA project web site, at http://www.ecologic-ipm.com.) Our analyses have shown that EPA could eliminate most of the risk associated with dietary OP and carbamate residues by targeting its regulatory actions against selected uses of just eight to ten pesticides.

**(2) Failure to Consider Available Alternatives**

Consumers Union has also shown in published analyses that multiple and cost-effective alternative pest-management options are available for nearly all high-risk OP and carbamate uses. (*See Worst First: High-Risk Insecticides, Children's Foods and Safer Alternatives*, Consumers Union, September 1998, also available at the web address above.)

The Harvard analysis-like an earlier AFBF-sponsored study by Texas A&M University, on which the HCRA analysts relied-dismisses alternatives to OP and carbamate insecticides as more costly, and makes no effort to assess chemical or non-chemical control options that would replace specific banned uses. The study assumes massive losses of effective pest control, with severe associated economic losses and food cost increases. These assumptions are unfounded, and the projected economic impacts are completely unrealistic.

There are many existing, proven alternatives to high-risk insecticides. Some of these are lower-risk OP and carbamate uses that will survive FQPA reassessments, which the Harvard study assumed out of existence. In addition, spurred in part by pressure the FQPA has created to phase out older, high-risk chemicals, the pest-control industry has been introducing new products at a record pace. EPA's just released biennial report lists over 50 new active ingredients registered, more than half of which meet the agency's "reduced risk" criteria. The HCRA analysis ignores these effects of market-driven innovation and progress made by growers in adopting biointensive Integrated Pest Management (IPM). (See ***Pest Management at the Crossroads***, Consumers Union, October 1996; also see, http://www.pmac.net.)

The HCRA assertion that alternatives are "too costly" is based on no analysis of actual costs and is simply not credible. The facts are that pesticide prices and expenditures in the U.S. are falling across the board. The dozens of new products registered in most crop markets have unleashed something of a price war, with some new products discounted to gain market share. In other crop markets, new products are more costly per acre but they are worth more because they work better and are less disruptive to beneficial organisms on the farm.

In summary, we hope both USDA and EPA will look very critically at the flaws in this alarmist Harvard study and widely publish your criticisms. The FQPA was passed unanimously by both houses of Congress, a testament to the hard work its sponsors devoted to reaching a consensus that all sides could live with. The reforms embodied in the FQPA were urgently needed to replace a regulatory system that all agreed was outdated and ineffective in protecting the health of children. It is the AFBF's overt attempts to undermine that compromise, and the willingness of academic researchers to lend their prestige and biased analysis to that campaign, that pose a danger to public health, not the FQPA itself.

We urge USDA and EPA to redouble your efforts to fully and fairly implement the Food Quality Protection Act. The nation's children need you to carry this fight forward on their behalf.

Thank you very much.

Sincerely,

Adam J. Goldberg
Pesticide Policy Analyst
Consumers Union

Edward Groth III, Ph.D.
Senior Scientist
Consumers Union

Charles M. Benbrook, Ph.D.
FQPA Consultant

http://www.consumersunion.org/food/hcradc400.htm

All information ©2000 Consumers Union

## *No Comment II:*

## NATURAL RESOURCES DEFENSE COUNCIL LETTER TO THE WASHINGTON POST ABOUT HCRA'S DAVID ROPEIK[355]

**********

10 August 2000

Letters to the Editor, *The Washington Post*
1150 15th Street, NW
Washington, D.C. 20071-0070

Dear Editor:

**Science for Sale?**

Isn't it ironic that David Ropeik in his August 6 op-ed ("Let's Get Real About Risk") calls for the creation of a trustworthy, unbiased, non-governmental risk assessment institute when his own organization breaches this ethical code?

While Mr. Ropeik taps the credibility that comes with his affiliation with Harvard University, he fails to publicly disclose his center's corporate ties. Most of the funders of the Harvard Center for Risk Analysis are industry groups including the Chemical Manufacturers Association, Chlorine Chemistry Council, American Crop Protection Association, Monsanto, and International Paper.

The Harvard Center for Risk Analysis recently completed a study which concluded that the hazards of talking on a cell phone while driving are relatively small. The study was funded by AT&T Wireless Communications. Earlier this year the Center issued a report in which its comparative analysis of pollution from diesel and natural gas heavy duty trucks echoed the position of the company that paid for the report - Navistar - one of the few diesel engine manufacturers that does not make natural gas engines. Furthermore, a 1999 Center report, based on admittedly extreme assumptions, concluded that stopping the use of older, highly toxic pesticides would oddly result in an increase in premature deaths. This study was widely criticized for its twisted application of risk assessment techniques. The study was funded by the American Farm Bureau Federation, which opposes restrictions on pesticides.

An openly neutral evaluation of risk cannot be accomplished in the presence of financial conflicts of interest. Ropeik and his center appear to be satisfied with the veiled appearance of such neutrality. And on that disingenuous count they invite our trust.

Steven Gurney, M.S.
Gina Solomon, M.D., M.P.H.
Health & Environment Program, Natural Resources Defense Council

# PART FOUR

## Appendix A
## In His Own Words

John Graham has a somewhat unique view of the world. A sample of his statements to the media and Congress on risk issues over the past decade is presented below.

**On the value of human life:**

"We do hold, as a society, I think a noble myth that life is priceless but we shouldn't confuse that with reality. Everyday in our lives, we make decisions that put ourselves at risk in exchange for other benefits that we desire." Andrew Holtz, "Risk Analysis Aims to Help People Assess Danger," *CNN Health Works*, July 19, 1993 (quoting Graham).

**On the role of environmental regulation:**

"[E]nvironmental regulation should be depicted as an incredible intervention in the operation of society." "Risk-Expert Graham as Political Guru," *Air/Water Pollution Report's Environment Week*, Feb. 2, 1996 (quoting Graham's talk at a Heritage Foundation event).

**On the public's affliction with a risk "syndrome":**

"The public's general reaction to health, safety and environmental dangers may best be described as a syndrome of paranoia and neglect." John D. Graham, "Making Sense of Risk: An Agenda for Congress," in Risks, Costs and Lives Saved (Robert Hahn, ed., Oxford University Press 1996).

**On the tradeoffs between "our" environmental protection resources (i.e., industry's foregone profits) and other social and political goals:**

"[T]he reality of scarcity is more apparent today than ever before. Indeed, the scarce human and material resources devoted to environmental protection are resources that we cannot use to combat crime, educate our children, reduce poverty, improve health care, strengthen national defense, and meet the basic needs of citizens and their families." Testimony of John D. Graham before the Senate Energy And Natural Resources Committee on Risk Analysis in Environmental Policy-Making, Nov. 9, 1993.

**On the 'statistical murder' committed by environmental controls:**

"The failure to compare the costs of toxin control rules to rules on health care and injury prevention and to allocate resources based on those comparisons is resulting in 'statistical murder.' " David Lore, "Determining Toxic Risks Is Costly Voodoo, Lawyer Says," *The Columbus Dispatch*, Nov. 24, 1995 (quoting Graham).

**On the "statistical murder" of statistical citizens:**

"The real cost of making ill-informed public health decisions is the 'statistical murder' of citizens who die or suffer from proven, yet neglected hazards." John D. Graham, "There's A Deadly Confusion About Health Risks," *The Houston Chronicle*, Nov. 29, 1996.

**On the paralysis that could be caused by speculation about risks:**

"[T]he highest priority for our children should be preventing the known risks before we become paralyzed by speculation. So let's get on with bicycle helmets, poisoning prevention, and immunizations." "More Worrisome News About Electromagnetic Fields," *Child Health Alert*, Dec. 1992 (quoting Graham).

**On the importance of cheap, but pesticide-laden, fruits and vegetables for public health:**

Graham was quoted as concurring with the author's suggestion that pesticide regulation will backfire because it raises food prices. Graham said, "The economics is at the most basic level. If the prices of fruits and vegetables go up, people are likely to eat fewer fruits and vegetables. This is not rocket science [and] journalists do not need advanced degrees from Harvard" to conclude that raising prices will make the population less healthy. David Shaw, "It's All So Scary: Americans A Bunch of Chicken Littles: Is It the Media's Fault," *The Plain Dealer*, Oct. 2, 1994.

**On problems in public understanding and the role of "powerful interests":**

Graham said the results of a risk perception survey he did in 1999 were due to "the intuitive problems that people have understanding probabilities. It may also reflect the fact that there are powerful interests in society who benefit from efforts to frighten people. Furthermore, the media has a tendency to focus on all the bad things that could happen to people." "Health Risks: Public Overestimates, Says New Poll," *American Health Line*, Jan. 28, 1999.

**On women and a study that showed their more protective attitude toward risk:**

In a study that purported to show that women believe in "widely reported, but unproven, 'hazards,' " Graham found that women were more likely than men to believe in these kinds of risks by a margin of 10 points or more, and stated, "Some suggest that because women give birth, protect and care for their children, they may naturally tend to be more nurturing than men, therefore they may be more concerned about hazards that may harm their families . . . Another possible explanation is that women are less familiar with science and technology than men, and are generally more fearful of it, especially in relation to nuclear power and chemicals." Special Report, "Women's Magazines: A Liberal Pipeline to Soccer Mom," *Media Research Center*, Nov. 21, 1996 (see <www.mediaresearch.org/scripts/temp/Doc3892.html>).

**On the Clean Air Act's lack of sufficient indoor pollution controls:**

"Congress recently wrote a 1,000 page law aimed at cleaning up the last 10 percent or so of pollutants in outdoor air, even though public health is more determined by the quality of air indoors, where people spend most of their time." Testimony of John D. Graham before the House Government Affairs Committee on Regulatory Revision, Feb 15, 1995.

**On the risk of several members of Congress being hit by a crashing airplane near the U.S. Capitol during a hearing:**

To demonstrate how small a one in a million risk of cancer from pesticides is, Graham told a Senate committee: "How small is this risk? By way of comparison, there is a tiny yet non-zero chance that during this hearing an airplane will inadvertently miss National Airport, crash near the Capitol, and strike several Members of Congress. It turns out that a baby born today has not one chance but roughly five chances in a million of suffering this outcome in his or her lifetime." Testimony of John D. Graham before the Senate Energy and Natural Resources Committee on Risk Analysis in Environmental Policy-Making, Nov. 9, 1993.

**On the EPA's emphasis upon safety (rather than "willingness to pay," an industry-slanted economic tool that asks how much the public would pay polluters to stop polluting):**

"Unfortunately, EPA is often guilty of 'asking the wrong questions' (such as asking what is 'safe' rather than considering how much we are willing to pay for various amounts of risk reduction)." Testimony of John D. Graham before the Senate Energy and Natural Resources Committee on Risk Analysis in Environmental Policy-Making, Nov. 9, 1993.

# Appendix B

## LIST OF HARVARD CENTER FOR RISK ANALYSIS

## FUNDING SOURCES

The Harvard Center for Risk Analysis receives financial support from a vast number of private corporations and trade associations, as well as a few government agencies and conservative advocacy groups. According to information provided over the phone by staff at HCRA and the Center's Conflict of Interest policy, these lists are "cumulative," showing all HCRA donors, past and future. There is no mention of the amount of the donation, or list of companies that support the Center on a regular basis. Therefore, the presence of an entity on this list could represent a single donation or a tradition of ongoing support. These organizations provide funding to the HCRA either in the form of restricted or unrestricted grants. The information on products and companies below is from the named corporation's official Web site, unless otherwise specified. Information on dioxin producers is from a partial list created by the Center for Health, Environment and Justice. Unrestricted grants are sorted by industry. Funders may be listed in more than one category.

**Unrestricted Grants: List of Donors**

**Agribusiness**

- American Crop Protection Association *(Dioxin Producer)*
- Dow Chemical Company *(Dioxin Producer)*
- DowElanco (Dioxin Producer)
- DuPont Agricultural Products *(Dioxin Producer)*
- E.I. DuPont de Nemours & Company
- Hoeschst Marion Roussel *(Dioxin Producer)*
- Monsanto Company *(Dioxin Producer)*
- Novartis Corporation
- Novartis International
- Pharmacia

**Chemicals**

- Air Products and Chemicals, Inc. *(Dioxin Producer)*
- 3M *(Dioxin Producer)*
- ARCO (Atlantic Richfield Company) Chemical Company *(Dioxin Producer)*
- BASF *(Dioxin Producer)*
- BP America Inc. *(Dioxin Producer)*
- Cabot Corporation Foundation *(Dioxin Producer)*
- Chemical Manufacturing Association (now the American Chemistry Council) *(Dioxin Producer)*
- CIBA-GEIGY Corporation *(Dioxin Producer)*
- Cytec Industries *(Dioxin Producer)*

- Dow Chemical Company *(Dioxin Producer)*
- Eastman Chemical Company
- E.I. DuPont de Nemours & Company
- Exxon Corporation *(Dioxin Producer)*
- FBC Chemical Corporation *(Dioxin Producer)*
- The Geon Corporation *(Dioxin Producer)*
- Hoeschst Celanese Corpration
- Hoeschst Marion Roussel
- Hoffman-LaRoche Inc.
- ICI Americas Inc. *(Dioxin Producer)*
- Louisiana Chemical Association *(Dioxin Producer)*
- Lyondell Chemical Company *(Dioxin Producer)*
- Millennium Chemical Company
- Mobil Foundation, Inc. *(Dioxin Producer)*
- Olin Company Charitable Trust *(Dioxin Producer)*
- Praxair, Inc. *(Dioxin Producer)*
- Rohm and Haas Company *(Dioxin Producer)*
- Union Carbide Foundation ($10,000 to HCRA) *(Dioxin Producer)*

**Consumer Products**

- Eastman Kodak Company *(Dioxin Producer)*
- Procter & Gamble Company
- Reynolds Metals Company Foundation *(Dioxin Producer)*
- Rohm and Haas Company *(Dioxin Producer)*

**Financial Services and Insurance Companies**

- Aetna Life & Casualty Company
- Boatmen's Trust

**Food**

- E.I. DuPont de Nemours & Company
- The Coca-Cola Company
- Frito-Lay
- Grocery Manufacturers of America
- Kraft Foods
- National Food Processors Association
- PepsiCo Inc.
- Procter & Gamble Company

**Heavy Industrial**

- Alcoa Foundation *(Dioxin Producer)*
- American Automobile Manufacturers Association
- Astra AB
- Bethlehem Steel Corporation *(Dioxin Producer)*
- Cement Kiln Recycling Coalition *(Dioxin Producer)*
- Emerson Electric
- Ford Motor Company
- General Electric Fund
- Inland Steel Industries *(Dioxin Producer)*
- National Steel *(Dioxin Producer)*
- Nippon Yakin Kogyo *(Dioxin Producer)*
- North American Insulation Manufacturers Association
- Westinghouse Electric Corporation *(Dioxin Producer)*

**Mining**

- Alcoa Foundation *(Dioxin Producer)*
- ASARCO
- Reynolds Metals Company Foundation *(Dioxin Producer)*

**Oil & Gas**

- American Petroleum Institute *(Dioxin Producer)*

  *From the API Web Site:* The API's "most pressing issues today revolve around public perceptions and government policies toward the industry." The API "strives to reduce the financial impact of government oversight on industry operations." Under a section entitled "FIGHTING UNNECESSARY REGULATION," API celebrates three victories over the EPA:

  1) API "saved" the industry $9 billion, most of it in the upstream sector, by demonstrating why the US EPA should exempt most oil and gas production facilities and service stations from unnecessary risk management regulations.

  2) At API's urging, the EPA changed gasoline detergent certification rules, "saving" the industry $2.5 billion in needless upgrades to terminal equipment.

  3) API won a federal court decision overturning EPA's attempts to require the use of ethanol in reformulated gasoline, "saving" the industry almost $1 billion annually.
- ARCO (Atlantic Richfield Company) Chemical Company *(Dioxin Producer)*
- Ashland Inc. Foundation
- BASF *(Dioxin Producer)*
- BP America Inc. *(Dioxin Producer)*
- Charles G. Koch Foundation *(Dioxin Producer)*
- Chevron Research & Technology Company *(Dioxin Producer)*
- CITGO Petroleum Company *(Dioxin Producer)*
- Exxon Corporation *(Dioxin Producer)*
- Mobil Foundation, Inc. *(Dioxin Producer)*
- Oxford Oil *(Dioxin Producer)*
- Oxygenated Fuels Association *(Dioxin Producer)*
- Shell Oil Company Foundation ($15,000 to HCRA) *(Dioxin Producer)*
- Texaco Foundation *(Dioxin Producer)*
- Unocal *(Dioxin Producer)*

**Paper and Lumber**

- Boise Cascade Corporation *(Dioxin Producer)*
- Fort-James *(Dioxin Producer)*
- Georgia-Pacific Corporation *(Dioxin Producer)*
- International Paper *(Dioxin Producer)*
- The James River Corporation Foundation *(Dioxin Producer)*
- Mead Corporation Foundation *(Dioxin Producer)*
- Potlatch Corporation *(Dioxin Producer)*
- Westvaco *(Dioxin Producer)*

**Power Utilities**

- Carolina Power and Light
- Edison Electric Instititute
- Electric Power Research Institute *(Dioxin Producer)*
- New England Power Service *(Dioxin Producer)*
- New England Electric Service

**Pharmaceuticals**

- E.I. DuPont de Nemours & Company *(Dioxin Producer)*
- Glaxo-Wellcome, Inc.
- Hoffman-LaRoche Inc.
- Janssen Pharmaceutical
- Johnson & Johnson
- Merck & Company
- Monsanto Company
- Novartis Corporation
- Novartis International
- Pfizer
- Pharmacia
- Procter & Gamble Company
- Schering-Plough Corporation

**Transportation**

- American Automobile Manufacturers Association
- Association of American Railroads
- Ford Motor Company
- General Motors Corporation
- The Goodyear Tire & Rubber Company
- USX Corporation

**Waste Management**

- WMX Technologies, Inc. *(Dioxin Producer)*

**Restricted Grants: List of Donors**

- Alfred P. Sloan Foundation
- American Crop Protection Association

  The ACPA, which was formed in 1933, is a nonprofit trade organization representing the major manufacturers, formulators and distributors of crop protection, pest control, and biotechnology products.
- American Industrial Health Council
  The American Industrial Health Council assesses the regulation of risks associated with human health effects and ecological effects.
- Andrew Mellon Foundation
- Bradley Foundation
  The Lynde and Harry Bradley Foundation are devoted to the support of limited government and an open economic market.
- Brookings Institution
- California Avocado Commission
- Chemical Manufacturers Association

  The CMA is now called the American Chemistry Council (ACC). "The ACC is the voice of the U.S. Chemical Industry."
- Chiang Ching-Kuo Foundation for International Scholarly Exchange
- Chlorine Chemistry Council
- "The Chlorine Chemistry Council was established in 1993 to participate in the public policy debate surrounding chlorine chemistry." "It facilitates comparative risk and risk benefit analyses through the collection, development, and use of scientific data on health and environmental issues surrounding chlorine chemistry. CCC believes that public policy, regulatory actions and industry stewardship regarding chlorine chemistry should be based on sound science and focus on comparative risk assessment."
- Congressional Research Service
- Electric Power Research Institute
- Elsa U. Pardee Foundation
- International Life Science Institute/Risk Science Institute
- Health and Environmental Sciences Group
- National Association of Home Builders
- Pfizer, Inc.
- Society for Risk Analysis (corporate-funded — *see* list of Graham's affiliations).

**Government Funding**

- National Institute of Justice
- U.S. Centers for Disease Control
- U.S. Department of Agriculture
- U.S. Department of Energy
- U.S. Department of Health and Human Services
- U.S. Department of Transportation
- U.S Environmental Protection Agency
- U.S. National Oceanic Atmospheric Administration
- U.S. National Science Foundation

## Appendix C
## Graham's Record on the EPA's Dioxin Science Advisory Board

Dioxin is the name given to a group of highly toxic chemicals that are produced when chlorine is burned, and were made infamous as an ingredient in Agent Orange.[356] The draft EPA risk assessment that was released last year showed that, even at very low levels of exposure, dioxin is linked to cancer, infertility, immune system damage and learning disabilities. More than 90 percent of dioxin exposure comes through the food we eat, especially fish, meat and dairy products. The agency has been completing its reassessment of dioxin since 1995.

The EPA's draft dioxin reassessment document found that the public faces much higher risks of cancer and noncancer health harms from dioxin than was previously understood and over a hundred studies in animals and humans show that dioxin causes cancer at low doses. The assessment is currently undergoing routine review by the agency's Science Advisory Board (SAB), on which Graham serves as a consultant. Citing only two studies, at a meeting of the SAB in November 2000, Graham claimed that the studies showed that low levels of dioxin can actually protect against cancer, and urged the SAB to include in its official comments language stating that dioxin may be an "anti-carcinogen."

Graham suggested drawing this conclusion based on two very limited, outlying studies. Based on the transcript of the meeting, Graham wanted the SAB to tell EPA to revise its report to include the following statement: "It is not clear whether further reductions in background body burdens of TCDD [dioxin][357] will cause a net reduction in cancer incidence, a net increase in cancer incidence, or have no net change in cancer incidence."[358] If EPA were to adopt this approach in spite of the agency's overwhelming evidence to the contrary, the EPA's risk assessment on dioxin may have failed to provide a basis for federal regulators to ask companies to curtail dioxin emissions.[359]

Other scientists on the panel acknowledged that there were scientific gaps in the EPA's draft risk assessment, but argued that those gaps do not prevent the recognition of dioxin as a human carcinogen and that, in fact, testing for anti-carcinogens was out of step with normal EPA practice and resources. In response to Graham, another SAB member, Dr. Thomas Umbreit, stated: "If you're now going to start looking for competing good effects, then we start getting into the imaginary or least as far as our assays [tests] can detect things. But I don't think we really have too much that we can say about that, not too much that we can analyze for that. *And I think to try to impose on or to suggest to EPA that they discuss this is going to be difficult because its a whole new field essentially.* So I think if EPA takes a cautious approach in discussing the risks, that's about as well as they can do." [360]

The EPA has not yet issued its final risk assessment on dioxin.

# Appendix D

## RISK ASSESSMENT AND RISK MANAGEMENT

**Three Steps From Hard Science to Risk Analysis**

| *STEP 1*: **Scientific Laboratory and Field Work:** | *STEP 2*: **Risk Assessment** | *STEP 3*: **Risk Management** |
|---|---|---|
| Exposure data from Chemistry, Biology, Geology, Physics, Toxicology, Epidemiology, etc. | Combines data from chemistry, etc., with statistics, medicine, data modeling, science policies to produce risk estimate | Combines risk assessment and economics, politics, political science, law, social values to produce regulatory policy |

### Step 2
### Risk Assessment

Risk assessment uses data produced by chemists, biologists, geologists, toxicologists, physicists, epidemiologists and other scientists to ascertain the risk of an activity or substance to human health. In human health terms, risk is a measure of the chance that a person or population will experience injury, disease, or death (a hazard) under certain circumstances or exposures. It is a combination of the probability that an undesired event will occur and the consequences of that event. The practice of risk assessment is rife with policy judgments about particular issues. Risk assessments use four steps in the analysis:

- **Hazard Identification:** What health problems are caused by the pollutant?
- **Exposure Assessment:** How much of the pollutant do people inhale during a time period? How many people are exposed? What is the route for exposure?
- **Dose-Response Assessment:** What are the health problems of different exposures?
- **Risk Characterization:** What is the extra risk of health problems in the exposed population?

Risk assessment tools are useful in some situations, but in order to better understand what the numbers mean, many qualifications are in order. For example:

- ***To whom* does the risk data apply?** Data that describe the risk to the general population (an "**average exposed person**" who, for example, has eaten some amount of contaminated food) have different policy implications than data that describe the risk to a known group of people with a high exposure to the risky substance (i.e., workers in a highly contaminated area, known as the "**most exposed individuals**").

- **In the first case**, policy solutions may involve a large-scale intervention such as a general regulation. Also, in the first case, the risks may be more difficult to measure due to the "background," or pre-existing, exposure of individuals to a wide variety of substances and the difficulty of determining the precise amount of risky substance that a person has eaten.
- **In the second case**, policy solutions might be more workplace or site-specific. Health testing of the exposed people might be possible and cost-effective, and there would likely be more data about the kinds of vulnerabilities in that population (asbestos workers who also smoke cigarettes, for example, have greatly increased risks of asbestos-related cancer due to interactive effects of asbestos and tobacco).[361]
- As the EPA points out, to understand risk information it is critical to know **which kinds of data** are at issue: "*Omitting the qualifier 'average' or 'most exposed' incompletely describes the risk and* ***would mean a failure in risk communication.***"[362]

- **What do the numbers mean?** Each part of the risk assessment involves many estimates and extrapolations, which at worst can make the results uncertain, and at best reflect numerous *policy choices*. A researcher at the EPA noted that, "Rarely is there a single answer to an environmental risk assessment question."[363]
- Some questions that will determine the *quality and meaning* of a risk assessment are:[364]
  - How extensive is the database used for the risk assessment?
  - Do the data include human epidemiological data and experimental data?
  - What endpoints are included?
  - Do they include test data on more than one species?
  - Where are the 'data gaps'-- the missing pieces or next questions?
  - What are the scientific uncertainties?
  - What 'default assumptions" were used to fill in uncertainties and gaps?
  - What science policy decisions informed these assumptions?
  - Based on all of this and any other relevant factors, what is the overall "confidence level" of the assessment results?
- **What kinds of uncertainty can affect the risk assessment?**
  - **Measurement uncertainty** affects the predictive range of the data or a particular value, and can reflect a normal variance that will have different implications depending on the policy choices that the problem or exposure involves.
  - **Data gaps** can result from a lack of information on the precise effects of a substance, from missing pieces of specific information, or from a fundamental lack of understanding about a scientific phenomenon.
  - **Variability in results** can be caused by the use of data from different disciplines that use different assumptions, or by varying interpretations of the same data.

**Step 3**

**Risk Management:**

**Is Graham's risk "analysis" actually "sound science"?**

**What is risk management?**

As everyone is aware, statistical information can be used in deceptive ways. Because of this problem, it is imperative that decision makers and the public have access to the best — and most complete— information available. Graham's field of "risk *management*" uses statistical and other data and modeling methods, including the results of risk *assessments*, to examine our choices about assessing risks to public health and safety.[365] As in any other statistical method, the assumptions that researchers use affect the validity of the result.[366] Because any evaluation of the end result depends upon knowing the precise policy decisions and information criteria that were used in the beginning — *conclusions in risk management are based on policy values and categories that have little to do with science.*

Risk management is a "social science" like economics, not a hard science like biology or chemistry, or even a public health-based science like epidemiology or toxicology.[367] Although risk managers may use data collected by toxicologists or physicists, practitioners deal exclusively with numbers, not with a lab or actual patients. And unlike the practice in medicine, statisticians do not promise, in a Hippocratic oath, to do no harm.

**Risk Assessment Versus Risk Management:**

- **A risk *assessment*** is an estimate of the likelihood that some activity or substance will harm human health or the environment, using epidemiological, toxicological or other data. Risk assessment asks: "How risky is this situation?"
- **Risk *management*** refers to a scheme of policy decision making that uses the results of risk assessments to recommend specific policy choices. Risk management asks a normative question: "What should we *do* about the risk?

***Objectivity Spectrum:***
**Risk Management is Political**

**SCIENCE ----- POLICY ----- POLITICS**

| **"Hard" Sciences:** | **Risk Assessment:** | **Risk *Management*:** |
|---|---|---|
| Biology, Chemistry, Physics, etc. | *Policies* Fill in Gaps, But Require Judgment | Too Many Unknowns Makes Answers Political |
| ***Science Asks:*** What Information Do We Have? | | ***Politics Asks:*** What Should We *Do* With That Information? |

## Appendix E
## The Misuse of Comparative Risk "Analysis"

**Enlarging the role of comparative risk management at OMB is a deeply flawed idea.**

Graham and his allies have frequently proposed the centralization of comparative risk management in a manner that would essentially grant a regulatory veto to the OMB. The over-broad application of this still-developing economic tool should strain the credulity of even the most optimistic proponents of risk assessment and risk management.

- **Institutionalizing more economic analysis at OMB would hinder the further development of risk management and risk assessment as social science tools.** The lack of consensus on risk management principles is an insurmountable stumbling block for its broader application. As the National Academy of Sciences observed: "Formal cost-benefit analysis of health and safety risks in regulation is at present *only a limited and incomplete part* of a large, complex analytic and decision-making process."[368] The Carnegie Commission on Science, Technology and Government is another group that opposes the idea of centralizing risk assessments done by the government.[369] In 1993, the Carnegie Commission noted that:[370]

> Centralizing risk assessment in a single entity would be likely to diminish substantially *the healthy diversity of views about risk* that is found in our current multiagency system.

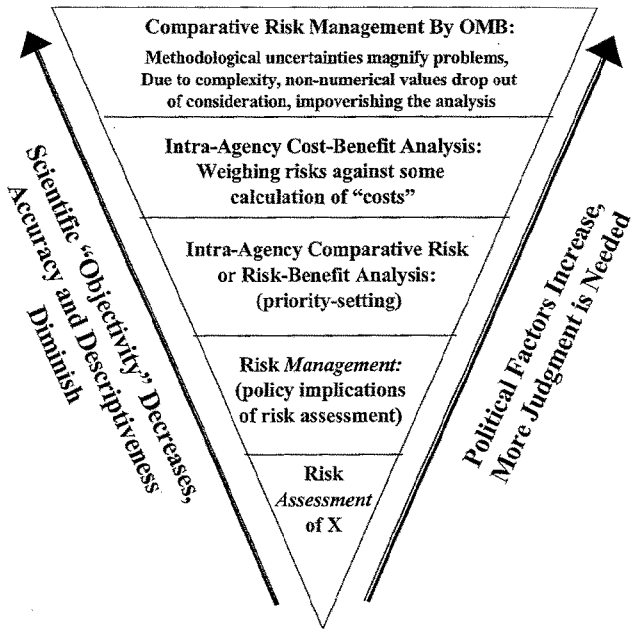
- **The complexity of the issues quickly outgrows the ability of risk management to provide useful information.** As the chart on the next page depicts, the value of a risk assessment decreases dramatically as more is asked of it. When risk assessment tools are more narrowly applied to one particular substance or activity, uncertainties or gaps in the data can be clearly flagged and may even be accounted for by data modeling or other techniques. As more and more information crowds the picture, however, there is less and less room for the caveats and qualifications that make those data valuable. And as the accuracy of the project decreases, there is more room for pure politics to charade as "scientific" conclusions. *Each level of additional complexity diminishes objectivity, and increases exponentially the number of non-scientific judgments and possibilities for political influence of the outcome.*

- **OMB-administered economic analysis is not science but politics.** Proponents of economic analysis would like decision makers to believe that it is a one-size-fits-all tool — but this is a fallacy. *At its broadest application, it is actually politics, masquerading as science.* This is why risk management proposals are the ideal third-party vehicle for industries that want to save their energy — and lobbying efforts — for influencing the "risk experts" who lay down the rules of the game.

# *How A Social Science Becomes Swiss Cheese*

## The Value of Risk Assessment and Risk Management Diminishes With Complexity

**Larger Questions = More Politics, Little Objectivity**




**Narrower Application = (Relatively) Better "Science"***

* Within the field of risk assessment, the quality of the data used as inputs and the nature of the default assumptions varies widely. Thus, different risk assessments will vary widely in quality and usefulness. Non-numerical values, such as non-cancer health risks, scenic views, etc., are described in the text but cannot be calculated accurately.

## ENDNOTES

1. HCRA funders are listed within this document and on the HCRA Web site at <www.hcra.harvard.edu>.
2. Quotations in the media are at least partially listed in the conflicts chart at the end of Part One. For examples of his testimony before Congress without disclosure of funding sources for HCRA, see, e.g., Testimony of John D. Graham before the Senate Energy & Natural Resources Committee on Risk Analysis in Environmental Policy-Making, Nov. 9, 1993; Testimony of John D. Graham, before the House Government Affairs Committee on Regulatory Revision, Feb. 15, 1995 (Graham said only "In response to requests from federal agencies, state agencies and private industry, I have offered advice on the importance of risk analysis to sound decision making"); Testimony of John D. Graham, before the Senate Governmental Affairs Committee, Hearing on S. 981, "The Regulatory Improvement Act of 1997," Sept. 12, 1997. In his testimony before Congress, Graham has repeatedly said that his comments represented his own opinion and not those of Harvard. Therefore, his failure to disclose could be viewed as less problematic. However, the subject of his testimony often involved highly specific discussions on topics such as air bags, MTBE additives to gasoline, etc., and regulations regarding which would directly impact his funders. See, e.g., Testimony of John D. Graham before the Senate Committee on Regulatory Affairs on S. 746, April 29, 1999. In his comments to the media that are analyzed within this report, no such qualification on his part was reported. Indeed, he was widely represented by the media as a neutral "expert" from the Center or the Harvard School of Public Health.
3. See <www.hcra.harvard.edu/unrestricted.html>; <www.hcra.harvard.edu/restricted.html>.
4. See <www.hcra.harvard.edu/executive.html>.
5. See < www.hcra.harvard.edu/advisory.html>.
6. See Testimony of John D. Graham before the Senate Committee on Governmental Affairs on S. 746, the "Regulatory Improvement Act of 1999," April 21, 1999 (Graham said: "I earned my BA and MA degrees in public policy from Wake Forest University (1978) and Duke University (1980), respectively).
7. See letter at the end of Case Study #2.
8. On the SAB, Graham criticized the EPA draft report. See "Science Advisory Board Questions Major Parts of EPA Dioxin Report," *Air Water Pollution Report*, May 22, 1995.
9. Dioxin is the name given to a group of highly toxic chemicals that are produced when chlorine is burned. Dioxin is produced during incineration, the manufacturing of paper, metal smelting and refining, the manufacturing of chlorinated chemicals including pesticides, herbicides and polyvinyl chloride plastic, petroleum refining and industrial and utility oil and coal combustion. The draft EPA risk assessment, released in 2000, showed that, even at very low levels of exposure, dioxin is linked to cancer, infertility, immune system damage and learning disabilities. More than 90 percent of dioxin exposure comes through the food we eat, especially fish, meat and dairy products. The US EPA has been finalizing its reassessment of dioxin since 1995.
10. Noah Adams, "EPA Report on Dioxin is Released and Confirms a Cancer Risk Exists to All Americans," *All Things Considered, National Public Radio*, June 15, 2000.
11. See the conflicts chart at the end of Part One for a list of HCRA funders that are dioxin producers.
12. The settlement requires the documents to be available at www.pmdocs.com, and are searchable by "bates" no, the number used to mark legal documents. The citation is therefore: Bates no. 2050240317.
13. Bates no. 2050240317.
14. Bates no. 2050240317. CIIT does not directly fund HCRA. But CIIT is itself supported by many of the same companies that fund HCRA, such as Air Products and Chemicals, BASF, Celanese, Chevron, Dow Chemical, E.I. du Pont de Nemours, Eastman Chemical, ExxonMobil, General Electric, Lyondell, Rohm and Haas, Texaco, Union Carbide and Unocal. See <www.ciit.org/SUPPC/suppc.html>.
15. For just one example, in 1995 Margaret Kriz wrote in the National Journal that "[s]ome conservative think tanks, including the Cato Institute and the Competitive Enterprise Institute, say they hope that today's risk assessment debate will pave the way for a revolution in environmental policy. They suggest *eliminating all federal environmental laws* and substituting a system of personal responsibility." Margaret Kriz, "Risky Business," *National Journal*, Feb. 18, 1995.
16. The OMB analyzes the agencies' "regulatory impact analyses" or RIAs. Clinton's Executive Order 12866 requires RIAs that are, for the most part, cost-benefit analyses and the OMB's OIRA produces a "Best Practices" document that provides guidelines for the RIAs.
17. Cindy Skrzycki, "Lining Up to Lobby for Rule Recision," *The Washington Post*, Feb. 6, 2001.
18. Id.

19. Id. The *Post* wrote that his comments reflected "the sentiment of the business community that the agencies have been over-aggressive regulators over the past eight years."
20. "Risk-Expert Graham as Political Guru," *Air/Water Pollution Report's Environment Week*, Feb. 2, 1996 (emphasis added).
21. John D. Graham, "Making Regulatory Reform a Reality," *Heritage Foundation Reports*, Jan. 31, 1996.
22. "Excessive Reports of Health Risks Examined," *The Patriot Ledger*, Nov. 28, 1996, at 12.
23. See Case Study #1 on Philip Morris.
24. See Testimony of John D. Graham before the Senate Committee on Governmental Affairs, Hearing on S. 981, "The Regulatory Improvement Act of 1997," Sept. 12, 1997; John D. Graham, "Making Sense of Risk: An Agenda for Congress," in *Risks, Costs and Lives Saved* (Robert W. Han, ed., Oxford University 1996).
25. Brief of Robert E. Litan, Counsel of Record for the AEI-Brookings Joint Center For Regulatory Studies, in the case American Trucking Associations, Inc., et al,. v. Carol M. Browner, Administrator of the EPA, On Writ of Certiorarti To the United States Court of Appeals (for Cross Petitioners, the American Trucking Association).
26. See discussion of S. 746 at the end of Case Study #3.
27. According to the Insurance Institute for Highway Safety, NHTSA records show that air bags have saved 6,377 lives through Dec. 2000.
28. In 1997, Graham advocated for a sweeping requirement that would have imposed a formal risk assessment, including a "peer review" by committees likely to be staffed with industry-friendly "experts" and centralized clearance through the White House Office of Science and Technology Policy for all risk-related determinations — even if the federal agency was merely sharing information on a hazard which had not been not part of any formal rulemaking.
29. Patricia Pena, "We Need Laws For Cell Phones," *USA Today*, April 27, 2000.
30. See discussion of Graham's study in Case Study #2.
31. In his view, before issuing a regulation, a federal regulatory agency should be required to: 1) estimate the scope of the health, safety or environmental problem to be regulated and the improvements likely to result from regulation; 2) estimate the cost of the regulation; 3) express these benefits and expenses in common units, and 4) weigh the costs of the proposed regulation against the expected benefits. Testimony of John D. Graham before the Senate Committee on Regulatory Affairs on S. 746, April 29, 1999. At each step, of course, it matters greatly who is empowered to write the technical rules about what kinds of costs and benefits are considered.
32. See <www.hcra.harvard.edu/executive_education.html>.
33. Kimberly Thompson, "Kids at Risk," *Risk in Perspective*, Harvard Center for Risk Analysis, April 2000.
34. See, e.g., Child Health Alert, Inc., "More Worrisome News About Electromagnetic Fields," *Child Health Alert*, Dec. 1992.
35. In his testimony on April 21, 1999, Graham told the Senate Governmental Affairs Committee in a hearing on cost/benefit analysis of federal regulations: "I earned my BA and MA degrees in public policy from Wake Forest University (1978) and Duke University (1980), respectively. My Ph.D. dissertation at Carnegie-Mellon University (1983) was a benefit-cost analysis of automobile airbag technology and was conducted while in residence at the Brookings Institution in Washington, D.C." Testimony, John D. Graham, Senate Governmental Affairs Committee, Hearing on Cost/benefit Analysis of Federal Regulations, April 21, 1999.
36. Conversation between Public Citizen and representative of the Wake Forest University alumni office, Feb. 7, 2001. See also <www.wfu.edu/academic_resources/acad_dir.html#e>, which lists Wake Forest's undergraduate academic departments.
37. David Lore, "Determining Toxic Risks is Costly Voodoo, Lawyer Says," *The Columbus Dispatch*, Nov. 24, 1995.
38. See <www.hcra.harvard.edu/unrestricted.html>; <www.hcra.harvard.edu/restricted.html>.
39. See <www.hcra.harvard.edu/executive.html>.
40. Id. On Gray's role in the transition, see Lee Walczak & Richard S. Dunham, "The Man Who Would Be Reagan," *Business Week*, Jan. 29, 2001. Gray was also counsel to a Reagan administration task force on "regulatory relief," see Neil Strassman, "Critics: Bush May Favor Industry," *Chattanooga Times*, Dec. 24, 2000. A panel Feb 8, 2001 at the Heritage Foundation that included Gray addressed "how best to deal with some of the more substantive problems dumped on President Bush's doorstep during the waning days of the old Clinton regime: *executive orders*, recess appointments, land grabs and treaties." John MacCaslin, *The Washington Times*, Jan. 30, 2001 (emphasis added).
41. Gray's many connections to chemical, agribusiness and industrial
interests were well documented by a 1998 profile in *The New Republic*. As Hanna Rosin wrote, "So many different money trails lead to, by and through Gray it is bewildering."

42. See < www.hcra.harvard.edu/advisory.html>.
43. See Testimony of John D. Graham, before the Senate Committee on Environment and Public Works, hearing on "Impacts of Regulatory Reform on Environmental Law," Mar. 22, 1995. The Harvard group proposed, among other things, the authorization of a science advisor to assess and rank all risks addressed by federal agencies, requiring flexibility for industry to comply with rules, and devolvement of regulation to states and localities. Graham also advocated for a bill which over-rides agency mandates to impose cost-benefit and risk-benefit criteria, regardless of an agency's direction from Congress.
44. See section on Graham and Philip Morris at Case Study #1.
45. See <www.hcra.harvard.edu/conflict.html>.
46. See the list of Graham's affiliations at the end of Part One.
47. Making Regulatory Reform a Reality, Heritage Foundation Reports, A Heritage Foundation Symposium, No. 559, Jan. 31, 1996 (quoting Graham).
48. Industries' funneling of tax-exempt dollars into this system of organizations was at least partially outlined in a report by the Center for Responsive Philanthropy in 1997 entitled *Moving A Public Policy Agenda: The Strategic Philanthropy of Conservative Foundations*. Sally Covington, "Moving A Public Policy Agenda: The Strategic Philanthropy of Conservative Foundations," *National Committee for Responsive Philanthropy*, July 1997.
49. "Making Regulatory Reform a Reality," Heritage Foundation Reports, A Heritage Foundation Symposium, No. 559, Jan. 31, 1996 (quoting Graham).
50. Testimony of John D. Graham before the Senate Committee on Regulatory Affairs on S. 746, April 29, 1999.
51. Id. Many of the others are cited in this endnotes to this report.
52. See the conflicts of interest chart at the end of Part One.
53. See, e.g., Statement of Frederick Webber, President and Chief Executive Officer, Chemical Manufacturers Association, Hearing on Regulatory Reform before the Senate Committee on Governmental Affairs, Mar. 8, 1995 (citing Graham's testimony). In relation to later "rollback" efforts, see also Statement of Thomas F. Walton, General Motors Corp., on behalf of Alliance USA: The Alliance for Understandable, Sensible, and Accountable Government Rules, on S.981, the "Regulatory Improvement Act of 1997," before the Senate Committee on Governmental Affairs, Sept. 12, 1997 (Walton cites Graham's research in his testimony. Alliance USA was a group that included the Business Roundtable, the National Association of Manufacturers, the U.S. Chamber of Commerce, the American Plastics Council, and the Chemical Manufacturers Association.).
54. See Case Study #1 on Philip Morris.
55. Curt Suplee, "Assessing the Risk in Contract's 'Cost-Benefit' Curb on Regulations," *The Washington Post*, Feb. 28, 1995. For example, one House bill, the "Risk Assessment and Cost-Benefit Act of 1995," required a formal risk assessment for any proposed rule likely to result in annual increases in costs to government, industry and consumers, of more than $25 million annually, or "about 10 cents per American per year." Id. Based on the assessment, the agency could regulate only if: 1) the risk reduction or benefits are "likely to justify, and be reasonably related to, the incremental costs," and 2) all other alternatives are "less cost-effective," or provide "less flexibility" to those being regulated, such as businesses. Id. The bill also had a *comparative* risk component, requiring federal agencies to compare any risk they estimate with other risks in daily life, and to take account of "substitute risks" — which are hazards that happen because of efforts to eliminate risk.
56. Testimony of John D. Graham before the Senate Committee on Regulatory Affairs on S. 746, April 29, 1999. Although his testimony specifically criticized regulatory programs affecting the gasoline additive MTBE, fuel economy standards, and the controversy over passenger-seat air bags, he did not identify any of the funders of his Center.
57. See, e.g., Emily T. Smith, "Voodoo Regulation?" *Business Week*, Mar. 13, 1995; Curt Suplee, "Assessing the Risk in Contract's 'Cost-Benefit' Curb on Regulations," *The Washington Post*, Feb. 28, 1995; see also Irv Chapman, "GOP Bill Would Repeal Ban on Some Pesticides," *CNN Moneyline*, July 12, 1995 (quoting Graham as a "scientist" who supported Sen Dole's reform bill as "based upon sound scientific principles").
58. Making Regulatory Reform a Reality, *Heritage Foundation Reports: A Heritage Foundation Symposium; No. 559*, Jan. 31, 1996.
59. Margaret Kriz, "Risky Business," *National Journal*, Feb. 18, 1995. As is typical, the article does not disclose any of the relevant sources of funding for Graham's Center. Other groups with an interest in opposing regulation argued that the responsibility for reviewing the effectiveness of regulation should be given to OMB, rather than Congress. Id.
60. Id.
61. John D. Graham, "Making Sense of Risk: An Agenda for Congress," in *Risks, Costs and Lives Saved* (Robert W. Han, ed., Oxford University 1996).
62. Testimony of John D. Graham before the Senate Committee on Regulatory Affairs on S. 746, April 29, 1999.

