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REGULATORY IMPROVEMENT ACT OF 1999

R E P O R T

OF THE

COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

TOGETHER WITH

MINORITY VIEWS

TO ACCOMPANY

S. 746

TO PROVIDE FOR ANALYSIS OF MAJOR RULES, TO PROMOTE THE
PUBLIC'S RIGHT TO KNOW THE COSTS AND BENEFITS OF
MAJOR RULES, AND TO INCREASE THE ACCOUNTABILITY AND
QUALITY OF GOVERNMENT



JULY 20, 1999.—Ordered to be printed

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REGULATORY IMPROVEMENT ACT OF 1999

JULY 20, 1999.—Ordered to be printed

Mr. THOMPSON, from the Committee on Governmental Affairs,
submitted the following

REPORT

[To accompany S. 746]

The Committee on Governmental Affairs, to which was referred the bill (S. 746) to provide for the analysis of major rules, to make the regulatory process more efficient and effective, and for other purposes, having considered the same, reports favorably thereon with amendments and recommends by a vote of 11–5 that the bill as amended do pass.

I. PURPOSE AND SUMMARY

S. 746 is a bipartisan effort to achieve meaningful and lasting improvements to the federal regulatory process through important changes in the procedural requirements for issuing federal regulations. S. 746 would subject all “major rules” to rigorous economic and scientific analysis before being issued. By elevating the use of modern decisionmaking tools such as cost-benefit analysis and risk assessment, the legislation would promote more open, better-informed, and more accountable regulatory decisions. Upon introduction of S. 746, Senator Levin stated:

Those of us who believe in the benefits of regulation to protect health and safety have a particular responsibility to make sure that regulations are sensible and cost effective. . . . I feel strongly that this bill will improve the regulatory process, will build confidence in the regulatory programs that are so important to this society’s well-being, and will result in better, more protective regulations because we will be directing our resources in more cost-effective ways.¹

¹ 145 Cong. Rec. S 3481–82 (daily ed. March 25, 1999).

In the same vein, Chairman Thompson stated:

The Regulatory Improvement Act is an effort by many of us who want to improve the quality of government to find a common solution. . . . The supporters of this bill represent a real diversity of political viewpoints, but we share the same goals. We want an effective government that protects public health, well-being and the environment. . . . in the most sensible and efficient way possible.

The Regulatory Improvement Act is based on a simple premise: people have a right to know how and why government agencies make their most important and expensive regulatory decisions. This legislation also will improve the quality of government decision making—which will lead to a more effective Federal government. And it will make government more accountable to the people it serves.²

Senator Voinovich, an original co-sponsor of S. 746, stated:

The challenge facing public officials today is in determining how best to protect the health of our citizens and environment with limited resources. . . . we need to do a better job of setting priorities and spending our resources wisely. I believe that the Regulatory Improvement Act will achieve these goals.³

A brief synopsis of the major provisions of the bill follows:

A. COST-BENEFIT ANALYSIS

Federal agencies would be required to perform a cost-benefit analysis for major rules (rules imposing costs over \$100 million or having other material adverse effects). The cost-benefit analysis would be done at the proposed and final rulemaking stages and would include: An estimate of the anticipated benefits of the rule (quantifiable and nonquantifiable); An estimate of the anticipated costs of the rule (quantifiable and nonquantifiable); An analysis of a reasonable number of regulatory alternatives, including flexible regulatory options; A reasonable determination: (1) whether the benefits of the rule are likely to justify the costs; (2) whether the rule is likely to achieve the rule making objectives in a more cost-effective manner, or with greater net benefits, than the other alternatives; and (3) whether the rule adopts a flexible regulatory option.

If the agency determines that the rule is not likely to satisfy these conditions, the agency shall explain the reasons for selecting the rule notwithstanding such determination, including identifying any statutory provision that required the agency to select such rule, and describe any reasonable alternative that would satisfy such conditions.

B. RISK ASSESSMENT

Agencies would be required to follow risk assessment principles for: (1) major rules with the primary purpose of addressing risks

²*Id.* at S 3482.

³*Id.* at S 3485.

to health, safety, or the environment; and (2) any risk assessment not related to a rule making that the OMB Director anticipates is likely to have an annual effect on the economy of \$100 million or more.

To promote transparent and scientifically objective risk assessment, agencies would be required to: identify and explain significant assumptions made when estimating risks; notify the public when the agency is conducting a risk assessment and allow the public to submit relevant and reliable information; and disclose relevant information about the risk, including the range and distribution of the risk, including central and high-end estimates, and the corresponding exposure scenarios for the potentially exposed population and for highly exposed subpopulations. When appropriate scientific information is reasonably available, the agency would be required to compare the risk being analyzed with other reasonably comparable risks familiar to and routinely encountered by the public.

C. PEER REVIEW

Cost-benefit analyses for major rules that are anticipated to have an annual effect on the economy of \$500 million, and risk assessments required by the Act, would be subject to independent peer review, prior to issuance of a notice of proposed rulemaking, if feasible. Only one peer review would be required during a rule making.

D. JUDICIAL REVIEW

The legislation would provide for judicial review to ensure that agencies conduct required regulatory analyses. The regulatory analysis, including the cost-benefit analysis, cost-benefit determination, and risk assessment, would be included in the rulemaking record for purposes of judicial review, and would, to the extent relevant, be considered by the court in determining whether the final rule is arbitrary or capricious.

E. GUIDELINES, INTERAGENCY COORDINATION, AND RESEARCH

The Director of the Office of Management and Budget (“OMB”) would consult with the President’s Council of Economic Advisors, the Director of the Office of Science and Technology Policy (“OSTP”), and the relevant agencies to: develop guidelines for cost-benefit analysis, risk assessment, and peer review; improve agency analytical practices; and arrange for research to improve regulatory analysis.

F. COMPARATIVE RISK ANALYSIS

OMB, in consultation with OSTP, would arrange for a study to compare and rank health, safety, and environmental risks; to improve methodologies for comparing various risks; and to make recommendations on using comparative risk analysis to set agency priorities for reducing such risks. Each relevant agency would use the results of the study to inform the agency in the preparation of its budget and strategic plans and performance plans under the Government Performance and Results Act.

G. EXECUTIVE OVERSIGHT

OIRA would supervise and oversee implementation of the requirements of this legislation and would systematically review agencies' regulatory proposals, subject to public disclosure requirements.