63. Id.
64. "Unintended Consequences of the S.746 Regulatory Obstacle Course," Public Citizen's Congress Watch, May 1999.
65. What constitutes justification is unclear, as are the benchmarks for cost-efficiency. Real benchmarks of economic efficiency would have be different for each kind of regulation that is examined. For example, the HCRA study on air bags discussed in Case Study #3 uses the cost-efficiency of seat belts as the "comparator" for the cost-efficiency of air bags. That means, in practice, that the existing state of technology, and protection, can function as the baseline on costs, rather than some, future, more protective goal.
66. Testimony of John D. Graham before the Senate Committee on Governmental Affairs, Hearing on S. 981, "The Regulatory Improvement Act of 1997," Sept. 12, 1997.
67. See Testimony of John D. Graham, before the Senate Committee on Environment and Public Works, hearing on "Impacts of Regulatory Reform on Environmental Law," Mar. 22, 1995. The Harvard group proposed, among other things, the authorization of a science advisor to assess and rank all risks addressed by federal agencies, requiring flexibility for industry to comply with rules, and devolvement of regulation to states and localities. Graham also advocated for a bill which over-rides agency mandates to impose cost-benefit and risk-benefit criteria, regardless of an agency's direction from Congress.
68. See Testimony of John D. Graham before the Senate Governmental Affairs Committee, Hearing on "The Role of Risk Analysis and Benefit-Cost Analysis In regulatory Reform Legislation (S.291)," Feb. 15, 1995 ("Enabling statutes should be superseded by the general requirement that each rule's identified benefits must justify its identified costs.").
69. American Trucking Associations, Inc., et al,. v. Whitman, Administrator of the EPA, No. 99-1257 (slip. op.) Feb. 27, 2001.
70. Brief of Robert E. Litan, Counsel of Record for the AEI-Brookings Joint Center For Regulatory Studies, in the case American Trucking Associations, Inc., et al,. v. Carol M. Browner, Administrator of the EPA, On Writ of Certiorarti To the United States Court of Appeals (for Cross Petitioners, the American Trucking Association).
71. Charles Lane, "Clean-Air Authority of EPA Is Upheld, Court: Law Bars Costs Consideration," *The Washington Post*, Feb. 28, 2001.
72. Scott Allen, "US Accepts $129 M for Cleanup of Love Canal; Some Say Set a Wrong Course," *The Boston Globe*, Dec. 22, 1995.
73. Id.
74. See the conflict of interest chart at the end of Part One.
75. Making Regulatory Reform a Reality, *Heritage Foundation Reports: A Heritage Foundation Symposium; No. 559*, Jan. 31, 1996.
76. Id.
77. Id.
78. Noah Adams, "EPA Report on Dioxin is Released and Confirms a Cancer Risk Exists to All Americans," *All Things Considered,* National Public Radio, June 15, 2000.
79. Id. (emphasis added).
80. Listed on the HCRA Web site by its former name, the Chemical Manufacturers Association.
81. Thomas O. McGarity, "A Cost-Benefit State" 50 Ad. L. Rev. 1 (1998).
82. John D. Graham, "Making Sense of Risk: An Agenda for Congress," in Risks, Costs and Lives Saved (Robert W. Han, ed., Oxford University 1996).
83. See Clinton's Executive Order 12866 (defining "economically significant").
84. ABC News Special, Transcript #346, April 21, 1994; A rehash of John Stossel's ABC News show posted on the Web at <www.ewtn.com/library/BUSINESS/SCARE.HTM> pits Graham against Ralph Nader: "Reason is not always politically correct and point to a government mandate: Ralph Nader thinks that $1800 more to put belts on school buses is money well spent. But the Harvard school of public health found that belts would not make much of a difference. Children are much more likely to get killed when they get off the bus. Reason also deals with truthful facts and reaches logical conclusions: if school bus belts could save about 12 lives a year aren't [they] worth it? No says Dr. Graham: 'You are engaging in statistical murder. When you decided to spend $50 millions to save a few lives when you could spend the $50 million to save a hundred lives or a thousand lives, that's statistical murder." See also conflicts chart the end of Part One.
85. See chart at Appendix C, which depicts how the relative objectivity of a simple risk assessment is greatly complicated by its aggrandizement to the risk analysis context. Because of the increasing complexity of the inquiry, many of the qualifications which make risk assessment valuable must drop out as the risk analysis grows more ambitious.
86. See Thomas O. McGarity, "A Cost-Benefit State" 50 Ad. L. Rev. 1 (1998) at 55.

87. See Testimony of John D. Graham, before the House Government Affairs Committee on Regulatory Revision, Feb. 15, 1995 (recommending that guidelines for the agencies' risk assessment and risk characterization be subject to review, revision and approval by the President's Office of Science and Technology Policy).
88. Testimony of John D. Graham, before the Senate Governmental Affairs Committee, Hearing on S. 981, "The Regulatory Improvement Act of 1997," Sept. 12, 1997.
89. Thomas O. McGarity, "A Cost-Benefit State" 50 Ad. L. Rev. 1 (1998) at 55.
90. Id.
91. Id.
92. This was true in the cotton dust case handled by OSHA.
93. Curt Suplee, "Assessing the Risk in Contract's 'Cost-Benefit' Curb on Regulation," *The Washington Post*, Feb. 26, 1995 (quoting EPA spokeswoman Sylvia K. Lowrance).
94. Id. (quoting Gregory Wetstone of the National Resources Defense Council).
95. John Carey, "So Many Chemicals, So Few Answers," *Business Week*, Mar. 13, 1995.
96. Id.
97. Adam Finkel, "Who's Really Crying Wolf?" *American Scientist*, Sept.-Oct. 1996.
98. Thomas O. McGarity, "A Cost-Benefit State" 50 Ad. L. Rev. 1 (1998).
99. Id.
100. See Appendix A.
101. Dorothy Patton, "The ABCs of Risk Assessment," *EPA Journal*, Jan/Feb/Mar 1993. (emphasis added).
102. Id.
103. Adam Finkel, "Who's Really Crying Wolf?" *American Scientist*, Sept.-Oct. 1996.
104. Milloy's position on EPA's more protective risk numbers can be found in his book, Science Without Sense, and is indicated in many places on the www.junkscience.com Web site.
105. The National Academy of Sciences' National Research Council is a private, non-partisan organization of outside academics and researchers chartered by Congress to advise the government.
106. *Conclusions*, in Valuing Health Risks, Costs, and Benefits for Environmental Decision Making by the National Academy of Sciences' National Research Council at 189, 206 (1990).
107. Emily T. Smith, "Voodoo Regulation?" *Business Week*, Mar. 13, 1995.
108. Testimony of John D. Graham, before the House Government Affairs Committee on Regulatory Revision, Feb. 15, 1995.
109. Id.
110. John D. Graham, et al, In Search of Safety: Chemicals and Cancer Risk, at 177 (1988).
111. Id. at 204. Graham's suggestion was intended to provide a remedy for what he viewed as a history of overly precautionary risk assessment decisions on the part of regulators. Id. See also Thomas O. McGarity, "A Cost-Benefit State" 50 Ad. L. Rev. 1 (1998) at 27.
112. Hearings Before the Subcomm. on Health and Environment and the Subcomm. on Commerce, Trade and Hazardous Materials of the House Comm. on Commerce, 104th Congress (1995) (statement of Ellen Silbergeld) (emphasis added).
113. Ellen K. Silbergeld, "The Risks of Comparing Risks," N.Y.U. Environ. Law. J. 3 (1994).
114. Thomas O. McGarity, "A Cost-Benefit State" 50 Ad. L. Rev. 1 (1998).
115. Douglas E. MacLean, "Comparing Values in Environmental Policies: Moral Issues and Moral Arguments," in Valuing Health Risks, Valuing Health Risks, Costs, and Benefits for Environmental Decision Making (1990). See also, e.g., Lisa Heinzerling, "Reductionist Regulatory Reform," 8 Fordham Envtl. Law J. 459 (1997); Richard L. Revesz, "Environmental Regulation, Cost-Benefit Analysis, And the Discounting of Human Lives," 99 Colum. L. Rev. 941 (May 1999); David A. Wirth & Ellen K. Silbergeld, "Book Review: Risky Reform," 95 Colum. L. Rev. 1857 (Nov. 1995); Mark Sagoff, The Economy of the Earth 46 (1988), Margaret Radin, Contested Commodities; Lisa Heinzerling "Discounting Our Future," (unpublished manuscript on file with Public Citizen).
116. Thomas O. McGarity, "A Cost-Benefit State" 50 Ad. L. Rev. 1 (1998) at 24, (emphasis added), and 59 (citing to a portion of Graham's Congressional testimony) (emphasis added).
117. "'Dateline' Story Riddled With Errors, Environmentalists Say," *Pesticide and Toxic Chemical News*, Oct. 2, 1996.
118. Jay D. Wexler, Book Review, 30 Conn. L. Rev. 225, 248 (Fall 1997).
119. Branden Johnson, "Advancing Understanding of Knowledge's Role in Lay Risk Perception," *Risk*, Summer, vol. 4 (2000). On the Internet at <www.fplc.edu/risk/vol4/summer/johnson.htm>. See also Ellen K. Silbergeld, "The Risks of Comparing Risks," N.Y.U. Environ. Law. J. 3 (1994).

120. Wingspan Conference on Implementing the Precautionary Principle, January 1998. For more information on the precautionary principle, see the Science and Environmental Health Network Web site: <www.sehn.org>.
121. See <www.sehn.org>.
122. See <www.hcra.harvard.edu/precautionary.html>.
123. John D. Graham, "The Precautionary Principle: Refine it or Replace It?" *Risk in Perspective*, May 1999; <www.mediatransparency.org/funders/koch_family_foundations.asp>.
124. "EPA: Here's Hoping Whitman Brings Much-Needed Balance to the Job," *Charleston Daily Mail*, Feb. 1, 2001.
125. "Risk-Expert Graham as Political Guru," *Air/Water Pollution Report's Environment Week*, Feb. 2, 1996 (emphasis added).
126. ABC News Special, Transcript #346, April 21, 1994.
127. An exception to this pattern of non-disclosure is the cell phone study that was funded by AT&T and is discussed in *Science for Sale*, Case Study #2.
128. Thomas O. McGarity, "A Cost-Benefit State" 50 Ad. L. Rev. 1 (1998) at 54.
129. The companies listed are HCRA supporters. See <www.hcra.harvard.edu/restricted.html>; <www.hcra.harvard.edu/unrestricted.html>.
130. Telephone conversation, Feb. 16, 2001, between Public Citizen and the Harvard Center for Risk Analysis.
131. "Science Advisory Board Questions Major Parts of EPA Dioxin Report," *Air/Water Pollution Report*, May 22, 1995. Graham was reported as saying that "[t]he report overstates the carcinogenic risks that dioxins and related compounds may pose and fails to seriously analyze uncertainties about these chemical sand to show how incremental changes in exposure could affect health."
132. A report on dioxin posted on the Greenpeace Web site describes Graham's participation in the EPA process on the dioxin reassessment. See <www.enviroweb.org/issues/dioxin/dow_brand_dioxin.txt>.
133. Dioxin producers were identified by the Center for Health and Environmental Justice.
134. Several projects have attempted to map the reach and finances of this corporate network. A Web-based project in its early stages is being developed by NCRP/Media Transparency on the Web site <www.mediatransparency.org>. Another project on the part of the Clearinghouse on Environmental Advocacy and Research (CLEAR), now abandoned, can be found on the Web at <www.ewg.org/pub/home/clear> and <www.ewg.org/pub/home/clear/by_clear/ShowMe.html>. PR Watch also frequently publishes exposes of particular groups or campaigns, *see* <www.prwatch.org>.
135. See <www.ewg.org/pub/home/clear/by_clear/ShowMe.html>.
136. See note 133. These numbers are according to Clearinghouse on Environmental Advocacy and Research (CLEAR), Media Transparency, a grants search from the Foundations Center, and an article by Sheldon Rampton & John Stauber, "The Junkyard Dogs of Science," *New Internationalist*, July 1999.
137. "Science Watchdog Group Celebrates Third Anniversary With Renewed Commitment to Exposing Use of Junk Science," *PR Newswire*, Dec. 3, 1996.
138. As Public Citizen extensively documented in relation to the debate over limits on corporate liability (called "tort reform" by corporate allies. "The CALA Files: The Secret Campaign by Big Tobacco and Other Major Industries to Take Away Your Rights," Public Citizen and the Center for Justice & Democracy, July 26, 2000; "Smoke and Mirrors: The Tobacco Industry's Influence on the Phony 'Grassroots' Campaign for Liability Limits" (March 1996); see also <www.prwatch.org/prwissues/1996Q3/cohen.html>; Sheldon Rampton and John Stauber, "How Big Tobacco Helped Create the Junkman," *PR Watch*, Third Quarter 2000, <www/prwatch/org/prwissues.2000Q3/junkman.html>.
139. Elisa K. Ong, "Tobacco Industry's Efforts Subverting International Agency for Research on Cancer's Second-Hand Smoke Study," *The Lancet*, April 8, 2000.
140. "Science Watchdog Group Celebrates Third Anniversary With Renewed Commitment to Exposing Use of Junk Science," *PR Newswire*, Dec. 3, 1996.
141. John Stauber and Sheldon Rampton, Tobacco's Secondhand Science and Smoke-filled Rooms," *PR Watch*, Third Quarter 2000. See <www.prwatch.org/prwissues/2000Q3/secondhand.html>.
142. See <http://jama.ama-assn.org/issues/v281n4/ffull/jmn0127-3.html>.
143. The list is no longer posted, but was available on the SRA Web site at <www.sra.org> a year ago. There is a printed copy on file with Public Citizen.
144. See <www.aei.brookings.org/about/advisory.asp>.
145. See <www.mediatransparency.org.>.
146. Jack O'Dwyer, "Ketchum Launches Litigation Practice," *Jack O'Dwyer's Newsletter*, Jan. 26, 2000.
147. The Philip Morris documents Web site is located at <www.pmdocs.com> and is searchable by the Bates number, a legal identifier, of the document. Therefore, the Bates number is provided in the cites below.

148. 2023012753
149. Id.
150. 2024713141
151. 2024713155
152. Id. (emphasis in original).
153. Id.
154. 2023029219, 2024224722
155. 2046597149; <www.prwatch.org.prwissues/2000Q3/junkman.html>.
156. 2046597149
157. See <http.www.prwatch.org/prwissues/2000Q3/junkman/html>.
158. 2024224722.
159. Logue's position is identified in 2024102916.
160. Gray's role is explained above, in the footnotes to Part One.
161. 2025535614.
162. 2023545705
163. Id.
164. Id. (emphasis added).
165. 202354707
166. The document that shows the check is 2025534593 and the stop payment is 2025534592.
167. It is speculation, but it is possible that Graham had reconsidered whether he wanted to publicly accept money directly from Philip Morris.
168. 2025534554 (emphasis added) (the notes was cc'd to Logue); see also 2025534553 (indicating that Logue supports the efforts).
169. 2025534555
170. 2025534555
171. Regarding the Executive Order 12886, issued Sept. 1993). Jonathan Wiener's Faculty Profile on the Duke University School of Law Web site www.law.duke.edu/fac/wiener/profile.html
172. 2025477181
173. 2025477181
174. 2025477181
175. See the HCRA Web site's full list of funders. Graham and Wiener would later write a book together on comparative risk assessment, called *Risk v. Risk: Tradeoffs in Protecting Health and the Environment*, and both testified in 1995 on regulatory reform before the Senate Committee on Governmental Affairs.
176. Elisa K. Ong, "Tobacco Industry's Efforts Subverting International Agency for Research on Cancer's Second-Hand Smoke Study," *The Lancet*, April 8, 2000.
177. Id.
178. Id. In 1994, Philip Morris (PM) and its public relations firm, Burson Marsteller, was organizing a "sound science" front group in Europe that would favorably influence politicians and legitimize the company's position on second-hand smoke and other issues. Anne Landman, American Lung Association of Colorado, "Daily Doc: Philip Morris' Sound Science Project," Aug. 2, 2000, see <www.tobacco.org/Documents/dd/ddsoundscience.html>. A memorandum written by Stig Albinus, of Burson-Marstellar, to several PM officials was called the "Sound Science Project and European Seminar in the Autumn." Memorandum from Stig Albinus to David Bushong and Matt Winokur, Burson-Marsteller Copenhagen, Re: Sound Science Project and European Seminar in the Autumn, June 17, 1994. See <www.pmdocs.com/getallimg.asp?DOCID=2025493066/3069>.

Albinus recounted the results of his interviews with several scientists, and attached 45 pages of faxed notes. The interviews were designed to scope out the receptiveness of the scientists to a networking project that would standardize "sound science" and "good epidemiology" practices. Although Albinus neglected to mention in the interviews that funding for the project was provided by PM, it appears that a few scientists had perhaps smelled a rat and mentioned the issue on their own. Albinus noted that "some of the scientists have themselves raised the question of relations to the tobacco industry as a critical issue." Because the interviews were done on the sly, Albinus cautioned PM not to publicly mention his results, which would have revealed PM's involvement to the targeted scientists: "Please note that you must not use the outcome of this research and references to the interviews with scientists in a Philip Morris approach to the identified scientists *because that could distort and jeopardize the entire operation.*"

Any tobacco industry taint could render the study and the seminar's impact worthless as science, thus destroying the value of Philip Morris' investment in the research. Therefore, Albinus wrote, securing a broader base of funding for the planned seminar was critical for its credibility: "It is absolutely vital that we succeed in

getting funding of the seminar from a broader group of sponsors than just PM and Tetra Pak, because otherwise we would not be able to ensure the credibility of the seminar in relation to the scientists. And if the seminar has not got that credibility, the outcome of the meeting will not have great value."

The corporations that hope to fund industry-friendly science often find themselves dependent on great secrecy and stealth because of a dilemma. Without controlling the scope and substance of a study, their corporate investment could be "wasted," or even made counterproductive, if results are unfavorable to their profits. But if a corporation does appear to exercise control, the results will not be accepted as independent research because they lack credibility. That is one reason why it was necessary for Albinus to carefully vet all of the scientists before floating any real proposal. It appears that the easiest way for industry to have its cake and eat it too is to handpick, in advance, a stable of industry-friendly scientists who are willing to do their bidding.

179. 2050240421
180. 2024102916
181. 990 info for AdT
182. 2040303701
183. John D. Graham, et al., "Making Regulatory Reform a Reality," *The Heritage Foundation Reports*, No. 559, Jan. 31, 1996 at 8.
184. 2025534553
185. 2023551159
186. 2025535594
187. 2023551078
188. It was posted last year on the Web at <http://ww.sra.org/fellows.htm>.
189. 2060579190
190. Id.
191. Id.
192. See <www.hcra.harvard.edu>.
193. Christine Wicker, "Common road habits can take deadly toll; Food-eaters, phone-talkers, radio-dialers among 'good' drivers causing fatal crashes" *Dallas Morning News*, Jan. 31, 1999.
194. Id.
195. "Drivers Not Risking Much on the Horn, Study Says," *The Providence Journal-Bulletin*, July 25, 2000.
196. Peter J. Howe, "Harvard Study Downplays Risk of Cell Phone Use by Drivers," Boston Globe 7/24/2000, a3
197. "Drivers Not Risking Much on the Horn, Study Says," *The Providence Journal-Bulletin*, July 25, 2000.
198. Id.
199. *Risk in Perspective:* Cellular Phones and Driving: Weighing the Risks and Benefits, Harvard Center for Risk Analysis, July 24, 2000, at 2 (emphasis added).
200. Id. at 5.
201. Id. at 3.
202. See "Introduction" at <www.nhtsa.dot.gov/people/injury/research/wireless/#exec>.
203. "Drivers Not Risking Much on the Horn, Study Says," *The Providence Journal-Bulletin*, July 25, 2000.
204. Id. at 4.
205. Id. at 4.
206. Charles Osgood, "New Study Funded by AT&T Says That Using Cell Phones While Driving is Safer Than Driving Without a Seat Belt On," *The Osgood File*, July 25, 2000.
207. Jay Lindsay "Harvard study says risks of driving with cell phones are overstated," *Associated Press*, July 24, 2000.
208. Id.
209. "Drivers Not Risking Much on the Horn, Study Says," *The Providence Journal-Bulletin*, July 25, 2000 (emphasis added).
210. The study is based on current cell phone use and does not account for the rapidly increasing purchase and use of cell phone by U.S. drivers.
211. See "Introduction" at <www.nhtsa.dot.gov/people/injury/research/wireless/#exec>.
212. Id.
213. *Risk in Perspective:* Cellular Phones and Driving: Weighing the Risks and Benefits, Harvard Center for Risk Analysis, July 24, 2000, at 2 (emphasis added) at 6.
214. This is also due to discounting, as is discussed in Appendix B.
215. Used with permission from Car Talk.
216. Steve Filmer & Charles Gibson, "Highlight: Questions About Passenger Airbag Safety,"ABC Good Morning America, Mar. 17 1997, Transcript # 97031706-j01.

217. "Air Bag Pioneer Reverses Support; Costs, risk to children too great, he says," *The Atlanta Journal and Constitution*, Mar. 17, 1997.
218. Aaron Zitner, "Air-bag Fears Could Threaten Common Sense," *The Boston Globe*, Dec. 1, 1996.
219. "Air Bag Pioneer Reverses Support; Costs, risk to children too great, he says," *The Atlanta Journal and Constitution*, Mar. 17, 1997.
220. Id.
221. Id.; Corrections, *Star Tribune*, April 5, 1997.
222. Warren Brown, "Air Bags More Cost Effective for Drivers Than Passengers, Study Says" *The Washington Post*, Nov. 5, 1997; "One Size Doesn't Fit All: Washington Should Let Motorists Turn Their Air Bags Off," *The Kansas City Star*, Oct. 15, 1997.
223. Janet Fix, "Air Bags Killing More Children Than They're Saving, Expert Says," *Knight Ridder/Tribune News Service*, Mar. 19, 1997.
224. Letter from Michael Finkelstein to John Graham, May 13, 1997 (on file with Public Citizen).
225. Public Citizen Auto Safety Alert, Released Weds. Mar. 19, 1997 (on file with Public Citizen).
226. John D. Graham, et al, "The Cost-Effectiveness of Air Bags by Seating Position," *Journal of the American Medical Association*, Nov. 5, 1997.
227. Press Release, "Study Shows Air bags a Worthwhile Investment: Risk to Children Must Be Addressed," Harvard School of Public Health, Embargoed for Nov. 4, 1997 (on file with Public Citizen).
228. John D. Graham, et al, "The Cost-Effectiveness of Air Bags by Seating Position," *Journal of the American Medical Association*, Nov. 5, 1997, at 1419 ("the analysis adopts the societal perspective and incorporates information on all risks, costs, and benefits resulting from these strategies, regardless of who incurs them).
229. Letter to the Editor of the Journal of the American Medical Association from Joan Claybrook, President of Public Citizen, Nov. 14, 1997 (on file with Public Citizen).
230. Press Release, "Study Shows Air bags a Worthwhile Investment: Risk to Children Must Be Addressed," Harvard School of Public Health, Embargoed for Nov. 4, 1997, at 2 (quoting Graham) (on file with Public Citizen).
231. Elisa R. Braver, et al, "Reductions in Deaths in Frontal Crashes Among Right Front Passengers in Vehicles Equipped With Passenger Air Bags," *Journal of the American Medical Association*, Nov. 5 1997.
232. "Air Bag Pioneer Reverses Support; Costs, risk to children too great, he says," *The Atlanta Journal and Constitution*, Mar. 17, 1997.
233. John D. Graham, et al, "The Cost-Effectiveness of Air Bags by Seating Position," *Journal of the American Medical Association*, Nov. 5, 1997, at 1424.
234. Michael Lasalandra, "Air Bags Kill More Kids Than They Save," *The Boston Herald*, Nov. 5, 1997.
235. Id. See chart at 1439.
236. "Health Risks: Public Overestimates, Says New Poll," *American Health Line*, Jan. 28, 1999.
237. Branden Johnson, "Advancing Understanding of Knowledge's Role in Lay Risk Perception," *Risk*, Summer, vol. 4 (2000).
238. Patricia Braus, "Everyday Fears," *American Demographics*, Dec, 1994; Branden Johnson, "Advancing Understanding of Knowledge's Role in Lay Risk Perception," *Risk*, Summer, vol. 4 (2000).
239. Richard Saltus, "Gender Called Factor in Scientists' View of Technological Perils," *The Boston Globe*, Feb. 8, 1999.
240. *Unintended Consequences of the S. 746 Regulatory Obstacle Course*, Public Citizen Congress Watch, May 1999.
241. Testimony, John D. Graham before the Senate Governmental Affairs Committee, "Cost/Benefit Analysis of Federal Regulations," April 21, 1999 (Federal Document Clearing House Congressional Testimony).
242. Graham admits as much in his testimony, saving the thrust of his argument on air bags for the peer review portion of the bill. Id.
243. Kathy Boccella, "Expert Campaigning for Public Awareness," *The Sunday Gazette Mail*, Mar. 23, 1997.
244. Warren Brown, "Air Bags More Cost-Effective for Drivers Than Passengers, Study Says," *The Washington Post*, Nov. 5, 1997.
245. Joan Claybrook, "The Auto Industry, The Air Bag," *The Washington Post*, Dec. 1, 1996; Joan Claybrook, "The Safest Air Bag of All," *The Washington Post*, Aug. 12, 1997.
246. Id.
247. According to the Insurance Institute for Highway Safety, NHTSA records that air bags have saved 6,377 lives through Dec. 2000.
248. "'Dateline' Story Riddled With Errors, Environmentalists Say," *Pesticide and Toxic Chemical News*, Oct. 2, 1996.

249. Sally Covington, "Moving A Public Policy Agenda: The Strategic Philanthropy of Conservative Foundations," *National Committee for Responsive Philanthropy*, July 1997.
250. "Risk-Expert Graham as Political Guru," *Air/Water Pollution Report's Environment Week*, Feb. 2, 1996 (*emphasis added*).
251. John D. Graham, "Making Regulatory Reform A Reality," *Heritage Foundation Reports*, Jan. 31, 1996.
252. See John Shanahan, "How to Talk About the Environment," Heritage Talking Points: Heritage Foundation Reports, Sept. 6, 1996; John Shanahan & Adam Thierer, "How to Talk About Risk: How Well-Intentioned Regulations Can Kill," Heritage Talking Points: Heritage Foundation Reports, April 23, 1996. On media articles, see e.g., L. Brent Bozell III, "When the Media Looks At Risk," *The Washington Times*, Oct. 17, 1994 (quoting Graham on the limits of the EPA). Bozell works for the "Media Research Center," a corporate-funded media "watch" group allied with Consumer Alert. See also David Shaw, "It's All So Scary: Americans A Bunch of Chicken Littles: Is It the Media's Fault," *The Plain Dealer*, Oct. 2, 1994 (quoting Graham as arguing that pesticide controls raise food prices and "if the prices of fruits and vegetables go up, people are likely to eat fewer fruits and vegetables," which will make them less healthy); Bob Sector, "Confusing Health Advice Has Public Scared Sick," *Chicago Sun-Times*, July 31, 1994 (quoting Graham, as well as Whelan of ACSH and conservative biochemist Bruce Ames); Andrew Holtz, "Risk Analysis Aims To Help People Assess Danger." *CNN Health Works*, June 19, 1993. Other examples of Graham's media handiwork can be found in the conflicts chart at the end of Part One.
253. See the conflicts chart at the end of Part One.
254. David Lore, "Determining Toxic Risks is Costly Voodoo," *The Columbus Dispatch*, Nov. 24, 1995.
255. For example, within risk management disputes there are such articles as: Adam Finkel, "A Second Opinion on An Environmental Misdiagnosis: The Risky Prescriptions of Breaking the Vicious Cycle," NYU. Env. L . J. (1995); on the divide between experts and the public over preventive and precautionary approaches, see, e.g., Kristin S. Frechette, "Evaluating the Expertise of Experts," Risk, vol. 6, see www.fplc.edu/risk/vol6/spring/shafrec/htm>; Jeanette M. Trauth, "A Case Study of Health Risk Communication: What the Public Wants and What It Gets," Risk, Vol. 5 <www.flpc.edu/risk/vol5/winter/trauth.htm>; Jeffrey J. Rachlinski, "Book Review," 6 Cornell J.L. & Pub. Pol'y 673 (Spring 1997)." The above is but a small sampling of the rich academic literature on risk issues.
256. Douglas E. MacLean, "Comparing Values in Environmental Policies: Moral Issues and Moral Arguments," in Valuing Health Risks, Valuing Health Risks, Costs, and Benefits for Environmental Decision Making (1990). See also, e.g., Lisa Heinzerling, "Reductionist Regulatory Reform," 8 Fordham Envtl. Law J. 459 (1997); Richard L. Revesz, "Environmental Regulation, Cost-Benefit Analysis, And the Discounting of Human Lives," 99 Colum. L. Rev. 941 (May 1999); David A. Wirth & Ellen K. Silbergeld, "Book Review: Risky Reform," 95 Colum. L. Rev. 1857 (Nov. 1995); Mark Sagoff, The Economy of the Earth 46 (1988), Margaret Radin, Contested Commodities.
257. The National Academy of Sciences' National Research Council is a private, non-partisan organization of outside academics and researchers chartered by Congress to advise the government.
258. *Conclusions*, in Valuing Health Risks, Costs, and Benefits for Environmental Decision Making 189, 206 1990; Thomas O. McGarity, "A Cost-Benefit State" 50 Ad. L. Rev. 1 (1998).
259. Linda-Jo Schierow, "The Role of Risk Analysis and Risk Management in Environmental Protection," *CRS Issue Brief*, Updated Feb. 17, 2000.
260. See Dolores Kong, "Scientists Warn Against Panic Over Electromagnetic Field Effect," *The Boston Globe*, Nov. 13, 1992.
261. Thomas O. McGarity, "A Cost-Benefit State" 50 Ad. L. Rev. 1 (1998).
262. Adam Finkel, "Who's Really Crying Wolf?" *American Scientist*, Sept.-Oct. 1996.
263. Thomas O. McGarity, "A Cost-Benefit State" 50 Ad. L. Rev. 1 (1998).
264. Id.
265. See list of articles in which he is quoted in the conflicts chart at the end of Part One.
266. Dorothy Patton, "The ABCs of Risk Assessment," *EPA Journal*, Jan/Feb/Mar 1993. (emphasis added).
267. Id.
268. Kristin S. Frechette, "Evaluating the Expertise of Experts," Risk, vol. 16, see <www.fplc.edu/risk/vol6/spring/shafrec/htm>.
269. See list of Graham's affiliations at the end of Part One.
270. See <www.prwatch.org>.
271. See list of Graham's affiliations at the end of Part One.
272. See Case, Andrea Golaine, "ACSH's Message Reaches Millions . . . .Anonymously," *Alt HealthWatch*, June 30, 1994 (quoting Graham). As the May 1994 issue of Consumer Reports noted, ACSH derives much of its funding from industry groups, including but not limited to the following companies: American Cynamid, American Meat Institute, Amoco, Bristol-Myers Squibb, Burger King, Chevron, Coca-Cola, Dow Chemical, DuPont, Exxon, Ford,

Mobil, Monsanto, National Agricultural Chemicals Association, Nestle, Pepsi-Cola, Pfizer, Procter and Gamble, Shell, Union Carbide and Uniroyal Chemical. Many of these companies also provide funding for Graham's HCRA.
273. See list of Graham's affiliations at the end of Part One.
274. See Sheldon Rampton & John Stauber, "The Junkyard Dogs of Science," *New Internationalist*, July 1999.
275. This is not the only time that ABC's reporter Stossel has served as a mouthpiece for the agenda of organizations like Graham's HCRA or ACSH. To get across his pro-industry ideological message, Stossel shows have also suggested that Mother Teresa was insufficiently greedy and have misquoted, in a way that reversed his meaning, the liberal economist James Galbraith. Ted Rose, "Laissez_faire TV: ABC's John Stossel is A Man on A Mission: To teach Americans About the Evils of Government Regulation and the Rewards of Free Enterprise," *Brill's Content*, Mar. 2000. Stossel has also been accused of unethical investigative conduct in a case involving a 1989 story on dentistry, see Robert Schmidt, "Stossel in Court," *Brill's Content*, Mar. 2000, an attack piece on Ben & Jerry's ice cream's alleged dioxin problem, see <www.ewg.org/pub/home/reports/givemeafaje/marash11032000.html>, and a "sting" involving a doctor who specializes in chemical sensitivity disorders, see Mark Schapiro, "Strange Bedfellows: Journalists as Corporate Shills," *Salon*, 1996, <www.salon.com/media/media961022.html>. Stossel's angle should come as no surprise. He has received speaking fees as high as $11,000 from the American Industrial Health Council, a trade association that includes Du Pont, Pfizer, and Procter & Gamble, and is also a HCRA funder. Id. *Brill's Content* reported that Stossel got $263,000 from 1998 to 2000 for speaking engagements before such groups as the Federalist Society, the National Petrochemical and Refiners Association and the Michigan Petroleum Society. Id. More recently, Stossel has come under fire for working with the ultraconservative Palmer R. Chitester Fund and the corporate-backed Olin Foundation, which is also a HCRA funder, to turn his antiregulatory programming into video and classroom study guides. The videos and guides, which are produced under the ABC logo and sent out to schools, draw almost exclusively on materials from conservative sources such as the Heritage Foundation and Young Americas Foundation. ABC has said that Stossel donates the money to charities. But the charity he has claimed donating to is the same Palmer Chitester Fund that has arranged with him to make the video and classroom guides. Donna Ladd, "Cyberfugtive: Beleagured Stossel Takes Shelter Under Right Wing," *The Village Voice*, Sept. 20-26, 2000. According to Media Transparency, the Chitester Fund was created with startup funding from the Bradley Foundation to create right wing "popular media." The Fund's "Idea Channel" distributes videos depicting conversations between mostly members of the right wing discussing politics and economics. See Media Transparency Project at <www.mediatransparency.org/recipients/pcf.asp>. This arrangement was recently questioned by Salon magazine. See David Mastio, "Prime-time Propagandist: Is ABC's John Stossel a reporter or a right-wing apparatchik?" *Salon*, Feb. 25, 2000, <www.salon.com/media/feature/2000/02/25/stossel/index.html>.

And last August, after running a show which suggested that eating organic foods could be fatal, ABC admitted that Stossel's report referred to testing that had never occurred in one instance and that the show had badly distorted test results in another. According to the *New Haven Register*, "Stossel and his producer knew that they didn't have the proof three months before the attack piece on organic food first aired, but ran (and then re-ran) the piece anyway." Brendan DeMelle, 20/20 Journalists Debunked," *New Haven Register*, Feb.20, 2001. Brian Halwell, a staff researcher at Worldwatch Institute, has traced this particular piece of misinformation to Dennis Avery, of the agribusiness funded Hudson Institute. Halwell wrote in the *San Francisco Chronicle*: "Last year, Avery manipulated data from the Centers for Disease Control in order to back his claim that organic produce carries a greater risk of E. coli than nonorganic produce. CDC officials have stated that their data do not support Avery's claim— a fact that might deter most journalists (even TV journalists) from relying on Avery as a source." Brian Halwell, "Cultivating the Truth About Organics," *San Francisco Chronicle*, Aug. 21, 2000.

Following a reprimand, Stossel was required to apologize on the air for the mistake but was not fired. Stossel's notoriously halfhearted apology is available on abc.com: <http://www.abcnews.go.com/onair/2020/2020_000811_stossel_apology_feature.html>. See also David Bauder, "Stossel, Producer Disciplined for 20/20 Report," *The Washington Post*, Aug. 10, 2000."Stossel Reprimanded But Not Fired," *Environmental Working Group*, Nov. 3 2000, <http://www.ewg.org/pub/home/reports/givemeafake/home.html>; Donna Ladd, "Cyberfugtive: Beleagured Stossel Takes Shelter Under Right Wing," *The Village Voice*, Sept. 20-26, 2000. More on Stossel's history of omissions and mischaracterizations in the service of a right-wing agenda can be found on the Fairness and Accuracy in Reporting Web site, the Environmental Working Group Web site, and TomPaine.common sense.

How valuable for the antiregulatory movement is Stossel? Stephen Moore, of the libertarian Cato Institute, says, "I think one John Stossel segment taking a skeptical look at government is worth a million dollars to the movement." See Ted Rose, "Laissez_faire TV: ABC's John Stossel is A Man on A Mission: To teach Americans About the Evils of Government Regulation and the Rewards of Free Enterprise," *Brill's Content*, Mar. 2000. After environmentalists protested the weakness of the ABC reprimand, the corporate Competitive Enterprise

Institute set up a Web site: *www.SaveJohnStossel.com*. And just to bring the issue full circle, what can Web surfers find behind a link on the site labeled "nomorescares.com"? A 74-page treatise on so-called "Fear Profiteers" written by Elizabeth Whelan, the Director of ACSH, and Steven Milloy, the former Executive Director of TASSC. The report purports to show that public interest groups such as Public Citizen "profit" from health and safety-related "scares." Stossel used to win Emmys for his coverage of consumer affairs. But in an interview with *Brill's Content*, Stossel pointed to a risk assessment chart behind his desk as his way of explaining his conversion from consumer reporter to regulation critic. See Ted Rose, "Laissez_faire TV: ABC's John Stossel is A Man on A Mission: To teach Americans About the Evils of Government Regulation and the Rewards of Free Enterprise," *Brill's Content*, Mar. 2000. His first show after that "conversion" was the hour-long special featuring Graham.
276. According to Fairness and Accuracy in Reporting, the other "public health experts" that consulted with Stossel were probably from the conservative Manhattan Institute, which had produced a book called "Health, Lifestyle and Environment: Countering the Panic." Peter Huber of the Manhattan Institute appeared on Stossel's late-evening follow-up show. Karl Grossman, "Victor Neufield's Anti-Environmental Spin Continues," *Extra! Update*, June 1994, <www.fair.org/extra/9406/neufield-stossel.html>.
277. ABC News Special, Transcript #346, April 21, 1994.
278. See Case, Andrea Golaine, "ACSH's Message Reaches Millions . . . .Anonymously," *Alt HealthWatch*, June 30, 1994.
279. ABC News Special, Transcript #346, April 21, 1994.
280. See list of Graham's affiliations at the end of Part One.
281. *Id.* (emphasis added)
282. "'Dateline' Story Riddled With Errors, Environmentalists Say," *Pesticide and Toxic Chemical News*, Oct. 2, 1996.
283. Id.
284. Id.
285. "Science Watchdog Group Celebrates Third Anniversary With Renewed Commitment to Exposing Use of Junk Science," *PR Newswire*, Dec. 3, 1996.
286. Elisa Ong writes: "From 1993 to 1994, PM and public relations firm APCO Associates worked to launch The Advancement of Sound Science Coalition (TASSC), a "grassroots" organisation advocating "sound science" in policy decision making." Elisa K. Ong, "Tobacco Industry's Efforts Subverting International Agency for Research on Cancer's Second-Hand Smoke Study," *The Lancet*, April 8, 2000.
287. See Ken Silverstein, Smoke and Mirrors, Public Citizen's Congress Watch 1996.
288. See The CALA Files: The Secret Campaign by Big Tobacco and Other Major Industries to Take Away Your Rights, Public Citizen and the Center for Justice & Democracy, July 26, 2000.
Ken Silverstein, Smoke and Mirrors, Public Citizen's Congress Watch 1996, at 3 ("APCO Associates [is] a Washington consulting firm which concocts "grassroots" support for its corporate clients, including several big tobacco firms and insurance companies.").
289. Id. (emphasis added).
290. Milloy and TASSC
291. "Science Watchdog Group Celebrates Third Anniversary With Renewed Commitment to Exposing Use of Junk Science," *PR Newswire*, Dec. 3, 1996.
292. Milloy does not stop there, however. His Web site, *www.junkscience.com*, still posts drippingly sarcastic ridicule about environmental, health and safety issues, and hocks such items as a poster entitled "*The Earth is Fine, Save Yourself*" as an educational tool which relieves "consumer fears." Other postings on the site argue that there are no demonstrated negative health effects from pesticides, second-hand smoke, global warming, the widespread use of antibiotics, cellular phones, beef growth hormones or dioxin, just to name a few. Milloy also contends that the U.S. ban on the pesticide DDT "kills," and in an echo of Stossel's program, puts down the health benefits of organic food. Sadly, Malloy's Web site at least claims that "Junkscience.com was the sixth most popular web site in the category "General Science" in January 2001, according to Top9.com. Junkscience.com had 168,000 unique visitors, ranking behind only NationalGeographic.com, Discover.com, SciAm.com (*Scientific American*), Sciencemag.org (the journal *Science*) and Lycaeum.com."
293. See "Panic Attack: ACSH Fears Nothing But Fear Itself: Fear not Facts," *PR Watch*, <www.prwatch.org/prwissues/1998Q4/panic.html>. The pamphlet can be downloaded from the ACSH Web site at <www.acsh.org/publications/reports/factsfears.html>.
294. Id. *PR Watch* also refutes the charges made in the pamphlet that DDT restrictions have triggered a worldwide growth in mosquito-borne malaria, responding to an argument made by Whelan in her book, *Toxic Terror*.
295. Jane Brody, "Health Scares That Weren't So Scary," *The New York Times*, Aug. 18, 1998.

296. Hilary Shenfield, "The Environment Often Seems Far More Hazardous to Your Health Than It Really Is," *Chicago Daily Herald*, Mar. 15, 1999.
297. See, e.g., J. Madeleine Nash, "Keeping Cool About Risk," *Time*, Sept. 19, 1994.
298. See conflicts chart at the end of Part One for two of these; see also Bonar Menninger, "Creating A Zero-Risk Environment," *Kansas City Business Journal*, Nov. 25, 1994 (mentioning Alar but not ACSH and quoting Graham as saying, "We go after minuscule risks, such as pesticide residue in food, and at the same we're tolerant and neglectful of major problems in daily life.")
299. J. Madeleine Nash, "Keeping Cool About Risk," *Time*, Sept. 19, 1994.
300. Adam Finkel, "Who's Really Crying Wolf?" *American Scientist*, Sept.-Oct. 1996.
301. Id.
302.. Peter De Groot, "Review," *New Scientist*, Jan. 6, 1996.
303. See <www.prwatch.org/prwissues/1998Q4/panic.html>. In fact, the main author of the report, Adam Lieberman, has since recanted and published an explanation of his indoctrination as a conservative ideologue in *Mother Jones*. Lieberman's name still appears on the ACSH Web site version of the report although with a parenthetical date that indicates his departure from the project. Id.
304. See, for example, the advertisement for a talk he gave in June 2000 to the Pacific Research Institute, on the Web at <www.pacificresearch.org/events/june00.html>.
305. See <www.hcra.harvard.edu>.
306: Dan Holtz, "Risk Analysis Aims to Help People," *CNN Health Works*, June 19, 1993.
307. Dolores Kong, "Scientists Warn Against Panic Over Electromagnetic Field Effect,"*The Boston Globe*, Nov. 13, 1992.
308. See John D. Graham, "Making Sense of Risk: An Agenda for Congress," in *Risks, Costs and Lives Saved*, (Robert W. Hahn, ed., Oxford University Press 1996).
309. David Lore, "Determining Toxic Risks is Costly Voodoo, Lawyer Says," *The Columbus Dispatch*, Nov. 24, 1995.
310. Graham frequently suggests that we not worry about a health risk potentially caused by a company which provides funding for his operation, and that we worry instead about a diffuse or controversial health problem which, studies have shown, the public views as a matter of personal responsibility.
311. See "Risk. Health and Environment. Facing Our Fears," *Consumer Reports*, Dec. 1996.
312. Id.
313. Mark Sagoff, The Economy of the Earth 46 (1988).
314. Id. (pointing out the factors of control over the risk and the voluntary assumption of the risk are important for risk perception).
315. Id: (Quoting Roger Kasperson, a researcher on risk perception from Clark University, discussing the fairness of risk distribution: "the public is saying that if you're benefiting from that activity, but I'm being exposed to the risk, have been told nothing about it, and have no recourse, I'm outraged that there's any risk at all.")
316. Patricia Braus, "Everyday Fears," *American Demographics*, Dec. 1994 (discussing risk perception findings that there is greater public outrage where hazards are involuntary or the result of profit-making ventures).
317. See "Risk. Health and Environment. Facing Our Fears," *Consumer Reports*, Dec. 1996.
318. Id. (discussing prevention of catastrophic risks.
319. Branden Johnson, "Advancing Understanding of Knowledge's Role in Lay Risk Perception," *Risk*, Summer, vol. 4 (2000), at 4.
320. In contrast, Graham's research efforts are sometimes directed at depicting the differences between lay and expert perceptions of risk as a justification for expert-directed risk analysis. See, e.g., "Surveys & Polls," *America Health Line*, Jan. 28, 1999; Richard Saltus, "Gender Called Factor in Scientists' View of Technological Perils," *The Boston Globe*, Feb. 8, 1999.
321. Some risk assessment specialists are very attentive to the importance of these and other aspects of risk perception, arguing that any government action must take meaningful account of these factors on both practical and moral grounds. Branden Johnson, "Advancing Understanding of Knowledge's.Role in Lay Risk Perception," *Risk*, Summer, vol. 4 (2000). In the face of this critical debate within his own field, Graham's repeatedly pejorative characterization of our public "fears" as irrational appears callous and not a little arrogant.
322. See <www.hcra.harvard.edu>.
323. Dolores Kong, "Scientists Warn Against Panic Over Electromagnetic Field Effect," *The Boston Globe*, Nov. 13, 1992.