II. BACKGROUND AND NEED FOR LEGISLATION

Since 1946, the federal regulatory process has been guided by the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551–558. The APA was enacted following the dramatic delegation of discretionary authority to Executive Branch agencies stemming from the New Deal. It has served for over 50 years as the blueprint for how agencies issue regulations.

With the rapid growth of complex and wide-ranging regulatory programs since the late 1960s, the limited procedures of the APA have been faced with new challenges. This has moved the Committee over the years to review the adequacy of the regulatory process. Since 1981, four comprehensive bills have been reported by the Committee, though none of these has been enacted into law. S. 746, the "Regulatory Improvement Act of 1999," is the latest product of the Committee's work and experience in this area.

A. EXECUTIVE BRANCH ACTION ON REGULATORY REFORM

The Committee's concern about the adequacy and effectiveness of the federal regulatory process has paralleled a growing interest in centralized control and review by the President. The assertion of presidential authority over the rulemaking process began in 1971, when President Richard Nixon established "Quality of Life Reviews" for certain U.S. Environmental Protection Agency ("EPA") regulations. Every President since Richard Nixon has implemented executive oversight of the regulatory process. President Gerald Ford required agencies to conduct an inflationary impact analysis for major rules. President Jimmy Carter established the Regulatory Analysis Review Group to review important regulations. He also required an economic impact analysis for major rules under Executive Order 12044.

President Ronald Reagan implemented the most dramatic reform over the rulemaking process when he issued Executive Order 12291 in 1981. This was a significant extension of an evolving centralized review process, and it required that all rules be reviewed by the Office of Information and Regulatory Affairs in the Office of Management and Budget before being issued in proposed or final form. It also required that each agency analyze the costs and benefits of each major rule and that, to the extent permitted by law, agencies issue rules only if the potential benefits of the rule outweighed the potential costs. President Reagan also issued E.O. 12498 in March 1985, directing agencies to prepare a yearly agenda of all significant regulatory actions for the coming year. When he took office in 1989, President George Bush continued President Reagan's Executive Orders.

In 1993, President Bill Clinton replaced E.O. 12291 with E.O. 12866, which continues the requirement for centralized review of rules. E.O. 12866 applies only to "significant rules," not all rules,

but it maintains the requirement for a cost-benefit analysis of significant rules—primarily those that have an annual effect on the economy of \$100 million or more—and it requires that, to the extent permitted by law, agencies issue rules “only upon a reasoned determination that the benefits of the intended regulation justify its costs.” Centralized regulatory review by the President, using OMB, is critical to achieving the goals of this legislation: thorough analyses of regulatory proposals, balanced consideration of diverse viewpoints, effective coordination among agencies, and a cost-effective regulatory system.

B. THE NEED FOR REGULATORY REFORM LEGISLATION

By any measure, federal agencies have long engaged in, and continue to engage in, an enormous volume of regulatory activity. In a 1997 report to Congress, OMB reported that there are over 130,000 pages of federal regulations, “with about 60 federal agencies issuing regulations at a rate of about 4,000 per year. . . . Federal regulations now affect virtually all individuals, businesses, State, local and tribal governments, and other organizations in virtually every aspect of their lives or operations.”⁴ In recent reports, GAO noted that the November 1998 edition of the Unified Agenda of Federal Regulations contained 4,560 entries describing planned or ongoing federal regulatory actions,⁵ and that federal agencies issued more than 11,000 final rules between April 1996 and December 1998.⁶

The Committee is well aware of the importance of sensible regulation in improving the quality of life for the American people. Regulation can help achieve important social and economic goals such as a clean environment, safe products, a safe workplace, and reliable economic markets. Over the past 25 years, the nation has made tremendous progress protecting public health, safety, and the environment and improving our quality of life. We no longer have rivers catching fire. Our air is cleaner.⁷ And American technology and expertise is in demand around the world. But more challenges lie ahead.

Achieving the benefits of regulatory programs does not come without cost. In recent reports, the annual cost of regulation of the environment, health, safety and the economy has been estimated on the order of several hundred billion dollars, with the cost of “social regulations” (*i.e.*, environmental, health, and safety rules) mak-

⁴Office of Management and Budget, Office of Information and Regulatory Affairs, *Report to Congress on the Costs and Benefits of Federal Regulations* (Sept. 30, 1997). The OMB report was required by the Regulatory Accounting Amendment of Senator Ted Stevens, who was then the Chairman of the Governmental Affairs Committee. The Stevens Regulatory Accounting Amendment was modeled on the earlier and more detailed regulatory accounting provision in S. 291, the “Regulatory Reform Act of 1995.” The Stevens Amendment was contained in Section 645 of the Treasury, Postal Services and General Government Appropriations Act, 1997 (Pub. L. 104-208), 1996 U.S.S.C.A.N. (110 Stat. 3009): 1088-89.

⁵GAO, *Regulatory Flexibility Act: Agencies’ Interpretations of Review Requirements Vary*, GAO/GGD-99-55, at 19, April 2, 1999.

⁶Statement for the Record of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, GAO, before the Senate Governmental Affairs Committee, *Federalism: Implementation of Executive Order 12612 in the Rulemaking Process*, GAO/T-GGD-99-93, May 5, 1999.

⁷See Testimony of Carol M. Browner, Administrator, U.S. Environmental Protection Agency, before the Senate Committee on Governmental Affairs, S. Hearing 104-419, March 8, 1995.

ing up approximately 75 percent of the total.⁸ These costs are often passed on indirectly to the American consumer and taxpayer through higher prices, diminished wages, increased taxes, or reduced government services.⁹ Although deregulation in the 1970s and 1980s reduced the burden of economic regulation, the total cost of noneconomic or “social” regulation has been rising substantially. At the same time, there is strong public support for the benefits that well-designed regulations can produce.

As the public demands better results while the costs of regulation rise, the need for a smarter, more cost-effective approach to regulation is more important than ever. The depth of this need is not widely appreciated because the costs of regulation are not as obvious as many other costs of government, such as taxes, and the benefits of regulation often are diffuse. But there is substantial evidence that the current regulatory system often misses opportunities for greater benefits and lower costs. As noted by the President’s then-chief spokesperson on regulatory policy:

Regrettably, the regulatory system that has been built up over the past five decades * * * is subject to serious criticism * * * [on the grounds] that there are too many regulations, that many are excessively burdensome, [and] that many do not ultimately provide the intended benefits.¹⁰

The new challenges facing the regulatory system were not envisioned by the drafters of the Administrative Procedure Act some 50 years ago. While the APA has successfully adapted to many changes in the regulatory process, it was not designed to address the current regulatory landscape. Since the APA was passed, the goal of much federal regulation has changed from curbing monopoly power to addressing risks to the environment, health, and safety; the form of most federal regulation has changed from adjudication to informal rulemaking; and the scope of federal regulation has vastly expanded from single industries to economy-wide activity.

These dramatic changes have been accompanied by growing problems that must be solved: agencies may fail to balance the benefits and costs of regulations, fail to find flexible and cost-effective solutions, or fail to consider unintended harms. Moreover, the rule-making process is not sufficiently understandable to the public, nor is it as accountable as it should be.

To date, cost-benefit analysis, so important to the development of economically significant rules, has been generally required only through executive order and not through a statutory framework. There are no government-wide requirements for conducting risk assessments. Much of the analytical work of a rulemaking agency is

⁸ See Office of Management and Budget, Office of Information and Regulatory Affairs, *Report to Congress on the Costs and Benefits of Federal Regulations* at 17–19 (1998); see also, Office of Management and Budget, Office of Information and Regulatory Affairs, *Report to Congress on the Costs and Benefits of Federal Regulations* (Sept. 30, 1997). Other studies, which include the full costs of paperwork and economic transfers, estimate that regulation costs about \$700 billion annually. See, e.g., U.S. Small Business Administration, *The Changing Burden of Regulation, Paperwork, and Tax Compliance on Small Business: A Report to Congress* (Oct. 1995).

⁹ See, e.g., Resources for the Future, *Public Policies for Environmental Protection* (Paul R. Portney, ed. 1990); Thomas D. Hopkins, “Cost of Federal Regulation” 3, reprinted in *Regulatory Policy in Canada and the United States*, Rochester Inst. Tech., (1992).

¹⁰ Testimony of Sally Katzen, Administrator of OIRA, before the Senate Committee on Governmental Affairs, S. Hearing 104–372, February 22, 1995.

done before the public has the opportunity to comment, and both the policy and scientific basis for the agency's choices are often unclear to the public, through obscure and hard-to-read rulemaking files or through the failure of the agency to make its thinking clear and readily available to the public.¹¹ While Executive Order 12866 sets out procedures intended to result in better rules and enhanced public confidence, compliance is not uniform or complete.¹²

S. 746 seeks to address these problems. Central to that effort is the use of accurate and thoughtful cost-benefit analysis and risk assessment. We know that analyzing the costs and benefits of regulatory proposals is no longer an intellectual curiosity or academic exercise: it is a necessity. In its 1997 Report to Congress on the Costs and Benefits of Federal Regulations, OMB concluded:

[R]egulations (like other instruments of government policy) have enormous potential for both good and harm. Well-chosen and carefully crafted regulations can protect consumers from dangerous products and ensure they have information to make informed choices. Such regulations can limit pollution, increase worker safety, discourage unfair business practices, and contribute in many other ways to a safer, healthier, more productive, and more equitable society. Excessive or poorly designed regulations, by contrast, can cause confusion and delay, give rise to unreasonable compliance costs in the form of capital investments, labor and on-going paperwork, retard innovation, reduce productivity, and accidentally distort private incentives.

The only way we know how to distinguish between the regulations that do good and those that cause harm is through careful assessment and evaluation of their benefits and costs. Such analysis can also often be used to redesign harmful regulations so they produce more good than harm and redesign good regulations so they produce even more net benefits.¹³

Current practices in this regard need significant improvement. In 1996, Robert Hahn of the American Enterprise Institute published one of the most comprehensive analyses of the benefits and costs of recent environmental, health, and safety regulation.¹⁴ Hahn concluded that about half the final rules analyzed in the study would

¹¹ See, e.g., Testimony of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, GAO, before the Senate Committee on Governmental Affairs, S. Hearing 105-335, September 12, 1997; Statement of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, GAO, before the Senate Committee on Governmental Affairs, February 24, 1998; GAO, *Regulatory Reform: Changes Made to Agencies' Rules Are Not Always Clearly Documented*, GAO/GGD-98-31 (Jan. 1998); GAO, *Cost-Benefit Analysis Can Be Useful in Assessing Environmental Regulations, Despite Limitations*, GAO/RCED-84-62 (April 6, 1984).

¹² See, e.g., GAO, *Regulatory Reform: Agencies Could Improve Development, Documentation, and Clarity of Regulatory Economic Analyses*, RCED-142 (May 1998); GAO, *Regulatory Reform: Changes Made to Agencies' Rules Are Not Always Clearly Documented*, GAO/GGD-98-31 (Jan. 1998); Hearing before the Senate Committee on Governmental Affairs, Subcommittee on Financial Management and Accountability, "Oversight of Regulatory Review Activities of the Office of Information and Regulatory Affairs," S. Hrg. 104-825, 104th Cong., 2d Sess. (Sept. 25, 1996).

¹³ Office of Management and Budget, Office of Information and Regulatory Affairs, *Report to Congress on the Costs and Benefits of Federal Regulations* (Sept. 30, 1997), at 10.

¹⁴ Robert W. Hahn, "Regulatory Reform: What Do the Government's Numbers Tell Us?," in *Risks, Costs, and Lives Saved*, (Robert W. Hahn, ed. 1996). See also, Testimony of Robert W. Hahn before the Subcommittee on Financial Management and Accountability, Senate Committee on Governmental Affairs, S. Hearing 104-825, September 25, 1996.

not pass a cost-benefit test. Hahn's study also showed that the quality of federal agency cost-benefit analyses varies widely "from very poor to very good" and that we could "realize significant gains by more carefully targeting regulations." In 1997, Richard Morgenstern, an EPA official on leave with Resources for the Future, published a thorough analysis of 12 major rules from EPA subject to economic analysis.¹⁵ Morgenstern concluded that the economic analyses helped reduce the costs of all 12 of the rules and, at the same time, helped increase the benefits of five of them. Studies by the U.S. General Accounting Office ("GAO") have echoed such findings.¹⁶

There is broad support for reforming the regulatory process and the tools to accomplish that goal, including cost-benefit analysis, market-based mechanisms, risk-assessment, and comparative risk analysis. This support comes from diverse sources, such as the National Research Council,¹⁷ the Harvard Center for Risk Analysis,¹⁸ the American Enterprise Institute,¹⁹ the Brookings Institution,²⁰ the Clinton Administration,²¹ Justice Stephen Breyer,²² the Carnegie Commission,²³ Resources for the Future,²⁴ and other think

¹⁵ Resources for the Future, *Economic Analyses at EPA* (Richard D. Morgenstern, ed. 1997).