324. Graham testified at hearings on regulatory rollback and risk assessment proposals Nov. 11, 1993, Feb. 15, 1995, Mar. 25, 1995. He also testified at a joint hearing on pesticides Sept. 21, 1993. Graham was mentioned in the floor debate on May 18, 1994, in the debate on the Department of Energy Risk Management Act of 1995 on Feb. 2, 1995, and on the Risk Assessment and Cost-Benefit Act of 1995 on Feb. 27 and 28, 1995.
325. Graham testified at hearings on regulatory rollback and risk assessment proposals Nov. 11, 1993, Feb. 15, 1995, Mar. 25, 1995.
326. H.R. 965, as signed into law, provides funds for the National Highway Traffic Safety Administration to make grants that encourage the use of bicycle helmets by children, and authorizes the Consumer Product Safety Commission to set standards for helmets.
327. J. Madeleine Nash, "Keeping Cool About Risk," *Time*, Sept. 19, 1994.
328. Thomas O. McGarity, "A Cost-Benefit State" 50 Ad. L. Rev. 1 (1998).
329. "Consumer Product Safety Commission— Better Data Needed to Help Identify and Analyze Potential Hazards," *General Accounting Office*, Sept. 19, 1997, GAO/HEHA-97-147.
330. Id. at 29.
331. See <www.atsdr.cdc.gov/tfacts53.html>. The Agency for Toxic Substances and Disease Registry.
332. Exposure occurs when people breath residential and indoor air contaminated with styrene vapors from building materials, use consumer products with styrene, are exposed to tobacco smoke; drink contaminated water; live near industrial facilities or hazardous waste sites; smoke cigarettes or eat a lot of food packaged in polystyrene containers. www.atsdr.cdc.gov/tfacts53.html. The Agency for Toxic Substances and Disease Registry.
333. Id. When animals breathed styrene vapors in short-term studies, they damaged the lining of their noses. Long-term exposure damaged their livers.
334. Styrene is also known as vinylbenzene, ethenylbenzene, cinnamene, or phenylethylene. It's a colorless liquid that evaporates easily. <www.atsdr.cdc.gov/tfacts53.html.> The Agency for Toxic Substances and Disease. Registry, Department of Health and Human Services. The Environmental Protection Agency (EPA) set a maximum limit of 0.1 part of styrene per million parts of water (0.1 ppm) for drinking water. The EPA requires that all spills or accidental releases into the environment of 1,000 pounds or more of styrene be reported. The Occupational Health and Safety Administration (OSHA) has limited workers' exposure to an average of 100 ppm for an 8-hour workday, 40-hour work week.
335. See <www.dow.com/environment/debate/d8.html> (emphasis added). A search of the HCRA Web site did not turn up a copy of the Dow styrene study.
336. Elisa K. Ong, "Tobacco Industry's Efforts Subverting International Agency for Research on Cancer's Second-Hand Smoke Study," *The Lancet*, April 8, 2000.
337. Id. According to Ong, TASSC and its European counterpart, also established by APCO, issued joint press releases and published at least one opinion piece in the European Wall Street Journal calling the health risk from the anticipated EST study "trivial or nonexistent." Graham was on the Advisory Board of TASSC, according to a 1996 news report entitled "Science Watchdog Group Celebrates Third Anniversary With Renewed Commitment to Exposing Use of Junk Science," *PR Newswire*, Dec. 3, 1996.
338. Rick Weiss & Gary Lee, "Pollution's Effect on Human Hormones," *The Washington Post*, Mar. 31, 1996.
339. Id. (emphasis added).
340. Id. (emphasis added).
341. "Science Watchdog Group Celebrates Third Anniversary With Renewed Commitment to Exposing Use of Junk Science," *PR Newswire*, Dec. 3, 1996.
342. Id.
343. See <www.junkscience.com/jan00/osf.htm>.
344. See the ACSH Web site for a copy of the "Fact, not Fear report."
345. Karen Rothmeyer, "Citizen Scaife," *Columbia Journalism Review*, (July/August, 1981): at 48-50.
346. Trip Report by Mayada Logue of Philip Morris, June 1, 1992, Bates no. 2025523685.
347. Mike Musgrove, "Cancer-Risk Study Clears Cell Phones," *The Washington Post*, Feb. 7, 2001 (quoting George Carlo).
348. Elisa Ong described PM's coordinated attack upon the largest European study of the relationship between second-hand smoke and lung cancer rates in non-smokers. The study was funded by a branch of the World Health Organization and results showed a 16 percent increase from ETS in estimated risk in lung cancer for nonsmokers. Nonetheless, as Ong documents, due in part to the efforts of PM, these results were obfuscated— and the study was widely misreported as *not* having demonstrated any increased cancer risk. Elisa K. Ong, "Tobacco Industry's Efforts Subverting International Agency for Research on Cancer's Second-Hand Smoke Study," *The Lancet*, April 8, 2000.

349. According to Ong, TASSC and its European counterpart, also established by APCO, issued joint press releases and published at least one opinion piece in the European *Wall Street Journal* calling the health risk from the anticipated EST study "trivial or nonexistent." Id. Graham was on the Advisory Board of TASSC, according to a 1996 news report entitled "Science Watchdog Group Celebrates Third Anniversary With Renewed Commitment to Exposing Use of Junk Science," *PR Newswire*, Dec. 3, 1996. According to previous Public Citizen reports on APCO, the organization was registered as a lobbyist for Philip Morris until 1993. See Ken Silverstein, *Smoke and Mirrors*, Public Citizen's Congress Watch 1996, at 3 ("APCO & Associates [is] a Washington consulting firm which concocts "grassroots" support for its corporate clients, including several big tobacco firms and insurance companies.").
350. Mike Musgrove, "Cancer-Risk Study Clears Cell Phones," *The Washington Post*, Feb. 7, 2001.
351. Id.
352. See Case Study #2.
353. Mike Musgrove, "Cancer-Risk Study Clears Cell Phones," *The Washington Post*, Feb. 7, 2001 (emphasis added).
354. Used with permission from Consumers Union.
355. Used with permission from the Natural Resources Defense Council.
356. Dioxin is produced during incineration, the manufacturing of paper, metal smelting and refining, the manufacturing of chlorinated chemicals including pesticides, herbicides and polyvinyl chloride plastic, petroleum refining and industrial and utility oil and coal combustion.
357. According to the National Institutes for Health Web site, TCDD stands for "TETRACHLORODIBENZO-*p*-DIOXIN." See <ntp-server.niehs.nih.gov/htdocs/8_RoC/RAC/TCDD.html>. The center for Health and Environmental Justice Web site at www.chej.org/policy.html: Dioxin belongs to a family of chemicals with related properties and toxicity. There are 75 different dioxins, or polychlorinated dibenzodioxins (PCDDs), 135 different furans, or polychlorinated dibenzofurans (PCDFs), and 209 different polychlorinated biphenyls (PCBs). Each different form is called a "congener." Not all of the "dioxin-like" chemicals have dioxin-like toxicity, and the toxic ones are not equally toxic. Only 7 of the 75 dioxins, 10 of the 135 furans, and 12 of the 209 PCBs have dioxin-like toxicity. These 29 different dioxins, furans, and PCBs all exhibit similar toxic effects caused by a common mechanism: binding to a particular molecule known as the aryl hydrocarbon or "Ah" receptor (see Chapter 5 of the TSD). It is believed that the tighter the binding to the Ah receptor, the more toxic the chemical. The most potent member of this family is 2,3,7,8-tetrachlorodibenzo-p-dioxin or TCDD, which also has the greatest affinity for the Ah receptor. The word "dioxin" is often used imprecisely. Some people restrict its use only to 2,3,7,8-TCDD, the most toxic and most studied dioxin. Others extend its use to the whole class of chemicals with similar toxicity and whose effects are controlled or triggered by the Ah receptor. In this report, the terms "dioxin" and "dioxins" are used to refer to any of the dioxin family members that bind to the Ah receptor and elicit dioxin like effects.
358. US EPA, SCIENCE ADVISORY BOARD DIOXIN REASSESSMENT SUBCOMMITTEE OF THE EXECUTIVE COMMITTEE, Nov. 1-2, 2000 at 512.
359. When Graham was asked at an SAB meeting about his potential conflicts of interest in regard to this dioxin issue, according to conversations with attendees at the SAB meeting, he responded that there was no conflict of interest between his funding and his independence as an SAB consultant. He emphasized that he does not personally receive money from dioxin emitting companies. Instead, the funding from those companies goes to his Center. *See* list of dioxin emitting funders of HCRA in the conflicts graph at the end of Part One.
360. US EPA, SCIENCE ADVISORY BOARD DIOXIN REASSESSMENT SUBCOMMITTEE OF THE EXECUTIVE COMMITTEE, Nov. 1-2, 2000 at 618 (emphasis added).
361. Ellen K. Silbergeld, "The Risks of Comparing Risks," N.Y.U. Environ. Law. J. 3 (1994).
362. Dorothy Patton, "The ABCs of Risk Assessment," *EPA Journal*, Jan/Feb/Mar 1993.
363. Id.
364. Id.
365. Id.
366. Id.
367. Id. (distinguishing risk assessment from sciences like biology and chemistry).
368. Carnegie Commission on Science, Technology and Government, *Risk and the Environment: Improving Regulatory Decision Making* (1993) at 206.
369. Thomas O. McGarity, "A Cost-Benefit State" 50 Ad. L. Rev. 1 (1998).
370. Carnegie Commission on Science, Technology and Government, *Risk and the Environment: Improving Regulatory Decision Making* (1993), at 83.

ISSUES IN SCIENCE AND TECHNOLOGY

National Academy of Sciences
National Academy of Engineering

The Cecil and Ida Green Center for the Study of Science and Society at The University of Texas at Dallas

Reprinted from ISSUES IN SCIENCE AND TECHNOLOGY, Volume XVII, Number 2 © 2001 The University of Texas at Dallas

JOHN D. GRAHAM

# Civilizing the Sport Utility Vehicle

*We can reduce the health, safety, and environmental risks of light trucks without decreasing their advantages for consumers.*

Now that the media craze about the Firestone-Ford tire and sport utility vehicle (SUV) controversy is winding down, it's time to take a broader and more patient look at the impact that the growing popularity of SUVs and other light trucks is having in the United States. The good news is that the U.S. consumer has found that light trucks, particularly the SUV, offer an unprecedented combination of size, comfort, and versatility. The same vehicle can be used to go to and from work, fulfill carpooling responsibilities, haul cargo or tow boats on recreational trips, and take older children to and from college. The bad news is that sales of light trucks, which also include passenger vans and pickup trucks, have increased so rapidly that regulators and vehicle manufacturers have not devoted adequate attention to the consequences for safety and environmental objectives. Before discussing solutions, two rather extreme positions on this issue must be dismissed.

One extreme view is that vehicle manufacturers should be permitted to sell whatever product consumers want to buy, without any consideration of the consequences for environmental protection or occupant safety. This position ignores the reality of health, safety, and environmental risks that are not controlled effectively in free markets. Agencies such as the Environmental Protection Agency and the National Highway Transportation Safety Administration (NHTSA) are in business precisely because the public demands greater protection against risk than is typically provided by market transactions.

Another extreme position is that the U.S. government should prohibit, restrict, or discourage light truck sales in an effort to revitalize consumer demand for small passenger cars. Citing the European consumer's continued interest in small passenger cars, advocates of this position argue that there is something perverse about the American consumer's interest in the SUV. But this position ignores the fact that European governments tax both vehicles and gasoline (up to $4 per gallon) for revenue-generating purposes, that geography and patterns of urban development in the United States are more suited to a transport system based on private vehicles that travel both short and long distances, that U.S. households are larger than European households, and that the typical American consumer can better afford expensive light trucks because of superior U.S. economic perfor-

John D. Graham (jgraham@hsph.harvard.edu) is director of the Harvard Center for Risk Analysis.

mance. Interestingly, a small but growing number of affluent European consumers are also buying SUVs, even though many urban European streets are typically much narrower than U.S. streets.

What is needed in the United States is a concerted multiyear effort by regulators and vehicle manufacturers to "civilize" light trucks. By civilize I mean that we need to reduce the adverse societal consequences of this class of vehicles without significantly reducing their utility to consumers. Some of this progress can be accomplished by voluntary cooperative efforts, some can be induced by creative use of incentive mechanisms, and some will require old-style command-and-control regulation. Success will require a mix of near-term and long-term policies, including a variety of targeted research programs. There are already models of success in this arena that can be built on in the years ahead.

## Reducing rollover crashes

Light trucks improve safety in a variety of ways. Their extra size and mass offer greater protection to their occupants in single-vehicle crashes into fixed objects, in collisions with heavy trucks, and in collisions with other passenger vehicles. There are 20 percent fewer deaths when two SUVs collide than when two cars collide. There are, however, three important safety concerns about light trucks that have not been adequately addressed.

One concern, highlighted by the Firestone-Ford controversy, in which tire tread separation appears to have contributed to perhaps 100 fatal crashes, is the single-vehicle rollover crash. This type of crash deserves special consideration because it is more likely than other crash types to result in a fatality or serious injury to occupants. Rollovers account for 15 percent of the fatal crashes involving cars, 20 percent for vans, 25 percent for pickups, and 36 percent for SUVs. These percentages reflect both the extra safety provided by SUVs to occupants in nonrollover crashes as well as the greater tendency of SUVs to roll over. They also reflect the behaviors of the drivers of these different vehicle types.

Historically, there has been an inverse relationship between vehicle size and rollover probability. This pattern exists among passenger cars and among many light trucks, suggesting that consumers who purchase larger vehicles are lowering their risk of being involved in a rollover crash. Yet recent data suggest that some (though not all) SUVs and pickup trucks, including some of the larger ones, have an unexpectedly high rollover probability. A concerted research program is needed to determine the causes and solutions of the rollover problem in SUVs and pickup trucks. The Firestone controversy notwithstanding, tires do not appear to be the cause of most rollovers.

In recent legislation spurred by the Firestone-Ford fiasco, Congress gave NHTSA two years to develop and implement a new experimental rollover test that could be applied to new vehicles and used as a scientific basis for consumer information programs. The test would be dynamic in the sense that moving vehicles would be experimentally monitored in specified tests to determine their propensity to roll over. In favoring this dynamic testing, Congress expressed a lack of confidence in an alternative "static" system that simply compares vehicles based on the ratio of a vehicle's width to the height of its center of gravity. It will take more than two years for NHTSA to develop this test and validate it with real-world crash data, providing a science-based rating system to inform consumers about rollover risk.

In the long run, it may be appropriate for NHTSA to go beyond consumer information and develop a mandatory motor vehicle safety standard to reduce rollovers. Although engineering of vehicles, tires, and roads is important in rollovers, Congress has not done enough to encourage NHTSA to initiate an aggressive informational campaign to highlight the dominant role of driver behavior (inebriation, excessive speed and/or acceleration, and inattentiveness) in the causation of rollover as well as other crashes.

## Curbing "aggressivity"

A second, more complex safety concern involves the "aggressivity" of light trucks in two-vehicle crashes. This term refers to the vehicle's size, weight, shape, and construction characteristics. Analyses of the ratio of driver deaths in one vehicle to driver deaths in its collision partner are revealing: In head-on crashes involving full-sized vans and cars, six drivers die in cars for every driver who dies in the vans. When cars are struck in the side by light trucks, these "aggressivity" ratios are very bad for occupants of cars. Although light trucks as a whole account for only about one-third of the passenger vehicles on the road, they

are involved in crashes that account for about 60 percent of the occupant fatalities arising from two-vehicle fatal crashes.

When a light truck and a car collide, the occupants of the car suffer a disproportionate share of the injuries for at least three reasons. First, the average light truck is about 900 pounds heavier than the average passenger car. Second, light trucks tend to be designed with more stiffness than passenger cars (for example, the frame-rail designs of many light trucks are not as flexible as the unibody design usually used for cars). Finally, the geometry of many SUVs, aimed in part at providing a higher ride for SUV drivers, creates a mismatch in the structural load paths in head-on crashes and causes an SUV to override car door sills in side impacts. The location of the bumpers is not always the most important feature, because bumpers are largely ornamental in the light truck fleet and do not always play a major role in occupant protection. Research is needed to define the most important load-bearing members in the structures of different vehicles and devise standards to make sure that when vehicles collide, these load-bearing members in different vehicles will engage each other.

*Congress and state legislatures should pass tax credits or other incentives that encourage consumers to purchase vehicles with innovative engines and fuels.*

Although there are no quick fixes to the aggressivity problem, several observations can be made. It appears that adding vehicle mass and structure to small cars would do more for fleet-wide safety than would making light trucks smaller or lighter. Beefing up small cars is favored by safety experts in the insurance industry, even though there will be fuel economy compromises. Side-impact airbags, particularly those that offer head as well as lower-body protection, can also make a useful contribution to crash compatibility. In addition, vehicle manufacturers are already making changes to the geometry and structure of light trucks to improve the compatibility of these vehicles in collisions with cars, without reducing the consumer utility of SUVs. Finally, there also needs to be an inquiry into why station wagons have become virtually extinct. Station wagons can meet many of the needs of large families without the safety risks of SUVs. The lack of market interest in station wagons may be rooted in a regulatory perversity: Fuel economy regulators classify wagons as cars, not as light trucks. If vehicle manufacturers were instead permitted to count wagons as light trucks, they could simultaneously improve their fleet-wide fuel economy ratings for cars and light trucks. Automakers would then have an incentive to promote wagons more aggressively.

There is no way to eliminate the adverse safety effects of mismatches of vehicle masses, a problem that arises from basic laws of physics. Potential consumers of small cars, who now represent a small and declining share of new vehicle purchasers, need to be informed about the adverse safety implications of their choices. Providing this information to consumers will require a major change in the current safety ratings of new vehicles published by NHTSA and consumer groups. Currently, a vehicle's mass plays no role in the safety rating systems for new vehicles. The experimental crash tests used to inform safety ratings are often conducted with vehicles striking a fixed barrier that is immovable and impenetrable. This kind of fixed-barrier test downplays the safety advantages of larger vehicles, since even roadside objects struck by cars (guardrails, bushes, and trees) are somewhat penetrable or moveable. In rating vehicles on the basis of frontal crash tests, NHTSA says that because the test reflects a crash between two identical vehicles, only vehicles from the same weight class can be compared when examining frontal crash protection ratings.

## Vision clearance

A third concern often voiced by motorists is that large SUVs make it impossible for drivers in smaller vehicles to see the traffic ahead of them or to see the traffic flow when a driver is pulling out of a side street onto a major thruway. There is also concern that some large SUVs are excessively wide for some passenger lanes, increasing the probability of colli-

sions with other vehicles, cyclists, and pedestrians. Although the rapid growth in light truck sales has not been associated with an overall increase in collisions or traffic deaths in the United States, there is need for a concerted national research program to determine whether particular types of crashes have become more frequent or injurious because of the presence of light trucks. Indeed, Congress needs to make a much larger overall investment in light truck safety research. The Health Effects Institute, an industry-government partnership for environmental-health research that involves university-based researchers, provides a useful model for progress in the science and engineering of light truck safety.

Another promising process for developing voluntary safety standards was recently used to address concerns about the safety of side-impact airbags. Led by the Insurance Institute for Highway Safety, engineers from competing manufacturers and suppliers, with NHTSA specialists participating, informally developed a workable uniform standard to ensure the safety of side-impact airbags. If this voluntary standard works, it may prove to be a more expeditious model for solving future safety problems than the adversarial command-and-control process and could be applied to dealing with SUV safety concerns. The "stick" of a mandatory standard, however, needs to be there to stimulate the process.

## Greener SUVs

The rapid growth in light truck sales is disturbing to environmental scientists, who are increasingly confident that carbon dioxide emissions from vehicles and other sources are contributing to global climate change. The transportation sector accounts for about 25 percent of U.S. carbon dioxide emissions, and the passenger vehicle contribution is predicted to grow rapidly in the years ahead, without policy reforms.

Compliance with the Kyoto Treaty on climate change would require U.S. carbon emissions to be reduced below 1990 levels. Given the rapid rate of U.S. economic growth in the 1990s and its dependence on fossil fuels, this is not economically realistic. New energy technologies on the production and conservation sides have been proposed and would help meet the Kyoto reduction schedule, but these technologies are unproven, their cost is not currently competitive, and their adoption is uncertain. Compliance with the Kyoto accord is also politically unrealistic on a global scale, unless rapidly developing countries such as China and India become meaningful participants. Still, U.S. policymakers can and should take modest steps to slow the rate of growth of carbon dioxide emissions and contribute to worldwide efforts to slow the rate of global climate change.

The amount of carbon dioxide emitted by a vehicle is directly related to the amount of gasoline used, because emission control systems that are effective in reducing smog and soot do not reduce carbon dioxide emissions. Light trucks are typically less fuel efficient than passenger cars. In addition, NHTSA's current fuel economy standards are set at 27.5 miles per gallon (mpg) for passenger cars and 20.7 mpg for light trucks. Taking both cars and light trucks into account, the average fuel economy of the U.S. new passenger vehicle fleet has actually declined in recent years to 23.8 mpg, the lowest national value since 1980; a trend that reflects rising consumer incomes, declining real gasoline prices (until very recently), and growing consumer interest in light trucks.

Some energy conservation advocates favor tighter fuel economy standards for all passenger vehicles, especially for light trucks. They argue that vehicle manufacturers are simply refusing to implement known cost-saving technologies that will save fuel. Yet history suggests that tighter fuel economy standards, allowing manufacturers freedom to decide how to comply, lead to smaller and lighter vehicles, with adverse consequences for both personal and fleetwide safety. The key flaw in current fuel economy rules is that they give the same credit to all measures that save an equal amount of fuel, even those measures that reduce safety. They also discourage vehicle manufacturers from implementing new safety technologies (such as additional structural support and side-impact airbags) that increase vehicle weight and thereby reduce fuel efficiency.

Many economists recommend higher taxes on gasoline, though perhaps not as high as the taxes in Europe. The idea of using economics to induce consumer interest in fuel economy is a good one that has some support. But it runs into stiff objections on grounds of fairness from people living in regions where long-distance travel is a necessary part of life. Good economics is not necessarily fair or feasible in

the eyes of citizens and their elected officials from western states. Increased taxes on gasoline could also have negative consequences for the tourism industry, which is vital in many parts of the country. Currently, there is greater popular support for a reduction in the gasoline tax than for an increase in the tax.

A better idea is for Congress and state legislatures to pass tax credits or other incentives that encourage consumers to purchase vehicles with innovative engines and fuels. During the past decade, significant progress has been made in the engines/fuels arena through a cooperative industry-government research program. In order to offset the initial cost of innovative engines/fuels, consumer incentive programs should be expanded to include hybrid vehicles that combine electric propulsion with a small gasoline or diesel engine, or advanced diesel engines coupled with use of ultralow-sulfur fuels. A consumer tax credit program in Arizona was designed to encourage purchases of vehicles that run on clean fuels. Although this program has many technical and fiscal problems, it does demonstrate that new car buyers can be influenced by tax credits.

Toyota and Honda have recently introduced hybrid cars for sale in the United States that can travel more than twice the distance on a gallon of fuel as the typical car. General Motors projects that it will be offering hybrids by 2003. The same technology can be used in light trucks. Ford has announced plans to introduce in 2003 an SUV using hybrid technology that can achieve 40 miles per gallon instead of the 23 miles per gallon achieved by the basic four-cylinder version of the Ford Escape SUV. DaimlerChrylser also has a hybrid version of its Durango SUV under development. Toyota recently announced that it is planning to offer a full range of hybrid gasoline-electric vehicles, from tiny compacts to commercial trucks. For the truck market, Toyota is planning to introduce a diesel-electric hybrid.

Opposition to the diesel engine in the United States is spirited, often based on concerns that these engines contribute to smog and soot, pollutants that have been linked with cardiopulmonary problems and cancer. Yet the diesel engine can be much cleaner if used in conjunction with the low-sulfur fuels already in widespread use throughout Europe. Advanced diesel engine pollution control technology also promises sharp reductions in emissions of nitrogen oxides and particles, the precursors of smog and soot in the air. European environmental authorities are promoting the advanced diesel engine through tax and regulatory policies because the advanced diesel is 20 to 40 percent more fuel efficient than gasoline-powered engines, thus promising fuel cost savings as well as contributions to Europe's carbon-control commitments under the Kyoto Treaty. Audi is currently advertising one of its diesel-powered sedans in Europe with the claim that is environmentally superior. Policymakers in the United States, in California as well as in Washington, D.C., need to take a serious second look at the future of the advanced diesel engine in combination with low-sulfur fuel.

The virtue of these innovations in engines/fuels is that they can achieve large gains in fuel economy without reducing the size, mass, or safety of vehicles. Light trucks and cars with these new engines will cost more to build (at least in the short run because of low production volumes), but consumer tax credits can be used to minimize their cost disadvantage in the marketplace.

The concept of using consumer tax credits for motor vehicle policy already has significant national political support. For example, a clean fuels bill introduced by Sens. James Jeffords (R-Vt.) and Orrin Hatch (R-Utah) has attracted significant Democratic cosponsorship. The bill could readily be expanded to include credits for vehicles with hybrid engines or advanced diesels. Thus, there are grounds for believing that the incentive approach could generate bipartisan support.

## Collaboration, not combat

The explosion of consumer interest in light trucks is not simply a passing fad engendered by clever advertising campaigns from Detroit and Japan. It reflects the U.S. consumer's desire for a large, comfortable passenger vehicle that can be used for a variety of purposes in daily life. Yet there are safety and environmental concerns about light trucks that have not been addressed adequately by regulators and vehicle manufacturers.

The federal government needs to set in motion a multiyear program of research, incentives, voluntary standards, and mandatory regulations aimed at managing the health, safety, and environmental risks of light trucks. The issues involved are technologically

complex, involve tradeoffs between multiple social objectives, and will create complicated political problems for elected officials. Progress will not occur in a year or two, and policymakers and engineers will need to be persistent. Indeed, a successful program will require effective collaboration among federal agencies, state officials, nonprofit groups, and a variety of private-sector groups, as well as normally competing political interests. Such a program also needs to set clear ground rules to avoid uneven results because of competition among motor vehicle manufacturers, fuel companies, and related industries. Because several recent cooperative efforts have achieved important progress, there is reason for hope that our current slow-moving, adversarial process of regulation can be replaced by a fast-moving, incentive-based process that harnesses the scientific and competitive talents of the private sector.

*International Brotherhood of*

**BOILERMAKERS · IRON SHIP BUILDERS**

**BLACKSMITHS · FORGERS & HELPERS**

ANDE ABBOTT
ASSISTANT TO THE INTERNATIONAL PRESIDENT
DIRECTOR OF LEGISLATION
DIRECTOR OF SHIPBUILDING & MARINE DIVISION

2722 MERRILEE DRIVE, SUITE 360
FAIRFAX, VA 22031-2240
(703) 560-2584 FAX
(703) 560-1493

01 MAY -2 PM 7:03

May 2, 2001

The Honorable Fred Thompson
U.S. Senate Committee on Governmental Affairs
340 Dirksen Senate Office Building
Washington DC 20510-6250

Dear Senator Thompson:

On behalf of the men and women of the International Brotherhood of Boilermakers, Iron Ship Builders, Blacksmiths, Forgers and Helpers, AFL-CIO, I am writing to express our support for the confirmation of John D. Graham as Director of the Office of Information and Regulatory Affairs at the Office of Management and Budget. The Boilermakers are a diverse union representing over 100,000 workers throughout the United States and Canada in construction, repair, maintenance, manufacturing, professional emergency medical services, and related industries. With its headquarters in Kansas City, Kansas, the International Brotherhood of Boilermakers unites 420 local lodges throughout North America, providing numerous services for local lodges and individual members and uniting all our members in our common endeavor to improve the lives and lifestyles of our members.

Dr. Graham is the Director of the Center for Risk Analysis at Harvard's School of Public Health. Boilermakers share Graham's belief that the role of government in achieving environmental, health and safety objectives is too vital to proceed without sufficient understanding. Boilermakers build, operate and maintain industrial boilers, the workhorses of American industry. At the same time, we build, operate and maintain air pollution control devices and fuel substitution programs. In short, we recognize that federal regulatory policy must strike a balance to protect the natural environment *and* to protect a competitive environment for American workers. Dr. Graham's work, when viewed in context, seeks to maximize the benefit of government regulation by understanding and controlling for tradeoffs.

Boilermakers believe that Dr. Graham's articulate support for reasonable approaches to regulatory policy has been mischaracterized by some in the public interest community. We wish to be clear: Boilermakers do not oppose government regulation. Rather, we believe the national welfare of the United States is better enhanced when regulations are thoughtful and fair. Therefore, we are pleased to support Dr. Graham's confirmation as Director of OIRA.

Very truly yours,

Ande Abbott

Ande Abbott, Director of Legislation
International Brotherhood of Boilermakers

NATURAL RESOURCES DEFENSE COUNCIL

15 May 2001

The Honorable Fred Thompson
The Honorable Joseph Lieberman
Senate Governmental Affairs Committee

Dear Chairman Thompson and Senator Lieberman,

I am writing on behalf of the over 450,000 members of the Natural Resources Defense Council to make clear our strong opposition to the nomination of Dr. John D. Graham to direct the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget. We encourage you to very carefully consider his consistent anti-regulatory record and controversial risk management methodology during your confirmation proceedings.

The Administrator of OIRA plays an extremely powerful role in establishing regulatory safeguards for every agency of our government. This position requires a fair and even-handed judge of the implications of regulatory policies. Upon close review, we believe that you will agree that John Graham's record makes him an unsuitable choice for this important position.

Dr. Graham possesses a decision-making framework that does not allow for policies that protect public health and the environment. He has consistently applied controversial methodology based on extreme and disputable assumptions without full consideration of benefits to public health and the environment. Graham's record puts him squarely in opposition to some of the most important environmental and health achievements of the last two decades. His record of discounting the risks of well-documented pollutants raises questions about his ability to objectively review all regulatory decisions from federal agencies.

Complicating matters further, John Graham and his colleagues at the Harvard Center for Risk Analysis have been handsomely rewarded by industry funders who oppose regulations protective of public health and the environment and have directly benefited from Dr. Graham's work. These relationships form a disturbing pattern that makes it very difficult to imagine how Dr. Graham could effectively run this office free of conflicts of interests and with the public view in mind.

Dr. Graham's inherently biased record clearly demonstrates that he is not an objective analyst of regulatory policies and would not be a proper choice for this position. We therefore strongly urge you to oppose the nomination of Dr. Graham to be the Administrator of OIRA.

Sincerely,

John Adams
President

www.nrdc.org
1200 New York Avenue, NW, Suite 400
Washington, DC 20005
TEL 202 289-6868 FAX 202 289-1060
NEW YORK · LOS ANGELES · SAN FRANCISCO

100% Postconsumer Recycled Paper

**Citizens for Sensible Safeguards**

1742 Connecticut Ave, NW
Washington, DC 20009-1171

Tel: 202-234-8494
Fax: 202-234-8584

regs@ombwatch.org

May 15, 2001

The Honorable Fred Thompson
Chairman
Committee on Governmental Affairs
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

As chairman of Citizens for Sensible Safeguards – a broad-based coalition of more than 200 public interest organizations – I am writing to express our outrage that you have refused to allow witnesses at John Graham's confirmation hearing, despite receiving a number of requests from interested parties wishing to express their views.

Dr. Graham's nomination is opposed by environmental organizations, labor unions, public health and consumer groups, as well as a host of academics, including 11 from Harvard Medical School and the Harvard School of Public Health (where Dr. Graham's Center for Risk Analysis resides). The Committee and the public deserve to hear why.

Some very serious questions have been raised about Dr. Graham and his analytical methods. For example:

- Dr. Graham's Center is heavily funded by a vast array of corporate interests, which he has routinely helped in holding off new regulation. As administrator of OMB's Office of Information and Regulatory Affairs (OIRA), Dr. Graham will be in the position to reject regulations affecting these former benefactors. How will this potential conflict of interest affect his ability to be an objective and fair evaluator of agency rulemakings?

- In advocating regulatory reforms, Dr. Graham has testified before the Committee that we could save 60,000 additional lives at no additional cost if we shift resources from wasteful programs to cost-effective programs. This study, however, is mostly based on "regulations" that were never actually implemented – as pointed out in a recent critique by Lisa Heinzerling, professor at Georgetown Law Center – and thus tells us virtually nothing about our real-world system. Yet Senators clearly understood Dr. Graham to mean existing regulatory programs. Did Dr. Graham mislead the Committee, as well as the public, to promote his views on regulatory reform?

- Dr. Graham has used questionable analytical practices in critiquing government regulation, which he will be in position to implement as OIRA administrator. These practices have had the inevitable effect of deflating benefits relative to costs. The Committee needs to better understand what underlies this analysis. Are Dr. Graham's analytical assumptions inappropriately slanted to make most regulation appear cost-ineffective?

Unfortunately, without witnesses, these questions cannot be examined fully. During Sen. Roth's

tenure as chairman of this Committee, he allowed witnesses to testify on a number of controversial nominees (perhaps most notably James Miller, President Reagan's nominee to head the Office of Management and Budget). This approach allows for an open, public exchange of ideas in which members are able to probe various experts and arrive at a considered judgment.

OIRA is an extremely powerful office, with the responsibility to approve or reject agency rules. The administrator should have the credibility and objectivity to make crucial decisions regarding health, safety, and environmental protections. Accordingly, this Committee should take the time to carefully examine whether Dr. Graham is the right person for the job. By denying witnesses, you have denied such a thorough examination.

Sincerely,

Gary D. Bass
Executive Director
OMB Watch

OMB WATCH
1742 CONNECTICUT AVENUE, NORTHWEST
WASHINGTON, D.C. 20009-1171
TELEPHONE: (202) 234-8494/FAX: (202) 234-8584
e-mail: ombwatch@ombwatch.org
URL: http://www.ombwatch.org/ombwatch.html

May 16, 2001

The Honorable Joseph Lieberman
Ranking Member
Committee on Governmental Affairs
United States Senate
Washington, D.C. 20510

Dear Senator Lieberman:

We are writing to express our opposition to President Bush's nominee to head OMB's Office of Information and Regulatory Affairs, John Graham. We believe Dr. Graham's track record raises serious concerns that warrant the Committee's careful consideration. In particular:

- As director of the Harvard Center for Risk Analysis, which is heavily funded by corporate money, Dr. Graham has been a consistent and reliable ally of almost any industry seeking to hold off new regulation. As OIRA administrator, Dr. Graham will sit in ultimate judgment over regulation affecting his former allies and benefactors. This gives us great concern that OIRA will take a much more activist role in the rulemaking process, reminiscent of the 1980s when the office came under heavy criticism from Congress for continually thwarting crucial health, safety, and environmental protections. At a minimum, this raises serious concerns about his independence, objectivity, and neutrality in reviewing agency rules.

- In critiquing federal regulation, Dr. Graham has employed questionable analytical methods that have the inevitable effect of deflating benefits relative to costs. For example, he's downplayed the health risks of diesel engines, as well as second-hand smoke, and argued against a ban on highly toxic pesticides (all after receiving funds from affected industries). As administrator of OIRA, Dr. Graham will be in position to implement these analytical methods, which would not bode well for health, safety, and environmental protections.

- In pushing his case for regulatory reform, Dr. Graham has often invoked a study he conducted with one of his doctoral students. "[B]ased on a sample of 200 programs, by shifting resources from wasteful programs to cost-effective programs, we could save 60,000 more lives per year in this country at no additional cost to the public sector or the private sector," Dr. Graham told the Committee on Sept. 12, 1997. Senators clearly took this to mean existing regulatory programs. Yet in fact, most of the 200 "programs" were never actually implemented, as Lisa Heinzerling, a professor at Georgetown Law Center has recently pointed out. This includes 79 of the 90 environmental "regulations," which, not surprisingly, were scored as outrageously expensive. Despite repeated misrepresentations of his study by the press and members of Congress, Dr. Graham has never bothered to correct the record. In fact, he has perpetuated the myth by continually using the study to criticize our real-world regulatory system.

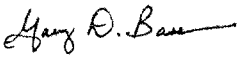
- Dr. Graham has taken the view that cost-benefit analysis should be the determinative criteria in deciding whether a rule goes forward. This position is frequently at odds

with congressional mandates that place public health considerations as the preeminent factor in rulemaking deliberations. This past summer, for instance, Dr. Graham was part of an amicus brief filed before the Supreme Court that argued EPA should consider costs in devising clean air standards (currently costs are considered during implementation), which the Court unanimously rejected. We are concerned that as regulatory gatekeeper, Dr. Graham would elevate the role of cost-benefit analysis in ways Congress never intended.

- Dr. Graham has little to no experience with information issues, which have taken on even greater importance with the advent of the Internet. OIRA was created in 1980 by the Paperwork Reduction Act, which gives the office chief responsibility for overseeing information collection, management, and dissemination. We fear that information policy will suffer with Dr. Graham at the helm, and that he is more likely to focus on regulatory matters – his natural area of interest and expertise. Ironically, Congress has never asked OIRA to review agency regulations. This power flows from presidential executive order.

Dr. Graham's track record does not demonstrate the sort of objectivity and dispassionate analysis that we should expect from the next OIRA administrator. Indeed, he has demonstrated a consistent hostility to health, safety, and environmental protection – once telling the Heritage Foundation that "[e]nvironmental regulation should be depicted as an incredible intervention in the operation of society." Dr. Graham's nomination threatens to bring back the days when OIRA acted as a black hole for crucial public protections. Accordingly, this nomination deserves very careful scrutiny and should be opposed.

Sincerely,



Gary D. Bass
Executive Director

**Randy**

**From:** "Randy Block" <beelock4@home.com>
**To:** <senator2@levin.senate.gov>
**Cc:** <Ethelinsolidarty@cs.com>
**Sent:** Monday, May 21, 2001 1:35 AM
**Subject:** Gray Panthers of Metro Detroit Oppose the Nomination of John Graham to Head OIRA

5/21/01

The Honorable Senator Carl Levin:

Gray Panthers of Metro Detroit, an intergenerational social justice organization, urges you to oppose the nomination of Dr. John Graham to head the Office of Information and Regulatory Affairs (OIRA) at the Office of Management & Budget (OMB).

The following issues concern us:

1. A primary function of the OIRA is to review regulatory analysis produced by federal agencies. This agency has a responsibility to assure the health and safety of the American public. The OIRA officials in the new Bush administration, as was the case during the Reagan-Bush administrations, are expected to be given broad discretion to review and block new standards created by federal agencies. As administrator for the OIRA, Dr. Graham would become the gatekeeper for all federal regulations. It is essential that the leader of this regulatory agency work with integrity for all Americans, not just for the interests of corporate business communities.

2. Dr. John Graham, a professor of marketing and international business, has maintained a career specialized in international business negotiations. He founded the Harvard Center for Risk Analysis (HCRA) which has received funding from more than 100 large corporations and trade associations including Dow, 3M, DuPont, Monsanto, and Exxon. He has provided consultation to executive groups from several major corporations including: Toyota Motor Sales, Western Automobile Leasing Association, TransAmerica Corporation, Honeywell Corporation, Hyundai Motor America, Ford Motor Co, AT&T, and the Prudential Insurance Company.

3. Dr. Graham, with his extensive corporate conflicts of interest, is the wrong choice to serve in this trusted position. In his position as head of the Harvard Center for Risk Analysis, Dr. Graham has taken biased cost analysis positions which inflated industry costs and downplayed ethical and moral factors – factors which support the value of human life and the environment. Congress has made progress in establishing policy positions which protect that the health and safety of the American people and their environment. Dr. Graham's views and actions are at odds with these policies.

Gray Panthers urges you to take leadership with your colleagues in the Senate Government Affairs Committee to urge President Bush to nominate an administrator of the OIRA who merit's the trust of all Americans. Senator Levin, it is our strong view that John Graham is not that person. We look forward to hearing your views on this issue.

Sincerely,

Randy Block

Randy Block, Co-Convener
Gray Panthers of Metro Detroit

April 17, 2001

The Honorable Fred Thompson
United States Senate
523 Dirksen Senate Office Building
Washington, DC 20510

APR 18 2001

Jim Courter
*Chairman*

Merrick Carey
*Chief Executive Officer*

Loren Thompson
*Chief Operating Officer*

Don Soifer
*Executive Vice President*

Philip Peters
*Vice President*

Bonner Cohen
Robert Holland
Phillip Thompson
*Senior Fellows*

Adrienne Murphy
*Director of Operations*

Dear Senator Thompson:

As chairman of the Senate Government Affairs Committee, you will soon be presiding over hearings on the nomination of Dr. John Graham to be director of the Office of Information and Research within the Office of Management & Budget.

I have followed with great interest the distinguished work Dr. Graham has undertaken as director of the Harvard Center for Risk Analysis. With his insistence that government carefully weigh the costs, risks, and benefits of its policies, Dr. Graham will bring much-needed accountability to the nation's regulatory policies. His pioneering approaches to safeguarding public health and safety include risk-trade-off analysis (sometimes called risk-risk analysis or benefit-cost analysis) which he argues is often easier than cost-benefit analysis because the units of measurement are physical rather than monetary quantities. For example, the units used in risk trade-off analysis might include the net number of lives saved, years saved, quality adjusted life-years saved, or even the net change in the amount of pollution emitted into the environment.

By pointing out that public health regulations can have unintended consequences, Dr. Graham and his able staff at Harvard have brought a new perspective to policies designed to protect the public. As director of OIRA, Dr. Graham will be charged with reviewing the thousands of rules and regulations issued by federal agencies. Because they ultimately affect the lives and livelihoods of Americans from all walks of life, it is vitally important that these regulatory actions be subjected to the most probing analysis the nation can provide.

Dr. Graham is uniquely qualified to carry out this task, and I wholeheartedly support his nomination.

Sincerely,

Merrick Carey, CEO

01 APR 18 PM 4:37

1655 North Fort Myer Drive, Suite 325 • Arlington, VA 22209 • Phone: 703.522.5828 • Fax: 703.522.5837
http://www.lexingtoninstitute.org email: mail@lexingtoninstitute.org

May 15, 2001

The Honorable Joseph I. Lieberman
United States Senate
SH-706 Hart Senate Office Building
Washington, DC 20510-0703

Dear Senator Lieberman:

I am writing on behalf of the National Environmental Trust (NET) to urge your opposition to the nomination of John Graham to head OMB's Office of Information and Regulatory Affairs. As Ranking Member on the Senate Government Affairs Committee, Mr. Graham's scheduled to come before you at a confirmation hearing on May 16, 2001.