¹⁶ See, e.g., Statement of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, GAO, before the Senate Committee on Governmental Affairs, February 24, 1998; Testimony of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, GAO, before the Senate Committee on Governmental Affairs, September 12, 1997; GAO, *Cost-Benefit Analysis Can Be Useful in Assessing Environmental Regulations, Despite Limitations*, GAO/RCED-84-62 (April 6, 1984).

¹⁷ See, e.g., National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society* (1996); National Research Council, *Science and Judgement in Risk Assessment*, National Academy Press, Washington, D.C. (1994); National Research Council, *Issues in Risk Management*, National Academy Press, Washington, D.C. (1993); National Research Council, *Valuing Health Risks, Costs, and Benefits for Environmental Decision Making*, National Academy Press, Washington, D.C. (1990); National Research Council, *Improving Risk Communication*, National Academy Press, Washington, D.C. (1989); National Research Council, *Risk Assessment in the Federal Government: Managing the Process*, National Academy Press, Washington, D.C. (1983).

¹⁸ See, e.g., Harvard Center for Risk Analysis, *Reform of Risk Regulation: Achieving More Protection at Less Cost* (March 1995); John D. Graham, "Making Sense of Risk: An Agenda for Congress," in *Risks, Costs, and Lives Saved* (Robert W. Hahn, ed. 1996); *The Greening of Industry: A Risk Management Approach*, Harvard University Press (John D. Graham & Jennifer Kassalow Hartwell, eds. 1997).

¹⁹ See, e.g., American Enterprise Institute & Brookings Institution, *An Agenda for Regulatory Reform* (Robert W. Hahn & Robert E. Litan, eds. 1997); American Enterprise Institute & Brookings Institution, *Improving Regulatory Accountability* (Robert W. Hahn & Robert E. Litan, eds. 1997); American Enterprise Institute, The Annapolis Center & Resources for the Future, *Benefit-Cost Analysis in Environmental, Health, and Safety Regulation* (1996); American Enterprise Institute, *Benefit-Cost Analysis of Social Regulation: Case Studies from the Council on Wage and Price Stability*, Washington, D.C., (James C. Miller & Bruce Yandle, eds. 1979); M.J. Bailey, *Reducing Risks to Life: Measurement of Benefits*, American Enterprise Institute, Washington, D.C. (1980); Robert W. Hahn & J.A. Hird, "The Costs and Benefits of Regulation," 8 Yale J. on Reg. 233 (Winter 1991).

²⁰ See, e.g., Lester Lave, *The Strategy of Social Regulation*, Brookings Institution, Washington, D.C. (1981); Lester Lave, *Quantitative Risk Assessment in Regulation*, Brookings Institution, Washington, D.C. (1982); Robert W. Crandall, *Controlling Industrial Pollution: The Economics and Politics of the Clean Air Act*, Brookings Institution, Washington, D.C. (1983).

²¹ Office of Management and Budget, Office of Information and Regulatory Affairs, *Report to Congress on the Costs and Benefits of Federal Regulations* (Sept. 30, 1997), at 2 (cost-benefit analysis significantly enhances the consideration of alternative approaches to achieving regulatory goals, ultimately producing more benefits and fewer costs); National Performance Review, *Creating a Government that Works Better and Costs Less*, Washington, D.C. (1993); National Performance Review, *Improving Regulatory Systems*, Washington, DC (Sept. 1993).

²² Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation*, Harv. Univ. Press, Cambridge, MA (1993); Stephen Breyer, *Regulation and its Reform* (1982).

²³ Carnegie Commission on Science, Technology, and Government, *Risk and the Environment: Improving Regulatory Decisionmaking*, Washington, D.C. (June 1993).

²⁴ J. Clarence Davies & Jan Mazurek, *Pollution Control in the United States*, Resources for the Future (1998); Paul R. Portney, *Public Policies for Environmental Protection*, Resources for the Future (1990); Paul R. Portney, "Economics and the Clean Air Act," 4 J. Econ. Perspectives 173 (Fall 1990); Resources for the Future, *Worst Things First?: The Debate Over Risk-Based Na-*

tanks, commissions, and independent scholars throughout the country.²⁵ The strong record on the need for regulatory reform and the tools to achieve it has contributed to this legislation.

C. GOVERNMENTAL AFFAIRS COMMITTEE ACTION ON REGULATORY REFORM THROUGH THE 105TH CONGRESS

The Committee has been involved in overseeing the regulatory decisionmaking process for over two decades. Through a variety of studies, hearings, legislative proposals, and oversight of the regulatory process, the Committee has developed a broad expertise on the strengths and weaknesses of the regulatory process and proposals for reform. This expertise has contributed to the development of S. 746.

In 1975, the Senate passed a resolution, S. Res. 71, directing the Governmental Affairs Committee to conduct a comprehensive study of Federal regulations, to assess the impact of regulatory programs, and to analyze the need for change. The Committee spent almost two years carrying out that mandate and concluded with a six-volume report on various aspects of the regulatory system, from public participation in the regulatory process, to the role of congressional oversight.²⁶ These volumes constitute the most thorough review of the regulatory process ever conducted by the Congress. The problems identified and solutions proposed have substantially informed subsequent debates on regulatory reform, both within and outside of the Committee, and have influenced the drafting of this legislation. The Study emphasizes, for example, that poor, costly, and burdensome agency regulations often are a product of defective preliminary analyses which fail adequately to account for costs, the

tional *Environmental Priorities*, Washington, D.C. (Adam N. Finkel and Dominic Golding, eds. 1994).

²⁵ See, e.g., Cass R. Sunstein, "Congress, Constitutional Moments, and the Cost-Benefit State," 2 Stan. L. Rev. 247 (1996); Cass R. Sunstein, "Health-Health Tradeoffs," 63 U. Chi. L. Rev. 1533 (1996); Cass R. Sunstein, *After the Rights Revolution*, Harv. Univ. Press, Cambridge, MA (1990); National Academy of Public Administration, *Resolving the Paradox of Environmental Protection: An Agenda for Congress, EPA & the States*, (Sept. 1997); Enterprise for the Environment, *The Environmental Protection System in Transition: Toward a More Desirable Future* (Jan. 1998); Marian R. Chertow & Daniel C. Esty, *Thinking Ecologically: The Next Generation of Environmental Policy* (1997); Murray L. Weidenbaum, *Business and Government in the Global Marketplace*, Prentice Hall, Englewood Cliffs, NJ (5th ed. 1995); W. Kip Viscusi, *Fatal Tradeoffs: Public and Private Responsibilities for Risk*, Oxford Univ. Press, NY (1990). See also, Administrative Conference of the United States, ACUS Recommendation 85-2, "Agency Procedures for Performing Regulatory Analysis of Rules" (1985); ACUS Recommendation 88-9, "Presidential Review of Agency Rulemaking" (1988); ACUS Recommendation 93-4, "Improving the Environment for Agency Rulemaking" (1993).

²⁶ The Governmental Affairs Committee published the following six volumes of the Study on Federal Regulation between January 1977 and December 1978:

1. Senate Committee on Government Operations, 95th Cong., 1st Sess., 1 *Study on Federal Regulation*, "The Regulatory Appointments Process" (Comm. Print 1977).
2. Senate Committee on Government Operations, 95th Cong., 1st Sess., 2 *Study on Federal Regulation*, "Congressional Oversight of Regulatory Agencies" (Comm. Print 1977).
3. Senate Committee on Governmental Affairs, S. Doc. 95-71, 95th Cong., 1st Sess., 3 *Study on Federal Regulation*, "Public Participation in Regulatory Agency Proceedings" (Comm. Print 1977).
4. Senate Committee on Governmental Affairs, S. Doc. 95-72, 95th Cong., 1st Sess., 4 *Study on Federal Regulation*, "Delay in the Regulatory Process" (Comm. Print 1977).
5. Senate Committee on Governmental Affairs, S. Doc. 95-91, 95th Cong., 2d Sess., 5 *Study on Federal Regulation*, "Regulatory Organization" (Comm. Print 1977).
6. Senate Committee on Governmental Affairs, S. Doc. 96-13, 96th Cong., 1st Sess., 6 *Study on Federal Regulation*, "Framework for Regulation" (Comm. Print 1978).

possibility of alternative regulatory solutions, or no regulation at all.²⁷

The Committee's Study provided the foundation for extensive hearings in the 96th²⁸ and 97th²⁹ Congresses. These led to the introduction of S. 1080, the "Regulatory Reform Act of 1981," which was jointly referred to the Governmental Affairs Committee and the Judiciary Committee. After receiving unanimous support in Committee, S. 1080 passed the full Senate in 1982 by a vote of 94–0. S. 1080 reflected the increasing concern that the costs of federal regulation in too many cases do not justify the benefits and that the scientific and policy assumptions underlying regulatory decisions often are questionable. Although S. 1080 was overwhelmingly endorsed by the Senate, it was not acted on in the House of Representatives and died there.

Early in the 104th Congress, Chairman Bill Roth introduced legislation to improve the regulatory process, S. 291, the "Regulatory Reform Act of 1995." S. 291 contained some of the basic elements of S. 1080, such as cost-benefit analysis, centralized regulatory review, and periodic review of existing rules. S. 291 added other requirements, such as risk assessment of major environmental, health and safety rules, regulatory accounting, and comparative risk analysis for setting more rational regulatory priorities. S. 291 was reported unanimously by the Committee.³⁰

Another regulatory reform bill, S. 343, the "Comprehensive Regulatory Reform Act of 1995," was introduced early in the 104th Congress. S. 343 covered many of the same issues as S. 1080 and S. 291, but differed in some significant respects. For example, the cost-benefit requirements were "decisional criteria" that would have amended the substantive standards of the statutes authorizing the regulations. The decisional criteria would have required agencies to select, as a matter of law, the regulatory alternative with the greatest net benefits. S. 343 also contained a process to allow parties to petition agencies to review existing rules. S. 343 was jointly referred to the Governmental Affairs Committee and the Judiciary Committee.

After the Governmental Affairs Committee unanimously passed S. 291, the Judiciary Committee reported out S. 343. S. 343 became the subject of extensive negotiations before it was brought to the

²⁷ The following conclusion from the 1978 Study rings true today:

The report finds that decisions when and how to regulate all too often are based on insufficient analysis and consideration of alternatives. Simply because a problem exists and, in theory is remediable, does not mean that regulation or other government intervention is desirable. Controls should only be undertaken where there is a clearly identified problem that cannot otherwise be solved, and where the anticipated achievements are significant and vitiated by projected adverse consequences.

We believe that before Congress or the agency adopts any proposed regulatory scheme, the possible economic justifications for regulation should be scrutinized. The discipline inherent in that procedure is a key element in helping to insure good regulatory decisions.

6 *Study on Federal Regulation*, pp. xi–xii.

²⁸ Hearings on Regulatory Legislation, Senate Committee on Governmental Affairs, 96th Cong., 1st Sess. (1979) (2 parts). These hearings, encompassing 11 days of testimony from 80 witnesses, are summarized in S. Rep. No. 96–1018, part 1, 52–55, 96th Cong., 2d Sess. (1980).

²⁹ Hearings on Regulatory Reform Legislation of 1981, Senate Committee on Governmental Affairs, 97th Cong., 1st Sess. (1981). See also, S. Rep. No. 97–305, 97th Cong., 1st Sess. 1981. The development of the reform legislation was in close cooperation with the Senate Judiciary Committee. See S. Rep. No. 96–1018, Part 2, 96th Cong., 2d Sess. (1980) (joint report of the Senate Governmental Affairs and Judiciary Committees).

³⁰ Many current members of the Governmental Affairs Committee voted for S. 291, including Senators Roth, Thompson, Stevens, Cochran, Lieberman, Levin and Akaka.

floor for consideration during the summer of 1995. The long floor debate ended after three unsuccessful cloture votes on S. 343 and a close vote defeating the Glenn-Chafee substitute amendment, which was based on S. 291.