Mr. Graham's approach to regulation includes heavy reliance on business friendly "risk analysis" and "cost-benefit analysis" creating a higher barrier for agencies to overcome in order to issue a rule other than the one which is most "cost effective". Furthermore, Mr. Graham is hostile to the very idea of environmental regulation. In 1996, Graham told political strategiests at the Heritage Foundation that "environmental regulation should be depicted as an incredible intervention in the operation of society." He has also stated that support for the regulation of chemicals in our water supply shows the public's affliction with "a syndrome of paranoia and neglect." ("Excessive Reports of Health Risks Examined," The Patriot Ledger, Nov. 28, 1996, at 12.)

We are also greatly concerned that Mr. Graham is being considered for this position given the Harvard Center for Risk Analysis' record of producing reports that strongly match the interests of those businesses and trade groups that fund them. For instance a 1999 Risk Analysis Center report found that banning older, highly toxic pesticides would lower agricultural yields and result in an increase in premature childhood deaths, because food production would be hampered. This widely criticized report was funded by the American Farm Bureau Federation, which opposes restrictions on pesticides.

In 1999, Mr. Graham supported the Regulatory Improvement Act of 1999 (S. 746). The late Senator John Chafee, then chairman of the Senate Environment and Public Works Committee promised to vehemently oppose this bill due to its omnibus approach to "regulatory reform". Under S. 746, regulations would have been subject to just the type of cost-benefit analysis and risk assessments that Mr. Graham advocates, *across the board*, regardless of the intent of the proposed regulation. This bill was strongly opposed by environmental, consumer, and labor groups.

For these reasons and more, Mr. Graham's appointment to the Office of Information and Regulatory Affairs within OMB represents a serious threat to public health and environmental protections. Please oppose his nomination to head OIRA.

Sincerely,

Philip E. Clapp
President

cc: Larry Novey

1200 Eighteenth Street, N.W., Washington, DC 20036 • Telephone 202 887-8800 • Fax 202 887-8877 • www.environet.org
*The Environmental Action Network for the 21st Century*

CSPI Center for Science in the Public Interest
Publisher of *Nutrition Action Healthletter*

April 9, 2001

The Honorable Fred Thompson
Chairman
Committee on Governmental Affairs
Room 340
Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Chairman:

On behalf of our 800,000 members, I write to urge you to oppose the nomination of John D. Graham as Administrator of the Office of Information and Regulatory Affairs at the Office of Management and Budget. The reasons for our opposition are set forth in more detail in the enclosed March 7, 2001 letter to President Bush, which we request be made part of the record of Mr. Graham's confirmation hearing.

Sincerely,

Benjamin Cohen
Senior Staff Attorney

enclosure

Tel: (202) 332-9110
Fax: (202) 265-4954
Home Page: www.cspinet.org
E-mail: cspi@cspinet.org

Suite 300
1875 Connecticut Ave., N.W.
Washington, D.C. 20009-5728

Michael F. Jacobson, Ph.D.
Executive Director

President George W. Bush
The White House
Washington, D.C. 20500

March 7, 2001

Dear President Bush:

We are troubled by the nomination of John D. Graham, currently the director of the Harvard Center for Risk Analysis (HCRA), to serve as the administrator of OMB's Office of Information and Regulatory Affairs. Given the enormous impact that office can have on the public welfare -- in matters ranging from environmental protection to occupational safety -- it is vital that the holder of that office both be and appear fair-minded.

Under Dr. Graham's direction the HCRA has received substantial funding from government and from such corporate entities as the American Petroleum Institute, Association of American Railroads, Boise Cascade Corporation, Ford Motor Company, Goodyear Tire & Rubber Company, Kraft Foods, Merck & Company, Monsanto Company, Dow Chemical Company, Frito-Lay, Novartis Corporation, Pfizer, and the Union Carbide Foundation. That funding suggests an allegiance to corporate interests that would be improper for the director of OIRA. More troubling, and as documented in the Public Citizen report, Dr. Graham's and HCRA's positions, studies, speeches, and testimonies all too regularly support the positions of their industry funders.

We are concerned that Dr. Graham's preoccupation with risk-benefit analyses will be invoked to prevent many vitally important regulations. Artfully chosen assumptions may be used by industry to create misleading estimates of risks and benefits that could then be used as an excuse to undermine needed regulations. Moreover, while risk-benefit analyses can be useful, too often they are inappropriate or impossible to conduct. The inability to conduct accurate analyses could be used to prevent the adoption of important federal regulations that could provide significant -- but non-quantifiable -- health and environmental benefits. For instance, protecting wilderness areas and improving the utility of food labels are perceived by the general public as beneficial, but may reflect values that do not lend themselves to computation on an economist's calculator.

We commend your oft-stated goal of adhering to high ethical standards. Appointing high-level officials with real or perceived conflicts of interest is, however, contrary to such goals. Even when an individual is academically qualified for a position, a real or perceived conflict of interest undermines ethical norms and is also likely to jeopardize public confidence in an agency.

1875 Connecticut Avenue, N.W. / Suite 300 / Washington, DC 20009-5728 / (202) 332-9110 / FAX (202) 265-4954
on the *Internet at www.cspinet.org* • Executive Director: Michael F. Jacobson, Ph.D.

Therefore, we oppose the confirmation of John D. Graham to head the Office of Information and Regulatory Affairs. Individuals with conflicts of interest or strong ties to the industries to be regulated ought not to serve in government positions such as the one for which Dr. Graham is being considered. Qualified individuals without such conflicts or ties can surely be found.

Sincerely yours,

Michael F. Jacobson

Michael F. Jacobson, Ph.D.
Executive Director

Ronald Collins

Ronald Collins
Director, Integrity in Science Project

COLLEGE AND GRADUATE SCHOOL OF BUSINESS
THE UNIVERSITY OF TEXAS AT AUSTIN

*Legal Environment of Business Faculty - Department of Management Science and Information Systems*
*CBA 5.202 - Austin, Texas 78712-1175 - (512) 471-3322 - FAX (512) 471-0587*

Senator Fred Thompson, Chairman
Senate Committee on Governmental Affairs
Room 340, Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Thompson:

My name is Frank B. Cross, and I am the Herbert D. Kelleher Centennial Professor of Business Law at the McCombs School of Business at the University of Texas and a Professor at University of Texas School of Law in Austin, Texas. I have been involved in the field of academic research regarding risk and regulatory policy for over a decade, and have published a number of scholarly articles on these and related subjects.

I write in support of the nomination of Professor John Graham of Harvard University's School of Public Health. While I am familiar with his scholarly qualifications and abilities, I would like to focus this letter on his personal capabilities. I have known John for 25 years, since we both were undergraduates. I have followed his career since that time and have had continuing contacts with him at conferences. From this, I know him to be a person of integrity of all respects and indisputably a person of intellectual integrity. Naturally, I was dismayed to discover that his integrity was being challenged by those who disagree with some of the conclusions of his research.

The criticisms of Professor Graham's experience seem to center on the fact that the research of the Harvard Center for Risk Analysis is somehow less than acceptable because the Center receives corporate support. These critics further contend that such support raises troubling questions regarding disclosure and conflicts of interest. As someone actively engaged in research in some of the same areas as the Center, I can tell you that this criticism is unwarranted, unfair and inconsistent with the clear pattern and practice of most (if not all) similarly situated research centers. Corporations fund research, and if corporate money were rejected, much critical research would not be done. Corporations fund research at the Harvard Center *because* of its credibility and integrity, not to influence its results. It is in the interest of everyone, especially the Harvard Center, that its research remain objective and entirely untainted.

The Harvard Center has taken numerous steps to preserve its integrity and credibility, steps that surpass those taken by comparable research institutions. Documentation on these policies is publicly available on the Internet. A comparison of this information to that available regarding eight similar institutions is quite revealing.[1] Like the Harvard Center, each of the comparable institutions has a

[1]The eight comparable institutions were: The Center for Epidemiology and Policy at Johns Hopkins University's School of Public Health at http://www.med.jhu.edu/cep/; the Center for Environmental Initiatives at the Massachusetts Institute of Technology at http://cei.mit.edu/About/; the Center for Risk Perception and Communication at the Carnegie

fine academic reputation, and each has participated directly or indirectly in matters intimately related to public policy in the United States. The following is a quick comparative review of policies of these research centers.

Donor Disclosure

The Harvard Center discloses its contributors to the public. Only two of the eight comparison institutions disclose contributors by name on publicly-accessible Internet sites.[2] As compared to those two institutions, the Harvard Center appears to make greater disclosure in two respects. First, the Harvard Center provides an easily accessible alphabetical listing of contributors, and labels them as such. Second, only the Harvard Center makes the relevant distinction between restricted and unrestricted grantors.[3] This distinction is important because unrestricted grants (which appears to represent the majority of grants to which activist attention has been directed) are not tied to any sort of supervisory relationship between researcher and subject. In essence, the Harvard Center provides the necessary information to reach judgments about the Center's operations in an open and transparent manner.

I do not mean to be at all critical of the other research centers reviewed. Indeed, in addition to the fine work they perform, they may acknowledge financial support in individual publications or in symposia conducted by the groups of which I am unaware. However, the Harvard Center clearly provides more systematic financial disclosure to the public.

Conflicts of Interest Policies.

The question of conflicts of interest provides an even more stark contrast. While many of the similar research centers have mission statements regarding their operations, none appears to have a separate and independent conflicts of interest policy. Of course, all of these organizations are subordinate to academic institutions which themselves have a range of conflicts policies.[4] However, only the

---

Mellon University at http://www.gsia.cmu.edu/research/risk.html; the Center for Study of American Business at Washington University in Saint Louis (see 2000 Annual Report at http://wc.wustl.edu/); the Institute for Risk Analysis and Risk Communication at the University of Washington at http://depts.washington.edu/irarc/; the Mercatus Center at George Mason University at http://www.mercatus.org/; the Risk Management and Decision Processes Center at the Wharton School of the University of Pennsylvania at http://grace.wharton.upenn.edu/risk/index.html; and the Yale Center for Environmental Law and Policy at the Yale Law School and the Yale School of Forestry and Environmental Studies at http://www.yale.edu/envirocenter/front/envirocenter.html.

[2]Wharton and the CSAB at Washington University in Saint Louis.

[3]See unrestricted and restricted grantors list at http://www.hcra.harvard.edu/funding.html.

[4]For example, see the Johns Hopkins University School of Public Health policy at http://www.jhsph.edu/faculty_handbook/ppm_faculty_4_conflicts_of_interest.html, the Carnegie Mellon University Policy on Conflict of Interest at http://gollum.mac.cc.cmu.edu/univ_policy/documents/IntConflict.html, and the Significant Financial Interest Disclosure Policy at the University of Washington (Grants Information

Harvard Center has a specially designed conflicts policy that addresses the unique circumstances that it faces as a research center. For example, rather than merely addressing disclosure, the Harvard Center policy commits the organization to maintaining a diversity of funding sources in order to try to eliminate even the perception of undue influence, to maximizing disclosure, and to disclaiming any conditions (for unrestricted grants) or research designs (for restricted grants). The director also declines to testify in adversarial proceedings, and any additional consulting fees received are directed to a scholarship fund.[5] The Harvard Center policy is unique among other similar research centers, and goes above and beyond the conflicts policies of parent institutions as described above. In my judgment, the financial disclosure and conflicts of interest policies of the Harvard Center meet or exceed the generally accepted practices of similar academic institutions.

In short, the complaints against the Harvard Center regarding financial disclosure and conflicts of interest are simply unfounded, when the Center is compared to its principal competition in the field of related academic research. Those offering this critique[6] have declined to place the Harvard Center in the context of the academic environment in which it operates, in an apparent attempt to marginalize its work. This criticism rings all the more hollow when one considers that the Public Citizen report, for example, was neither peer-reviewed nor did it disclose financial information related to the construction of the document.

I urge you to support the nomination of Professor Graham and would be happy to provide any other information that you might find useful.

Sincerely,

Frank B. Cross

---

Memorandum 10, June 16, 1997) at http://www.washington.edu/research/gcs/gim/gim10.html.

[5]The Harvard Center Conflict of Interest Policy is attached to this letter and is available at http://www.hcra.harvard.edu/conflict.html.

[6]See, e.g., the report of Public Citizen, Inc., at http://www.citizen.org/Press/pr-grahamreport.pdf.

HARVARD UNIVERSITY

DEPARTMENT OF ECONOMICS

CAMBRIDGE, MASSACHUSETTS 02138

May 10, 2001

Hon. Joseph Lieberman
Senate Governmental Affairs Committee
706 Hart Senate Office Building
Washington, DC 20510

Hon. Fred Thompson
Chairman, Senate Governmental Affairs Committee
511 Dirksen Senate Office Building
Washington, DC 20510

Re: Confirmation Vote for John Graham

Dear Senators Lieberman and Thompson:

I am writing to provide my support for the nomination of John Graham as Assistant Administrator of the Office of Management and Budget. I understand that the Senate Governmental Affairs Committee will be considering the nomination shortly.

I have known John as a colleague for many years. John is an extremely honest, up-front individual. I respect him and his work greatly, and see no reason why he should not be confirmed to the office. In the course of John's nomination, I have read about the issues surrounding the funding his research has received. Bias associated with funding issues is a matter that all academics treat seriously. Over the years, I have paid particular attention to John's research to see if there is evidence of such a bias. I have not detected any. John brings a solid analytic base to important public health problems. There is a lot of work on public health topics that is not well conducted; John's research stands out for its clarity of thought and implementation. It is this set of qualities, I believe, that accounts for the nature of the funding.

To give you a little of my background, I am a professor of economics in the department of economics and the Kennedy School of Government at Harvard. I worked in the Clinton Administration on the President's health reform proposal in 1993 and have consulted with various democratic campaigns in subsequent years. Thus, I do not feel ideologically in sync with many of the Bush Administration's likely policies. Still, that does not diminish my sense that the best people should serve in the Administration.

Sincerely,

David M. Cutler

David M. Cutler

June 28, 2001

The Honorable Joseph I. Lieberman
United States Senate
Washington DC 20510

Dear Senator Lieberman:

On behalf of the 1.4 million members of the United Food and Commercial Workers International Union (UFCW), I am writing to express our opposition to President Bush's nomination of John D. Graham, Ph.D., to head the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA).

As Administrator of OIRA, Dr. Graham would be the gatekeeper for all federal regulations, including those dealing with environmental protection, workplace safety, food and drug safety, and consumer safety. He has consistently viewed cost-benefit analysis as the determinative criteria in deciding whether a rule goes forward—a position that is frequently at odds with congressional mandates that place public health considerations as the preeminent factor in rule-making deliberations. In addition to our concerns regarding the fairness of Dr. Graham, we have strong concerns about his extreme versions of regulatory reform, which the Senate has considered but never approved and which we sought to defeat.

Furthermore, we are also concerned with Dr. Graham's close ties to industry. As Director of the Harvard Center for Risk Analysis, he has received financial support from more than 100 corporations and trade associations over the last 12 years. At the same time, Dr. Graham has produced numerous reports, given testimony, and provided media commentary that directly benefited those who have funded the Center, which include food processors, oil and chemical companies, and pharmaceutical industries. In addition, many of these companies have staunchly opposed new regulatory initiatives and have been leading proponents of extreme regulatory reform.

Dr. Graham's track record does not demonstrate the sort of objectivity and dispassionate analysis that we should expect from the next OIRA Administrator. Given his extreme views on regulatory policy, and his close ties with the regulated communities, we are deeply concerned about his ability to provide for a fair review of regulations that are needed to protect workers and the public.

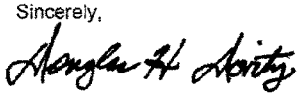
**Douglas H. Dority**
International
President

**Joseph T. Hansen**
International
Secretary-Treasurer

**United Food & Commercial Workers International Union, AFL-CIO & CLC**
1775 K Street, NW
Washington DC 20006-1598
(202) 223-3111 Fax (202) 466-1562

For these reasons, the UFCW urges you to oppose confirmation of John D. Graham, Ph.D., as Administrator of the Office of Information and Regulatory Affairs.

Sincerely,



International President

March 16, 2001

Hon. Fred Thompson, Chair
Governmental Affairs Committee
U.S. Senate
Washington, DC 20510

Hon. Joseph I. Lieberman, Ranking Member
Governmental Affairs Committee
U.S. Senate
Washington, DC 20510

Dear Senators Thompson and Lieberman:

We write as scholars working in environmental policy, health policy and related fields to endorse the nomination of Professor John Graham of the Harvard School of Public Health to be Director of the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget.

We know and respect John Graham as a distinguished professional colleague, an eminent scholar and a person of the highest personal and professional integrity. He is, for example, a distinguished former President of the international Society for Risk Analysis, as well as holding many other honors from his academic peers. While we don't always agree with John (or for that matter, with one another) on every policy issue, we do respect his work and his intellectual integrity. It is very regrettable that some interest groups that disagree with John's views on the merits of particular issues have chosen to impugn his integrity by implying that his views are for sale rather than confronting the merits of his arguments. Dialogue about public policy should be conducted at a higher level.

A bipartisan consensus exists over the last six Presidential Administrations that cost-benefit analysis at OIRA has an important role to play in improving public policy. The proper debate is about how to conduct such analyses and how much weight to give them. That John Graham is a knowledgeable, experienced expert in the use of cost-benefit techniques qualifies him rather than disqualifies him for the position of Director of OIRA.

Very truly yours,

E. Donald Elliott
Professor (adj) of Environmental Law , Yale Law School[1]
formerly, General Counsel, U.S. EPA

---

[1] Institutional affiliations are provided for purposes of identification only.

Robert N. Stavins,
Albert Pratt Professor of Business and Government, and Faculty Chair, Environment and Natural Resources Program,
John F. Kennedy School of Government
Harvard University

W. David Montgomery
Vice President
Charles River Associates Inc.
Washington, DC

James K. Hammitt
Associate Professor of Economics and Decision Sciences
Harvard School of Public Health
Harvard University

Alan J. Krupnick, PhD
Senior Fellow and Director, Quality of the Environment Division
Resources for the Future
Washington, D.C.

Robert Clemen,
Associate Professor
Fuqua School of Business
Duke University
Durham, NC

Cass R. Sunstein,
Karl N. Llewellyn Distinguished Service Professor
Law School and Department of Political Science
University of Chicago
Chicago, IL

W. Kip Viscusi
John F. Cogan Jr. Professor of Law and Economics
Director of the Program on Empirical Legal Studies
Harvard Law School

A. David Paltiel
Associate Professor
Yale School of Medicine / Yale School of Management
New Haven, CT

Richard Schmalensee
John C Head III Dean
MIT Sloan School of Management
Massachusetts Institute of Technology
Cambridge, MA

Joshua Cohen, Ph.D
Senior Research Associate
Harvard Center for Risk Analysis
Harvard University
Boston, MA

Robert W. Hahn
Director, American Enterprise Institute-Brookings Joint Center for Regulatory Studies
Washington, DC

Richard Wilson
Visiting Scholar
University of California at Berkeley
Berkeley, CA

Emmett Keeler
RAND Health
Santa Monica, CA

Chris DeMuth
American Enterprise Institute
Washington, DC

James T. O'Reilly
College of Law
University of Cincinnati

Thomas C. Schelling
Distinguished University Professor, University of Maryland, and
Lucius N. Littauer Professor, Emeritus,
Harvard University.

Peter Berck
Professor, Department of Agricultural and Resource Economics and Policy
University of California, Berkeley

Wendy Wagner
Professor, University of Texas School of Law

Visiting Professor, Columbia Law School
NY, NY

Leonard Shabman
Professor, Resource and Environmental Economics
Director, Virginia Water Resources Research Center
Virginia Tech
Blacksburg VA

Gordon Kaufman
Morris A. Adelman Professor of Management
Sloan School
MIT

Peter Reuter
Professor of Public Policy
School of Public Affairs
University of Maryland
College Park, MD

David Okrent
Professor Emeritus/Research Professor
Department of Mechanical and Aeronautical Engineering
U. of California, Los Angeles

Robert T. Deacon
Professor and Chair of Economics
University of California
Santa Barbara, CA

Jonathan Baron
Professor of Psychology
University of Pennsylvania
Philadelphia, PA

David F. Bradford
Professor of Economics and Public Affairs
Woodrow Wilson School
Princeton University
Princeton, NJ

Joe Newhouse
Harvard University

Jason Shogren
University of Wyoming

Louis Eeckhoudt
Professor of Economics
FUCAM
MONS, BELGIUM

Peter Neumann
Harvard University

Milt Weinstein
Harvard University

A. Myrick Freeman III
William D. Shipman Research Professor of Economics
Bowdoin College

Daniel C. Esty,
Director, Yale Center for Environmental Law and Policy
Associate Dean , Yale School of Forestry and Environmental Studies
and Associate Professor, Yale Law School
Yale University

Albert L. ("Nick") Nichols
Vice President
National Economic Research Associates
former Director of the Economic Analysis Division in EPA Policy Office
Cambridge, MA

Gilbert E. Metcalf
Professor of Economics
Tufts University
Medford, MA

George M. Gray, Ph.D.
Lecturer in Risk Analysis
Harvard School of Public Health
Harvard Center for Risk Analysis
Boston, MA

Thomas J. Kniesner
Krisher Professor of Economics

Center for Policy Research
Syracuse University
Syracuse, NY

Prof. Adam B. Jaffe
Chair, Department of Economics
Brandeis University
Waltham MA

Robert E. Litan
Vice President and Director of Economic Studies at the Brookings Institution
Co-Director of the AEI-Brookings Joint Center on Regulatory Studies
Washington, DC

Gail Charnley, Ph.D.
HealthRisk Strategies
Past President, Society for Risk Analysis
Washington, DC

Richard S. Eckaus,
Professor of Economics Emeritus
M.I.T.

Anthony C. Fisher
Professor and Chair
Dept. of Agricultural & Resource Economics
University of California
Berkeley, CA

John Evans
Harvard School of Public Health
Boston, MA

Lester Lave
Past President, Society for Risk Analysis
Carnegie Mellon University
Pittsburgh, PA

D. Warner North
President and Principal Scientist, NorthWorks, Inc., Belmont, CA
Consulting Professor, Department of Management Science and Engineering
Stanford University
President, Society for Risk Analysis, 1991-1992

Bill Pedersen
Shaw Pittman
Washington, DC
former, Deputy General Counsel, U.S. EPA

Mike Toman
Senior Fellow
Resources for the Future
Washington, DC

William W. Hogan
John F. Kennedy School of Government
Harvard University
Cambridge, MA

Arnold M. Epstein, M.D., M.A
John H. Foster Professor and Chair,
Department of Health Policy and Management,
Harvard School of Public Health
Boston, MA

Richard B. Norgaard
Professor of Energy and Resources and of Agricultural and Resource Economics
University of California at Berkeley

V. Kerry Smith
University Distinguished Professor
North Carolina State University

M. Granger Morgan
Head, Department of Engineering
and Public Policy
Lord Chair Professor in Engineering
Professor, EPP/ECE/Heinz
Carnegie Mellon University
Pittsburgh, PA

Jonathan B. Wiener
Professor, Law School and
Nicholas School of the Environment & Earth Sciences
Faculty Director, Center for Environmental Solutions
Duke University
Durham NC

Richard D. Morgenstern
Senior Fellow
Resources for the Future
Washington, DC

Billy Pizer
Fellow
Resources for the Future
Washington, DC
Visiting Scholar (2000-2001)
Stanford University

Hilary Sigman
Associate Professor of Environmental Economics
Yale School of Forestry and Environmental Studies
New Haven, CT

Richard S. Eckaus
M.I.T.

Lawrence H. Goulder
Department of Economics and
Institute for International Studies
Stanford University
Stanford, CA

Gary E. Marchant, Ph.D.
Associate Professor
Arizona State University College of Law
Tempe, AZ

Anthony T. Lo Sasso, Ph.D.
Research Assistant Professor
Institute for Health Services Research and Policy Studies
Northwestern University
Evanston, IL

Theodore Panayotou
John Sawhill Lecturer of Environmental Policy
Kennedy School of Government
Director, Environment & Sustainable Development, Center for International Development
Harvard University

Dr. John Loomis
Professor, Dept. of Agricultural and Resource Economics
Colorado State University
Fort Collins. CO

Dr. Joanne Linnerooth-Bayer
International Institute of Applied Systems Analysis
Laxenburg, Austria

Barton H. Thompson, Jr.
Vice-Dean and Robert E. Paradise Professor of Natural Resources Law
Stanford Law School
Stanford, California

Charles M. Harvey
Dept. of Decision and Information Sciences
University of Houston
Houston, TX

Ann Bostrom
Associate Professor
School of Public Policy
Georgia Institute of Technology
Atlanta, GA

Professor John P. Weyant
Department of Management Science and Engineering
Stanford University

Dale Hattis
George Perkins Marsh Institute
Clark University

Jim Salzman
Professor of Law
Washington College of Law
American University
Washington, DC

Dan Tarlock
Professor of Law
Chicago-Kent Law School
Chicago, IL

Ann Fisher
Senior Scientist and Professor
Department of Agricultural Economics & Rural Sociology
The Pennsylvania State University
University Park, PA

Mitchell J. Small
Professor, Civil & Environmental Engineering
Engineering & Public Policy
Carnegie Mellon University
Pittsburgh, PA

A. Denny Ellerman
MIT

Frank Cross
Herbert D. Kelleher Centennial Professor of Business Law
University of Texas at Austin
Austin, TX

Catherine L. Kling
Professor of Economics
Head, Resource and Environmental Policy Division
Center for Agricultural and Rural Development
Iowa State University
Ames, Iowa

Douglas J. Crawford-Brown
Chair: Environmental Curriculum Committee
Environmental Sciences and Engineering;
Public Policy Analysis; Ecology
University of North Carolina at Chapel Hill
Chapel Hill, NC

Richard B. Stewart
Emily Kempin Professor of Law
Director, Center on Environmental and Land Use Law
New York University School of Law
former Assistant Attorney General, Environmental and Natural Resources, U.S.
Department of Justice

Bernard D. Goldstein, MD
Dean, Graduate School of Public Health
University of Pittsburgh

Pittsburgh, PA
former Assistant Administrator, Office of Research and Development, U.S. EPA

R. Shep Melnick
Thomas P. O'Neill, Jr., Professor of American Politics
Boston College
Chestnut Hill, MA

Gloria E. Helfand, Ph.D.
Associate Professor of Environmental Economics
School of Natural Resources and Environment
The University of Michigan
Ann Arbor, MI

Alison Cullen
Associate Professor
Evans School of Public Affairs
University of Washington
Seattle, WA

William Evans
Department of Economics
University of Maryland
College Park, MD 20742

Paul R. Portney, President
Resources for the Future
Washington, DC

Additional Signers After March 16, 2001

Howard Kunreuther
Cecilia Yen Koo Professor of Decisions Sciences and Public Policy
Chairperson Operations and Information Management Department
Wharton School
University of Pennsylvania
Philadelphia, PA

Patrick L. Kinney, Sc.D.
Associate Professor
Columbia School of Public Health

Dr. Leonard Evans

President, Science Serving Society
Bloomfield Hills, MI

John Mendeloff
Graduate School of Public and International Affairs
University of Pittsburgh

Tammy O. Tengs, Sc.D.
Director, Health Priorities Research Group
Assistant Professor, Department of Urban and Regional Planning
University of California, Irvine
Irvine, CA

Maureen Cropper
Professor of Economics, University of Maryland
Lead Economist, World Bank.

Robin Cantor, Ph. D.
Principal and Managing Director
LECG, LLC
Washington, DC

Professor Tim McDaniels
Director, Eco-Risk Research Unit
Institute of Resources and Environment and
School of Community and Regional Planning
University of British Columbia
Vancouver, BC

Cary Coglianese
Associate Professor of Public Policy
Faculty Chair, Regulatory Policy Program
John F. Kennedy School of Government
Harvard University

Donald A. Redelmeier, MD
University of Toronto
Toronto, Ontario, CANADA

Tim McDaniels
Professor
Director, Eco-Risk Research Unit
Institute of Resources and Environment and
School of Community and Regional Planning

University of British Columbia
Vancouver, BC

Professor M. Elisabeth Paté-Cornell
The Burt and Deedee McMurtry Professor of Engineering
Chair, Department of Management Science and Engineering
(Risk Analysis)
Stanford University, Stanford CA

Matthew Adler
Professor of Law
University of Pennsylvania Law School
Philadelphia. PA.

Claire M. Mays
Secretary, Society for Risk Analysis Europe
Institut Symlog
94232 Cachan cedex FRANCE

John D Boice, Jr
Scientific Director
International Epidemiology Institute
Rockville, MD

David B. Spence
Assistant Professor of Law and Regulation
McCombs School of Business
University of Texas at Austin
Austin, TX 78712

Joseph K McLaughlin
President
International Epidemiology Institute
Rockville, MD

David W. Case,
Research Associate
Vanderbilt Center for Environmental Management Studies
Vanderbilt University
Nashville, Tennessee

Dr. William R. Hendee
Dean of the Graduate School of Biomedical Sciences
Professor and Vice Chair of Radiology

Professor of Radiation Oncology, Biophysics, Bioethics
Professor of Biomedical Engineering
Marquette University

John F. Ahearne
Lecturer in Public Policy
Duke University

Chris Whipple, Ph.D.
Past-president, Society for Risk Analysis
Principal
ENVIRON International Corporation
Emeryville, CA

Paul Slovic
Decision Research
Eugene, Oregon

Frank Cross
Herbert D. Kelleher Centennial Professor of Business Law
University of Texas at Austin
Austin, TX 78712

HARVARD UNIVERSITY

OFFICE OF THE PROVOST

MASSACHUSETTS HALL
CAMBRIDGE, MASSACHUSETTS 02138
(617) 496-5100
FAX (617) 495-8550

April 24, 2001

VIA FAX: 202-224-9603

The Honorable Fred Thompson
Committee on Governmental Affairs
Dirksen Senate Office Building SD-340
Washington, DC 20510-6250

Dear Senator Thompson:

I write to introduce a colleague, John D. Graham, who has been nominated by President Bush to head the Office of Information and Regulatory Affairs of the OMB. I first met Professor Graham when he joined the Harvard faculty in 1985. During my tenure as Dean of the Harvard School of Public Health (1984-1997), I advised him during the period that the Harvard Center for Risk Analysis (HCRA) was designed and developed.

In my opinion, John Graham is a superb choice for this critical position in OMB. He is a superb teacher of the analytic tools of regulatory analysis (e.g., risk assessment, cost-effectiveness analysis, and cost-benefit analysis), and he has a strong desire to see these tools used well in government. He also proved to be an outstanding institution builder and mentor to both graduate students and junior faculty. As a scholar, he is perhaps best known for his influential study comparing the cost-effectiveness of over 500 health, safety, and environmental policies in the USA.

I am aware that some well-intentioned critics have raised concerns about the funding of HCRA and Professor Graham's positions. I believe these concerns are misplaced and would like to offer my own perspective.

At the outset, it was recognized that HCRA should raise funding from multiple sources, including companies and trade associations. Throughout its twelve-year history, the Center has received substantial amounts of funding from both the public and private sectors, and these funding sources are routinely disclosed to the public.

The vast majority of industry funding has been in the form of unrestricted gifts to support the Center's overall mission to promote a more reasoned public response to health, safety, and environmental hazards. Most of these funds are used to support the salaries of young faculty, to provide student support, and to provide administrative support to the Center. In making

decisions about how to expend unrestricted funds, the Center Director and core faculty are guided by an external advisory committee of scientists from academia, government, industry, and non-profit organizations. This Committee of more than thirty leaders in the field meets regularly in Boston with HCRA faculty, staff, and students. More recently, the Center also established, with the assistance of the School's Development Office, a senior executive council of distinguished individuals from the private sector to begin the challenge of building a long-term funding base for the Center based on gifts from motivated individuals.

In those cases where industry or government fund a specific research project at the Center, the University's Office of Sponsored Research enforces rules to protect the intellectual freedom and independence of the participating faculty and students. HCRA faculty and staff are also expected to disclose in books or articles any sources of sponsored funding, regardless of the type of source.

At a more personal level, I can testify that Professor Graham has gained widespread respect inside and outside the Harvard community for his analytic ability, intellectual courage, and integrity. While John's political leanings have been more conservative than those of many of his associates at the Harvard School of Public Health, I have always found his professional style to be open-minded, fair, and deliberative. I also respect his decision, made in 1996, to decline certain kinds of industrial consulting income and speaking fees, and instead have these funds donated to the Howard Raiffa Scholarship Fund for students and fellows interested in risk analysis. This Fund has already accumulated over $100 thousand and is being invested for the benefit of future students.

In short, our nation needs public servants of John Graham's caliber, and I urge you to greet him with an open mind and to support his nomination.

Sincerely,

Harvey V. Fineberg

Harvey V. Fineberg

**MICHAEL FINKELSTEIN & ASSOCIATES**
1000 Connecticut Ave., NW Suite 304
Washington, DC 20036

Telephone 202-659-8844
Fax 202-293-3060
E-mail Mfinkel111@cs.com

April 13, 2001

The Honorable Fred Thompson
Chairman, Senate Committee on Governmental Affairs
United States Senate
Washington, DC 20510-6250

Dear Senator Thompson:

I am writing this letter to support Dr. John Graham's candidacy as Director of OMB's Office of Information and Regulatory Affairs (OIRA).

I am an independent consultant working on automotive safety and have known Dr. Graham for more than fifteen years. I first met him in the mid-1980s when he was doing research on airbags. Since then I have followed his work at the Harvard Center for Injury Control and more recently at the Harvard Center for Risk Analysis. His academic credentials are outstanding and there is little I could say that would add to his scientific accomplishments.

Rather the reason for this letter is to discuss Dr. Graham's integrity, both as a scientist and as a public health professional. The reason that I feel compelled to write is that I discovered that a 1997 letter that I wrote was used by Public Citizen in their recent report criticizing Dr. Graham's nomination as head of OIRA. Frankly, I was very surprised to see Public Citizen use my letter to criticize Dr. Graham. In fact, when a representative of Public Citizen contacted me to learn my views of Dr. Graham, I told them that I was strongly in favor of his possible appointment to any number of positions in the new Administration.

With respect to the specific issues surrounding that letter, in March of 1997, the National Transportation Safety Board (NTSB) held a public meeting on the subject of airbag injuries, particularly airbag injuries to children. Dr. Graham was completing an analysis of the cost effectiveness of airbags and made a presentation of his preliminary findings at that meeting. Given the media interest in the subject and Dr. Graham's prominence as an expert on airbags, he also was interviewed on one of the national morning news shows. (Since the NTSB meeting was open to the public, it was clear that his findings were inevitably going to be covered by the media, whether or not he appeared on that morning's newscast.)

I felt that his analysis was flawed, and given the publicity surrounding Dr. Graham's

preliminary conclusions, I wrote him a very strong letter raising a number of technical problems that I had with his research. And in fact, during the peer review that his research received prior to its publication, apparently a number of reviewers raised many of the same questions. And as a result, when the paper was published in the Journal of the American Medical Association (JAMA), it had been substantially revised. Had Dr. Graham not presented his preliminary findings at the NTSB meeting, there would have been much less feedback from the safety community and the quality of the final published paper may have been diminished.

In fact, given the importance of the subject, Dr. Graham's presentation of his preliminary findings at the NTSB hearing was reasonable. And while I disagreed with his conclusions, I certainly never questioned his motives for presenting that data. Further, when his research was subjected to the peer review process, he made a number of substantive changes, which did, in fact, change his conclusions. And it is the paper published in JAMA that is used today to characterize airbag cost-effectiveness.

Again, I have known Dr. Graham for more than fifteen years and believe him to be of the highest integrity. His contributions to the field of public health are impressive, and the nation is fortunate that a man of his caliber is willing to serve in the government.

Please contact me if you have any questions regarding this matter.

Sincerely yours,

Michael Finkelstein

cc: Dr. John Graham

May 17, 2001

The Honorable Fred Thompson
Chairman
Senate Governmental Affairs Committee
Washington, D.C. 20510

The Honorable Joseph I. Lieberman
Ranking Democrat
Senate Governmental Affairs Committee
Washington, D.C. 20510

Re: John D. Graham Nomination

Dear Senators:

We write as former federal regulators in response to the nomination of John D. Graham, Ph.D., to direct the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB). As OIRA Administrator, Dr. Graham would oversee the development of all federal regulations and he would help shape federal regulatory policy. His decisions will have profound effects on the health, welfare, and environmental quality of all Americans. We are concerned by many of Dr. Graham's expressed views and past actions as Director of the Harvard Center for Risk Analysis, and encourage the committee to conduct a thorough investigation into Dr. Graham's suitability for this position.

Since the early 1980s, both Republican and Democratic Presidents have issued Executive Orders granting the OIRA Administrator exceptionally broad authority to approve, disapprove, and review all significant executive agency regulations. In addition, under the Paperwork Reduction Act, the OIRA Administrator has the responsibility to approve and disapprove agency information collection requests, which agencies need to evaluate emerging public health and environmental threats. These powers give the OIRA Administrator a considerable role in determining how important statutes are implemented and enforced.

In his written work and testimony before Congress, Dr. Graham has repeatedly argued for an *increased reliance* on cost-benefit and cost-effectiveness analysis in the regulatory process. We agree that economic analysis generally plays an important role in policy making. But increasing the role that economic analysis plays in rulemaking threatens to crowd out considerations of equal or perhaps greater importance that are harder to quantify and to put in terms of dollars – for example, what is the dollar value of making public spaces accessible so a paraplegic can participate fully in community activities? How should we quantify the worth of protecting private medical information from commercial disclosure? Why is the value of preventing a child from developing a future cancer worth only a small fraction of the value of preventing her from dying in an auto accident? How do you quantify the real value of a healthy ecosystem?

In addition, we are concerned that Dr. Graham may have strong views that would affect his impartiality in reviewing regulations under a number of statutes. He has claimed that many health and safety statutes are irrational because they do not allow the agencies to choose the regulatory option that maximizes economic efficiency where doing so would diminish public protections. He has repeatedly argued, in his written work and testimony before Congress, that requirements to take the results of cost-benefit and cost-effectiveness analyses into account should *supercede* congressional mandates that do not permit their use, such as some provisions of the Clean Air Act. [John D. Graham, "Legislative Approaches to Achieving More Protection Against Risk at Less Cost," 1997 Univ. of Chi. Legal Forum 13, 49.] It is important to assure that he can in good conscience carry out the will of Congress even where he has strong personal disagreements with the law.

We are also concerned about Dr. Graham's independence from the regulated community. At the Harvard Center for Risk Analysis, Dr. Graham's major source of funding has been from unrestricted contributions and endowments of more than 100 industry companies and trade groups, many of which have staunchly opposed the promulgation and enforcement of health, safety and environmental safeguards. At HCRA, Dr. Graham's research and public positions against regulation have often been closely aligned with HCRA's corporate contributors. In coming years these same regulated industries will be the subject of federal regulatory initiatives that would be intensively reviewed by Dr. Graham and OIRA. It is thus fair to question whether Dr. Graham would be even-handed in carrying out his duties, including helping enforce the laws he has criticized. Might he favor corporations or industry groups who were more generous to his Center? Will he have arrangements to return to Harvard? Is there an expectation of further endowments from regulated industries? There is the potential for so many real or perceived conflicts of interest, that this could impair his ability to do the job.

We urge the Governmental Affairs Committee to conduct a thorough inquiry into each of these areas of concern. We believe that the health, safety, and quality of life of millions of Americans deserves such an appropriate response. Thank you for your consideration.

Sincerely,

Robert B. Reich
Former Secretary of Labor

Ray Marshall
Former Secretary of Labor

Edward Montgomery
Former Deputy Secretary of Labor

Charles N. Jeffress
Former Assistant Secretary of Labor for Occupational Safety & Health

Eula Bingham
Former Assistant Secretary of Labor for Occupational Safety & Health

Davitt McAteer
Former Assistant Secretary of Labor for Mine Safety and Health

W. Michael McCabe
Former Deputy Administrator
Environmental Protection Agency

Lynn Goldman
Former Assistant Administrator for Office of Prevention, Pesticides and Toxic Substances
Environmental Protection Agency

J. Charles Fox
Former Assistant Administrator for Water
Environmental Protection Agency

David G. Hawkins
Former Assistant Administrator for Air, Noise and Radiation
Environmental Protection Agency

Tara O'Toole
Former Assistant Secretary of Energy for Environment Safety and Health
Department of Energy

Joan Claybrook
Former Administrator
National Highway Traffic Safety Administration

Anthony Robbins
Former Director
National Institute for Occupational Safety and Health

Harvard Center for Risk Analysis

April 27, 2001

The Honorable Fred Thompson
Committee on Governmental Affairs
United States Senate
SD-340
Dirksen Senate Office Building
Washington, DC 20510

Members of the Senate Committee on Governmental Affairs,

Following the announcement by the Bush Administration of its intention to nominate John Graham as Administrator of the Office of Information and Regulatory Affairs, Public Citizen released a report[1] criticizing the academic integrity of Dr. Graham and the Harvard Center for Risk Analysis (HCRA). Public Citizen's report offered as an example a study sponsored by AT&T Wireless Services and conducted by HCRA that evaluated the risks and benefits of cellular phone use while driving[2]. This letter responds to the concerns raised by Public Citizen.

First, Public Citizen[1] (p. 48) claimed that HCRA incorrectly relied only on general fatality trend and cellular phone subscription data to reach our conclusion that the risks of cellular phone use and driving have been inadequately studied. HCRA's review of the recent literature was extensive, including evaluating driver test track/simulator performance studies, case reports, and epidemiological studies that take into account the behavior and characteristics of individual study subjects. We concluded that only one study, conducted by Redelmeier and Tibshirani[3], did not suffer from problems that substantially limit the inferences that can be drawn about real world risks. Public Citizen's statement that "*these* [general trend] *data form the basis of the* [HCRA] *study's position against banning the use of cell phones while driving*"[1] (p. 49) is inaccurate.

---

[1] Public Citizen. (2001). *Safeguards at risk: John Graham and corporate America's back door to the Bush White House.* [Author]: Washington, DC. ISBN No. 1-58231-022-X.
Available: www.citizen.org/press/pr-grahamreport.pdf

[2] Lissy KS, Cohen JT, Park MY, Graham JD. (2000). *Cellular phone use while driving: Risks and benefits.* Harvard Center for Risk Analysis, Harvard School of Public Health: Boston, MA.

[3] Redelmeier DA & Tibshirani RJ. (1997). Association between cellular-telephone calls and motor vehicle collisions. *New England Journal of Medicine, 336* (7), 453-458.

Harvard School of Public Health • 718 Huntington Avenue • Boston, Massachusetts 02115
telephone 617-432-4497 • facsimile 617-432-0190

Second, Public Citizen claims that the HCRA's comparisons of cellular phone/driving risks with other risks are invalid, stating that we should have instead compared these fatality risks to "*driving without a cellular phone under normal conditions*"[1] (p. 50). First, the statistic we computed (an incremental annual risk of 6.4 out of one million) is indeed a comparison to "normal" driving conditions. Second, our comparisons are valid because we compared the voluntary risk to the driver/cell phone user to other voluntary risks[2] (Table 3) and involuntary risks imposed by this technology on other roadway users to other involuntary fatality risks[2] (Table 4). Public Citizen concluded that HCRA's comparisons make no sense because in the case of cell phones, we can "*choose to live with no additional risk at all*"[1] (p. 50). But that choice applies to the comparison risks listed in Tables 3 and 4 of our report as well. In the case of voluntary risks, drivers could, for example, choose to purchase larger cars. In the case of involuntary risks, society could choose to ban large trucks. All of these risks are in this sense "unnecessary." Some drivers choose to avoid some of these risks, and society chooses to restrict some others. In many cases, however, we accept these risks, as individuals or collectively, because of the attendant benefits or because further action is expensive or difficult.