Following the contentious regulatory reform debate of the 104th Congress, Senators Levin and Thompson agreed to work together to develop bipartisan reform legislation. This led to the introduction in the 105th Congress of S. 981, the Regulatory Improvement Act, which is the predecessor to S. 746. Like S. 746, S. 981 was rooted in past Committee initiatives, particularly S. 291, but S. 746 was significantly streamlined and modified. The legislation is grounded in a philosophy of greater transparency, better informed decision making, and increased accountability. This philosophy was supported by the growing Committee record on the shortcomings of the regulatory process.

In 1996, Senator Thompson, then Chairman of the Subcommittee on Financial Management and Accountability, initiated oversight on the implementation of the Administration's Executive Order 12866 and other initiatives to reinvent regulation. The Committee heard testimony from many witnesses and reviewed investigations of the GAO indicating that E.O. 12866 and the Administration's "Cutting Red Tape" initiative were not performing as well as intended.

When Senator Thompson became Chairman of the Committee in 1997, he initiated a series of GAO investigations of the regulatory process with Ranking Member John Glenn. These investigations reviewed implementation of Title II of the Unfunded Mandates Reform Act of 1995; agency efforts to eliminate and revise existing regulations; agency documentation of changes made to regulatory proposals during the OMB review process; and agency use of cost-benefit analysis. All of these investigations indicated that the current regulatory process is inadequate.³¹

The Committee held two hearings on S. 981, in September 1997 and February 1998. S. 981 was supported by diverse groups and individuals representing, among others, State and local governments, agricultural interests, scientists, policy institutes, small businesses, and educators. Supporters testified that S. 981 would foster better federal protection of public health and safety and the environment; would expedite the development and issuance of rules; and lead to more reasoned decisionmaking. Others, including representatives of environmental, public safety, and labor groups, opposed the bill as restrictive of agency authority, likely to cause delays in issuing rules, and leading to agencies placing cost justification above other factors in determining the regulatory approach to follow.

The Committee considered at length the concerns raised by the witnesses opposed to S. 981. Many of the issues raised by the bill's opponents were addressed in the substitute amendment offered by Senator Levin and Chairman Thompson on February 4, 1998, and adopted at a markup on March 10, 1998. Others were addressed

³¹ See GAO, *Unfunded Mandates: Reform Act Has Little Effect on Agencies' Rulemaking Actions*, GAO/GGD-98-30 (Feb. 1998); GAO, *Regulatory Reform: Changes Made to Agencies' Rules Are Not Always Clearly Documented*, GAO/GGD-98-31 (Jan. 1998); GAO, *Regulatory Reform: Agencies' Efforts to Eliminate and Revise Rules Yield Mixed Results*, GAO/GGD-98-3 (Oct. 1997).

by the Committee as amendments during the markup of S. 981. S. 981 was voted out of the Committee 8–4 on March 10, 1998³² but did not receive floor consideration.

D. CHANGES IN THE REGULATORY IMPROVEMENT ACT FROM THE 105TH CONGRESS (S. 981) TO THE 106TH CONGRESS (S. 746)

Following the Committee’s reporting out of S. 981, Senator Levin and Chairman Thompson engaged in a series of discussions with the Administration. The starting point for these discussions was the letter from then-OMB Director Franklin Raines prior to the markup of S. 981 expressing the Administration’s concerns with a number of provisions in the substitute to S. 981. On July 1, 1998, Senator Levin and Chairman Thompson responded to Director Raines, accepting many of the changes proposed by the Administration. By letter dated July 15, 1998, Acting OMB Director Jacob Lew informed Senators Levin and Thompson that “if the bill emerges from the House and Senate as you now propose, with no changes, the President would find it acceptable and sign it.”³³

As introduced, S. 746 was identical to S. 981 as reported with the changes accepted by Senator Levin and Chairman Thompson in their July 1 letter. The key changes from S. 981 as reported and S. 746 as introduced follow:

1. *Judicial review*: S. 746 modifies S. 981 by adding language to clarify that the court shall consider the cost-benefit analysis, cost-benefit determination, and risk assessment only in determining under the statute granting the rule making authority whether the final rule is arbitrary and capricious. S. 746 also gives a court discretion on whether to remand or invalidate a rule if the agency fails to perform the analysis, assessment or determination, or provide for peer review, and requires a court to order the agency to perform any or all of these actions if the court allows the rule to take effect without one or more of them having been performed.

2. *Relationship of Regulatory Improvement Act to other statutes*: S. 746 adds two additional provisions to reiterate that S. 981 did not contain a “supermandate” that would override or alter substantive standards of authorizing statutes. The revisions confirm that S. 746 does not override the substantive standards under the statute authorizing the rule and that the agencies must consider the full range of regulatory options available under the authorizing statute. S. 746 also confirms that agencies are still entitled to the deference accorded to them by reviewing courts under the *Chevron* doctrine.

3. *Review of Rules*: S. 746 deletes S. 981’s provisions for the review of existing rules.

4. *Risk Assessment*: Like S. 981, S. 746 requires a risk assessment to be conducted for all major rules that have the primary purpose of addressing risks to health, safety, or the environment. S. 981 would also have applied to any risk assessment that is not the basis of a rulemaking if the OMB Director reasonably determined that the risk assessment might have a substantial impact on public

³² S. Rep. 105–188, 105th Cong., 2d Sess. (1998).

³³ In his written statement submitted into the record of the Committee’s April 21, 1999 hearing on S. 746, OMB Director Lew reiterated the Administration’s commitment that, as proposed, the President would sign S. 746.

policy or the economy. S. 746 changes the bill with respect to risk assessments that are not the basis of a rulemaking by making its risk assessment requirements applicable if the Director anticipates that the risk assessment could have an annual effect on the economy of \$100 million or more.

5. *Peer review*: S. 746 clarifies that members of agency advisory boards required by statute, and persons who serve as contractors or grantees to the agency are not precluded from serving as peer reviewers solely because the bill requires peer reviewers to be independent of the agency. S. 746 also raises the threshold for requiring agencies to conduct peer review of cost-benefit analyses for rules that are anticipated to have a \$500 million annual effect (as opposed to \$100 million under S. 981), and clarifies that an agency need conduct only one peer review of the cost-benefit analysis and the risk assessment.

6. *Net benefits*: S. 746 clarifies that application of the net benefits analysis is to include consideration of nonquantifiable as well as quantifiable benefits.

7. *Substitution risk*: S. 981 defined “substitution risk” as a significant risk to health, safety, or the environment reasonably likely to result from a regulatory option. S. 746 clarifies that agencies are expected to consider “reasonably identifiable” risks, and that risks attributable to the effect of a regulatory option on the income of individuals are not to be considered.

8. *Exemptions*: S. 981 as reported exempted from coverage “a rule or agency action that authorizes the introduction into commerce, or recognizes the marketable status of, a product.” S. 746 amends this exemption to include removal of a product as well as introduction into commerce, and it limits the exemption only to rules promulgated under the Federal Food, Drug and Cosmetic Act.

E. COMMITTEE CONSIDERATION OF S. 746

As with its predecessor bill, S. 981, many individuals and organizations representing a wide range of segments of American society have strongly supported S. 746. These include representatives of many State and local governments, including officials responsible for environmental protection and safety; small business owners; the National Academy of Sciences; many educational organizations; the GAO; John Graham, Director of the Harvard Center for Risk Analysis; the United States Chamber of Commerce; former Federal regulators; and many other scholars, officials, and experts on the regulatory process.

Testifying in favor of the bill, John Graham, Director of the Harvard Center for Risk Analysis, cited a study that found that:

[R]eallocation 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.³⁴

³⁴ Testimony of John D. Graham before the Senate Governmental Affairs Committee, April 21, 1999.

Witnesses testifying in favor of the bill included State and local government officials whose ability to protect their constituents' health, safety, and environmental surroundings is affected on a daily basis by federal regulations. These witnesses acknowledged the benefits of federal regulation, but testified that they believe that S. 746 will promote better prioritization and coordination between the state and local governments with the federal government, resulting in better use of limited resources. Robert E. Roberts is the Executive Director of the Environmental Council of States, which is comprised of the state and territorial officials who are responsible for environmental safety in their respective jurisdictions. Mr. Roberts told the Committee that:

We support the consideration of cost benefit analysis, because to do otherwise is to risk misapplication of limited resources. We support risk analysis because to do otherwise may be to attack the wrong programs. Expanding the participation of state and local government officials in the development of national environmental requirements can only strengthen the final products.³⁵

Similarly, in a letter filed concurrent with the hearing on S. 746, the leaders of the "Big 7" organizations³⁶ which represent the nation's state, county, and municipal government organizations, stated that:

The proposed bipartisan legislation would greatly assist state and local governments in assessing the costs and benefits of major regulations. This bill would lead to improved quality of federal regulatory programs and rules, increase federal government accountability, and encourage open communication among federal agencies, state and local governments, the public and Congress regarding federal regulatory priorities.³⁷

Scott Holman, testifying on behalf of the U.S. Chamber of Commerce, is owner and President of a small business, a manufacturer of custom steel castings for the automotive tooling, machine tool, steel mill, and construction industries. Mr. Holman testified that:

Information is power. This has never been as true as it is in today's "information age." S. 746 is about ensuring a healthy exchange of information on governmental decisions between the People and their government. One of the founding principles of our Nation was the ability of People to question their government. The Regulatory Improvement Act of 1999 provides power to the American people through greater information.³⁸

³⁵Testimony of Robert E. Roberts before the Senate Governmental Affairs Committee, April 21, 1999.

³⁶The National Governor's Association, the National Conference of State Legislatures, the Council of State Governments, the National Association of Counties, the National League of Cities, the U.S. Conference of Mayors, and the International City/County Management Association.

³⁷Letter from Governor Thomas R. Carper of Delaware et al., to Chairman Thompson and Senator Levin (April 21, 1999).

³⁸Testimony of Scott Holman before the Senate Governmental Affairs Committee, April 21, 1999.

Ronald A. Cass, Dean of the Boston University School of Law, told the Committee that:

S. 746 generally should make agency rulemaking correspond more closely to public interest. The changes S. 746 would effect primarily ask that agencies attend to considerations that should be relevant to regulatory rulemaking, that agencies assess critically information pertinent to their rulemaking decisions, and that agencies allow these assessments to be open to the sort of comparative evaluation common in other venues for similar analysis.³⁹

Dean Cass further refuted concerns raised by some that S. 746 would drive agencies to always select the least costly regulatory approach and promote a “one size fits all” regulatory approach. He stated that “S. 746 does not make formal cost-benefit analysis the sole input to agency decision-making, and the bill properly cautions attention to nonquantifiable as well as quantifiable variables”⁴⁰ and that “the risk assessment principles in S. 746 . . . do not handcuff regulatory agencies but merely promote better informed decision-making. . . . the requirement of thoughtful risk assessments, including explanations of the agency’s analysis of scientific evidence, is designed to improve the information relied on by the agency and the communication of agency decisions to the interested public.”⁴¹

Some expressed concern that the bill would alter the current mode of judicial review of regulations by enabling courts to review the validity of a cost-benefit analysis or risk assessment without regard to whether the rule itself is supportable by the facts and law. Dean Cass rebutted such concerns, noting that:

The judicial review provision in S. 746 seems well-tailored, neither insulating considerations that make regulatory analysis sound or unsound from review nor allowing judicial review to become a strategic tool of interests opposed to agency action.⁴²

Dr. Lester M. Crawford, a former federal regulator, also testified in support of S. 746, including the cost-benefit analysis, risk assessment, and peer review requirements. In regard to peer review, Dr. Crawford testified that it has been used effectively by the FDA, among other agencies, and stated that “peer review can and does broaden the expertise available to the government and it makes the process more open and democratic.”⁴³

Dr. Milton Russell, former Assistant Administrator of the EPA, told the Committee:

³⁹Testimony of Dean Ronald A. Cass before the Senate Governmental Affairs Committee, April 21, 1999.

⁴⁰*Id.*

⁴¹*Id.*

⁴²*Id.* See also Testimony of Warren Belmar, Chair, Section of Administrative Law and Regulatory Practice, American Bar Association, before the Senate Governmental Affairs Committee, S. Hrg. 105-468 (Feb. 24, 1998) (expressing ABA support for the judicial review provision of the Regulatory Improvement Act); Testimony of Ernest Gellhorn, Professor of Law, George Mason University School of Law, before the Senate Governmental Affairs Committee, S. Hrg. 105-335 (Sept. 12, 1997) (supporting the judicial review provision of the Regulatory Improvement Act).