Third, Public Citizen claimed that the HCRA report is out of step with the peer-reviewed literature, identifying the 1997 *New England Journal of Medicine* study by Redelmeier and Tibshirani[3] as a prime example. However, HCRA used the main finding of the Redelmeier and Tibshirani study, stating that use of a cell phone while driving quadruples the risk of a collision, in its fatality risk calculations. Moreover, while Redelmeier and Tibshirani said that the risk posed by cellular phones to other road users indicates that proposed regulation may be reasonable, their conclusion did not differ as substantially from HCRA's as Public Citizen suggests. Redelmeier and Tibshirani[3] stated (p. 457):

> *We caution against interpreting our data as showing that cellular telephones are harmful and that their use should be restricted. Even if a causal relation with motor vehicle collisions were to be established, drivers are vulnerable to other distractions that could offset the potential reductions in risk due to restricting the use of cellular telephones. Regulations would also mean reducing benefits; in Canada, for example, half a million calls to 911 emergency services are made from cellular telephones each year. Yet proposals for regulation are not unreasonable, since poor driving imposes risks on others. Public debate is needed, given that cellular telephones contribute to improvements in productivity, the quality of life, and peace of mind for more than 30 million people in North America alone.*

Dr. Redelmeier has publicly criticized HCRA for releasing the report prior to its acceptance in a refereed, peer-reviewed journal. Only a small fraction of HCRA's work

is released to the public prior to acceptance in a peer-reviewed journal. We decided that in this case, because legislation was pending in dozens of municipalities and state legislatures, and because journal-refereed peer review can take many months or even a year or more to complete, that publishing the report prior to journal acceptance was warranted. We attempted to mitigate the lack of outside input due to the absence of a journal-refereed peer review by sending a draft of our report to 13 experts, 3 of whom were internal HCRA faculty and 10 of whom worked externally as academics or researchers. Furthermore, several individuals were selected largely because we suspected they might be critical of our analytical methods and/or policy perspective. The draft report was substantially revised based on their feedback and suggestions, and we believe that we adequately addressed reviewer's concerns. Although Dr. Redelmeier has publicly criticized our pre-journal publication release of the final report, we are unaware of any public statements made by him – or any of the 12 other reviewers – critical of the analytical methodology itself.

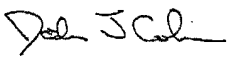
Fourth, Public Citizen claimed that HCRA's analysis assumed that the proportion of Americans with cellular phone subscriptions would not increase. We made no such assumption and made no statements indicating that our calculations were intended to reflect anything other than present conditions. Indeed, it would have been invalid for us to have made projections which take into account potential changes in one parameter (subscription rates) while not also taking into account potential changes in other parameters (*e.g.*, a continuing decrease in the automobile baseline fatality rate and hence risks associated with cell phones and driving).

Fifth, Public Citizen claimed that HCRA's cost-effectiveness estimates are suspect because we claimed cellular phone restrictions are more expensive (per year of life saved) than air bags even though cellular phone restrictions do not involve technology development and implementation costs. However, as our report explains, the cost of a ban mainly reflects the net value above subscription costs that consumers place on the (non-emergency) calls they can make with their cell phone while driving. This value amounts to $20 billion annually.

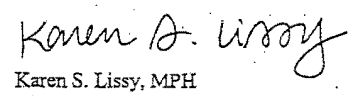
Sixth, Public Citizen claimed that "*HCRA assumes that regulation must be cost-effective in order to be warranted*"[1] (p. 51). However, the HCRA report noted that "*Economic efficiency is not necessarily a decisive factor in public policy but it is certainly a perspective worthy of consideration by policymakers*"[2] (p. 58). Cost-effectiveness is a yard stick to see if an intervention's tradeoffs are in line with what is generally deemed to be acceptable. In our analysis, we pointed out, for example, that the cost per year of life saved associated with reducing rural interstate highway speed limits from 65 mph to 55 mph is nearly 10 times <u>less</u> than the corresponding cost for restrictions on cellular phone use while driving. This comparison alone does not rule out the acceptability of such restrictions, but it does raise the question of why the restrictions should be considered to be acceptable if the speed limit reductions are not.

The HCRA report represents an effort to look objectively at both the risks and benefits of using a cellular phone while driving. We carefully studied the issue and wrote the report in an effort to make a serious contribution to this contentious public debate. We hope that we have successfully addressed the concerns that Public Citizen has raised about our integrity and commitment to rigorous, objective public health research.

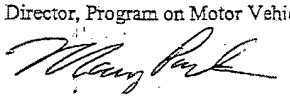
Sincerely,



Joshua T. Cohen, PhD
Senior Research Associate



Karen S. Lissy, MPH
Director, Program on Motor Vehicles and Public Health



Mary Y. Park, MS
Research Analyst (former)

cc: The Honorable Daniel Akaka
The Honorable Robert Bennett
The Honorable Jean Carnahan
The Honorable Thomas Carper
The Honorable Max Cleland
The Honorable Thad Cochran
The Honorable Susan Collins
The Honorable Pete Domenici
The Honorable Richard Durbin
The Honorable Judd Gregg
The Honorable Carl Levin
The Honorable Joseph Lieberman
The Honorable Ted Stevens
The Honorable Robert Torricelli
The Honorable George Voinovich

May 4, 2001

01 MAY -9 PM 1:59

The Honorable Fred Thompson, Chairman
340 Dirksen Senate Office Building
Washington, DC 20510

RE: Alumni Endorsement of John Graham to OIRA-OMB

Dear Senator Thompson:

As current and former students of Dr. John Graham, Professor of Policy and Decision Sciences at the Harvard School of Public Health (HSPH), we write to express our support for his nomination to Administrator of the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget.

We know Dr. Graham as an inspiring and fair-minded teacher, mentor, and advisor, who is vastly knowledgeable in the fields of risk assessment and cost-benefit analysis. Many of us have also had the opportunity to work with Dr. Graham at the Harvard Center for Risk Analysis (HCRA), where we were encouraged to express diverse viewpoints, explore new interest areas, challenge underlying assumptions, and conduct research of the highest quality. Through his intellectual curiosity and rigorous work ethics, Dr. Graham has been an inspiration for many students over the last 15 years.

Given his extensive teaching, publications, and research on risk assessment and cost-benefit principles, we believe that Dr. Graham is an excellent choice to serve in an administrative role in the Office of Management and Budget. His unique ability to champion and lead a highly professional and multidisciplinary research center provides further evidence of his strong leadership and management capabilities.

Based upon our collective experiences, we urge you to disregard any attacks on Dr. Graham's integrity or character as these are without merit. We wholeheartedly endorse his nomination as Administrator of OIRA, and believe him to be exceptionally qualified for this position.

Sincerely,

Pamela R. D. Williams

Pamela R. D. Williams, SM (1996), ScD (1999)
Environmental Health and Health Policy and Management
Program in Environmental Science and Risk Management

**Alumni Endorsement of John Graham to OIRA-OMB**

Miriam E. Adams, MSW, LICSW, SM (1987), ScD (1990)
Health Policy and Management

Nicole S. Bell, ScD (1994)
Health Policy and Management
Program Evaluation

Kevin P. Brand, SM (1994), ScD (1999)
Environmental Health

Timothy James Carrothers, ScD (2000)
Environmental Health and Health Policy and Management
Program in Environmental Science and Risk Management

Joshua T. Cohen, PhD (1994)
Graduate School of Arts and Sciences and Business School
Program in Decision Sciences

Phaedra Shaffer Corso, PhD (2000)
Graduate School of Arts and Sciences
Program in Health Policy

Alison Cullen, MS (1989), ScD (1992)
Environmental Health Management
Environmental Health Science

Thomas Stephen Dumyahn, SM (1994)
Environmental Health
Program in Environmental Science and Engineering

Nicholas Gertler, MS (1995), JD (1998)
Technology and Policy Program, MIT
Harvard Law School

Neil C. Hawkins, SM (1986), ScD (1988)
Environmental Health Sciences

James P. Laurenson, MS (1986)
Environmental Health
Program in Environmental Health Management

Jonathan Levy, ScD (1999)
Environmental Health and Health Policy and Management
Program in Environmental Science and Risk Management

**Alumni Endorsement of John Graham to OIRA-OMB**

Elizabeth Ann Miesner, MS (1987)
Environmental Health Science
Program in Environmental Health Management/Air Pollution

Susan W. Peck, SM (1987), ScD (1991)
Health Policy and Management

Lisa A. Prosser, PhD (2000)
Graduate School of Arts and Sciences
Program in Health Policy

Rick Reiss, ScD (1994)
Environmental Health
Program in Environmental Science and Engineering

Dana Gelb Safran, ScM (1998), ScD (1993)
Health Policy and Management

Eric B. Schupper, ScM (1997)
Environmental Health

Brad Shurdut, SM (1989)
Environmental Health Sciences

Joanna E. Siegel, ScD (1990)
Health Policy and Management
Program in Health Decision Sciences

Andrew E. Smith, SM (1990), ScD (1994)
Environmental Health
Program in Environmental Health Sciences

Sarah E. Spedden, SM (1982), ScD (1992)
Environmental Health
Program in Exposure Assessment and Engineering

Tammy Ora Tengs, ScD (1994)
Health Policy and Management
Program in Decision Sciences

Kimberly M. Thompson, ScD (1995)
Environmental Health

**Alumni Endorsement of John Graham to OIRA-OMB**

Edmond Toy, PhD (expected 2002)
Graduate School of Arts and Sciences
Program in Health Policy

Katherine von Stackelberg, ScM (1998), ScD (2002)
Environmental Health and Health Policy and Management
Program in Environmental Science and Risk Management

Katherine D. Walker, ScD (1999)
Environmental Science

Eve Wittenberg, PhD (2000)
Graduate School of Arts and Sciences
Program in Health Policy

Scott K. Wolff, ScD (2000)
Environmental Health
Program in Environmental Health Management

Sonia Yeh, MS (1997)
Environmental Health

Fumie Yokota, PhD (2002)
Graduate School of Arts and Sciences
Program in Health Policy

# WHO IS PROFESSOR JOHN D. GRAHAM? A SCHOLARLY RESPONSE TO PUBLIC CITIZEN

Prepared by Supporters of John D. Graham, Ph.D. (Professors John Evans, Sue Goldie, James Hammitt, Karen Kuntz, Peter Neumann, Kimberly Thompson and Milton Weinstein of the Harvard School of Public Health, 718 Huntington Avenue, Boston, MA 02115.)

April 25, 2001

## EXECUTIVE SUMMARY

President Bush has nominated Professor John D. Graham of the Harvard School of Public Health to the position of Administrator, Office of Information and Regulatory Affairs, US Office of Management and Budget. The nomination is subject to Senate confirmation.

Public Citizen, a group affiliated with Ralph Nader, has made numerous criticisms of Professor Graham and the Harvard Center for Risk Analysis. We believe Public Citizen's criticisms are inaccurate and misleading.

This report provides facts and perspectives from people who know Professor Graham well as a teacher, scholar, and leader. ***In short, Professor Graham is an objective, open-minded scholar who is exceptionally well qualified to serve as President Bush's chief regulatory analyst.***

TABLE OF CONTENTS


| Topic | Page |
|---|---|
| Credentials | 2 |
| Funding of Center | 2 |
| Regulatory Reform | 3 |
| The Rise of Analytic Tools | 4 |
| Why compare Risks? | 5 |
| Disclosure Issues | 6 |
| Graham's and HCRA's Independence from Funders | 6 |
| Conclusion | 11 |
| References | 11 |

CREDENTIALS

Professor Graham's BA (economics/politics), MA (public affairs), and Ph.D. (public affairs) degrees were earned at Wake Forest University, Duke University, and Carnegie-Mellon University, respectively. Graham's technical training at Duke (1978-80) and Carnegie-Mellon (1981-83) was concentrated in decision analysis, a branch of management science that is sometimes called managerial economics.

Professor Graham also has post-doctoral training in environmental science and public policy at the Harvard School of Public Health, where he took coursework in risk assessment and collaborated with physical scientists, biological scientists, and statisticians. Prior to joining Harvard, Graham staffed the Committee on Risk and Decision Making (1979-80) of the National Research Council/National Academy of Sciences, a multidisciplinary committee of eminent scientists. Thus, Professor Graham has considerable experience working with scientists from diverse fields.

Professor Graham is active in the international Society for Risk Analysis (SRA), a membership organization of 2,000+ scientists and engineers worldwide dedicated to advancing the methods and applications of risk analysis. SRA is not an industry organization but a scientific society of dues-paying members with a wide range of scientific backgrounds and political viewpoints. Graham served as elected President of SRA from 1994-95 and has been working for several years to plan the first World Congress on Risk Analysis in Europe.

Professor Graham has participated in the authorship or editing of seven books and over 100 articles. His most significant scholarly contributions concern automotive safety, environmental policy, chemical risk assessment, and regulatory reform. He was awarded a tenured Professorship in Policy and Decision Sciences at Harvard in 1991 at the age of 34.

For the past 15 years, Graham has taught the analytic tools of cost-benefit analysis and cost-effectiveness analysis to graduate students at the Harvard School of Public Health. He has mentored approximately 20 doctoral students interested in the application of these tools to public health, and these students have been placed in activist groups, academia, government, and industry. These are the same analytic tools that underpin the regulatory-review work of the Office of Information and Regulatory Affairs, US Office of Management and Budget (OMB).

**FUNDING OF CENTER**

In 1990 Professor Graham founded the Harvard Center for Risk Analysis (HCRA) at the Harvard School of Public Health. The mission of the Center is to promote more reasoned public responses to health, safety, and environmental hazards through formal education, research, and communications. Professor Graham has helped raise sufficient funds from

private industry, government, and other sources to sustain nine full-time faculty members, scores of graduate students and fellows, and a vigorous communications program.

In fiscal year 2000 the budget of the Center was approximately $3 million. Revenue sources were about 40% from unrestricted gifts from private industry and individuals, 30% from restricted government grants, 20% from restricted private grants, and 10% from unrestricted University support. The Center's public funds include multi-year grants from the National Science Foundation, the Centers for Disease Control, the Environmental Protection Agency (EPA), the National Cancer Institute, the Department of Agriculture and other federal agencies.

HCRA's restricted funding is raised and expended according to University regulations that protect the intellectual freedom of faculty and students to draw independent conclusions. In order to further guard against any real or perceived conflicts of interest, the Center adopted in 1997 an explicit conflict-of-interest policy that goes beyond standard University policy in several respects. This policy, and the Center's funding sources, are published in the Center's biennial report and summarized at www.hcra.harvard.edu.

The majority of the Center's work is published in peer-reviewed scientific, technical, and medical journals. Center publications undergo an internal peer review process. The Center faculty and students meet regularly with an independent advisory committee of scientists to review progress and set new goals. These advisory committee members are from diverse organizations and have different disciplinary backgrounds and political perspectives.

## REGULATORY REFORM

Professor Graham's interest in regulatory reform arises from a conviction that a smarter regulatory system, informed by careful analysis, can achieve more health and environmental benefits at less cost than is being accomplished by current regulatory activities. Professor Graham's view is not "anti-regulation" and his approach to regulatory reform is certainly not "hostile" to public health and environmental safeguards.

The tools of formal analysis and peer review do not necessarily slow down the rulemaking process. In his two books, HARNESSING SCIENCE FOR ENVIRONMENTAL REGULATION (1991) and THE GREENING OF INDUSTRY: A RISK-MANAGEMENT APPROACH (1997), Professor Graham uses case studies of EPA rulemakings to illustrate how formal analysis and peer review enhance the regulatory process. By increasing the competence and credibility of decisions, these tools reduce opposition from stakeholders and protect rulemakings from political and legal attacks.

Professor Graham's concern for the vitality of regulatory agencies is evident from his public positions on budgetary issues. He opposed Republican efforts to cut the budgets

of health agencies in 1994-95 and he has consistently coupled his advocacy of analytical requirements with requests that adequate resources, training, and career opportunities be made available to agency analysts (Graham, 1995a; Graham 1996; Graham, 1997).

Public Citizen charges that regulatory improvement legislation that Graham has supported, such as the Thompson-Levin bill in the last Congress, is a disguised effort to hamper regulators through "paralysis by analysis". These issues were discussed at the relevant Senate hearing and, after modest revisions to the bill, the Clinton-Gore Administration decided the bill was acceptable and several senior Senate Democrats, including Tom Dashle, joined Carl Levin and Fred Thompson as co-sponsors. A case can be made that the Thompson-Levin bill is too modest to have a dramatic effect but it is certainly a constructive step in the direction of more analytical and transparent regulatory decisions.

## THE RISE OF ANALYTIC TOOLS

When Professor Graham first began to study regulation in the 1970's, there was widespread resistance to the application of formal analytic tools to public health and environmental protection. Critics argued that these tools were inapplicable, unreliable and/or unethical. Many of the viewpoints expressed by Public Citizen echo these earlier criticisms.

The world has changed since the 1970's. Although many regulations offer substantial benefits, some regulations are quite costly to state and local governments, businesses, and private citizens. Each President since Gerald Ford has required some form of benefit-cost analysis of major regulatory proposals. Some court decisions and legislation have also required regulators to make use of formal analytic tools. Recently, Congress has required OMB to perform an annual accounting of the benefits and costs of the regulatory state.

Databases and information technology have also improved since the 1970s, making insightful analyses more feasible. The number of professional and graduate students trained with these tools has increased, as has the number of university-based centers and think tanks with expertise in regulatory analysis. Progress in the related fields of risk assessment, health economics, and environmental economics has been particularly rapid.

The analytic tools still have important limitations and thus no one should expect regulatory decisions to be executed by computer. Moreover, there are important value judgements to be made about ethics and justice that no analysis of economic efficiency can resolve. There are also concerns of citizens and stakeholders that must be addressed by accountable decision makers. In the final analysis, regulation requires political judgement but it is now feasible for that judgement to be informed by cost-benefit analysis.

Public Citizen fears that Professor Graham "worships" so much at the altar of economics that he would allow cost-benefit numbers to trump all other considerations. Yet a careful

review of Professor Graham's writings and testimony before Congress reveals a more nuanced view.

Graham consistently insists that qualitative or intangible factors (e.g., concern for equity or fairness) must accompany efficiency considerations in both analysis and the ultimate regulatory decision (Graham 1996; Graham, 1995a; Graham, 1995b; Harvard Group on Risk Management Reform, 1995; Graham and Hammitt, 1996). He also departs in important ways from classical economic approaches to benefit measurement that depend too heavily on a person's wealth or asset position.

The quality-adjusted life year (QALY) method of benefit measurement, now widely used in medicine and public health, assigns the same value to a healthy year of life, regardless of whether the person is rich or poor, male or female, and so forth. It does account for how many years of life are lost due to premature death. But this method also allows for direct consideration of "quality of life" concerns in regulatory analysis (e.g., the suffering and functional impairment arising from sicknesses that do not result in death). In promoting the QALY method, Professor Graham's thinking departs significantly from classical economic approaches.

Graham has also helped develop tools to quantify and illustrate the degree of uncertainty in estimates of benefits and costs, thereby allowing regulators to assign an appropriate degree of confidence to analytical results (Evans et al, 1994a; Evans et al, 1994b). In a study of the chemical chloroform funded by the Chemical Manufacturers Association, HCRA scientists found that the expected cancer risk from human exposure to chloroform was greater than predicted by standard EPA procedures, an insight that arises from use of the formal tools of uncertainty analysis (Evans et al, 1994b). In his most recent writings, Graham has sought to merge thinking about the precautionary principle with insights from "value-of-information" analysis, a subfield of decision analysis.

## WHY COMPARE RISKS?

Professor Graham is well known for promoting a "comparative-risk" perspective to the regulation of health, safety, and environmental hazards. Comparison of risks has three distinct purposes that are sometimes confused by Public Citizen.

First, comparison of risk is an educational tool intended to offer a sense of perspective about the size of a new, unfamiliar risk. To go further and draw a conclusion about whether the new risk is acceptable or unacceptable requires further information and value judgements. Graham agrees that acceptability judgements must include qualitative factors such as whether a risk is voluntary or involuntary. A key feature of HCRA's cell-phone study – which Public Citizen criticizes -- is a separate assessment of the voluntary and involuntary risks caused by the use of cell phones while driving.

Second, comparison of risk allows a decision maker to weigh a risk of disease that might be prevented (e.g., by a new drug) against a risk that might be created (e.g., a side effect of the drug). In more complex cases, reducing risk to some people may cause other

people to experience more risk (e.g., early airbag systems reduced risks to adults but increased risks to children). In RISK VERSUS RISK (Harvard Press, 1995) Graham and co-authors demonstrate that tradeoffs in regulatory decision making are pervasive and need to be considered carefully.

Third, comparison of risk can be used by decision makers to help set priorities – by targeting big risks before little risks or by favoring more cost-effective policies over less cost-effective policies. It was comparative risk assessment that was used by EPA in the late 1980s to help draw attention to the need for the US to take seriously the risks of global climate change. Professor Graham advocates greater use of risk-based priority setting because it will help agencies save more lives with the available agency resources. As one of Professor Graham's doctoral students, Tammy Tengs (now a faculty member at UC-Irvine), produced an influential dissertation quantifying the number of lives that could be saved in the USA (60,000 per year) through wiser resource allocation.

Public Citizen insists that comparing unrelated or dissimilar risks is a false dichotomy since people can reduce all risks. Yet the resources available to households, businesses and governments are limited. Professor Graham (and colleague March Sadowitz) have proposed creative approaches to community choice whereby a local community could decide how best to reduce risk. For example, should a locality expend all Superfund clean-up dollars on soil washing at an abandoned industrial site, or should they be permitted to spend some of these dollars on more promising risk-reduction measures (e.g., smoking prevention, violence prevention, or bicycle helmet promotion)? If a community can demonstrate, through comparative risk assessment, that the last 10% of soil-cleanup dollars would be better spent reducing risk from violence prevention, Graham and Sadowitz (1994) argue that the community should be permitted to do so. Thus, there is tremendous opportunity for Congress and localities to use risk comparisons in the pursuit of public health.

**DISCLOSURE ISSUES**

HCRA has a strong record of disclosing its unrestricted funding sources as well as its sources of restricted support for specific projects. In fact, Public Citizen uses HCRA's web site to document the industrial and governmental funding that has supported HCRA over the past decade.

In order to make disclosure an issue, Public Citizen charges that Graham has failed to disclose all his relevant funding sources whenever speaking with reporters. Yet no such disclosure standard has ever been imposed on other academics participating in the public policy process. When reporters have asked Graham about the Center's funding sources, which they frequently do, he has told them or directed them to the HCRA web site.

**GRAHAM'S AND HCRA'S INDEPENDENCE FROM FUNDERS**

Public Citizen states accurately that the findings of some HCRA studies, including some of the policy viewpoints of Professor Graham, are favorable to the interests of HCRA's

industrial funders. Yet Public Citizen fails to disclose the numerous instances where HCRA and Graham have used data and analysis in constructive ways that are contrary to the interests of HCRA's industrial sponsors. Here are ten examples:

1. INDOOR AIR POLLUTION IS A NEGLECTED HAZARD THAT DESERVES CONGRESSIONAL ATTENTION.

Professor Graham has repeatedly identified indoor air pollution as a major environmental health risk that has not been addressed adequately by Congress and regulatory agencies (Graham, Holtgrave and Sawey, 1989, p.171; Graham, 1996; Graham, 1997). In 1999 and 2000 testimony before the Senate Committee on Environmental and Public Works, Professor Graham urged greater priority be given to indoor air pollution. He has specifically cited second-hand smoke (environmental tobacco smoke) as an important component of the indoor air problem (Graham, 1989; Graham 2000). Professor Graham's surveys of scientists have also documented widespread scientific consensus that breathing second-hand smoke is hazardous to people's health (Graham et al, 2000). The recommended focus on indoor air quality is not in the commercial interests of several of HCRA's industrial donors.

2. DISEASES OTHER THAN CANCER DESERVE GREATER ATTENTION IN CHEMICAL RISK ASSESSMENT AND MANAGEMENT.

Professor Graham has expressed concern that EPA's cancer risk assessment procedures may exaggerate the dangers of low-level exposures to chemicals and radiation – a position that favors some HCRA funders. Yet Professor Graham has also emphasized for more than a decade that a variety of non-cancer health effects – reproductive and developmental effects, immune system disorders, neurological effects, and disruption of the endocrine system – need greater attention by both the scientific community and regulatory risk assessors (Sawey et al, 1989, p.30; Graham, 1991, p.16; Center for Risk Analysis, 1992, p.82; Walker et al, 1995, pp.30-32; Graham, 1995c, p.44). For example, Professor Graham served as a member of EPA's Science Advisory Board panel that reviewed EPA's dioxin risk assessment in 1995 and 2000. At both meetings, Professor Graham urged EPA scientists to give greater attention to the non-cancer health effects of human exposure to dioxin. Graham's colleagues at HCRA have been pioneers in development of new analytic tools to assess chemical toxicities other than cancer (e.g., see Baird et al, 1996, pp. 79+; Evans et al, 2000).

3. AGENCIES SHOULD DEVELOP "DEFAULT" CANCER POTENCY FACTORS FOR UNTESTED CHEMICALS.

Professor Graham and his colleagues at HCRA have expressed concern that many chemicals in widespread use have not yet been tested in rodents or humans for their cancer-causing potential (HCRA's OMB Workshop, 1991, p.8; Graham et al, 1992). Under current regulatory practice, it is assumed that these chemicals have zero carcinogenic potential. Graham and colleagues have objected to this practice (Graham, 1995c, pp.41-42). They have developed and advocated an approach that would assign a

"default" (preliminary) cancer potency number to each untested chemical until it has been tested properly. The preliminary number would be based on acute toxicity data and results from cellular DNA tests, which are more commonly available. A HCRA-affiliated doctoral student, Alison (Taylor) Cullen (now a faculty member at the University of Washington), devoted part of her dissertation to this topic. Federal and state agency use of default potency factors would create incentives for chemical producers and users to perform appropriate cancer tests on untested chemicals.

4. THERE IS A ROLE FOR "EQUITY" AND "INTANGIBLES" IN REGULATORY DECISION MAKING.

Those who have taken Professor Graham's courses or read his scholarly writings know that he appreciates the ethical limitations of economics and certainly sees a role for consideration of equity and intangible factors in regulatory analysis and decisions. His writings on regulatory reform are quite specific on this point (Graham, 1995a, p.14; Graham, 1995b, p.64; HGRMR, 1995, pp. 194-95; Graham and Hammitt, 1996, pp.105-106; Graham, 1996). Moreover, he chaired an EPA panel on chemical exposures that highlighted the need to collect data on highly exposed people in the community (Graham et al, 1992). He has also published work on how the poor living near coke plants incur a disproportionate share of the disease burden caused by air pollution from these plants (Graham et al, 1999). These viewpoints and findings reveal a commitment to economics in regulatory decision making that is qualified by concerns for fairness.

5. GASOLINE TAXES AND CONSUMER TAX CREDITS ARE WORTH CONSIDERING FOR AUTOMOBILE ENERGY CONSERVATION.

In order to promote fuel conservation in the transportation sector, Professor Graham has advocated for greater use of economic incentives instead of stricter fuel economy standards. He has written specifically about the need for a gradual increase in the gasoline tax or authorization of consumer tax credits for consumers who purchase vehicles with hybrid engines, advanced diesels, or alternate fuels (Crandall and Graham, 1991; Graham, 2000). Although these positions can be seen as favorable to the motor vehicle industry, they are also against the commercial interests of another segment of HCRA's industrial donors: the petroleum industry.

6. THERE IS A NEED TO REGULATE OUTDOOR PARTICULATE AIR POLLUTION.

As Center Director, Professor Graham supported the work of a team of faculty and students (led by Dr. John Evans) that have been making a scientific and economic case for increased regulation of fine particles in outdoor air. Graham helped advise two doctoral students, Scott Wolff and Timothy J. Carrothers, who have demonstrated the cost-effectiveness of additional controls on particles emitted from motor vehicles, electric power plants, and manufacturing facilities. Professor Graham co-authored a commentary in HCRA's newsletter (with Professor Douglas Dockery of Harvard) highlighting the health risks of particulate exposures, even at very low levels of exposure. In

congressional testimony Professor Graham has indicated that he believes that emission sources of particles should be regulated under a cost-benefit framework, and that new emissions rules covering particulates, if crafted carefully, are likely to be a cost-effective investment in public health protection. The case for stricter ozone rules, he has indicated, is much weaker. In order to highlight the health risks of fine particles for staff and members of Congress, Professor Graham mailed a copy of the book, PARTICLES IN OUTDOOR AIR (eds., Richard Wilson, John Spengler), to every member of the House and Senate during congressional deliberations on EPA's proposals to create new health standards for particles and ozone.

7. THERE IS A NEED FOR THE USA TO TAKE A LEADERSHIP ROLE ON GLOBAL CLIMATE CHANGE.

Using unrestricted HCRA funds, Professor Graham backed in 1993 the hiring of a new junior faculty member, Dr. James Hammitt, who is a specialist on the economics of global climate change. Hammitt has used cost-benefit tools in a series of technical papers that support the need for the US and the world to take long-term action to slow the rate of global climate change. Recently, Dr. Hammitt published an op-ed piece in the Washington Post calling for replacement of the Kyoto accords with a new system of national carbon taxes. Professor Graham's view is that the Kyoto accords were ill advised but that the US should now take modest, cost-effective steps to demonstrate our country's seriousness about the global climate issue and spur global policies (Graham, 2000). None of the work cited here is supportive of the "just say no" positions of some industrial contributors to HCRA.

8. THERE IS A NEED TO REGULATE SPORT-UTILITY VEHICLES FOR SAFETY AND ENVIRONMENTAL PROTECTION.

In a recent article published in Issues in Science and Technology (NAS), Professor Graham advocated a long-term, multi-year program of research and regulation to "civilize" the sport-utility vehicle (Graham, 2000). The program would include standards to reduce rollover risks and "aggressivity" in two-vehicle crashes, stricter safety measures for small cars, and consumer tax credits to encourage vehicles with hybrid engines, advanced diesels, or alternate fuels. One of Graham's doctoral students, Edmond Toy, is supported by unrestricted HCRA funds to undertake a thesis in this area. Again, the inquiries described here are likely to favor and harm diverse interests within HCRA's industrial donor base.

9. THE NEED TO IDENTIFY COST-EFFECTIVE MEASURES AGAINST MAJOR DISEASES IS PRESSING.

Professor Graham has deployed unrestricted HCRA funds as an insurance policy to back the hiring of new faculty members at Harvard who are working to find cost-effective solutions to the following health risks: Alzheimer's disease (Peter Neumann), children's health risks (Kimberly Thompson), inner-city health care (Sue Goldie), colon cancer (Karen Kuntz), and cardiopulmonary disease from pollution (Jonathan Levy). None of

the research agendas of these young faculty members could plausibly be considered a case of "science for sale" to industry, as Public Citizen charges.

10. AIRBAG REGULATIONS SHOULD BE STRENGTHENED BASED ON REAL-WORLD EXPERIENCE WITH THE TECHNOLOGY.

Professor Graham's 1983 doctoral dissertation included a cost-benefit analysis of airbag technology with results favorable to airbags. In fact, the results were later cited in pro-airbag rulings by both the US Supreme Court and Secretary of Transportation Elizabeth Dole. This line of work was in direct conflict with the "regulatory relief" agenda of the early Reagan Administration and the positions of major automakers.

In 1996 Professor Graham became concerned about highly publicized reports indicating that airbags were causing unexpected injuries to motorists. He therefore formed the Airbag Working Group at HCRA to investigate the issues. The Working Group, which includes physicians, engineers, survey specialists, statisticians, and economists has published over 10 studies since 1996 (e.g., see Graham et al, 1997; Graham et al, 1998; Segui-Gomez, 1999; Glass et al, 2000). Here are the key findings:

--The driver side airbag, though not as cost-effective as anticipated, is a reasonable investment despite occasional adverse side effects;

--Surveys of drivers, accompanied by direct physical measurements, found that most drivers, including most women, do not sit too close to the airbag housing in their normal driving posture;

--The driver airbag would probably be more cost-effective if it were redesigned to deploy less frequently in low-speed crashes, a finding that has created consternation among car companies and airbag suppliers;

--The passenger side airbag, though less cost-effective than the driver airbag, is a reasonable investment except for the fact that a specific subgroup of motorists, children under the age of 9, are placed at increased risk of death due to the presence of the passenger airbag;

--Both belted and unbelted children are placed at net risk by passenger airbags, which Professor Graham used as the basis for his recommendation that states enact laws requiring such children to sit in the rear (when a rear seat is available); four states have enacted such laws, and the Rhode Island law appears to be a modest success;

--For future passenger airbags, Professor Graham and colleagues favored a regulatory requirement that would shut off airbag deployment if sensors detect a child is seated in the front seat;

--Passenger airbags appear to protect 9-12 year olds while hurting 0-8 year olds, a finding that complicates the ability of airbag engineers to design child-friendly airbags.

Professor Graham's findings and viewpoints on airbags have been highly responsive to emerging data and peer comment. He has not been reluctant to acknowledge areas where he has made mistakes in previous analyses (e.g., his dissertation overestimated airbag effectiveness for unbelted adults and neglected the risks to children). In short, he has sought the truth in an open-minded and self-critical manner.

## CONCLUSION

Public Citizen charges that biases result from HCRA's acceptance of industrial funding. Yet biases can result from virtually any source of funding (e.g., government grants, individual gifts, or University support). Like all human beings, Professor Graham and his colleagues have personal biases and widely varying political viewpoints. Thus, the Center has been designed – through collaboration, advisory activities, and peer review -- to foster objectivity in teaching, research, and communications.

Although some HCRA studies do reach valid conclusions that happen to serve the interests of donors or sponsors, there are numerous examples of HCRA studies that reached valid conclusions that were indifferent to or in conflict with the interests of sponsors. Professor Graham's evaluations of airbag technology have been notably open-minded and objective, even though automotive interests and National Highway Traffic Safety Administration provide financial support to the Center. The most telling indicator of the quality of HCRA's work is the large number of publications in peer-reviewed scientific journals on topics of critical importance to medicine, public health, and environmental protection.

## REFERENCES

Baird SJ, Cohen JT, Graham JD, Shlyakhter AI, Evans JS, "Noncancer Risk Assessment: A Probabilistic Alternative to Current Practice," Human and Ecological Risk Assessment 2(1), 1996, pp. 79-102.

Crandall RW, Graham JD, "New Fuel Economy Standards?" The American Enterprise, March/April 1991, pp. 68-69.

Center for Risk Analysis, OMB Versus the Agencies: The Future of Cancer Risk Assessment, Boston, MA, June 1991.

Cullen A, Evans JS, McKone T, Risk Analysis, 13(4), 1993, pp.403-412.

Evans JS, Graham JD, Gray GM, Sielken RL, "A Distributional Approach to Characterizing Low-Dose Cancer Risk," Risk Analysis, 14(1), 1994a, pp. 25-34.

Evans JS, Gray GM, Sielken RL, Smith AE, Valdez-Flores Ciriaco, Graham JD, "Use of Probabilistic Expert Judgement in Uncertainty Analysis of Carcinogenic Potency," Regulatory Toxicology and Pharmacology, 20, 1994b, pp. 15-36.

Evans JS, Rhomberg L, Williams PL, Wilson AM, Baird S, "Reproductive and Developmental Risks from Ethylene Oxide: A Probabilistic Characterization of Possible Regulatory Thresholds," Risk Analysis, in press.

Glass RJ, Segui-Gomez M, Graham JD, "Child Passenger Safety: Decisions about Seating Location, Airbag Exposure, and Restraint Use," Risk Analysis 20(4), 2000, pp. 521-527.

Graham JD, "Improving Chemical Risk Assessment," Regulation, Fall 1991, pp.14-18.

Graham JD (ed), Harnessing Science for Environmental Regulation, Praeger/Auburn House, Westport, CN, 1991.

Graham JD, "The Safety Risks of Proposed Fuel Economy Legislation," Risk: Issues in Health and Safety, vol. 3, Spring 1992, pp. 95-126.

Graham JD, "Recommendations for Improving Cancer Risk Assessment," Center for Risk Analysis, Harvard School of Public Health, Boston, MA, July 1, 1992.

Graham JD, "Historical Perspective on Risk Assessment in the Federal Government," Toxicology, 102, 1995c, pp.29-52.

Graham JD, "Edging Toward Sanity on Regulatory Risk Reform," Issues in Science and Technology, Summer 1995b, pp. 61-66.

Graham JD, "The Future of Risk Regulation," in Strategies for Improving Environmental Quality and Increasing Economic Growth (eds., CE Walker, MA Bloomfield, and M Thorning), American Council for Capital Formation, Center for Policy Research, Washington, DC, August 1995a, pp. 3-18.

Graham JD, "Making Sense of Risk: An Agenda for Congress," in Risks, Costs, and Lives Saved: Getting Better Results from Regulation (ed., R Hahn), Oxford University Press, NY, 1996, pp. 183-207.

Graham JD, "Legislative Approaches to Achieving More Protection Against Risk at Less Cost," University of Chicago Legal Forum, 1997, pp. 13-58.

Graham JD, Wiener J (eds), Risk Versus Risk: Tradeoffs in Health and Environmental Protection, Harvard Press, Cambridge, MA, 1995.

Graham JD, Hartwell J (eds), The Greening of Industry: A Risk-Management Approach, Harvard Press/Harvard School of Public Health, 1997

Graham JD, "Civilizing the Sport Utility Vehicle," Issues in Science and Technology, Winter 2000-01, pp. 57-62.

Graham JD, Holtgrave DR, Sawey MJ, "The Potential Health Benefits of Controlling Hazardous Air Pollutants," CRS Report for Congress, January 1, 1989.

Graham JD, Walker KD, Berry M; Bryan EF, Callahan MA, Fan A, Finley B, Lynch J, McKone T, Ozkaynak H, Sexton K, "Role of Exposure Databases in Risk Assessment," Archives of Environmental Health, Vol 47(6), Nov/Dec 1992, pp.408-420.

Graham JD, Sadowitz MS, "Superfund Reform: Reducing Risk through Community Choice," Issues in Science and Technology, Summer 1994, pp. 35-40.

Graham JD, Hammitt JK, "Refining the Comparative Risk Analysis Framework," in Comparing Environmental Risks: Tools for Setting Government Priorities (ed., JC Davies), Resources for the Future, Washington, DC, 1996, pp. 93-109.

Graham JD, Richardson E, "Ranking Risk Inequities," Risk: Health, Safety, and Environment, 6, 1995, pp. 359-372.

Graham JD, Thompson KM, Goldie SJ, Segui-Gomez M, Weinstein MC, "The Cost-Effectiveness of Air Bags by Seating Position," JAMA 278(17), 1997, pp.1418-1425.

Graham JD, Goldie SJ, Segui-Gomez M, Thompson KM, Nelson T, Glass R, Simpson A, Woerner LG, "Reducing Risks to Children in Vehicles with Passenger Airbags," Pediatrics 102(1), 1998, e3.

Graham JD, Beaulieu ND, Sussman D, Sadowitz M, Li YC, "Who Lives Near Coke Plants and Oil Refineries? An Exploration of the Environmental Inequity Hypothesis," Risk Analysis vol. 19 (2), 1999, pp. 171-186.

Graham, JD, Clemente RJ, Glass RJ, Pasternak N, "Measuring Confidence in Hazard Claims: Scientists Versus Laypeople," Technology, vol. 6, 1999, pp.77-87.

Harvard Group on Risk Management Reform, "Special Report: Reform of Risk Regulation – Achieving More Protection at Less Cost," Human and Ecological Risk Assessment 1(3), 1995, pp.183-206.

Rosenthal A, Sawey MJ, Graham JD, "Incinerating Municipal Solid Waste: A Health Benefit Analysis of Controlling Emissions," CRS Report for Congress, April 21, 1989.

Segui-Gomez M, Levy J, Roman H, Thompson KM, McCabe K, Graham JD, "Driver Distance from the Steering Wheel: Perception and Objective Measurement," American Journal of Public Health, vol. 89(7), 1999, p.1109-1111.

Walker KD, Sadowitz M, Graham JD, "Confronting Superfund Mythology: The Case of Risk Assessment and Management," in Analyzing Superfund: Economics, Science, and Law (eds., RL Revesz, RB Stewart), Resources for the Future, Washington, DC, 1995, pp.25-53.

**HARVARD UNIVERSITY**
**Cambridge, MA 02138**

May 15, 2001

Hon. Fred Thompson
Chairman
Senate Governmental Affairs Committee
511 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Thompson:

We, the undersigned members of the Harvard University faculty, would like to go on record in strong and unequivocal support of the nomination of John D. Graham as Assistant Administrator of the Office of Management and Budget. We have known Professor Graham as an academic colleague, and we are familiar with his approach to scholarship, separation of funding sources from the content of research, and his impeccable scientific and personal integrity. We are Democrats, Republicans and Independents; liberals, moderates, and conservatives.

As Director of the Harvard Center for Risk Analysis, John Graham took the appropriate measures to ensure the scientific integrity of all of its research. In fact, notwithstanding the examples cited by the critics, many of the Center's studies that were funded by industry have produced results rather unfavorable to the sponsor.

We urge that the Senators responsible for approving his nomination examine the record and judge for themselves whether John Graham has been an example of scientific integrity to students and young faculty, and a leader in forging a model of a university-government-industry partnership in the interest of science and public policy.

Respectfully submitted,

Robert B. Blendon
Professor of Health Policy
Harvard School of Public Health

Paul Cleary
Professor of Health Care Policy
Harvard Medical School

John S. Evans
Senior Lecturer on Environmental Science
Harvard School of Public Health

Sue J. Goldie, M.D.
Assistant Professor of Health Decision Science
Harvard School of Public Health

James K. Hammitt
Associate Professor of Policy and Decision Science
Harvard School of Public Health

Karen M. Kuntz
Associate Professor of Health Decision Science
Harvard School of Public Health

Richard Monson, M.D.
Professor of Epidemiology
Director, Master of Public Health Program
Harvard School of Public Health

Peter J. Neumann
Assistant Professor of Health Decision Science
Harvard School of Public Health

Joseph P. Newhouse
MacArthur Professor of Health Policy
Director, Division of Health Policy Research and Education
Harvard University

R. Heather Palmer, M.D.
Professor of Health Policy and Management
Harvard School of Public Health

Deborah Prothrow-Stith, M.D.
Professor of Public Health Practice
(Formerly Commissioner of Public Health, Commonwealth of Massachusetts)
Harvard School of Public Health

Howard Raiffa
Frank P. Ramsey Professor of Managerial Economics
Harvard University

Robert Stavins
Albert Pratt Professor of Business and Government
Director, Environmental Economics Program
John F. Kennedy School of Government

Katherine Swartz
Associate Professor of Health Policy
Harvard School of Public Health

Kimberly Thompson
Assistant Professor of Risk and Decision Science
Harvard School of Public Health

Milton C. Weinstein
Henry J. Kaiser Professor of Health Policy and Management
Harvard School of Public Health

Richard Wilson
Mallinckrodt Professor of Physics
Harvard University

Richard J. Zeckhauser
Professor of Political Economy
John F. Kennedy School of Government

# Harvard Injury Control Research Center

Cop

April 11, 2001

Senator Kerry
One Bodoin Square
Boston, MA 02114

Dear Senator Kerry,

A colleague, John D. Graham, Ph.D, has been nominated by the Bush administration to the Office of Management and Budget. His hearings are set for early May.

I have worked with John for more than 15 years, at the Harvard Injury Control Research Center, and the Harvard Center for Risk Analysis. I have also attended many sessions where John has presented material, and taught students. John is an excellent scientist. His interest is in improving the nation's health in the most cost-effective manner. He is not an ideologue; his results and conclusions come from careful analysis of real world data.

I am a public health professional, and a Democrat. I agree with John's conclusions on many issues, and disagree on some. But I have always respected his science and his integrity. I think the current Administration in Washington has made some terrible decisions. However, I believe the appointment of John Graham is one of its best ones. John will serve the nation well; I do not know of a more appropriate person to be appointed to oversee regulatory issues at OMB.

Ed Hemenway

David Hemenway, Ph.D.
Professor of Health Policy
Director, Harvard Injury Control Research Center

**Harvard School of Public Health** 677 Huntington Avenue, Boston, MA. 02115-6096
Phone: 617-432-2123, FAX: 617-432-4494 http://www.hsph.harvard.edu/hicrc/

ROLLINS
SCHOOL OF
PUBLIC
HEALTH

Department of Behavioral Sciences
and Health Education

EMORY

April 26, 2001

Senator Max Cleland
U.S. Senate
461 Senate Dirksen Building
Washington, D.C. 20510

Dear Senator Cleland:

Greetings, and congratulations on a marvelous record of accomplishment this year. I write to you today to support the nomination of Professor John D. Graham to the position of Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget. Dr. Graham was my mentor when I did my post-doctoral research fellowship at Harvard University's School of Public Health in 1988-1989. He so influenced my work and career that I noted him in the dedication of my recent book.

Professor Graham's world-class accomplishments in policy, risk and decision analysis perfectly suit him to assume the position for which he is nominated. He founded the very important Harvard Center for Risk Analysis, and there grew a team dedicated to using analytic tools to tackle critical but complex public health issues. He has worked on numerous health issues including automobile safety, environmental health, and I was fortunate enough to collaborate with him on a paper covering HIV prevention. Often these public health issues are approached in a partisan way, but Dr. Graham is dedicated to using careful analysis to weight the costs and benefits of various approaches to making our world a safer, healthier place. He is truly a person of reason, and a person driven by data.

I was formerly employed by the Federal Centers for Disease Control and Prevention in Atlanta, and there I had occasion to interact with OMB from time to time. I believe that OMB must be a place of careful, rational analysis of programs; I also believe that Professor Graham brings exactly these tools to that Office. If I can answer any questions about this letter, please do not hesitate to phone me at 404-727-5401. I hope that you will consider viewing Dr. Graham's nomination favorably. Thank you sincerely, Senator, for your time and consideration in this matter.

Sincerely yours,

David Holtgrave

David Holtgrave, Ph.D.
Professor
Department of Behavioral Science and Health Education, and
Department of Health Policy and Management

The Robert W. Woodruff Health Sciences Center
Emory University
1518 Clifton Road, NE
Atlanta, Georgia 30322
Tel 404.727.8742
Fax 404.727.1369

*An equal opportunity, affirmative action university*

Johnston & Associates, LLC
The Willard Office Building
1455 Pennsylvania Avenue, N.W., Suite 200
Washington, D.C. 20004
(202) 737-0683 FAX: (202) 737-0693

April 30, 2001

The Honorable Fred Thompson
United States Senator
United States Senate
Washington, D.C. 20510

Dear Fred:

I am delighted to submit this letter of support on behalf of Professor John D. Graham, who has been nominated by President Bush to serve as Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget. Professor Graham is a superb scholar in the field of regulatory reform. During the past decade, he has volunteered significant amounts of his personal time to assist members and staff interested in better use of science and economics in the regulation of health, safety and environmental risks. I particularly appreciated Professor Graham's interest in risk comparisons because they are an educational tool that can help citizens and opinion leaders better understand the risks of daily life as well as the risks addressed by regulators.

I first worked with Professor Graham in the 103rd Congress when consideration was given to a bill that would have elevated EPA to Cabinet-level status. Professor Graham provided useful testimony to our Committee and offered constructive technical advice on an amendment that I offered that would have promoted the use of risk analysis and cost-benefit analysis at EPA> In the 104th Congress I again worked closely with Professor Graham on a bipartisan regulatory reform bill. Although these particular initiatives were not enacted into law, Professor Graham's risk-oriented ideas later found their way into a variety of laws including the Unfunded Mandates Act, the amendments to the Safe Drinking Water Act, and the Food Quality Protection Act.

During these legislative deliberations, I found that Professor Graham was eager to offer constructive advice to Members and staff of both parties and he did a superb job of explaining technical concepts in a rigorous yet clear manner. He always presented his views in a fair and incisive manner, but was quick to defer to others on issues outside his domain of expertise.

When I heard Professor Graham's name reported in the media as President Bush's choice to lead OMB-OKRA, I was encouraged. In my opinion, this nomination is one of the very best that has been made by the new Administration. I urge you to support Professor Graham's nomination and please do not hesitate to contact me if you have any questions or desire any additional information.

With warm personal regards, I am

Sincerely,

J. Bennett Johnston
Partner

May 7, 2001

The Honorable Fred Thompson
521 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Thompson:

It is a cardinal rule of scientific research to avoid at all costs any conflict of interest that could influence the objectivity of one's findings. This rule takes on added significance in the context of biomedical and public health research, for peoples' lives are at stake.

For more than a decade, John Graham, Director of the Center for Risk Analysis at the Harvard School of Public Health and candidate for the position of Director, Office of Information and Regulatory Affairs at the Office of Management and Budget, has repeatedly violated this rule. Time and again, Professor Graham has accepted money from industries while conducting research and policy studies on public health regulations in which those same industries had substantial vested interests. Not surprisingly, he has consistently produced reports, submitted testimony to the Congress, and made statements to the media that have supported industry positions, frequently without disclosing the sources of his funding.

For example:

o He has solicited money from Philip Morris while criticizing the EPA's risk assessment on the dangers of second hand smoke,

o He has greatly over-estimated the costs of preventing leukemia caused by exposure to benzene in gasoline while accepting funds from the American Petroleum Institute,

o He has downplayed EPA's warnings about cancer risk from dioxin exposure while being supported by several major dioxin producers, including incinerator, pulp, and paper companies,

o He has advocated against regulating driving while simultaneously talking on cellular phones in research underwritten by a $300,000. grant from AT&T Wireless Communication,

o And he has been a major spokesperson before the Congress on behalf of industries' "regulatory reform" agenda, while being supported by large grants of unrestricted funds from chemical, petroleum, timber, tobacco, automobile, electric power, mining, pharmaceutical, and manufacturing industries.

We, the undersigned, faculty members at schools of medicine and public health across the United States, go to great pains to avoid criticizing a colleague in public. Indeed, in most circumstances we would rejoice over the nomination of a fellow public health professional for a senior position in a presidential administration. Yet, in examining the record of John Graham, we are forced to conclude that there is such a persistent pattern of conflict of interest, of obscuring and minimizing dangers to human health with questionable cost-benefit analyses, and of hostility to governmental regulation in general that he should not be confirmed for the job of Director of the Office of Information and Regulatory Affairs. This position, critical to the setting of health, safety, and environmental regulatory policies that affect the lives of all Americans, demands an individual whose objectivity is beyond question.

Signed *

Eric Chivian M.D.
Director, Center for Health and the Global Environment
Harvard Medical School
Shared 1985 Nobel Peace Prize

Philip J. Landrigan M.D., MSc
Professor and Chairman
Department of Community and Preventive Medicine
Director, Center for Children's Health and the Environment
Mount Sinai School of Medicine

Lynn R. Goldman M.D., MPH
Professor of Environmental Health Sciences
Johns Hopkins University

Herbert L. Needleman M.D.
Professor of Psychiatry and Pediatrics
University of Pittsburgh School of Medicine

David Ozonoff M.D., MPH
Professor and Chair
Department of Environmental Health
Boston University School of Public Health

Howard Frumkin M.D., Dr.P.H.
Professor and Chair
Department of Environmental and Occupational Health
Rollins School of Public Health
Emory University

Anthony Robbins M.D.
Professor and Chair
Department of Family Medicine and Community Health
Tufts University School of Medicine
Philip R. Lee M.D.
Senior Scholar, Institute for Health Policy Studies
Professor of Social Medicine, Emeritus
School of Medicine
University of California at San Francisco
Former U.S. Assistant Secretary of Health

Robert S. Lawrence, MD
Edyth H. Schoenrich Professor of Preventive Medicine, Professor of Health Policy,
and Professor of Environmental Health Science
Director, Center for a Livable Future
Bloomberg School of Public Health, Johns Hopkins University

Mark R. Cullen MD
Professor of Medicine and Public Health
Yale University School of Medicine

Barry S. Levy, M.D., M.P.H.
Adjunct Professor of Community Health
Tufts University School of Medicine,
Past President, American Public Health Association

David C. Christiani M.D. MPH
Professor of Occupational Medicine and Epidemiology
Harvard School of Public Health
Professor of Medicine
Harvard Medical School

James M. Robins M.D.
Professor of Epidemiology and Biostatistics
Harvard School of Public Health

Richard Levins PhD, MPH
John Rock Professor of Population Sciences
Harvard School of Public Health

Daniel A. Goodenough Ph.D.
Takeda Professor of Cell Biology
Harvard Medical School

Alexander Leaf M.D.
Jackson Professor of Clinical Medicine, Emeritus
Harvard Medical School

David H. Bor M.D.
Associate Professor of Medicine
Harvard Medical School
Chief of Medicine, Cambridge Hospital

David U. Himmelstein, M.D.
Associate Professor of Medicine
Harvard Medical School

Steffie Woolhandler, M.D., MPH
Associate Professor of Medicine
Harvard Medical School

Paul R. Epstein M.D., MPH
Associate Director
Center for Health and the Global Environment
Harvard Medical School

Duncan C. Thomas Ph.D.
Professor and Director, Biostatistics Division
Department of Preventive Medicine
University of Southern California

Michael McCally M.D., Ph.D.
Professor of Community and Preventive Medicine
Mount Sinai School of Medicine

Peter Orris, MD, MPH
Professor of Internal and Preventive Medicine
Rush Medical College
Director of the Occupational Health Services Institute
University of Illinois School of Public Health

John M. Peters, MD
Hastings Professor of Preventive Medicine
Division of Occupational and Environmental Health
University of Southern California School of Medicine

John Wargo Ph.D.
Professor of Environmental Studies

Yale University

Richard W. Clapp, MPH, D.Sc.
Associate Professor of Public Health
Boston University School of Public Health

Mervyn Susser M.D., MPH
Sergievsky Professor of Epidemiology Emeritus
Mailman School of Public Health
Columbia University

Rob McConnell, MD
Associate Professor of Preventive Medicine
University of Southern California Medical School

Al Franzblau, MD
Associate Professor of Occupational and Environmental Medicine
Director, Occupational and Environmental Medicine Program
University of Michigan School of Public Health

Robin M. Whyatt, Dr.P.H.
Assistant Professor of Clinical Public Health
Mailman School of Public Health
Columbia University

* titles and affiliations are for identification purposes only

April 12, 2001

The Honorable Fred Thompson
Chairman
Senate Governmental Affairs Committee
SD-340
Washington, D.C. 20510

Dear Mr. Chairman:

**RE: John Graham OIRA Administrator Nomination**

We are writing to bring to your attention our concerns about the nomination of John D. Graham as Administrator of the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget, and to request your leadership in obtaining answers to critical questions about Mr. Graham's qualifications.

Candidates nominated for OIRA Administrator deserve careful review because of the significant responsibilities handled by the office. The OIRA Administrator oversees implementation of the Paperwork Reduction Act (PRA), which addresses government-wide management of information resources including agency collection and dissemination of information and oversight of our statistical agency infrastructure. Since creation of the office, every president has given the Administrator regulatory review responsibilities, effectively controlling the regulatory output of Executive Branch agencies. With a relatively small staff and little accountability, the OIRA Administrator can have virtual control over a vast array of internal agency operations, many of which have direct impact on public health and safety and the environment.

OIRA has always been a controversial office. Over the years, it has been accused of unnecessarily delaying urgently needed safeguards, forcing agencies to severely weaken the protective value of proposed safeguards, and even blocking regulatory initiatives from being implemented. Congress has noted that OIRA has often failed to carry out the statutory mandates required by the PRA and instead focused on agency regulatory reviews. In this role, OIRA has frequently insisted that agencies change the way in which they assess the value of human life and taken other steps to change the underlying analyses demonstrating the need for regulation or even collection of information. This has led many observers to believe that OIRA has, at times, been a backdoor channel for regulated industry to make one last stand to accomplish what it was not able to achieve through agency processes such as the public notice and comment process mandated by the Administrative Procedure Act.

The recent flurry of activity by the Bush Administration to review and in some cases reverse important regulatory initiatives of the Clinton Administration reminds us of how politically charged the regulatory process has become once again.

As the Director of the Harvard Center of Risk Analysis (HCRA), for more than a decade Mr. Graham has raised a majority of the Center's funding from industries that would be affected by the regulations and paperwork he would be reviewing and overseeing as OIRA Administrator.

Over the years, these companies and trade groups have poured millions of dollars into Mr. Graham's research and public education campaigns to oppose regulations affecting them. Such a level of support raises a host of questions about Mr. Graham's independence and impartiality that warrant close attention by the Committee.

Specifically, we believe it is essential for the Committee to understand the extent of collaboration between Mr. Graham, HCRA and industry supporters because it will help the Committee determine:

- the financial support derived from and the extent of Mr. Graham's relations with industries the regulation of which he would oversee as OIRA Administrator;

- whether Mr. Graham's former research and public advocacy activities in coordination with regulated industry would threaten the independence and neutrality required of the OIRA Administrator;

- the potential for Mr. Graham to conduct, or permit the OIRA staff, to have communications with industry outside the scope of transparency and accountability. This has been a major area of controversy between the White House and Congress in the past because it has been viewed as a backdoor opportunity for industry to subvert the scientific and policy judgments of federal agency regulators; and

- the potential for Mr. Graham to unilaterally impose regulatory review requirements that Congress has debated but not approved, such as increased use of cost-benefit analysis and comparative risk analysis in the decision-making process – ideas for which he has been a prominent and vocal supporter. As OIRA Administrator, Mr. Graham would have substantial authority to effectuate many changes without obtaining congressional approval.

There is one other area of inquiry that we urge the Committee to pursue: whether Mr. Graham can fairly administer the law given his public statements criticizing many of the laws he will play a role in implementing if confirmed.

For these reasons we urge the Committee to review these concerns about Mr. Graham and the Harvard Center of Risk Analysis described in the attached document and to pursue the questions outlined in it.

Sincerely,

Peg Seminario
Director Safety and Health
AFL-CIO
Charles M. Loveless
Director of Legislation
American Federation of State, County and Municipal Employees (AFSCME)

Michael F. Jacobson, Ph.D.
Executive Director
Center for Science in the Public Interest

Mark Shaffer
Senior Vice President for Programs
Defenders of Wildlife

Brent Blackwelder
President
Friends of the Earth

Alan Reuther
Legislative Director
International Union, United Automobile, Aerospace & Agricultural Implement Workers of America (UAW)

Thomas A. Wathen
Executive Vice President
National Environmental Trust

Alyssondra Campaigne
Legislative Director
Natural Resources Defense Council

Gary D. Bass
Executive Director
OMB Watch

Robert K. Musil, Ph.D., M.P.H.
Executive Director
Physicians for Social Responsibility

Joan Claybrook
President
Public Citizen

Frank Clemente
Director
Public Citizen Congress Watch

Debbie Sease
Legislative Director
Sierra Club

Gene Karpinski

Executive Director
U.S. Public Interest Research Group

cc: Sen. Joseph Lieberman, Ranking Democrat
Members, Committee on Governmental Affairs

**Suggested Information Request and Questions for John D. Graham**
**Proposed by Consumer, Environmental, Labor & Public Health Organizations**

1) **Budget and Funding Sources**

On October 21, 1991, Mr. Graham, Director of the Harvard Center of Risk Analysis (HCRA), wrote to the Vice President for Government Affairs at the Philip Morris Companies to seek a meeting to request $25,000 in funding for 1992 and 1993 [attached]. (Such a solicitation may have been in violation of a Harvard School of Public Health policy of not accepting tobacco money according to "Regulations Czar Prefers New Path," *The New York Times,* March 25, 2001 (attached).] Mr. Graham sought a contribution to "help the Center expand its public policy activities. It is important for me to learn more about risk-related challenges that you face," his letter stated.

Graham noted that the "Center has been launched primarily with gifts from the following corporations: the Amoco Company, Bethlehem Steel Corporation, British Petroleum, Chevron Corporation, The Coca Cola Company, Dow Chemical Company, Eastman Kodak Company, Exxon Corporation, General Electric Corporation, General Motors, Inland Steel Industries, Merck & Company, Mobil Oil Corporation, the Monsanto Company, Pepsico Incorporated, Rohm and Hass Company, Texaco, Union Carbide Corporation, and Westinghouse Corporation…The Center is now looking to a broader base of industrial sources to supply critical funding for the years ahead."

It appears that the Center has been quite successful at broadening its base of support over the last decade. According to HCRA's Web site more than 100 large corporations and trade associations fund or have funded the Center since it was founded in 1989, as well as several foundations that are connected to or heavily supported by regulated industries [attached]. Moreover, recent news accounts [*The New York Times, supra*; "Nominees Funding at Issue, Critics of Harvard Risk Analyst See Ties to Industry," *The Boston Globe*, March 18, 2001 (attached)] indicate that HCRA receives at least 60 percent of its funding from regulated industries, much of which comes in unrestricted grants.

Many of these regulated companies had a direct stake in the outcome of research, reports, testimony, advisory services and public relations efforts undertaken by Mr. Graham and HCRA. HCRA's efforts were used to question, and in many cases undermine support for, federal regulatory initiatives. Because most of the corporate and trade association support was labeled "unrestricted," or there is no indication when "restricted" grants from such entities were received, it is impossible to determine to what extent these funding sources directly sponsored Mr. Graham's and HCRA's work. If such direct support was provided, regardless whether labeled restricted or unrestricted, Mr. Graham would have been obliged to disclose his benefactors. In many cases he does not.

Given this high level of support to HCRA from regulated industry it is critical for the Committee on Governmental Affairs to get some baseline information about funding sources, amounts and dates of contributions. Such information will help determine to what extent Mr. Graham and

HCRA have acted as a research arm, think tank, consultant, lobbyist and public relations entity pursuing an anti-regulation agenda on behalf of industries, rather than as an independent institution producing objective scholarship. We suggest that Mr. Graham be asked to provide the following information to the Committee:

- A breakdown for each of the last 10 years of HCRA's total budget and of HCRA's income sorted by the following source categories: unrestricted corporate and trade association support, restricted corporate and trade association support, unrestricted foundation and think tank support, restricted foundation and think tank support, restricted support from federal agencies, unrestricted support from Harvard University, and restricted support from Harvard University.

- A list of the sources, dates and amounts of corporate and trade association, foundation and think tank, and government grants and contributions of $10,000 or more provided to HCRA for each of the last 10 years.

- A breakdown of the sources, dates and amounts paid to Mr. Graham for personal consulting services, speaking fees and board and advisory committee memberships by corporations and trade associations and public relations firms or other entities acting on behalf of corporations over the last 10 years.

- An explanation of the reasons for such an exceptional reliance on corporate and trade association support, especially unrestricted support, in light of HCRA's professed desire in its conflict of interest policy to "avoid[ ] any real or perceived conflicts of interest associated with the receipt of financial support from private companies, trade associations, and public-interest advocacy groups."

**2) HCRA Executive Council**

HCRA's Executive Council has 16 members [see attached list and annotated summary of their corporate and professional positions]. Nearly all of them maintain senior positions at some of America's largest companies or trade associations, or they work for major law firms representing the interests of corporations involved in litigation related to federal regulatory matters. We believe it is worth the Committee asking the following question:

- What are the duties and activities of the Executive Council with regard to setting HCRA priorities, suggesting research and public advocacy projects, fund-raising and coordinating joint projects with companies and trade associations?

- Given the composition of the executive council, which is almost exclusively comprised of representatives from regulated industry, please explain how HCRA obtains balanced input on regulatory priorities and policies from those constituencies that benefit from federal regulatory initiatives (such as consumers, workers, the disabled, public health experts, environmentalists, etc.)

Because of the lack of transparency about, and potential conflicts of interest posed by, HCRA's funding sources and Mr. Graham's work on behalf of regulated industry, we urge the Committee to learn more about each of the following regulatory case examples:

**3) Regulating Second-Hand Smoke**

During the next few years Congress may pass and President Bush could sign into law legislation that would grant the Food and Drug Administration (FDA) authority to regulate tobacco products and their effect. Such regulations would first need to be prepared by the FDA according to requirements and guidelines established by the Office of Information and Regulatory Affairs (OIRA), under Mr. Graham's leadership, and then be reviewed by OIRA officials and effectively approved, amended or rejected.

It appears that in the early 1990s, Mr. Graham and HCRA may have been actively involved in efforts being coordinated by the tobacco industry and Philip Morris to counter adverse government regulatory activities anticipated from an Environmental Protection Agency (EPA) assessment of the risks posed to non-smokers by environmental tobacco smoke (ETS), also known as second-hand smoke, and an Occupational Safety and Health Administration (OSHA) advanced notice of proposed rulemaking on indoor air quality.

As documented in a recent Public Citizen report, "Safeguards At Risk: John Graham and Corporate America's Back Door to the Bush White House" [see pages 39 to 47; available on the Web at http://www.citizen.org/Press/pr-grahamreport.pdf], and the attached documents that were contained in the Philip Morris tobacco archives, the following sequence of events appears to have taken place over several years:

- October 21, 1991: Mr. Graham writes to David L. Greenberg, V.P. of Government Affairs for the Philip Morris Companies (PM), asking to meet to discuss possible funding of $25,000 in 1992 and 1993.

- October 29, 1991: Memo from Robert A. Pages of Philip Morris's Scientific Affairs division to Steve Parrish, Philip Morris Vice President and General Counsel, suggesting that Parrish attend a meeting with David Greenberg and Graham. The memo also references that Mayada Logue, a Philip Morris official assigned to risk assessment/ETS issues from the company's "Worldwide Regulatory Affairs Group," is meeting with Graham in Washington the same day.

- January 21, 1992: Phillip Morris issued a $25,000 check for HCRA per Parrish authorization.

- February 6, 1992: Logue memo to Parrish notes that, as of that January, "[t]he decision has been made to ask John Graham for assistance." A meeting was scheduled with Graham for February 10 or 11 in Washington.

- February 13, 1992: Interoffice memo from Parrish requesting a stop payment on the HCRA check, and stating that the check was being returned. [*The New York Times,* March 25, 2001, notes that "Graham was ordered to return the money" because of the ban on accepting tobacco money.]

- March 2, 1992: Logue memo to Parrish that described a Logue-Graham lunch meeting. Logue wrote, "John Graham is writing a book about the unintended risks we take when attempting to avoid other risks. There will be a chapter on smoking in the book. He said that most of the information in that chapter is from the Surgeon General's Report and asked if we would review it for accuracy. Bob Pages has agreed to review it."

- March 2, 1992: Graham sends Logue a fax asking "Is the comment [he] made on page 432 correct? The reference was to an article by Thomas C. Schelling titled "Addictive Drugs: The Cigarette Experience."

- March 11, 1992: Logue fax and memo to Graham responding to his request for clarification on the Schelling article comment.

- June 26, 1992: Graham memo to Jonathan Wiener, Policy Counsel of the White House Office of Science and Technology Policy and Senior Staff Economist of the Domestic Policy Council under Bush I regarding "The Release of Risk Assessment as a Regulatory or Policy Action: The Case of ETS." In the letter, Graham suggested that the EPA's recent risk assessment process on ETS should have been part of a formal rulemaking. Despite having very recently solicited money from Philip Morris, Graham wrote to Wiener: "Since I am not an expert on ETS, I don't know whether EPA's report is based on good science . . . If one is trying to make a case against smoking, the EPA risk assessment is certainly good ammunition." The memo continued: "In light of this example, think more broadly about future EPA risk assessments of electromagnetic fields, video display monitors, styrene, formaldehyde, carbon dioxide emissions, and so forth. As matters stand now, the White House and the nation are very vulnerable to EPA (or other agency) risk assessments that are not based on sound science or do not adequately convey the degree of uncertainty in the science. . . A small, yet well-qualified group of risk assessors in the White House could make an enormous difference on these issues, particularly if they established credibility among agency risk assessors."

- August 12, 1992: Letter to Graham from Dr. Enrique J. Guardia, V.P of Scientific Relations for PM, noting that "This check from Kraft general Foods is a contribution of $10,000 per year for the next two years to support the work of the Center, in general, and your contributions to the food safety debate (Pesticides). Letter was copied to Logue who is an ETS expert, not a food safety expert.

- August 31, 1992: Logue memo to Parrish noting that "The attached documents [none were attached] attest to the fact that the meeting between myself, Dr. Guardia and

Graham was beneficial in that ...(HCRA) has launched an effort to address issues in food safety legislation." [*The New York Times* (March 25, 2001) noted that Graham "later accepted an equivalent gift from Kraft, a Philip Morris subsidiary."] It's curious that Logue would have attended this meeting since food safety was not her area of work. The letter was also copied to R. Pages, a PM tobacco expert.

- March 1, 1993: Logue memo to Parrish indicating she had met with Graham. The rest of the memo is filled with references to ETS and Indoor Air Quality.

- August 30, 1993: Revised Draft Agenda for a meeting held in Richmond, presumably at PM's Virginia Research Center, attended by Mayada Logue. Handwriting notes "*need a war of words European vs. USA: studies, etc. – J. Graham Int. Symposium."

- June 3, 1998: Graham letter on HCRA stationary to Thomas Borelli, Manager, Philip Morris USA, to solicit $50,000 for the Society for Risk Analysis (SRA) towards its goal of $250,000 for an international symposium in 2000 "to advance the theme of 'risk and governance.'" [Sustaining members of the SRA on April 5, 2000 were the Amoco Corporation, Chemical Manufacturing Association, Chevron Research & Technology Co., Dupont Haskell Laboratory, Exxon Biomedical Sciences, Inc., Procter & Gamble, and The Sapphire Group (list attached)]. According to the letter, "The symposium is also seen as a determined first step toward a first World Congress on Risk Analysis early in the 21st Century."

In light of this account, we believe the Committee would benefit from a more detailed understanding of Mr. Graham's relationship with Philip Morris during this period. We suggest that the following questions be asked of Mr. Graham:

- What was the purpose of the $25,000 in funding from PM to HCRA? Why did HCRA return the $25,000 from Philip Morris? Please provide copies of any funding proposals, reports, or correspondence regarding HCRA activities undertaken on behalf of the tobacco industry.

- Has Philip Morris, or any of its subsidiaries, ever provided any other direct or indirect funding to Mr. Graham or HCRA? If so, what were the dates, amounts, and purposes of the funding?

- Please provide the Committee with information about the dates of any meetings between Mr. Graham and PM officials, including the participants, topics of discussion, and information exchanged between the parties.

- If it was against Harvard School of Public Health policy to accept support from a tobacco company, why did Mr. Graham continue a relationship with PM through at least 1998?

- On what basis would an academic send their writings to a company for review?

- Did Mr. Graham collaborate with Philip Morris, the tobacco industry and its consultants (such as the Institute for Regulatory Policy, Multinational Business Services, APCO & Associates), regarding concerns about the development of a Bush I administration executive order that would have changed how agencies conducted risk assessments? Could such a change have benefited the tobacco industry in its efforts to avoid having EPA label ETS a class A carcinogen because it was *known* to cause lung cancer?

**4) Regulating Food Safety**

OIRA plays a central role in reviewing any new food safety regulations proposed by the FDA and the Department of Agriculture (USDA). On August 12, 1992, as previously noted, HCRA received a $20,000 check from Dr. Enrique J. Guardia, Vice President of Scientific Relations at Kraft General Foods, a subsidiary of Philip Morris, "to support the work of the Center, in general, and your contributions to the food safety debate (Pesticides)." [Note that Kraft Foods is listed as an *unrestricted* grant on the HCRA Web site.] Mr. Guardia stated that "I would like to meet from time to time to discuss topics of mutual interest."

That same day Guardia sent a second letter [attached] to Graham apparently in response to a letter Graham sent him regarding food industry support for HCRA. Graham's letter evidently had asked Guardia for the names of other potential corporate donors for the new project and had named the sum to be solicited from the food sector as $25 million. This amount of money was so high that Guardia demurred: "You know fund raising better than I, but your request of $25 M strikes me as excessive in a year like 1992. Ask yourself whether you would not be better off asking for $10 M."

In light of this account, we believe the Committee would benefit from a more detailed understanding of Mr. Graham's relationship with Kraft General Foods, the five other food companies (E.I. Dupont de Nemours & Company, The Coca-Cola Company, Frito-Lay, PepsiCo, Inc. and Procter & Gamble), and two trade associations (Grocery Manufacturers of America and the National Food Processors Association) that are listed as HCRA funders. Specifically, we suggest that the following questions be asked of Mr. Graham:

- Please provide the sources, dates and amounts of contributions of $10,000 or more raised from food companies and their trade associations towards HCRA's goal of $25 million described in the letter to Enrique Guardia referenced above. Please provide copies of any funding proposals, reports or correspondence regarding Mr. Graham and HCRA activities undertaken pursuant to food industry financial support and industry food safety regulatory activities described above.

- Please provide information about the dates of any meetings between Mr. Graham and food companies and trade associations, including the participants, topics of discussion, and information exchanged between the parties.

- Please provide the Committee with any information, including dates, related to positions that Mr. Graham and HCRA may have taken or recommended be taken with respect to food safety regulatory issues.

**5) Regulating Pesticides**

OIRA will play a key role in reviewing any new pesticide regulations that EPA may want to promulgate. Unfortunately, in August 1999 HCRA issued a biased and fundamentally flawed report ["Risk/Risk Tradeoffs in Pesticide Regulation: Evaluating the Public Health Effects of a Ban on Organophosphate and Carbamate Pesticides" (attached)] designed to obstruct the implementation of the unanimously passed Food Quality Protection Act (FQPA). The report used extreme assumptions to conclude that stopping the use of older, highly toxic pesticides would oddly result in an increase in premature deaths. The study suggested that implementation of the FQPA would result in banning all uses of certain pesticides, which could result in up to 1,000 premature deaths per year due to decreased food consumption. The report was criticized for its poor application of risk assessment techniques and unrealistic assumptions.

The report's most prominent flaws are the assumptions that FQPA implementation would cause a catastrophic shortage of insecticides available to farmers and that the readily available alternative chemical and non-chemical pest control options would not be used to replace the banned pesticides. The authors assumed that EPA would ban all uses of all organophosphate (OP) and carbamate insecticides. This complete ban of more than 50 chemicals is far outside the scope of any action EPA has considered necessary to achieve the goals of the FQPA. The report's authors acknowledge this fact, but then base their analysis on what they concede is a false assumption. They justify their decision on account of its "analytic virtue" (i.e., simplicity). The report's assertion that alternatives are too costly is not based on any analysis of actual costs and is simply not credible.

The truth is that pesticide prices and expenditures in the U.S. are falling across the board as dozens of new products have increased competition. There are many existing, proven alternatives to high risk insecticides. The pest control industry has been developing and introducing new products in response to FQPA's pressure to phase-out older, high-risk chemicals. Ironically, the HCRA analysis ignores the effects of market-driven innovation. The study also ignores the progress made by farmers in adopting bio-intensive Integrated Pest Management, or a least-toxic approach.

The study was funded by the American Farm Bureau Federation (see p. 35), which opposes restrictions on pesticides. The report, dubbed "The Truth from Harvard" by pesticide lobbyists, has been used to generate congressional support for rolling back FQPA's key public health provisions, which require that manufacturers prove pesticides are safe for children and infants.

In light of this account, we urge the Committee to ask the following questions of Mr. Graham:

- Please provide the sources, dates, and amounts of contributions of $10,000 or more raised for HCRAfrom pesticide manufacturers and their trade associations, including the American Farm Bureau Federation. Please provide copies of any funding proposals, reports or correspondence regarding Mr. Graham and HCRA activities undertaken pursuant to pesticide industry financial support and industry food safety regulatory activities described above.

- Please provide information about the dates of any meetings between Mr. Graham and pesticide manufacturers and trade associations, including the participants, topics of discussion, and information exchanged between the parties.

- Please provide information about discussions between the American Farm Bureau Federation and Mr. Graham or HCRA staff prior to, during, and after the production of the 1999 Center report, "Risk/Risk Tradeoffs in Pesticide Regulation: Evaluating the Public Health Effects of a Ban on Organophosphate and Carbamate Pesticides."

- Please provide information about the role that the American Farm Bureau Federation played in planning, writing, editing, and publicizing the report.

**6) Regulating the Use of Cell Phones**

During the next four years the National Highway Traffic Safety Administration (NHTSA) may decide that cellular phone usage in moving vehicles should be regulated in order to reduce accidents, injuries and death. Should such a regulation be promulgated the OIRA Administrator will play a key role in reviewing the rule for approval, but important questions have been raised about the quality of HCRA research in this area.

The "Safeguards at Risk" report (pp. 48-55) noted that Mr. Graham already has significant experience with this regulatory issue as HCRA received a $300,000 grant from AT&T Wireless Communications to assess the risks of using a cell phone while driving. In fact, in July 2000, one week after NHTSA held a public hearing on driver distraction and recommended that drivers pull over before using cell phones, Mr. Graham and HCRA published the AT&T-funded report, which concluded that further regulation of this issue was unwarranted. HCRA's report stated that "although there is evidence that using a cellular phone while driving poses risks to both the driver and others, it may be premature to enact substantial restrictions at this time. We simply do not have enough reliable information on which to base reasonable policy." [A summary of the report, "Cellular Phones and Driving: Weighing the Risks and Benefits," is attached.]

Mr. Graham's report, which was self-published and reviewed by 12 independent specialists chosen by Mr. Graham, came under significant criticism from the authors (Donald A. Redelmeier, M.D. and Robert J. Tibshirani, Ph.D.) of a peer-reviewed study published in 1997 in the prestigious *New England Journal of Medicine* [attached]. That study had concluded that the risk of car crashes is four times greater when a driver uses a cell phone. Dr. Redelmeier, the

*NEJM* author who was also one of the 12 reviewers of the Graham study, told reporters that the "Harvard researchers left the report open to conflict-of-interest questions because they didn't publish it in a scientific journal or take other steps to demonstrate the study's fairness." There were numerous methodological problems with the Graham/HCRA report, according to "Safeguards at Risk."

In light of this account, we believe the following questions should be asked of Mr. Graham:

- What was the source, dates and amounts of financial support received from AT&T Wireless Communications and any other companies or trade associations that contracted with HCRA or Mr. Graham to conduct research on the risks of cellular phone usage? Were these restricted or unrestricted grants?

- Please provide copies of any funding proposals, reports, or correspondence relating to the AT&T Wireless Communications grant to HCRA(or any other related grants), including plans for the possible uses of the research product.

- Please provide the dates of any meetings between Mr. Graham, AT&T Wireless Communications, or the cellular phone trade association, including the participants, topics of discussion, and information exchanged between the parties.

- Please provide information about the role that AT&T Wireless Communications played in planning, writing, editing, and publishing the report, including the timing of its release.

7) **Regulating Air Bags**

As OIRA Administrator, Mr. Graham would pass judgment on a host of regulatory proposals from the National Highway Traffic Safety Administration (NHTSA) – perhaps even a new air bag standard. But the research and advocacy Mr. Graham has done in recent years raises concerns about the quality of his analytical work and whether it has been slanted to favor HCRA contributors.

According to the report "Safeguards at Risk" [pages 2 and 56-66], in the early 1980s Graham's research was cited by the Secretary of Transportation, Elizabeth Dole, in support of a passive restraint air bags mandate. But by March of 1997, in news appearances and testimony before the National Transportation Safety Board, Graham reversed course and argued that a new, unpublished HCRA report had convinced him that passenger air bags were not cost effective enough to justify being mandated. Graham's research suggested that the $399,000 price tag for each life saved using passenger side air bags was too high compared to the $70,000 per life-year saved of driver side air bags.

Mr. Graham's announcement of his new study findings, engineered with considerable media fanfare, occurred as NHTSA was preparing to issue for OIRA review a proposed rule pushed by the auto industry that would have permitted manufacturers to depower air bags.

Mr. Graham's study came under harsh criticism by transportation safety experts because it had not been peer reviewed and it was based on questionable data. Subsequently, it was peer-reviewed by the prestigious *Journal of the American Medical Association (JAMA),* and the revised Graham study had reversed course [attached]. The revised study found that driver-side air bags cost only $24,000 for each life-year saved, rather than Mr. Graham's original $70,000 estimate, and that the passenger-side air bag cost estimate had declined from $399,000 to $61,000 – a very "cost effective" estimate, according to some measures used and to Graham's researchers. While the *JAMA* article indicated that funding for the *JAMA* study had been provided by the Centers for Disease Control to the Graham-run Harvard Injury Control Center at the Harvard School of Public Health, HCRA has received unrestricted support from the Ford Motor Company, General Motors, and the Goodyear Tire & Rubber Company.

At the same time, Mr. Graham's Injury Control Center and HCRA released a public opinion survey ["The Airbag's Teflon Image: A National Survey of Knowledge and Attitudes," March 17, 1997 (attached)] about Americans' knowledge of airbags. The report's press release contended that Americans' widespread support for air bags was founded upon bad information. Some have speculated that the survey fit with the political strategy of the auto industry at the time, which was waging a campaign to deflect attention from the need for more advanced air bag systems by focusing on the public's knowledge of safety issues involving air bags.

The public opinion survey did not mention who funded the 1,000 person sample. Source of funding was not noted for the NTSB testimony or the *JAMA* article either.

To better understand the relationship between Mr. Graham and the auto industry, we urge the Committee to pursue the following questions:

- Have Mr. Graham, and other HCRA staff, and auto industry representatives discussed the possibility of HCRA conducting research, public opinion surveys and any other activities on air bag issues in the last 10 years? Please provide the dates of any meetings, including the participants and the subject matter, as well as any written correspondence related to such activities.

- What were the sources, dates and amounts of financial support provided to HCRA by auto industry companies or trade associations?

- What is the explanation for the dramatic reversal of findings on the passenger-side air bag issue between HCRA's initial finding presented to the NTSB and the final study published in *JAMA*?

- Were the HCRA air bag study and public opinion survey of March 17, 1997 undertaken to influence air bag regulatory actions pending at NHTSA or to influence public opinion about air bag safety issues? Were the results discussed with the auto industry before being released? Did the auto industry play any role in planning, writing, editing, and publicizing the study and survey?

**8) Regulating Dioxin**

As OIRA Administrator, Mr. Graham will sit in judgment should the EPA decide to propose new regulations to control exposure to dioxin, the name given to a group of highly toxic chemicals that are produced when chlorine is burned. Since 1995 EPA has been conducting a dioxin reassessment, which is under review by the agency's Science Advisory Board (SAB). Graham served as a consultant on the 1995 SAB Dioxin Reassessment Review Committee and until his recent resignation, was a member of the current SAB Dioxin Reassessment Review Committee.

According to the "Safeguards at Risk" report (p. 2-3, 109-110), last year EPA prepared a draft risk assessment that showed the public faces much higher risks of cancer and non-cancer health harms (infertility, immune system damage and learning disabilities) from dioxin, even at very low levels of exposure, than was previously understood. The risk assessment was based on more than 100 studies in animals and humans showing that dioxin caused cancer at low doses. More than 90 percent of dioxin exposure comes through the food we eat, especially fish, meat and dairy products.

At a meeting of the SAB in November 2000, citing only two limited outlying studies, Graham claimed that low levels of dioxin may actually protect against cancer. He urged the SAB to include in its official comments language stating that dioxin may be an "anti-carcinogen." The report noted, "Based on the transcript of the meeting, Graham wanted the SAB to tell EPA to revise its report to include the following statement: 'It is not clear whether further reductions in background body burdens of TCDD [dioxin] will cause a net reduction in cancer incidence, a net increase in cancer incidence, or have no net change in cancer incidence.' If EPA were to adopt this approach its dioxin risk assessment might fail to provide a basis for federal regulators to ask companies to curtail dioxin emissions." The Washington Post has reported that at the November meeting, "[a]bout a third of the 21 panel members were scientists and scholars who have worked as paid consultants to the chemical industry. They included John D. Graham -- long a critic of the notion that dioxin and cancer are linked and founder of the industry-backed Harvard Center for Risk Analysis[.]" ["Dioxin Report by EPA on Hold, Industries Oppose Finding of Cancer Link, Urge Delay," *The Washington Post*, April 12, 2001 (attached).]

The Safeguards at Risk report notes that HCRA has received financial support from at least 48 different dioxin producers, including incinerator companies, pulp and paper companies, cement kilns, copper smelters, PVC manufacturers, PCB producers, and the petroleum industry.

Despite the conflict of interest created by Mr. Graham's obligation to serve as an objective expert as a consultant to the SAB and his real or perceived obligations to HCRA's dozens of dioxin-producing supporters, Mr. Graham continued to participate in the SAB process as a vocal proponent for industry's position. Even when two scientists – Frederica Perera and Ellen Silbergeld – recused themselves from the SAB because of their close association with environmental organizations that were pushing for tighter controls of dioxin, Mr. Graham still failed to resign. ["Expert Panel Backs EPA Dioxin Study," The Charleston Gazette, October 1, 1995 (attached)] (Perera, an environmental health sciences professor at the Columbia University School of Public Health, was a board member of the Natural Resources Defense Council.

Silbergeld, an epidemiologist at the University of Maryland, was a former staffer for the Environmental Defense Fund.)

Further, in the month prior to the Science Advisory Board meeting, HCRA organized a high-profile conference on drinking water and health risks, "financed by a grant from the Chlorine Chemistry Council and the Chemical Manufacturers' Association." [Greenpeace Report, "Dow Brand Dioxin: Dow Makes You Poison Great Things," September 1995, citing the CCC Executive Newsline, April 3, 1995 (attached).] The root source of most dioxin in the environment is produced as a byproduct of industrial chlorine chemistry.

In light of the issues described above, we recommend that the Committee ask Mr. Graham the following questions:

- Does Mr. Graham have a particular expertise or scientific training with respect to the harmful effects posed to the public by dioxin? Has Mr. Graham or HCRA published research or reports on the health effects posed by exposure to dioxin?

- What were the sources, dates and amounts of contributions of $10,000 or more provided to HCRA from companies that generate dioxin emissions or discharges? Were these restricted or unrestricted grants? Please provide copies of any funding proposals, reports, or correspondence related to these contributions.

- Please provide the dates of any meetings between Mr. Graham and dioxin producers, including the participants, topics of discussion, and information exchanged between the parties.

- Has Mr. Graham ever discussed with any HCRA financial supporters the need to counter EPA efforts to reassess the risks posed by dioxin and to provide information to the SAB? What was the nature of those conversations? How were the two-outlier studies submitted by Mr. Graham to the SAB brought to his attention?

- How does Mr. Graham justify the suggestion that dioxin may be an anti-carcinogen when its carcinogenicity and cumulative impact are well documented?

- Does Mr. Graham believe that the government should not step up efforts to reduce production of dioxin and exposure to dioxin?

**9) Non-Disclosure of Regulated Industry Funding**

Throughout the "Safeguards at Risk" report it is suggested that Mr. Graham regularly fails to disclose the source of HCRA funding when interviewed by the media or even when testifying before Congress. With respect to congressional testimony, on at least six occasions that were reviewed, Mr. Graham failed to disclose HCRA funders, in both his written and oral testimony. Those occasions were January 31, 1995, House Committee on Science; February 2, 1995, House Subcommittee on Commerce, Trade, and Hazardous Materials and Subcommittee on Health and

Environment; February 15, 1995, Senate Committee on Governmental Affairs; March 22, 1995, Senate Committee on Environment and Public Works; June 10, 1998, House Committee on Science; and April 21, 1999, Senate Committee on Governmental Affairs.

In light of these numerous instances, we urge the Committee to ask the following questions:

- Why is Mr. Graham reticent to publicly reveal his funding sources? Is there a concern that revealing HCRA's funding sources could raise questions of a conflict-of-interest between objective research and sponsorship by regulated industries?

- What is the reason Mr. Graham does not disclose in his testimony to Congress that HCRA receives funding from sources that stand to profit from his testimony?

**10) Disclosure at OIRA**

The concerns raised about Mr. Graham's funding sources and his substantive policy positions, as described above, raise important questions about his ability to be independent and impartial as OIRA Administrator. Accordingly, we suggest that Mr. Graham be asked to provide specific information to the Committee about how his actions at OIRA can be monitored for accountability purposes:

- Will Mr. Graham make publicly accessible through the Internet and other means information about communications he and other OIRA and White House staff have with individuals and organizations outside of government regarding rules and paperwork under review at OIRA or being developed in the agencies, including the substantive elements of such communications?

- Will Mr. Graham make publicly accessible through the Internet and other means the rationale for any changes OIRA recommends to specific rules and paperwork reviewed by OIRA? Will oral communications with agencies pertaining to the outcome of the review be placed in writing and made publicly accessible?

- Will Mr. Graham make publicly accessible through the Internet and other means all communications with agencies regarding methods and procedures for submitting paperwork and regulations to OIRA?

# AFSCME®

*American Federation of State, County and Municipal Employees, AFL-CIO*

Gerald W. McEntee
President
William Lucy
Secretary-Treasurer
Vice Presidents
Ronald C. Alexander
Columbus, OH
Linda Ard
Indianapolis, IN
Henry L. Bayer
Chicago, IL
Peter J. Benner
St. Paul, MN
George Boncorsaglio
New York, NY
James H. Butler
New York, NY
Anthony Caso
Boston, MA
Jan Corderman
Des Moines, IA
Danny Donohue
Albany, NY
Chris Dugovich
Everett, WA
Michael Fernucci, Jr.
New Britain, CT
David R. Fillman
Plymouth Meeting, PA
Albert Garrett
Detroit, MI
Sherryl Gordon
Trenton, NJ
Helen Greene
New York, NY
Edward J. Keller
Harrisburg, PA
Josephine LeBeau
New York, NY
Roberta Lynch
Chicago, IL
Glenard S. Middleton Sr.
Baltimore, MD
Patricia A. Moss
Worthington, OH
Michael D. Murphy
Madison, WI
Henry Nicholas
Philadelphia, PA
Russell K. Okata
Honolulu, HI
George E. Popyack
Oakland, CA
Greg Powell
Austin, TX
Lawrence A. Roehrig
Lansing, MI
Joseph P. Rugola
Columbus, OH
Kathy J. Sackman
Pomona, CA
Mary E. Sullivan
Albany, NY
Garland W. Webb
Baton Rouge, LA
Jeanette D. Wynn
Quincy, FL

1625 L Street, N.W., Washington, D.C. 20036-5687
Telephone: (202) 429-1000
Fax: (202) 429-1293
TDD: (202) 659-0446
Website: http://www.afscme.org

June 7, 2001

Dear Senator:

On behalf of the 1.3 million members of the American Federation of State, County and Municipal Employees (AFSCME), I write to express our strong opposition to the nomination of John D. Graham, Ph.D. to serve as director of the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB).

As gatekeeper for all federal regulations, the Administrator of OIRA has an enormous impact on the health and safety of workers and the public. Yet Dr. Graham's record as Director of the Harvard Center for Risk Analysis demonstrates that he would minimize consideration of worker and public health in evaluating rulemaking and instead rely almost exclusively on considerations of economic efficiency.

Dr. Graham's approach to regulatory analysis frequently ignores the benefits of federal regulation, indicating that reviews under his leadership will lack balance. His anti-regulatory zeal causes us to question whether he will be able to implement regulations that reflect decisions by Congress to establish health, safety and environmental protections. We are also deeply concerned that Dr. Graham's extreme views and close alliance with regulated entities will prevent the OIRA from providing a fair review of regulations that are needed to protect workers and the public.

For the foregoing reasons, we urge you to oppose Dr. Graham's confirmation as Administrator of the Office of Information and Regulatory Affairs.

Sincerely,

Charles M. Loveless
Director of Legislation

CML:bcd

MELISSA A. MCDIARMID, MD, MPH
416 NORTHWAY
BALTIMORE, MARYLAND 21218

May 21, 2001

Re: John D. Graham Nomination

Dear Senator:

I write to express my disappointment and dismay at the nomination of John D. Graham, to direct the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB). As a public health professional, I have been alarmed at the opinions Dr. Graham has argued in testimony and his written work promoting increased reliance on cost-benefit and cost-effectiveness analysis. I understand the importance of economic considerations in deliberations regarding federal rule-making responses to threats to the public safety and health of our people. I am also acquainted however, with Dr. Graham's excesses in this argument to the point of proposing a 'risk-risk' analysis for any regulation the governmental agencies charged with assuring the nation's public health consider.

Curiously, his promotion of an over-reliance on the economics fails to account for the "costs of failing to act" when his arguments prevail in influencing or all together de-railing necessary public health interventions. Most disturbing is the transparency of his strong and well-funded ties to the very constituencies he would be regulating. There is clear evidence of a conflict of interest here.

Surely there are other candidates for this position who are both agreeable to the administration, are more appropriately qualified and who hold more balanced views than those of Dr. Graham. I respectfully request that you not support Dr. Graham's nomination to this important position.

Yours Sincerely,

Melissa A. McDiarmid, MD, MPH

DON MILLAR & Associates, Inc.
*Consulting in Occupational and Environmental Health*

J. Donald Millar, MD, DTPH (Lond.), Pres

| | |
|---|---|
| To Senator Cleland | From J. D. Millar, MD |
| Co. U.S. Senate | Co. Don Millar & Associates, Inc. |
| Phone # | Date 4/26/2001 |
| Fax # | Fax # 202-224-0072 |

404-331-5439

April 26, 2001

The Honorable Max Cleland
United States Senator
461 Dirksen Building
Washington, DC 20510

Dear Senator Cleland:

As a constituent of yours, I am writing in strong support of the confirmation of Dr. John Graham to the position of Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget.

Dr. Graham is superbly qualified for the position of OIRA Administrator and would bring to the position a wealth of expertise and a profound sense of good government and sound regulatory policy.

I have worked closely with John on activities of the Public Health Policy Advisory Board, where we looked at ways to improve meeting the health needs of children and other Americans at risk.

Thanking you for your consideration, I am,

Sincerely,

J. Donald Millar, MD

P.S. if you would like to discuss Dr Graham with me, please feel free to call me

"Hanover Hall"
6320 Brady Road, Murrayville, Georgia 30564, USA
Phone: (770) 983-5705 Fax: (770) 983-0622

NATIONAL ENVIRONMENTAL ORGANIZATIONS

May 22, 2001

The Honorable Fred Thompson
The Honorable Joseph Lieberman
Members of the Senate Governmental Affairs Committee
United States Senate
Washington, DC 20510

Dear Senator,

We write to make clear our strong opposition to the nomination of Dr. John D. Graham to direct the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget. We encourage you to very carefully consider his consistent anti-regulatory record and controversial risk management methodology during your confirmation proceedings.

The Administrator of OIRA plays an extremely powerful role in establishing regulatory safeguards for every agency of our government. This position requires a fair and even-handed judge of the implications of regulatory policies. Upon close review, we believe that you will agree that John Graham's record makes him an unsuitable choice for this important position.

OIRA is the office in the Executive Office of the President through which major federal regulations and many other policies must pass for review before they become final. The office has great leeway in shaping proposals it reviews or holding them up indefinitely.

One of the principal ways in which OIRA influences rulemakings is through its use of risk assessment and cost-benefit analysis. Graham has a perspective on the use of risk assessment and cost-benefit analysis that would greatly jeopardize the future of regulatory policies meant to protect average Americans. This analytical framework systematically reinforces the worse tendencies of cost-benefit analysis that tend to understate benefits and overstate costs, instead of correcting them. As head of OIRA, he would be in a position to superimpose this approach throughout the government.

Graham's approach has led him to challenge -- either directly or through his support of others who use the approach -- some of the most valuable environmental requirements that exist. For example:

- Graham criticized the 1990 change by Congress to the air toxics section of the Clean Air Act that shifted from a risk assessment approach to a technology requirement for setting regulations. Since the adoption of the change, 46 new standards have been set for dangerous toxics, compared to eight in the previous 18 years when the decision making suffered from "paralysis by analysis."

- Graham's center at Harvard released a study paid for by American Farm Bureau Federation that concluded that restricting certain pesticides under the Food Quality Protection Act would actually increase the loss of life because of disruptions to the food supply, a completely unrealistic assumption.

- Graham serves on an organization's advisory council whose study on the benefits of regulating arsenic concluded that, not only was the EPA level of 10 parts per billion (ppb) not justified, but that the current level of 50 ppb may be too protective.

Furthermore, Dr. Graham uses comparative risk assessments to rank different kinds of risk and then uses it to argue that society should not take actions to reduce environmental risks as long as there are other risks that can be reduced more cheaply. He uses this comparative perspective to argue against environmental risk reduction even when those reductions could be done cost-effectively.

Finally, he makes no distinction between risks that are assumed voluntarily and those that are imposed involuntarily. As a result, this framework would find it equally acceptable for a company to profit by exposing individuals to pollution, as long as the increase in risk was not greater than risks those individuals would bear willingly if they were getting the benefits. This view contradicts basic notions of equity in society.

Graham's considerable financial support from industry and his close relationship with them in his work at his center raises serious questions about potential conflicts of interest and his ability to be truly objective. His close ties to regulated industry will potentially offer these entities an inside track and make it difficult for Dr. Graham to run OIRA free of conflicts of interests and with the public view in mind.

For these reasons, Graham cannot reasonably be expected to execute his responsibilities in a fair and objective manner, and could be expected to institutionalize an approach to reviewing government regulations that will have an adverse effect on policy reviews for years to come after his departure. For these reasons we strongly urge you to oppose the nomination of Dr. Graham to be the Administrator of OIRA.

Sincerely,

John H. Adams
President
Natural Resources Defense Council

Phil Clapp
President
National Environmental Trust

Brent Blackwelder
President
Friends of the Earth

Stephen D'Esposito
President
Mineral Policy Center

Vawter Parker
President
Earthjustice Legal Defense Fund

Betsy Loyless
Political Director
League of Conservation Voters

Rebecca R. Wodder
President
American Rivers

Mark Shaffer
Senior Vice President
Defenders of Wildlife

Robert K. Musil, Ph.D., M.P.H.
Executive Director and CEO
Physicians for Social Responsibility

John Passacantando
Executive Director
Greenpeace

William H. Meadows
President
Wilderness Society

Larry Young
Executive Director
Southern Utah Wilderness Alliance

**Attention:**
**Environmental LA**
**Worker Safety LA**
**Food Safety LA**

---

**National Organizations Opposing John D. Graham**
**Nominated to be Administrator,**
**Office of Information & Regulatory Affairs**
**Office of Management & Budget**

**As of June 8, 2001**

AFL-CIO
American Federation of State, County & Municipal Employees (AFSCME)
American Rivers
Center for Science in the Public Interest
Defenders of Wildlife
Earthjustice Legal Defense Fund
Friends of the Earth
Greenpeace
League of Conservation Voters
Mineral Policy Center
National Environmental Trust
Natural Resources Defense Council
OMB Watch
Physicians for Social Responsibility
Public Citizen
Sierra Club
Southern Utah Wilderness Alliance
International Union, United Automobile, Aerospace & Agricultural Workers of America, UAW
U.S. Public Interest Research Group
Wilderness Society

For additional information on John Graham go to:
http://www.citizen.org/congress/regulations/graham.html

CORNELL
UNIVERSITY

NEW YORK PRESBYTERIAN
HOSPITAL

Joan and Sanford I. Weill
Medical College

Office of the Chairman
Department of Pediatrics

525 East 68th Street, M-622
New York, NY 10021
Tel: 212 746-3450
Fax: 212 746-0300

01 APR 17 PM 4:06

April 12, 2001

APR 16 2001

Fred Thompson
511 Dirksen Senate Office Building
Washington , DC 20510

Dear Senator Thompson,

As Chairman of the Department of Pediatrics at Weill Medical College of Cornell University, I am vitally interested in the well being of children in the United States. As a result, I was selected to be a member of the Public Health Policy Advisory Board (PHPAB) chaired by Lou Sullivan, former Commissioner of Health. PHPAB was created to promote health policy for children.

It is in this regard that I write in support of the nomination of Dr. John Graham for the position of Administrator of OMB's Office of Information and Regulatory Affairs.

Dr. Graham is a Professor of Policy and Decision Sciences at the Harvard School of Public Health and founding director of the Harvard Center for Risk Analysis. He has dedicated his life to pursuing cost-effective ways to save lives, prevent injuries and illness, and protect the environment.

I recommend Dr. Graham for the position of Administrator of OMB's Office of Information and Regulatory Affairs without reservation. If I can provide any additional information, please contact me at 212-746-3450.

Sincerely,

Maria I. New, M.D.
Professor and Chairman, Department of Pediatrics
Chief, Pediatric Endocrinology
Harold and Percy Uris Professor of Pediatric Endocrinology and Metabolism

HARVARD UNIVERSITY
DIVISION OF HEALTH POLICY RESEARCH AND EDUCATION

HARVARD MEDICAL SCHOOL
JOHN F. KENNEDY SCHOOL OF GOVERNMENT
HARVARD SCHOOL OF PUBLIC HEALTH
FACULTY OF ARTS AND SCIENCES

JOSEPH P. NEWHOUSE, Ph.D., Director
John D. MacArthur Professor
of Health Policy and Management
180 Longwood Avenue
Boston, MA 02115-5899
(617) 432-1325 FAX: (617) 432-0173
newhouse@hcp.med.harvard.edu

11 April 2001

The Honorable Edward M. Kennedy
315 Russell Senate Office Building
United States Senate
Washington, DC 20510

Dear Senator Kennedy:

I am writing to express my support for Professor John Graham's confirmation to be Associate Director of OMB for Information and Regulatory Affairs. I have known John as a colleague at the School of Public Health since coming to Harvard in 1988, although I have not formally collaborated with him nor am I a member of the Center for Risk Analysis which he directs. I have always found John to be fair and judicious in his scholarly work and in our informal conversations. I find the attacks on John by Public Citizen and NDRC as having been "bought by industry" just to not ring true.

John, like most economists, believes that costs are relevant to environmental, health, and safety regulation. Although I suspect this is the principal reason for the public opposition to his appointment, such a view is hardly that of a fanatic. Indeed, Justice Breyer in his book Breaking the Vicious Circle makes a powerful case for this view.

I hope you will offer your support for his confirmation.

Sincerely yours,

Joseph P. Newhouse

cc: David Nexon

MARGARET S. O'DONNELL

May 13, 2001

Fred Thompson, Chairman
Senate Governmental Affairs Committee
United States Senate
521 Dirksen Senate Building
Washington, DC 20510

Dear Senator Thompson:

I am writing in support of the Stop Dioxin Exposure Campaign urging you to deny confirmation to John Graham as head of the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget. The Campaign is composed of community and religious leaders, scientists, health professionals, labor representatives, and health groups working to protect public health by eliminating dioxin.

On April 3, the Stop Dioxin Exposure Campaign released Behind Closed Doors in twenty cities across the US. The report documents chemical industry involvement in concealing evidence and influencing policy with regard to established links between dioxin exposure and cancer risk, outlined in the EPA's dioxin reassessment. review. In contradiction to numerous independent scientific conclusions to the contrary, and while a member of the EPA's Science Advisory Board Dioxin Review, Mr. Graham has consistently argued that dioxin is not a human carcinogen. He has stated this position while receiving funding from sixty dioxin-polluting industries. Thus while acting as a chemical industry backed consultant, Mr. Graham has compromised his participation on the EPA Board by advocating the industry position and forfeiting the health and safety of the American public.

The Office of Information and Regulatory Affairs has a critical role in shaping environmental policies that are reasonable and protective of public health. The head of this office must be above all fair and objective. Unfortunately, Mr. Graham's behavior and financial indebtedness to the chemical industry must eliminate him as a creditable candidate for this important position.

Sincerely,

Margaret O'Donnell

Margaret S. O'Donnell

365 ATWELLS AVENUE • PROVIDENCE, RI • 02903

May 3, 2001

The Honorable Fred Thompson
Chairman
Committee on Governmental Affairs
United States Senate
Washington, DC 20510

The Honorable Joe Lieberman
Ranking Democrat
Committee on Governmental Affairs
United States Senate
Washington, DC 20510

Dear Mr. Chairman and Senator Lieberman:

The undersigned are former administrators of the Office of Information and Regulatory Affairs (OIRA), which was established within the Office of Management and Budget by the Paperwork Reduction Act of 1980.[1] We are writing to urge prompt and fair-minded Senate review of Professor John D. Graham's nomination to be OIRA Administrator.

The "R" in OIRA involves the regulatory aspects of the Office. These are an important part of the OIRA Administrator's overall responsibilities. The five of us - like the Presidents we worked for – have differing views of the appropriate role of government regulation in the economy and society. All of us, however, came to appreciate three essential features of regulatory policy during our tours at OIRA.

First, regulation has come to be a highly important component of federal policy-making, with significant consequences for public welfare. Second, the importance of regulatory policy means that individual rules should be subject to solid, objective evaluation before they are issued. Third, the regulatory process should be open and transparent, with an opportunity for public involvement, and final decisions should be clearly and honestly explained. In our view, objective evaluation of regulatory costs and benefits, and open and responsive regulatory procedures, serve the same purpose: to avert policy mistakes and undue influence of narrow interest groups, and

---

[1] Former Administrators Douglas H. Ginsburg and S. Jay Plager are now United States Circuit Judges. Canon 7 of the Code of Conduct for United States Judges provides that a judge may not "endorse...a candidate for public office."

to ensure that federal rules provide the greatest benefits to the widest public.

We believe that John Graham understands and subscribes to these principles. His professional field, risk assessment, lies at the heart of many of the most important health, safety, and environmental rules. Despite some of the criticisms of Professor Graham's work that have appeared since his nomination was announced, we are confident that he is not an "opponent" of all regulation but rather is deeply committed to seeing that regulation serves broad public purposes as effectively as possible.

The Senate's role in the appointment process is a critical one, and Professor Graham's nomination merits careful scrutiny and deliberation in the same manner as other senior Executive Branch appointments. At the same time, the President is entitled to the services of qualified appointees as soon as possible -- and this is a particularly important factor today, when many regulatory issues of great public importance and heated debate are awaiting decision by the President's political officials. We therefore urge prompt and fair-minded Senate review of Professor Graham's nomination.

Respectfully,

James C. Miller III (January, 1981 - September, 1981)

Christopher DeMuth (October, 1981 - May, 1984)

The Honorable Fred Thompson
The Honorable Joe Lieberman
Page Three

Wendy L. Gramm

Wendy L. Gramm (October, 1985 - February, 1988)

Sally Katzen

Sally Katzen (June, 1993 - February, 1997)

John Spotila

John Spotila (July, 1999 - December, 2000)

**IDENTICAL LETTERS SENT TO CHAIRMAN THOMPSON AND SENATOR LIEBERMAN**

INSURANCE INSTITUTE
FOR HIGHWAY SAFETY

April 30, 2001

The Honorable Fred Thompson
Committee on Governmental Affairs
340 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Thompson:

I am writing in response to an inquiry from Mr. Paul Noe, Senior Counsel to the Committee on Governmental Affairs, who called the Institute about any comments we might have regarding the nomination of John Graham to the position of Administrator, Office of Information and Regulatory Affairs within the Office of Management and Budget.

The Institute is a research organization that, over the years, has used relevant research findings to advance effective motor vehicle and highway safety regulatory and policy issues at the federal, state and local levels. As a research group we are very familiar with the work published by Professor Graham on motor vehicle regulatory policy and injury reduction. His work, such as *Preventing Automotive Injury, New Findings from Evaluation Research,* has advanced motor vehicle and highway safety by presenting public policy makers with important information about scientific approaches that can save lives and prevent injuries in highway crashes.

Although we have not always agreed with the positions taken by Professor Graham on motor vehicle and highway safety regulatory policy, we have found his research to be scholarly and objective. Most importantly, his work and that of his colleagues at the Harvard Center for Risk Analysis are regularly submitted for thorough peer review, and like all good researchers, John and other members of his group have exhibited a willingness to revise their work as a result of the review process. The fact that his Harvard group uses the well-established independent peer review process should eliminate questions about any sponsor bias that might creep into work.

We have every expectation that if John is confirmed by the Senate to lead the Office of Information and Regulatory Affairs, he will apply an objective scientific approach in reviewing regulatory decisions.

Sincerely,

Brian O'Neill
President

1005 N. GLEBE RD., ARLINGTON, VA 22201 TEL. 703/247-1500 FAX 703/247-1678 www.highwaysafety.org

# Oppose John Graham for OIRA Administrator

***Senate Vote Pending - Take Action!***

**HCRA Financial Support**
>HCRA Funders
>Graham Letter to Philip Morris Requesting $25,000
>$25,000 Check from PM to Harvard School of Public Health
>PM Memo: Stop Payment on Check to HCRA
>Kraft Foods Letter to Graham on HCRA Fund Raising Efforts

**Ties to Big Business**
>HCRA Funders
>HCRA Executive Council Members
>HCRA Executive Council Industry Ties
>Society for Risk Analysis Sustaining Members

**Working With Philip Morris**
>PM Memo: Comment on Letter from Graham
>Copy of $25,000 Check from PM to Harvard SPH
>PM Memo: Monthly Activities Include Meeting with Graham
>PM Memo: Stop Payment on Check to HCRA
>Graham Asks PM to Review Book for Accuracy and Discussed Meetings with Thorne Auchter and Boyden Gray
>Graham Writes PM to ask "that some arrangement can be made with Kraft."
>Graham Thanks Mayada Logue of PM for "efforts to expedite

## *Bush Nominee for Key Position Would Thwart Protective National Health, Safety and Environmental Safeguards*

Very soon, the Senate will vote on whether to confirm Bush nominee John Graham for an obscure but extremely influential government position -- Administrator of the Office of Information and Regulatory Affairs (OIRA), within the Office of Management and Budget (OMB). In this role, Graham would serve as the nation's regulatory gatekeeper, passing judgment over all major national health, safety, and environmental standards. Over the past decade, Graham has been an ally of the business community and played a leading role opposing strong government safeguards. If confirmed Graham would have the power to accomplish much of his agenda to roll back vital public health, workplace and environmental protections.

We have already seen a major attack on new public protections by the President. Bush reversed his pledge to control carbon dioxide emissions and supported a congressional override of the ergonomics standard designed to prevent repetitive stress injuries. Bush also has overturned or pared down many Clinton administration rules, including those that reduce arsenic in drinking water, end new road construction in national forest wilderness areas, limit hard rock mining to reduce water pollution and improve energy efficiency standards for air conditioners.

The Senate Governmental Affairs Committee on May 23 voted 9-3 (11-4 counting proxies) in favor of Graham. Senators Lieberman (CT), Durbin (IL), Torricelli (NJ), and Cleland (GA) fortunately stood up for strong public protections and opposed Graham. It is urgent that other Senators be encouraged to take a stand against Graham when the full Senate votes on his confirmation. Tell your Senators to vote against John Graham, and to oppose Bush's other efforts to weaken or eliminate national health, safety and environmental standards. Call the Capitol switchboard at 202-224-3121, or click here to send your Senators a free fax.

| | | |
|---|---|---|
| **Background** | **Opposition Statements and Letters** | **Philip Morris and Kraft Documents** |
| **Take Action** | **Testimony** | **Graham in the News** |

**Background**
Background on the John Graham Nomination (May 14, 2001)

Kraft Foods, Inc. gift of $20,000"
>PM Memo: Discussing Food Safety Legislation with Graham
>Graham Letter to PM Soliciting $50,000 for Risk Symposium
>Graham Letter to Jonathan Wiener on Risk Assessment and Second Hand Smoke
**Click for more Philip Morris and Kraft Documents**

**Reports**
>Dow Brand Dioxin: Dow Makes You Poison Great Things
>Safeguards at Risk: John Graham and Corporate America's Back Door to the Bush White House

**Scholarship**
>Risk/Risk Tradeoffs in Pesticide Regulation: Evaluating the Public Health Effects of a Ban on Organophosphate and Carbamate Pesticides
>HCRA Study Finds that Restricting Cell Phones While Driving May be Premature. Benefits May Outweigh Risk; Summary of Study
>New England Journal of Medicine: Association between Cellular-Telephone Calls and Motor Vehicle Collisions
>JAMA: The Cost-Effectiveness of Air Bags by Seating Position
>Use and Safety of Air Bags Misunderstood
>Airbags's Teflon Image: A National Survey of Knowledge and Attitudes

Background on the John Graham Nomination (May 14, 2001)

Industry Ally John Graham is Wrong Choice to Be Nation's Regulatory Gatekeeper (May 17, 2001)

Public Citizen Report - Safeguards at Risk: John Graham and Corporate America's Back Door to the Bush White House (March 12, 2001)
- Letter to Sen. Fred Thompson, Senate Governmental Affairs Committee Chairman, Regarding the Safeguards at Risk Report (March 13, 2001)

OMB Watch Analysis of OIRA: Assurances Needed for Transparency, Accountability at OIRA (May 5, 2001)

OMB Watch Summary of Concerns with John Graham
(May 5, 2001)

**Take Action**
Fax Your Senator to Oppose the John Graham Nomination

**Opposition Statements and Letters**
National Organizations Opposing John D. Graham (May 30, 2001)

Sen. Joe Lieberman Votes Against Graham; Believes Nominee Would Weaken Environment, Health and Safety Protections (May 23, 2001)

AFSCME Opposes the Graham Nomination in Letter to Senate Governmental Affairs Committee (May 21, 2001)

Former Federal Regulators Raise Concerns About Graham
(May 17, 2001)

AFL-CIO Letter to Sen. Fred Thompson, Senate Governmental Affairs Committee Chairman, Opposing the Graham Nomination (May 17, 2001)

OMB Watch Letter to Sen. Fred Thompson, Senate Governmental Affairs Committee Chairman, Opposing the Graham Nomination (May 16, 2001)

National Environmental Trust: Graham Nomination Threatens Environmental Protections (May 15, 2001)

Natural Resources Defense Council Letter to Senate Governmental Affairs Committee Criticizing Graham's Anti-Regulatory Record (May 15, 2001)

Natural Resources Defense Council Press Release Opposing Graham
(March 8, 2001)

UAW Letter to Sen. Fred Thompson, Senate Governmental Affairs Committee Chairman, Opposing the Graham Nomination (May 11, 2001)

Senate Dear Colleague Letter from Sen. Richard Durbin (D-Ill.): Why the Nomination of John Graham as Administrator of OMB/OIRA Should be Opposed
(May 10, 2001)

Harvard University Faculty Opposed to Graham Nomination (May 10, 2001)

53 Scholars and Academics Write the Senate Governmental Affairs Committee Opposing the Graham Nomination
(May 9, 2001)

30 Scholars Oppose Graham and Raise Conflict of Interest Concerns
(May 7, 2001)

National Organizations Make the Case Against John Graham to the Senate Governmental Affairs Committee (April 12, 2001)

Center for Science in the Public Interest Writes President Bush Criticizing Graham's Strong Ties to Industry (March 7, 2001)

**Testimony**
Statement of Public Citizen President Joan Claybrook on the John Graham Nomination to the Senate Governmental Affairs Committee (May 16, 2001)

Governmental Affairs Committee Chairman Thompson Criticized for Refusing Witnesses Opposed to Graham
(May 15, 2001)

Testimony of Professor Lisa Heinzerling, Georgetown University Law Center, Concerning the Nomination of John Graham (May 10, 2001)

**Graham in the News**
Tom Paine.com: Harvard University's Gift to the Nation: Goodbye to Meddlesome Health, Environment, and Workplace Safety Rules (June 1, 2001)

Plastics News: Bush's OIRA Appointee Graham Could Lend Clout to Plastics
(May 7, 2001)

Washington Post: Nominee's Business Ties Criticized (May 15, 2001)

Washington Post: Dioxin Report by EPA on Hold (April 12, 2001)

New York Times: Regulations Czar Prefers New Path (March 25, 2001)

Boston Globe: Nominee's Funding At Issue; Critics of Harvard Risk Analysis See Ties to Industry (March 18, 2001)

Charleston Gazette: Expert Panel Backs EPA Dioxin Study (October 1, 1995)

June 29, 2001

RECEIVED
BY 7/6

The Honorable Joseph Lieberman
Chairman Senate Governmental Affairs Committee
706 Hart Senate Office Building
Constitution Ave & 2nd Street NE
Washington, DC 20510

Dear Chairman Lieberman:

On behalf of the 68,000 members of the American Federation of State, County and Municipal Employees (AFSCME) in California, I write to express our strong opposition to the nomination of John D. Graham, Ph.D. to serve as director of the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB).

As gatekeeper for all federal regulations, the Administrator of OIRA has an enormous impact on the health and safety of workers and the public. Yet Dr. Graham's record as Director of the Harvard Center for Risk Analysis demonstrates that he would minimize consideration of worker and public health in evaluating rulemaking and instead rely almost exclusively on considerations of economic efficiency.

Dr. Graham's approach to regulatory analysis frequently ignores the benefits of federal regulation, indicating that reviews under his leadership will lack balance. His anti-regulatory zeal causes us to question whether he will be able to implement regulations that reflect decisions by Congress to establish health, safety and environmental protections. We are also deeply concerned that Dr. Graham's extreme views and close alliance with regulated entities will prevent the OIRA from providing a fair review of regulations that are needed to protect workers and the public.
For the foregoing reasons, we urge you to oppose Dr. Graham's confirmation as Administrator of the Office of Information and Regulatory Affairs.

Sincerely,

Willie L. Pelote, Sr.
Political & legislative Director, California

cc: Chuck Loveless

1121 L Street • Suite 904 • Sacramento, California 95814-3926 • (916) 441-1570 • (916) 441-3426 FAX

William K. Reilly

01 APR 31 PM 6: [illegible] 0 1 2001

April 27, 2001

The Honorable Fred Thompson
Chairman
The Honorable Joseph I. Lieberman
Ranking Minority Member
Committee on Governmental Affairs
Senate Dirksen Office Building
Washington, DC 20510-6250

Dear Senators Thompson and Lieberman,

I am writing to support the nomination of John Graham to head OMB's Office of Information and Regulatory Affairs.

Throughout a distinguished academic career, John has been a consistent champion for a risk-based approach to health, safety and environmental policy. He is smart, he has depth, and he is rigorous in his thinking. I think that he would bring these qualities to the OIRA position and would help assure that the rules implementing our nation's health and environmental laws are as effective and as efficient as they can be in achieving their objectives.

There is a difference between Graham's work at Harvard's Center on Risk Analysis and the responsibilities which he would exercise at OIRA/OMB, and I think he understands that. At Harvard, he has concentrated on research about the elements of risk and their implications for policymakers, as well as on communicating the findings. At OMB, the charge would be quite different, involving the implementation of laws enacted by Congress, working with the relevant federal agencies – in short, taking more than cost-effectiveness into account.

I have no doubt that you and your colleagues on the Committee will put tough questions to him during his confirmation hearing and set forth your expectations for the position and his tenure should he be confirmed by the Senate. And I expect he will give the reassurances you require, of impartial and constructive administration of OIRA, and of avoiding the stalemates that have characterized OIRA-EPA relations, for example, in years past. The position at OIRA is fraught with potential for conflict and obstruction, but the advent of a thoroughgoing professional who has committed his career to the analysis and exposition of risk should be seen as positive. In sum, my interactions over the years with John Graham have impressed me with his rigor, fair-mindedness and integrity.

With every good wish.

Sincerely yours,

Bill

William K. Reilly

THE TASK FORCE FOR CHILD SURVIVAL
AND DEVELOPMENT

April 24, 2001

The Honorable Max Cleland
United States Senate
461 Dirksen Senate Building
Washington, DC 20510

Dear Senator Cleland:

I write to offer my enthusiastic support of the President's nomination of Professor John D. Graham of Harvard to serve as Administrator, Office of Information and Regulatory Affairs, OMB. I have known John for over ten years and have worked with him closely to advance the cause of injury and violence prevention in the United States.

I am aware that some activist groups have raised concerns about John's commitment to public health and safety but I can assure you, based on personal experience, that Professor Graham has been a powerful and influential proponent of injury prevention programs at CDC and elsewhere in the federal government. Please let me give several examples of Professor Graham in action.

First, in a classic 1995 study of the cost-effectiveness of over 500 lifesaving programs in the USA, Professor Graham found that injury prevention is highly cost-effective. He did not simply publish this result in the peer-reviewed literature. He also presented his results at briefings for congressional staff and prepared op-ed pieces for newspapers and trade publications. In numerous speeches throughout the country, Professor Graham highlighted injury prevention as a worthy, cost-effective pursuit of policy makers and the public. When leading the CDC injury-prevention program, I personally witnessed Professor Graham lead a coalition of university-based trauma scientists in advocacy of expansion of the CDC program. Although Professor Graham is certainly a Republican who favors limited government, he advocated expansion of CDC's injury prevention program because his own research showed that these programs were cost-effective investments in public health.

Second, when CDC's firearms research program came under political attack in the 1990s, the injury prevention community needed a respected scientist and Republican to go to congressional leaders and defend the value of CDC's research into gun-related injuries. Professor Graham volunteered to offer a helping hand and he certainly did so. Using contacts he had developed through regulatory reform hearings in Congress, Graham made personal visits to the offices of both Senator Robert Dole and Trent Lott. Professor

750 COMMERCE DRIVE • SUITE 400 • DECATUR, GEORGIA 30030
PHONE: 404/371-0466 • FAX: 404/371-1087

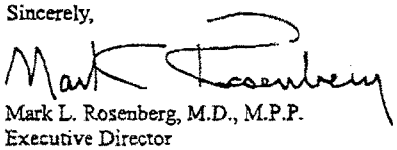
Graham did not make these trips because he would personally benefit from firearms-related research. That was not his personal field of inquiry. I believe he did it because he is deeply concerned about firearm-related injury in the USA and believes that scientific research, the type of applied work conducted at CDC, can help to identify cost-effective solutions which don't require a total ban on firearms (e.g., child safety locks on firearms).

Finally, I recall vividly a Senate hearing called by Senator Daniel Patrick Moynihan on the subject of firearm violence in the United States. I had the opportunity to serve on the same panel of witnesses with Professor Graham. In his testimony, Professor Graham argued that successes in firearm injury prevention need to follow the path that has brought successes in automobile safety. That path included creation of publicly funded data systems to quantify the frequency and cost of injuries as well as analytical research to identify the most cost-effective solutions, whether they involve changes in citizen behavior through education or alterations in the design of firearms by manufacturers. Professor Graham also supported the need for federal regulatory leadership such as we now have in automobile safety.

In short, I see in Professor Graham a no-nonsense, analytical leader who knows the difference between a good government regulation and a wasteful one. I also know Professor Graham as an open-minded scholar who thrives in an environment where he weighs the viewpoints of different interests. That is precisely the kind of person who should be Administrator of OMB-OIRA. I urge you to approach his nomination with an open mind and to vote for his confirmation. If you or your staff should have any questions, please do not hesitate to contact me.

In closing, let me just wish you well and thank your for the extraordinary service you have rendered to your country. I have known you, albeit indirectly, and followed your progress over the years. I worked with your cousin, Mary Lynn Harris, at CDC for 8 years. She is a wonderful and kind person and always speaks highly of you. In addition, I saw you at Alan Stoudemire's memorial ceremony and though we did not have a chance to speak that day I was touched by your presence. Alan was a friend for a very long time and he was, as you know, quite a special person. I hope we will get a chance to meet. In the meantime, thank you so much for all that you do.

Sincerely,



Mark L. Rosenberg, M.D., M.P.P.
Executive Director
The Task Force for Child Survival and Development

cc: Fred Thompson
Joseph Lieberman

INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE & AGRICULTURAL IMPLEMENT WORKERS OF AMERICA – UAW

STEPHEN P. YOKICH, President RUBEN BURKS, Secretary-Treasurer

VICE PRESIDENTS

ELIZABETH BUNN • RON GETTELFINGER • NATE GOODEN • BOB KING • RICHARD SHOEMAKER

IN REPLY REFER TO

1757 N STREET, N.W.
WASHINGTON, D.C. 20036
TELEPHONE: (202) 828-8500
FAX (202) 293-3457

May 11, 2001

The Honorable Fred Thompson
Chair
Committee on Governmental Affairs
United States Senate
Washington, D.C. 20510

Dear Chairman Thompson:

On May 17, 2001, the Committee on Governmental Affairs is holding a hearing on the nomination of John Graham to head the Office of Information and Regulatory Analysis of the Office of Management and Budget. On behalf of 1.3 million active and retired UAW members and their families, we urge you to oppose the nomination of John Graham. In this critical job, he would oversee the promulgation, approval and rescission of all federal administrative rules protecting public health, safety, and the environment as well as those concerning economic regulation. We believe his extreme positions on the analysis of public health and safety regulations render him unsuited for this job.

The UAW strongly supports Occupational Safety and Health Administration standards to protect against workplace hazards. We are also concerned about clean air, clean water, toxic waste, food, drug and product safety, and consumer protection rules. The OIRA serves as the gatekeeper for these standards and rules as well as for government collection of information on which to base public health protections.

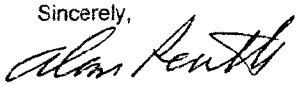
The Harvard Center for Risk Analysis, which John Graham founded, has been the academic center for the deconstruction of our public health structure. Mr. Graham and his colleagues have advocated the full range of obstructions of new public protections: cost-benefit, cost-per-lives saved, comparative risk analysis, substitution risk, and so-called "peer review" which would give regulated industries a privileged seat at the table before the public could comment on a rule. Mr. Graham has testified before Congress in favor of imposing such obstacles on all public health agencies and all public health laws. His academic work is entirely in support of this agenda as well.

opeiu494

It already takes decades to set a new OSHA standard. Our members and their families need stronger public health protections, and Mr. Graham has demonstrated his opposition to such protections. We are concerned that, with Mr. Graham as the head of OIRA, public health and safety regulations will be further delayed, protections on the book now will be jeopardized, and the interests of workers and consumers will not be given adequate weight.

For these reasons, we urge you to vote against the nomination of John Graham to head OIRA.

Sincerely,



Alan Reuther
Legislative Director

AR/BCS:fcg
Opeiu494
cc: Members, Committee on
Governmental Affairs

AMERICAN FEDERATION OF LABOR AND CONGRESS OF INDUSTRIAL ORGANIZATIONS

815 SIXTEENTH STREET, N.W.
WASHINGTON, D.C. 20006

JOHN J. SWEENEY
PRESIDENT

RICHARD L. TRUMKA
SECRETARY-TREASURER

LINDA CHAVEZ-THOMPSON
EXECUTIVE VICE-PRESIDENT

**LEGISLATIVE ALERT!**

(202) 637-5090

May 17, 2001

The Honorable Fred Thompson, Chairman
Senate Committee on Governmental Affairs
340 Dirksen Senate Building
Washington, D.C. 20510

Dear Mr. Chairman:

I am writing to convey the opposition of the AFL-CIO to the nomination of John D. Graham, Ph.D. to direct the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB).

As Administrator of OIRA, Dr. Graham would be the gatekeeper for all federal regulations. In our view, Dr. Graham, with his very strong anti-regulatory views, is simply the wrong choice to serve in this important policy making position.

For years as Director of the Harvard Center for Risk Analysis, Dr. Graham has repeatedly taken the position that cost and economic efficiency should be a more important, if not the determinative consideration, in setting standards and regulations. He has argued for the use of strict cost-benefit and cost-efficiency analysis, even though for many workplace safety and environmental regulations, such analyses are not appropriate or possible or are explicitly prohibited by the underlying statute. If Dr. Graham's views dictated public policy, workplace regulations on hazards like benzene and cotton dust would not have been issued because the benefits of these rules are hard to quantify and are diminished because they occur over many years. Similarly, regulations pertaining to rare catastrophic events such as chemical plant explosions or common sense requirements like these for lighted exit signs couldn't pass Dr. Graham's strict cost-benefit test.

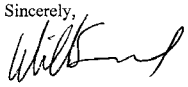
In enacting the Occupational Safety and Health Act, the Clean Air Act and other safety and health and environmental laws, Congress made a clear policy choice that protection of health and the environment was to be the paramount consideration in setting regulations and standards. Dr. Graham's views and opinions are directly at odds with these policies.

We are also deeply concerned about Dr. Graham's close ties to the regulated community. The major source of Dr. Graham's funding at the Harvard Center for Risk Analysis has been from companies and trade associations who have vigorously opposed a wide range of health, safety and environmental protections. Much of Dr. Graham's work has been requested and then relied upon by those who seek to block necessary protections.

Given Dr. Graham's extreme views on regulatory policy and close alliance with the regulated communities, we are deeply concerned about his ability to provide for a fair review of regulations that are needed to protect workers and the public. If he is confirmed, we believe that the development of important safeguards to protect the health and safety of workers across the country would be impeded.

Therefore, the AFL-CIO urges you to oppose Dr. Graham's confirmation as Administrator of the Office of Information and Regulatory Affairs.

Sincerely,



William Samuel, Director
DEPARTMENT OF LEGISLATION

c: Members of Senate Governmental Affairs Committee

May 9, 2001

The Honorable Members
Senate Governmental Affairs Committee
United States Senate
340 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators,

We write as scholars of law, medicine, economics, business, public health, political science, psychology, ethics and the environmental sciences to oppose the nomination of John Graham to direct the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget. We hope that the Governmental Affairs Committee will conclude that Professor Graham is the wrong person to supervise the nation's system of regulatory safeguards.

Professor Graham's controversial risk management methodology discounts the real risks of well-documented pollutants such as dioxin and benzene, and makes use of extreme and highly-disputed economic assumptions. Professor Graham has shown his willingness to over-ride health, safety, environmental, civil rights, and other social goals in applying crude cost-benefit tools far past the point at which they can be justified by existing scientific and economic data.

In his statements to the media and Congress, he has undermined regulatory efforts by understating many of the potential benefits of health, safety and environmental regulation and overstating their costs. Moreover, Professor Graham has publicly rendered many opinions on complex and imperfectly understood scientific phenomena, such as the etiology of cancer and other diseases, despite his lack of a degree in the hard sciences.

Graham's work has, overall, demonstrated a remarkable congruency with the interests of regulated industries. In contrast, the position at OIRA requires a much more even-handed approach. Reviewing officials should respect the democratic process by which Congress assigns legislative mandates to the agencies, consider the investment of the public and stakeholders in the regulatory process and its results, and defer to the expert technical and scientific judgments of federal agencies.

We also have serious concerns about Professor Graham's disregard for widely-accepted fundraising and research norms within academia. He has solicited and accepted unrestricted funds from corporations with a direct financial interest in particular regulatory issues addressed by his work, without acknowledging the role of his corporate benefactors. Unlike many research scientists, he has often operated without the guidance of restricted-funding contracts designed to minimize conflicts of interest and to protect credibility and public trust.

Graham's record shows that he is unlikely to serve as an honest broker as OIRA director. Because we view his candidacy as an invitation for undue industry influence in the regulatory process and as a vehicle for application of a highly controversial methodology, we urge you to oppose John Graham's nomination to Administrator of the Office of Information and Regulatory Affairs.

Sincerely,

Frank Ackerman, Ph.D.
Global Development and Environment Institute
Tufts University
Medford Massachusetts

William L. Andreen
Clarkson Professor of Law
University of Alabama School of Law
Tuscaloosa, Alabama

Barbara A. Babcock
Judge John Crown Professor of Law
Stanford Law School
Stanford, California

Dr. John H. Baldwin
Planning, Public Policy and Management Department
University of Oregon
Eugene, Oregon

Candice Bauer
Department of Biological Sciences
University of Notre Dame
Notre Dame, Indiana

Lisa A. Bero, Ph.D.
Associate Professor
Institute for Health Policy Studies
Department of Clinical Pharmacy
University of California, San Francisco
San Francisco, California

Amanda Behrens
Department of Environmental Health Sciences
Bloomberg School of Public Health
Johns Hopkins University
Baltimore, Maryland

Patricia Blanchette
Associate Professor
Department of Philosophy
University of Notre Dame
Notre Dame, Indiana

John Bonine
Professor, School of Law
University of Oregon
Eugene, Oregon

David C. Christiani, M.D.
Professor
Harvard Medical School and
Harvard School of Public Health
Boston, Massachusetts

Richard Clapp
Associate Professor
Department of Environmental Health
Boston University School of Public Health
Boston, Massachusetts

Michael H. Davis
Professor of Law and Registered Patent Attorney
Cleveland State University College of Law
Cleveland, Ohio

Michael R. DePaul
Associate Professor of Philosophy
University of Notre Dame
Notre Dame, Indiana

Martin Donohoe, M.D., F.A.C.P.
Assistant Professor of Medicine and Senior Scholar
Center for Ethics in Health Care
Oregon Health Sciences University
Portland, Oregon

David Driesen
Associate Professor
Syracuse University College of Law
Syracuse, New York

Paul Farmer, M.D., Ph.D.
Department of Social Medicine
Harvard Medical School
Boston, Massachusetts

Thomas G. Field, Jr.
Professor of Law
Franklin Pierce Law Center
Concord, New Hampshire

James K. Galbraith
Professor of Economics
Lyndon B. Johnson School of Public Affairs
The University of Texas at Austin
Austin, Texas

John Gartner, Ph.D.
Clinical Assistant Professor of Psychiatry
Johns Hopkins University School of Medicine
Baltimore, Maryland

Eileen Gauna
Professor of Law
Southwestern University School of Law
Los Angeles, California

Linda Ginzel
Clinical Professor of Managerial Psychology
The Graduate School of Business
The University of Chicago
Chicago, Illinois

Robert Glicksman
Professor of Law
University of Kansas School of Law
Lawrence, Kansas

Leonard Greenhalgh, Ph.D.
Professor of Management
Amos Tuck School of Business
Dartmouth College
Hanover, New Hampshire

Matthew R. Glucksberg
Department of Biomedical Engineering
Northwestern University
Evanston, Illinois

Sam Glucksberg
Psychology Department
Princeton University
Princeton, New Jersey

Claude Guillemard
Department of Romance Languages and Literatures
Johns Hopkins University
Baltimore, Maryland

Michael R. Harbut, M.D., M.P.H., F.C.C.P.
Past Chair, Occupational and Environmental Health
American College Of Chest Physicians
Assistant Professor, Internal Medicine, Wayne State University
Detroit, Michigan

Michael P. Healy
Professor, College of Law
University of Kentucky
Lexington, Kentucky

Philip Johnson-Laird
Psychology Department
Princeton University
Princeton, New Jersey

Boaz Keysar
Associate Professor of Psychology
University of Chicago
Chicago, Illinois

Professor R. A. Kinchla
Department of Psychology
Princeton University
Princeton, New Jersey

Howard A. Latin
Professor of Law and Justice John J. Francis Scholar
Rutgers University School of Law
Newark, New Jersey

Richard Levins
Professor, Harvard School of Public Health
Harvard University
Boston, Massachusetts

Charles Levinstein, Ph.D., M.S.O.H.
Professor of Work Environment Policy
Department of Work Environment
Francis College of Engineering
University of Massachusetts Lowell
Lowell, Massachusetts

Thomas McGarity
W. James Kronzer Chair
University of Texas School of Law
Austin, Texas

Don Milton, M.D., Dr.P.H.
Associate Professor of Occupational and Environmental Health
Harvard School of Public Health
Boston, Massachusetts

Paul Mushak, Ph.D.
The Children's Hospital at Montefiore
Albert Einstein College of Medicine & PB Associates
Durham, North Carolina

Herbert L. Needleman, M.D.
Professor of Psychiatry and Pediatrics
University of Pittsburgh School of Medicine.
Pittsburgh, Pennsylvania

Jerome A. Paulson, M.D.
Associate Professor of Medicine, Pediatrics & Community Health
Mid-Atlantic Center for Children's Health & the Environment
George Washington University
Washington, D.C.

David N. Pellow, Ph.D.
Assistant Professor, Departments of Sociology and Ethnic Studies
University of Colorado
Boulder, Colorado

Zygmunt J.B. Plater, S.J.D.
Professor of Law
Boston College Law School
Newton Centre, Massachusetts

Marc R. Poirier
Professor of Law
Seton Hall University School of Law
Newark, New Jersey

Margaret Jane Radin
William Benjamin Scott and Luna M. Scott Professor of Law
Stanford Law School, Stanford University
Palo Alto, California

Adrienne Randolph, M.D., M.Sc.
Department of Pediatrics
Harvard Medical School
Boston, Massachusetts

Professor Clifford Rechtschaffen
Golden Gate University School of Law
San Francisco, California

Lynne M. Reder
Professor of Psychology
Carnegie Mellon University
Pittsburgh, Pennsylvania

John Rosen, M.D.
Professor of Pediatrics
Albert Einstein College of Medicine
Bronx, New York

Sidney A. Shapiro
Professor of Law
University of Kansas School of Law
Lawrence, Kansas

Kristin Shrader-Frechette
O'Neill Chair of Philosophy
and Concurrent Professor of Biological Sciences
University of Notre Dame
Notre Dame, Indiana

Steven Sloman
Associate Professor
Cognitive and Linguistic Sciences
Brown University
Providence, Rhode Island

Mark Squillace
Professor of Law
University of Wyoming College of Law
Laramie, Wyoming

Rena Steinzor
Professor
University of Maryland Law School
Baltimore, Maryland

Sandra R. Waxman
Professor of Psychology
Department of Psychology
Northwestern University
Evanston, Illinois

May 10, 2001 **(Sent to Sen. Levin, Carper, Cleland and Carnahan)**

The Honorable Carl Levin
United States Senate
269 Senate Russell Building
Washington, DC 20510

Dear Senator Levin:

The Senate Governmental Affairs Committee will soon consider the nomination of John Graham to be the director of the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB). Mr. Graham's experience as the Director of the Harvard University Center for Risk Analysis make him uniquely qualified to advise OMB Director Daniels and the President on risk and benefit issues pertaining to agency regulatory initiatives.

Farm Bureau has consistently called on regulators and legislators to base regulatory initiatives on sound science and a reasonable balancing of risks and benefits. Mr. Graham's leadership at OIRA will help steer the federal regulatory process to a more reasonable balance between risks and benefits. We urge you to support Mr. Graham's nomination when considered by the Senate Governmental Affairs Committee.

Sincerely,

Bob Stallman
President

BS:bl/jj
F:\stm\recommendation\omb-graham01.510

**PUBLIC**
**HEALTH**
**POLICY**
**ADVISORY**
**BOARD**

May 1, 2001

01 MAY -2 PM 3:02

BOARD OF TRUSTEES
CHAIRMAN

Louis W. Sullivan, M.D.
*President,*
Morehouse School of Medicine
*Former Secretary,*
U.S. Department of Health and Human Services

DISTINGUISHED FELLOWS

Patricia A. Buffler, Ph.D., M.P.H.
*Dean Emerita, Professor of Epidemiology,*
School of Public Health,
University of California, Berkeley

J. Donald Millar, M.D., D.T.P.H. (Lond.)
*Vice Chair, Programs Committee,*
*President,* Don Millar & Associates, Inc.
*Former Director,* National Institute for Occupational Safety and Health

Maria I. New, M.D.
*Chairman,* Department of Pediatrics,
The New York Hospital,
Cornell Medical Center

Ciro V. Sumaya, M.D., M.P.H.T.M.
*Dean and Cox Endowed Chair of Medicine*
The Texas A & M University System
Health Science Center

John J. Cohrssen, M.Sc., J.D.
*Executive Director*

2175 K Street, NW
Washington, DC 20037
(202) 775-1110
(202)-775-1767 (fax)

E-mail:phpab@phpab.org
www.phpab.org

The Honorable Fred Thompson
Chairman
Committee on Governmental Affairs
United States Senate
340 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Thompson:

I am writing in support of the swift confirmation of Dr. John Graham to the position of Administrator of the Office of Information and Regulatory Affairs.

Dr. Graham is an alumnus of the Public Health Policy Advisory Board, having worked closely on the Board with myself, Dr. J. Donald Millar, former Director of NIOSH, Dr. Antonio Novello, former Surgeon General, Dr. Maria New, Chairman of the Department of Pediatrics, Cornell Medical School, Dr. Patricia Buffler, Dean Emerita, UC Berkeley School of Public Health, and Dr. Ciro Sumaya, former HRSA Administrator and Deputy Assistant Secretary for Health.

Dr. Graham is superbly qualified to be the OIRA Administrator. He has an extraordinary grasp of the complexities of regulatory matters, and winning ability to find agreement on difficult issues. In addition to his impressive academic credentials, he has first hand experience assisting Federal agencies, he has extensive substantive knowledge in risk assessment and cost benefit, and, he has written widely on the important subject of government regulation.

On behalf of the Public Health Policy Advisory Board, I am,

Sincerely,

Louis W. Sullivan, M.D.

Chairman of the Board

THE UNIVERSITY OF CHICAGO
THE LAW SCHOOL
1111 EAST 60TH STREET
CHICAGO • ILLINOIS 60637-2786

CASS R. SUNSTEIN
KARL N. LLEWELLYN DISTINGUISHED SERVICE
PROFESSOR OF JURISPRUDENCE

TELEPHONE: 773.702.9498
FAX: 773.702.0730

March 28, 2001

Senator Joseph Lieberman
Senate Hart Office Building
Washington, DC 20510

Dear Senator Lieberman:

I am writing to express the strongest possible support for John Graham's nomination to be head of the Office of Information and Regulatory Affairs. This is an exceptional appointment of a truly excellent and nonideological person.

I've know John Graham for many years. He's a true believer in regulatory reform, not as an ideologue but as a charter member of the "good government" school. In many ways his views remind me of those of Supreme Court Justice, and Democrat, Stephen Breyer (in fact Breyer thanks John in his most recent book on regulation). Unlike some people, John is hardly opposed to government regulation as such. In a number of areas, he has urged much more government regulation. In the context of automobile safety, for example, John has been one of the major voices in favor of greater steps to protect drivers and passengers.

A good way to understand what John is all about is to look at his superb and important book (coauthored with Jonathan Wiener), Risk vs. Risk (Harvard University Press). A glance at his introduction (see especially pp. 8-9) will suffice to show that John is anything but an ideologue. On the contrary, he is a firm believer in a governmental role. The point of this book is to explore how regulation of some risks can actually increase other risks -- and to ensure that government is aware of this point when it is trying to protect people. For example, estrogen therapy during menopause can reduce some risks, but increase others at the same time. What John seeks to do is to ensure that regulation does not inadvertently create more problems than it solves. John's concern about the possible problems with CAFE standards for cars -- standards that might well lead to smaller, and less safe, motor vehicles -- should be understood in this light. Whenever government is regulating, it should be alert to the problem of unintended, and harmful, side-effects. John has been a true pioneer in drawing attention to this problem.

John has been criticized, in some quarters, for pointing out that we spend more money on some risks than on others, and for seeking better priority-setting. These criticisms are misplaced.. One of the strongest points of the Clinton/Gore "reinventing government" initiative was to ensure better priority-setting, by focusing on results rather than red-tape. Like Justice Breyer, John has emphasized that we could save many more lives if we used our resources on big problems rather than little ones. This should not be a controversial position. And in emphasizing that

environmental protection sometimes involves large expenditures for small gains, John is seeking to pave the way toward more sensible regulation, not to eliminate regulation altogether. In fact John is an advocate of environmental protection, not an opponent of it. When he criticizes some regulations, it is because they deliver too little and cost too much.

John has also been criticized, in some quarters, for his enthusiasm for cost-benefit analysis. John certainly does like cost-benefit analysis, just like President Clinton, whose major Executive Order on regulation requires cost-benefit balancing But John isn't dogmatic here. He simply sees cost-benefit analysis as a pragmatic tool, designed to ensure that the American public has some kind of account of the actual consequences of regulation. If an expensive regulation is going to cost jobs, people should know about that -- even if the regulation turns out to be worthwhile. John uses cost-benefit analysis as a method to promote better priority-setting and more "bang for the buck" -- not as a way to stop regulation when it really will do significant good.

I might add that I've worked with John in a number of settings, and I know that he is firmly committed to the law -- and a person of high integrity. He understands that in many cases, the law forbids regulators from balancing costs against benefits, or from producing what he would see as a sensible system of priorities. As much as anyone I know, John would follow the law in such cases, not his own personal preferences.

A few words on context: I teach at the University of Chicago, in many ways the home to free market economics, and I know some people who really are opposed to regulatory programs as such. As academics, these people are excellent, but I disagree with them strongly, and I believe that the nation would have real reason for concern if one of them was nominated to head OIRA. John Graham is a very different sort. He cannot be pigeonholed as "conservative" or "liberal"; on regulatory issues, he's unpredictable in the best sense. I wouldn't be at all surprised if, in some settings, he turned out to be a vigorous voice for aggressive government regulation. In fact that's exactly what I would expect. When he questions regulation, it is because he thinks we can use our resources in better ways; and on this issue, he stands as one of the most important researchers, and most promising public servants, in the nation.

From the standpoint of safety, health, and the environment, this is a terrific appointment, even an exciting one. I very much hope that he will be confirmed.

Sincerely,

Cass R. Sunstein

Katherine Swartz, Ph.D.
Associate Professor
617-432-4325
Email: kswartz@hsph.harvard.edu

April 11, 2001

The Honorable Edward M. Kennedy
United States Senate
315 Russell Senate Office Building
Washington, DC 20510

RE: nomination of John Graham as Director of OIRA within the Office of Management and Budget

Dear Senator Kennedy,

I am writing in support of my colleague, John Graham, as a nominee for the Director of the Office of Information and Regulatory Affairs within the Office of Management and Budget. I have been a member of the Harvard School of Public Health faculty for nine years, and have known John since September 1992. I have worked closely with John in connection to the development and administration of the PhD in Health Policy Program at Harvard, and he has been one of three faculty most concerned about my career development while at HSPH. Although I do not always agree with his analyses of health policy issues, I also feel strongly that John is one of the fairest, most even-handed people I have known. John is an excellent administrator, one who seeks out all the opinions of people involved in a decision and then seeks to create consensus. He also works hard to energize people and build enthusiasm within a group. However, John is also quite willing to speak up for what he believes to be "right," even if it costs him political points. I speak to this point from personal experience -- John was only one of two full professors in my department who went to the Dean and spoke forcefully about how I and other women in my department were being unfairly treated. My respect for John grew further after learning about that "stand up" meeting.

In sum, John will be an excellent Director of OIRA. I urge you to support his nomination to be the next Director.

Sincerely,

Katherine Swartz
on leave as
Visiting Scholar 2000/2001
Russell Sage Foundation

UNIVERSITY OF CALIFORNIA, IRVINE

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

16 PM 4:17

Health Priorities Research Group
http://www.healthpriorities.uci.edu

School of Social Ecology
Irvine, Ca 92697-7076
FAX (949) 824-8286

May 14, 2001

Senator Fred Thompson
Chairman, Committee on Governmental Affairs
511 Dirksen Senate Office Building
Washington, DC 20510

Senator Thompson,

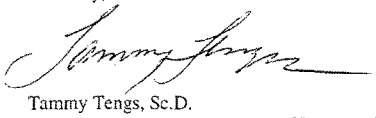
I am writing to clarify the substance of my collaborative research with John Graham who has been nominated to direct the Office of Information and Regulatory Affairs at the OMB. Lisa Heinzerling of Georgetown Law School has circulated on the Hill a chapter titled "The Humbugs of the Anti-Regulatory Movement" and submitted testimony to your committee criticizing two papers I wrote with Professor Graham:

> Tengs T, Graham J. The opportunity costs of haphazard societal investments in life-saving. In R Hahn (Ed.) *Risks, Costs, and Lives Saved: Getting Better Results from Regulation,* Oxford University Press, 1996.
>
> Tengs T, Adams M, Pliskin J, Safran D, Siegel J, Weinstein M, Graham J. Five-hundred life-saving interventions and their cost-effectiveness. *Risk Analysis*, 1995, 15(3), 369-390.

Ms. Heinzerling's written commentary on these papers contains a number of factual errors and she mischaracterizes the purpose of our research. I am writing to set the record straight. Because Ms. Heinzerling's testimony is very similar in substance to the chapter that was circulated, I will limit my comments to the latter. Attached please find a detailed point-by-point refutation of her many misstatements.

I enthusiastically support John Graham's appointment to the OMB and I hope the committee will find the attached analysis useful.

Sincerely,



Tammy Tengs, Sc.D.
Assistant Professor, Department of Urban and Regional Planning
Director, Health Priorities Research Group

**Detailed Rebuttal of**
**"The Humbugs of the Anti-Regulatory Movement"**

Heizerling: "...these researchers found that these cost ranged vary widely across interventions....toxin control was the most costly..." (p. 3)

**Tengs: No, we found that the cost-*effectiveness* varies widely, not the *cost*. The median toxin control intervention was less cost-effective than the median injury reduction or medical intervention. Cost-effectiveness is the ratio of incremental cost to incremental effectiveness. This glaring error leads me to wonder if Professor Heinzerling, a legal scholar, really understands the field of economic analysis. Or perhaps she hasn't read our paper carefully?**

"...Graham and Tengs's numbers are even more arresting than Morrall's: whereas the most expensive regulation on Morrall's table cost a 'mere' $72 billion for every life saved, the most expensive intervention on Graham and Tengs' table cost $99 billion for every year of life saved." (p. 4)

**That's true. Although we sought to include Morrall's analyses when we could locate them, we also included additional analyses, especially those published more recently. The $99 billion figure is based on a 1990 paper that Morrall would not have had access to. Heinzerling seems to imply that there is something suspicious about our data set. It is simply more recent and more complete than Morrall's.**

"...they flagrantly misrepresent the output of the regulatory system" ...(p. 4)

**We did not conduct an analysis of the output of the regulatory system, nor do we imply otherwise. Our intent was to study "life-saving interventions," some of which happen to be regulations.**

"The first problem...is that they include many life-saving interventions that have never been implemented by any agency; indeed, they include many interventions that have never even been proposed by any agency....Graham and Tengs do not limit themselves to discussing measures, or potential measures, under existing regulatory programs" (p. 4, 5)

**It is true that we did not restrict our paper to only those lifesaving interventions that are fully implemented. Doing so would have meant leaving out precisely 92% of the 587 interventions. This would have made for a very short list (plus, we would have had to change the name of the paper from "Five-hundred lifesaving interventions and their cost-effectiveness" to "Forty seven lifesaving interventions...") Limiting our analysis to interventions that had been fully implemented would mean that we would not have included heart transplants which, due to the lack of available organs and insurance coverage, are not received by everyone who might need one. As**

**another example, we would not have included mammograms because not every woman in the US gets breast cancer screening. Similarly, we would not have included a host of toxin controls, which, as Heinzerling points out, are often not fully implemented. We reported the cost-effectiveness of all 587 interventions however because we believe that all are *potential* measures. Certainly someone must scholars have considered these measures viable at some point or why would an economic analysis have been performed and made public? Finally, we say quite clearly in Tengs et al (1995) "...the lifesaving interventions described in this report include those that are fully implemented, those that are only partially implemented, and those that are not implemented at all. These interventions are best thought of as opportunities for investments. While they may offer insight into actual investments in life-saving, the cost-effectiveness of possible and actual investments are not equivalent."**

"...these studies...translate political objections to environmental regulation into numerical form..." (p. 4)

**The focus of our research was not on environmental regulations. We sought cost-effectiveness information for interventions that saved lives. Only 124 out of 575 cost-effectiveness ratios were related to reducing environmental risks.**

"...their analysis did not include information on the extent to which any given intervention was actually implemented...a very large number of the toxin controls studied by Graham and Tengs were never implemented by any agency..." (p. 5)

**This is correct. It is also true that many of the medical and injury reduction interventions are either poorly implemented or not implemented at all. Although Heinzerling seems to imply that we singled out toxin control in this regard, her point is correct for all interventions – few are fully implemented.**

"...An equally large number of these controls were never even proposed by any agency..." (p. 5)

**This may well be true. However we made no claim that all or even most controls were "proposed" by an agency. It is clear from the references cited in Tengs et al (1995) whether they were agency proposals or not. For example, reference 497 is from the Federal Register "National emission standards for hazardous air pollutants: *Proposed standards* for inorganic arsenic." On the other hand reference 1266, which corresponds to radon remediation, is a chapter in a book called Radon and Its Decay Products in Indoor Air. It is clear from viewing the bibliographic references, listed for every analysis, which cost-effectiveness estimates were for agency proposals and which cost-effectiveness estimates did not come, at least directly, from an agency proposal.**

"Indeed, although nine of the ten most expensive life-saving interventions in the entire study involved toxin control, not one of these nine interventions was ever implemented by a regulatory agency." (p. 5)

**This may well be true. If so, that's good news. Again, we did not claim otherwise.**

"Despite the (subtle) concessions of these researchers that their cost estimates include measures that were not implemented, it is easy enough to take away from these studies the impression that they describe the systematic workings, and failures, of current regulation." (p. 5)

**In Tengs et al (1995) we stated clearly (see above for quote) that many of these interventions were only fully or partially implemented. A full paragraph on this point appeared in the article – it was straightforward and to the point – there was nothing subtle about it. Further, few readers believe that every woman receives an annual pap smear, or that every child is immunized, or that every smoker receives a prescription for nicotine gum – all examples in our paper – so why would readers assume that that all toxin regulations were implemented? A final important point is that the toxin control interventions in our paper vary by stringency. Consequently, it is nonsensical to think that 1,3 Butadiene could conceivably regulated at *both* a standard of 2 ppm *and* 10 ppm PEL in polymer plants, for example. The astute reader would know that if one level is chosen, other levels are not chosen. Thus it is inherent in the way we defined "intervention" that few of our toxin control "interventions" would be implemented.**

"...a large problem with the studies of the costs of environmental regulation is that they rely on incomplete and questionable assessments of the harms caused by toxic substances. These assessments are incomplete because evaluating environmental programs based on their life-saving potential alone is to ignore many significant benefits of these programs. Most obviously, a fixation on lives saved ignores nonfatal harms to human health and hams to ecosystems..." (p. 6)

**This is true and we acknowledge it clearly in Tengs et al (1995): "Finally, we recognize that many of these interventions have benefits other than survival, as well as adverse consequences other than costs. For example, interventions that reduce fatal injuries in some people may also reduce nonfatal injuries in others; interventions designed to control toxins in the environment may have short-term effects on survival, but also long-term, cumulative effects on the ecosystem...." Note also that our intent was not to perform a complete analysis of the costs and benefits (e.g., non-lifesaving benefits) of environmental regulation. The purpose of our study was to explicitly compare the cost and effectiveness of *lifesaving* interventions. These interventions had two things in common: they all cost money and they all saved lives. Hence we compared them on these two features. I do not believe that this work offers a complete prescription for decision making, including regulatory decision making, and we do not claim otherwise in our published papers.**

"In quite a few instances, the very same lifesaving intervention appears in two or more places in their list, with very different costs attached to it. In these cases, the large cost differentials found by Graham and Tengs must be attributed to differing scientific estimates of risk rather than to capricious agency decision making, but Graham and Tengs do not mention this possibility..." (p. 7)

**We faithfully reported varying cost-effectiveness estimates for the same intervention when different estimates were described in the secondary literature. To do otherwise would give the impression of consensus where no consensus exists. Variation occurred most often because different authors used different methods and data to arrive at their estimate of cost-effectiveness. Variation in cost-effectiveness estimates is not limited to toxin control – it occurs for the 55 mph speed limit, dialysis for end-stage renal disease, pneumonia vaccination, and a host of other interventions. Cost-effectiveness differentials, even for toxin control, do not occur solely because of differing scientific estimates of risk. They might occur for a host of other reasons including different estimates of the cost of the regulation, different estimates of the risk reduction potential offered by the control method, different estimates of the population size affected, or differences in the stringency of the regulation. We do not mention in the journal article that variation may be attributed to different scientific estimates of risk because this is not the sole, or even most important, reason for the differences. Further, the paper was not focussed on toxin control, so it would not have made sense to focus on reasons for variation limited to toxin control. Finally we do not claim in our papers that these differences are due to capricious agency decision making as this was not the focus of our research.**

"A third problem with these studies...involves ...assumptions about whose life is worth saving. Neither Morrall's nor Graham and Tengs' study assumes that all human lives endangered by human action are equally valuable. On the contrary, these studies assume that lives saved in the future are worth less than lives saved today...They assume that it is better to save the lives of the young than the lives of the told, and they operationalize this assumption by focussing on the number of life-years, and not the number of lives, saved by an intervention."

**Historically, economists have valued lives based on the "human capital" approach which attaches a monetary value to human life based wages. Men were worth more than women; women who work outside the home were worth more than women who work inside the home; the elderly, who consumed resources but no longer contributed to the economy had effectively negative value. This historical approach did make assumptions about the value of different lives, attaching a different monetary value depending on the person's contribution to the GNP – but our approach does not make such assumptions – we treat all people of equal value, regardless of whether they are rich or poor, black or white, male or female. We do, however, define effectiveness by counting years of life gained when a premature death is averted. The value of this is that it recognizes that lives are never really "saved." Death is inevitable – we all have to go sometime – all policy makers can do**

**is affect the timing of death. All things being equal, it seems better to live a longer time than a shorter time, so we measure time with years. Note that we do not measure lifesaving benefits with years because we intend to give weight to the young over the old. Our intent is to value more years of life over fewer years of life. Doing so does, in general, favor the young who usually have more years of life to live. However, note that our method of characterizing lifesaving effectiveness would be indifferent between extending the life of a 20 year old by 10 years and extending the life of a 50 year old by 10 years. It's not the age of the person that matters per se. Finally, discounting effectiveness, in this case life-years, is acknowledged by virtually every economist as prudent. They may argue about the discount rate, but virtually all favor some form of discounting of benefits, including life-saving benefits. The failure to discount benefits while still discounting costs leads to a perverse situation called the Keeler-Cretin paradox. If we follow Heinzerling's advice and discount costs but not benefits, the strange implication is that we'd prefer to postpone toxin control investments forever. This is because spending money next year is always better than spending it this year (because of discounting), however lifesaving benefits are the same (because we didn't discount) so why not wait and regulate tomorrow? This is clearly perverse, hence to avoid this paradoxical situation we must discount benefits (lifesaving) if we discount costs.**

"Absent these assumptions, the cost-benefit ratios of the life-saving measures evaluated by ...Graham and Tengs, especially those involving toxin control, would have been very different." (p. 7)

**They would not be as different as Henzerling thinks. One of the most important reasons that toxin control measures are not generally cost-effective is that they prevent only a few cases of cancer at very high cost. Discounting is one factor, but it doesn't affect the reality of poor effectiveness and exorbitant cost. In my own database of cancer control interventions here at the Health Priorities Research Group at the University of California, Irvine, 34 out of 37 toxin control interventions are expected to prevent less than 10 cases of cancer. Contrast this with eating five fruits and vegetables a day, exercising, or tobacco cessation which would likely prevent hundreds of thousands of cases of cancer annually.**

"Both discounting and the focus on life-years rest on normatively contestable assumptions." (pg. 8)

**The Office of Disease Prevention and Health Promotion's Panel on Cost-Effectiveness (Gold MR, Siegel JE, Russell LB, et al. Cost-Effectiveness in Health and Medicine. New York: Oxford University Press; 1996) recommends the use of life-years or quality-adjusted life-years (QALYs). Measuring effectiveness as years of life saved is widely accepted in medicine and public health. In fact, it is far more common than counting lives saved.**

"Rather than discounting from the year in which a person saved by a regulatory intervention would otherwise have died, Graham and Tengs discount from the year in which the year saved by the regulatory intervention would otherwise have been lived"

**This is a correct statement and our method is sound as explained above.**

"There are several problems with this approach to discounting. First, it is inconsistent with Graham and Tengs' use of life-years saved rather than lives saved, as the metric of evaluation of life-saving interventions....Discounting life-years saved...trivializes the final years of life of young people whose lives are saved today – exactly the opposite of what the life-years saved approach purports to do...resulting in a shift of resources from the young to the old..." (p 11)

**Again, it is not our intent, or the intent of the life-years saved approach, to give weight to the young over the old. Our intent is to value more life-years over fewer life-years and this is what we have achieved. There is nothing internally inconsistent about it.**

"Graham and Tengs found..." (p 12.) "Graham and his co-author..." (p 15).

**Note that the authorship order on the book chapter was Tengs first and Graham second. In scholarly circles it would be correct to cite this chapter as: Tengs and Graham (1996). Indeed, if Heinzerling had submitted her chapter to a scholarly journal for publication, the journal editor would surely have pointed out the error and requested hat she revise it as it is simply incorrect to reverse authorship order. The authorship order on the "Five-hundred..." paper was Tengs first and Graham seventh. This paper should be cited as: Tengs et al (1995). In referring to these publications as "Graham and Tengs," in that order, or worse "Graham and his (unnamed) co-author," Heinzerling is deliberately misrepresenting the contribution of other scholars in her effort to criticize Graham, the Bush nominee.**

"Most of the interventions Graham and Tengs consider in the area of toxin control have never been implemented, and they never will be." (p 13)

**The purpose of this study was not to look at toxin control in isolation. It is true, however, that among the toxin control interventions included in the set of 185, most have never been implemented fully. Note however, that a single regulation might be divided into multiple "interventions," each, for example, with a different stringency. Thus implementing one stringency means not implementing a competing stringency. Also, even though rules were never promulgated, some are nevertheless partially implemented. Further, some that were promulgated were never fully implemented. Thus we sought estimates from two experts on "percent implementation."**

"...that table shows only about a dozen 'zero percent implementation' interventions. Thus despite what they say, Graham and Tengs cannot have incorporated the non-implemented status of most of the toxin regulations into their analysis." (p. 14)

**There are 20 interventions with 0 implementation reflected in the figure. Toxin control interventions that were never promulgated (or even considered) by the EPA might nevertheless have some percent implementation, at least according to the experts we interviewed. These would be plotted in the figure at some level higher than 0%, explaining the discrepancy that Heinzerling says that we "cannot have incorporated." In the chapter we say "Because some degree of implementation can exist even in the presence of a 'no-go' decision or can be absent even with a 'go' decision...we also collected data on 'percent implementation....To gather data on percent implementation, we elicited independent estimates from two experts...."**

"Graham and Tengs appear to have made no effort to identify those cost-effective regulations that have been implemented..." (p. 14)

**Our method of identifying economic analyses did not take into account cost-effectiveness information – indeed, we were unaware of what the cost-effectiveness numbers would show when we retrieved analyses. It would have given a biased impression to seek out those that were especially cost-effective or cost-ineffective and would be inconsistent with rigorous scientific method.**

"There are certainly highly efficacious environmental measures still to be implemented, but they are for the most part not found in Graham and Tengs' study."

**Highly efficacious measures are not necessarily cost-effective if they are also high in cost. If they're not in our study then that may be because we could find not economic analyses meeting our inclusion criteria, e.g. direct costs, lives saved, etc.**

"The toxin controls that fared well in Graham and Tengs' analysis have already been implemented..." (p 15).

**Let's assume, for the moment, that Heinzerling is correct. In fact, let's take the extreme case and suppose that the most cost-effective toxin control interventions (e.g., those costing less than $1,000,000/life-year) are always implemented while those that are not cost-effective are never implemented. Heinzerling would say this is good news, evidence that the regulatory apparatus is working. However, consider that if we shifted resources from the regulations costing, say, $500,000-$900,000 per life-year saved to other public health interventions that cost more like $10,000-$50,000/life-year, we'd save more life-years at less cost. Thus, even if it is true, that within the regulatory world, the most cost-effective intervention are implemented, one must look beyond government regulation in order to judge overall efficiency of our efforts to promote the nation's health.**

"In effect, then, what Graham and Tengs are really arguing for is a wholesale shift of EPA's responsibilities from the regulation of pollution of the air, water and land through mandatory controls on polluters to the encouragement of residential radon remediation ...through loans and tax incentives." (p. 16)

**No where in either paper do we advocate for, or even discuss , shifting EPA responsibilities, radon, or loans and tax incentives. These papers are simply not focussed on the EPA. To say otherwise is a grave and deliberate misrepresentation of our work.**

American Trauma Society

01 APR 30 PM 5:54

APR 30 2001

April 27, 2001

The Honorable Fred Thompson
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Joseph I. Lieberman
706 Hart Senate Office Building
Washington, DC 20510

Dear Senators:

I am pleased to submit this letter in support of President Bush's nomination of Professor John Graham to the position of Administrator, Office of Information and Regulatory Affairs, OMB. He and I have worked closely together for many years and I know him well. His character, his commitment to public service and his passion for good science makes him an ideal candidate for this position. Although he is perhaps best known as a cost-benefit analyst and advocate of regulatory reform, I know him because of his scientific contributions to the field of injury control and prevention. Indeed, Professor Graham has been recognized by the Surgeon General of the United States for his outstanding contributions in setting a national agenda for injury prevention and control in the USA.

I am aware that Public Citizen has produced a report that questions Professor Graham's commitment to injury prevention programs such as bicycle helmet use and airbag protection. I respectfully disagree. Professor Graham has worked diligently and effectively in Washington, DC to advance the cause of injury prevention. I have personally collaborated with him in the following two endeavors.

First, several years ago, through the Association for the Advancement of Injury Control, I organized a congressional breakfast on injury prevention for selected House Members and their staffs. Professor Graham came to Washington, DC at his own expense to speak at this breakfast. The theme of his remarks, based on his Center's research, was that injury prevention is one of the most cost-effective investments in medicine and public health. He urged the audience to make sure that agencies such as NHTSA, OSHA and CDC, which are concerned with safety, be allocated adequate staff, resources, and political support to carry out their missions. The CDC program, in particular, has been noted for its support of community-based bicycle helmet programs. NHTSA of course is the champion of airbags. OSHA has a critical role in occupational safety.

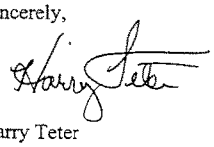
8903 Presidential Parkway, Suite 512, Upper Marlboro, MD 20772-2656
301-420-4189 • 800-556-7890 • Fax: 301-420-0617
e-mail: atstrauma@aol.com

Second, the firearms research program at CDC came under fire in the mid-1990s due to concerns about whether the federal government was subsidizing advocacy of gun control policies. Professor Graham, I and others looked into these charges and concluded that, although CDC did need to make sure that only science based work on firearms was funded, the CDD research program on injury prevention should be sustained and strengthened. Again at his own expense, Professor Graham came to Washington, DC and personally delivered this message to the offices of key Senators (Dole and Lott) and an important House member (Dickey). If Professor Graham had not made these visits, it is possible that the CDC injury control program would have been cut severely.

Based on both of these experiences, I am quite convinced that Professor Graham does care about injury prevention, and I believe he cares because his own research has demonstrated that it is highly cost-effective compared to other investments in public health and medicine. That is why I believe that Public Citizen's claims that Professor Graham does not care about public safety and injury prevention are erroneous.

I trust these thoughts are instructive as the Senate deliberates on Professor Graham's nomination. Professor Graham has made many important and significant contributions to the field of injury control. He is uncompromising in his work. He has the highest ethical standards. His character, his commitment to public service and to the well being of the people of this nation, and his passion for good science make him an ideal candidate for this position. I urge you to vote for his nomination.

Sincerely,



Harry Teter
Executive Director
American Trauma Society

HT/dfc

May 13, 2001

Senator Fred Thompson, Chairman
340 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Thompson:

I have been a colleague of Professor John Graham for more than a decade. I know him to be a careful scholar whose work has been thoughtful and objective. I enclose a copy of a letter in support of Professor Graham that I wrote recently to the leadership of the American Public Health Association.

I write now to challenge the criticism of Professor Graham based on his acceptance of financial support for research from companies and industries with an interest in the regulatory issues examined in that research. These critics argue that any such support creates, ipso facto, an unacceptable conflict of interest for the investigator.

Industry has been an important source of support for scientific and technological research. While the basis of industry interest – future profits – is singled out for criticism, it can be argued that industry is by no means the only source of research support that is interested in the outcome. The argument that needs to be made is not to bar or even discourage any source of support but to build in methods for assuring that the research is insulated from any influence on results based on funding source.

To achieve this goal, individual researchers and their universities should require that:

1) sources of support be fully disclosed, and
2) there be no contractual or implicit constraints on the freedom of the investigator to publish the results as they interpret them in the peer-reviewed literature.

Harvard University and the Harvard Center for Risk Analysis both have clear and longstanding policies on these issues. It is critical to protect the independence and objectivity of university-based research. I hope, however, that the scientific community will not make the mistake of criticizing their colleagues because they have received industry support. Instead, they should focus on the quality and objectivity of the work. That is the proper way to move science forward.

Finally, I want to make it clear that these are my views as an individual. This letter is not intended to represent the views of the Harvard School of Public Health or Harvard University as institutions.

Sincerely,

James H. Ware

April 12, 2001

Michael E. Bird, MSW, MPH
President
American Public Health Association
800 I Street, NW
Washington, DC 20001-3710

Dear President Bird,

I write to you concerning the nomination of Professor John Graham for administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget.

I have known John for more than fifteen years and have followed his career with great interest. He has been a leader in the development of quantitative risk analysis as an academic discipline and has built an outstanding program here at the Harvard School of Public Health. He is currently the director of the Harvard Center for Risk Analysis, a group of about ten faculty members studying various issues in risk and decision science. The group is recognized as one of the best in the country. His election as president of the Society for Risk Analysis reflects his standing in the field. He also has an exceptional record of influential research on the risks and benefits of a wide range of regulatory policies.

John's nomination to be administrator of the Office of Information and Regulatory Affairs has elicited a negative reaction from some organizations, including Public Citizen. These organizations have been critical of the use of quantitative risk analysis in regulatory decision making and have also been critical of the Harvard Center for Risk Analysis for accepting industry support for some of its work. I would like to comment on both of these issues.

Regarding the first issue, quantitative risk assessment has become a controversial methodology in the environmental policy arena because it is seen by some as a tool for delaying action. It is important that the debate about the role of quantitative risk analysis not be confounded with the assessment of Dr. Graham's qualifications. His research has always been objective and rigorous, and it has been reported in the peer-reviewed literature. Based on this research, John has sometimes supported regulatory initiatives and sometimes opposed them.

I have been involved in environmental research for more than two decades and have served on the Clean Air Science Advisory Committee. I support action to protect the environment. At the same time, as the sensitivity of environmental measurements increases and the choices between economic activity and environmental protection become more difficult, we will need to evaluate the health benefits and economic impact

of environmental regulations. Risk analysis will surely play an increasing role in regulatory decision making, and we are fortunate that strong scientists like Professor Graham are leading the development of the field. Those who oppose such evaluation seem to believe that we can do everything and also overlook the value to public health of a prosperous society.

Concerning the issue of support, about half of the funding for the Center for Risk Analysis comes from either pharmaceutical companies or companies affected by regulatory policies. The remainder comes from a variety of governmental sources and from the School of Public Health. Moreover, the center's faculty members disclose any relevant sources of support in their publications and in the center's annual report. Though sources of support should always be disclosed, perhaps even more comprehensively than they now are, no observer has challenged either the scientific validity of Professor Graham's work or his findings regarding risk and benefit.

In summary, Professor Graham is an excellent scientist who has encouraged rationality in the regulatory process in this country and has made enormous contributions to the work of public health—in the domains of environmental health, automobile safety, and evaluation of the cost and effectiveness of many clinical and public health interventions. Moreover, he is an educator in the broadest and best sense. In addition to teaching risk and cost-benefit analysis to graduate students at the School of Public Health, he has also made a point of communicating invaluable information about health risks (food contaminants, AIDS exposures) to the larger public. Lastly, I would like to stress Professor Graham's integrity. He has been scrupulous in his management of his relationships with industry, and they have not compromised the objectivity of his research.

I urge the American Public Health Association to endorse Professor Graham for the position of administrator for the Office of Information and Regulatory Affairs, one for which he is highly qualified and to which he will devote his considerable talents and energy.

Sincerely,

James H. Ware

JHW/ej

Enclosures

AMERICAN COUNCIL
ON SCIENCE AND HEALTH
1995 BROADWAY, 2ND FLOOR, NEW YORK, NY 10023-5860
TELEPHONE: (212) 362-7044 • FAX: (212) 362-4919
URL: http://www.acsh.org • GENERAL E-MAIL: acsh@acsh.org

**BOARD OF DIRECTORS**

FREDRIC M. STEINBERG, M.D.
CHAIRMAN OF THE BOARD, ACSH
HERTFORDSHIRE, ENGLAND

TERRY L. ANDERSON, Ph.D., M.S.
POLITICAL ECONOMY RESEARCH CENTER

ELISSA P. BENEDEK, M.D.
UNIVERSITY OF MICHIGAN

NORMAN E. BORLAUG, Ph.D.
TEXAS A&M UNIVERSITY

MICHAEL B. BRACKEN, Ph.D., M.P.H.
YALE UNIVERSITY SCHOOL OF MEDICINE

CHRISTINE M. BRUHN, Pr.D.
UNIVERSITY OF CALIFORNIA

TAIWO K. DANMOLA, C.P.A.
ARTHUR ANDERSEN LLP

THOMAS R. DiGREGORI, Ph.D.
UNIVERSITY OF HOUSTON

HENRY I. MILLER, M.D.
HOOVER INSTITUTION

A. ALAN MOGHISSI, Ph.D.
INSTITUTE FOR REGULATORY SCIENCE

JOHN H. MOORE, Ph.D., M.B.A.
GROVE CITY COLLEGE

ALBERT G. NICKEL
LYONS LAVEY NICKEL SWIFT, INC.

KENNETH M. PRAGER, M.D.
COLUMBIA COLLEGE OF PHYSICIANS AND SURGEONS

FREDRICK J. STARE, Pr.D., M.D.
HARVARD SCHOOL OF PUBLIC HEALTH

STEPHEN S. STERNBERG, M.D.
MEMORIAL SLOAN-KETTERING CANCER CENTER

MARK C. TAYLOR, M.D.
PHYSICIANS FOR A SMOKE-FREE CANADA

LORRAINE THELIAN
KETCHUM PUBLIC RELATIONS

KIMBERLY M. THOMPSON, Sc.D.
HARVARD SCHOOL OF PUBLIC HEALTH

ELIZABETH M. WHELAN, Sc.D., M.P.H.
AMERICAN COUNCIL ON SCIENCE AND HEALTH

ROBERT J. WHITE, M.D., Pr.D.
CASE WESTERN RESERVE UNIVERSITY

**PRESIDENT**

ELIZABETH M. WHELAN, Sc.D., M.P.H.
PUBLISHER
*PRIORITIES FOR HEALTH*

**ACSH STAFF**

MELISSA CRESPO
ADMINISTRATIVE ASSISTANT

JUDITH A. D'AGOSTINO
ADMINISTRATIVE ASSISTANT

ASHLEE DUNSTON
ASSISTANT DIRECTOR OF PUBLIC HEALTH

RUTH KAVA, Ph.D., R.D.
DIRECTOR OF NUTRITION

PATRICIA A. KEENAN
EXECUTIVE ASSISTANT TO THE PRESIDENT

A. MARCIAL C. LAPEÑA
ACCOUNTANT

CHERYL E. MARTIN
ASSOCIATE DIRECTOR

YELENA PONIROVSKAYA
ART DIRECTOR

JACK RASO, M.S., R.D.
DIRECTOR OF PUBLICATIONS

GILBERT L. ROSS, M.D.
EXECUTIVE AND MEDICAL DIRECTOR

JEFF STIER, ESQ.
ASSOCIATE DIRECTOR

April 20,2001

The Honorable Senator Fred Thompson, Chairman
Senate Government Affairs Committee
521 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Thompson:

I write to express support for the nomination of Dr. John D. Graham, Ph.D. to the position of Administrator, Office of Information and Regulatory Affairs, OMB. Professor Graham is a well-respected scholar in the field of public health who also serves as a volunteer on the Board of Advisors of the American Council on Science and Health (ACSH), where I serve as president. My specific purpose in writing is to expose some of the erroneous and misleading charges in the Public Citizen report on Professor Graham, particularly those that relate to tobacco, smoking, and second-hand smoke.

First, I have followed the work of Dr. Graham's Center for over ten years and have personally seen him speak before large audiences in New York City. Both the Center and Professor Graham have consistently presented a science-based portrait of smoking as the number one killer in America. The comparative-risk methods that Professor Graham and his colleagues have pioneered have been particularly useful to our organization and others in efforts to highlight the health dangers of smoking.

Second, there is a suggestion in the Public Citizen report that Professor Graham is an advisor to a network of right-wing groups that collaborate to protect the interests of the tobacco industry. ACSH is mentioned specifically in the report. Yet Public Citizen should know better than to imply that ACSH is part of the pro-tobacco lobby. It is well known that ACSH is a science-based group that has given priority in its public communications to the dangers of both smoking and second-hand smoke. As an advisor to ACSH, Professor Graham has always encouraged ACSH to target the dangers of smoking, including second-hand smoke, in our organization's activities.

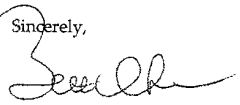
Finally, readers should beware that the Public Citizen report employs innuendo and guilt by association on the tobacco issue. The report does not cite primary references to the work of Professor Graham or the Center on tobacco-related issues. For example, the report does not even mention the 1996-97 annual report of the Harvard Center for Risk Analysis, which indicates that scientists surveyed by the Center believe

that the health risks of second-hand smoke are better proven than a variety of other speculative risks (e.g., ingesting pesticide residues on foods). It is precisely this sense of perspective for citizens that Professor Graham provides on complex health questions.

I believe that Public Citizen's real concern is that Professor Graham uses sound science and excellent communications skills to debunk the unfounded scares—completely unrelated to smoking—that Public Citizen often promotes. Ironically, it is their health scares that distract the public from the real causes of illness and death, such as cigarette smoking.

In summary, I am confident that Professor Graham will be an outstanding Administrator of the Office of Information and Regulatory Affairs. His academic training and Center-management skills are superb training for the job. We urge the Senate to reject the dirt thrown by Public Citizen in favor of the comparative-risk insights provided by Professor Graham.

Sincerely,



Elizabeth M. Whelan, Sc.D., M.P.H.
President