⁴³Testimony of Dr. Lester M. Crawford, Director, Georgetown University Center for Food and Nutrition Policy before the Senate Governmental Affairs Committee, April 21, 1999.

In contrast to previous proposals, which I did not support, I believe that [the Regulatory Improvement Act] casts the correct balance in encouraging appropriate analysis to assure effective and efficient regulation, in avoiding counterproductive, excessive review by the courts, and in ensuring that regulation moves swiftly to implementation to protect the health and safety of the American people and the environment.⁴⁴

L. Nye Stevens, Director, Federal Management and Workforce Issues of the General Government Division of GAO, who testified in the 105th Congress in favor of S. 981, submitted a statement for the record expressing similar support for S. 746. Mr. Stevens cited a 1998 GAO report⁴⁵ in which GAO found that cost-benefit analyses prepared under Executive Order 12866 did not incorporate the “best practices” elements recommended by OMB, lacking sufficient, if any, discussion of alternative regulatory approaches or explanation of assumptions, limitations, and uncertainties in cost-benefit analyses. Analyses also lacked executive summaries that could help Congress, decisionmakers, or the public quickly identify key information addressed in the agency analyses. Mr. Stevens told the Committee that:

S. 746 addresses many of these areas of concern Enactment of the analytical, transparency, and executive summary requirements in S. 746 would extend and underscore Congress’ previous statutory requirements that agencies identify how regulatory decisions are made. We believe that Congress and the public have a right to know what alternatives the agencies considered and what assumptions they made in deciding to regulate. . . . Passage of S. 746 would provide a statutory foundation for such principles as openness, accountability, and sound science in rulemaking.⁴⁶

In his testimony on S. 981, the predecessor bill to S. 746, Dr. Bruce Alberts, President of the National Academy of Sciences, told the Committee:

[M]any scientists and engineers who have devoted their careers to working on environmental problems are puzzled as to why anyone might oppose [the Regulatory Improvement Act].⁴⁷

Others, including representatives of environmental, public safety, and labor groups, opposed the bill. Despite changes made to the Regulatory Improvement Act following the reporting out of S. 981 last year, witnesses expressed concern about the requirement that agencies state whether the proposed rule the agency selected is

⁴⁴ Testimony of Dr. Milton Russell, Senior Fellow, Joint Institute for Energy and Environment, Professor Emeritus of Economics at the University of Tennessee, before the Senate Governmental Affairs Committee, S. Hrg. 105-468 (Feb. 24, 1998).

⁴⁵ *Regulatory Reform: Agencies Could Improve Development, Documentation, and Clarity of Regulatory Economic Analyses*, GAO/RCED-98-142 (May 26, 1998).

⁴⁶ Statement for the Record of L. Nye Stevens before the Senate Committee on Governmental Affairs, April 21, 1999.

⁴⁷ Testimony of Dr. Bruce Alberts, President, National Academy of Sciences, before the Senate Committee on Governmental Affairs, February 24, 1998.

likely to have benefits that justify the costs or is likely to be more cost-effective or have greater net benefits than the other regulatory alternatives considered by the agency. One witness stated that “the take home message of S. 746 to agencies is to optimize the economic benefits of regulation relative to costs.”⁴⁸ Some witnesses also testified that S. 746 would require counterproductive analysis and would “result in extensive delays in the time it takes for regulatory decisions to be made”⁴⁹ to the already lengthy process of proposing and issuing rules.⁵⁰ They also argued against the peer review requirements of the bill, claiming that, among other things, they will give an undue advantage to industry representatives in shaping health and safety rules.⁵¹

After careful consideration of all views, the Committee disagrees with the analysis of the organizations opposing the bill for the reasons identified and explained throughout this report.

III. LEGISLATIVE HISTORY AND COMMITTEE CONSIDERATION

A. COMMITTEE HEARINGS

On April 21, 1999, the Governmental Affairs Committee held a hearing on S. 746. This hearing built on the Committee’s extensive hearing record and legislative history on regulatory reform from the 104th and 105th Congresses. Testifying at this hearing were: Gregory S. Lashutka, Mayor of Columbus, Ohio, for the National League of Cities; Robert E. Roberts, Executive Director, Environmental Council of States; Scott Holman, Chairman, Regulatory Affairs Committee of the U.S. Chamber of Commerce; Ronald A. Cass, Dean of Boston University School of Law; Dr. Lester Crawford, Director, Georgetown University Center for Food and Nutrition Policy; Patricia G. Kenworthy, Vice President for Government Affairs, National Environmental Trust; John D. Graham, Director, Harvard Center for Risk Analysis; David C. Vladeck, Director, Public Citizen Litigation Group; and Dr. Franklin E. Mirer, Director of Health and Safety, International Union, United Automobile, Aerospace, and Agricultural Workers of America. Jacob J. Lew, the Director of OMB, and L. Nye Stevens, Director of Federal Management and Workforce Issues, GAO, submitted statements for the record.

B. AMENDMENTS AND COMMITTEE ACTION

On May 20, 1999, the Committee on Governmental Affairs marked up and favorably reported S. 746 by a vote of 11 to 5. Voting in the affirmative were Senators Roth, Stevens, Collins, Voinovich, Domenici, Cochran, Specter, Gregg, Levin, Cleland, and Thompson. Voting in the negative were Senators Lieberman, Akaka, Durbin, Torricelli, and Edwards.

A number of amendments were offered, debated and voted upon. The following amendment was adopted: Senator Durbin offered an

⁴⁸ Testimony of David C. Vladeck, Director, Public Citizen Litigation Group before the Senate Governmental Affairs Committee, April 21, 1999.

⁴⁹ Testimony of Patricia G. Kenworthy for the National Environmental Trust before the Senate Governmental Affairs Committee, April 21, 1999.

⁵⁰ *Id.*

⁵¹ See Testimony of Franklin E. Mirer, Director of Health and Safety, United Auto Workers, before the Senate Governmental Affairs Committee, April 21, 1999.

amendment, which was amended by Senator Levin's second degree amendment, to require OMB to submit to Congress in 2002 an accounting statement and report containing an estimate of the total annual incremental benefits and costs of complying with the provisions of subchapter II added by this Act for each agency.

The following amendments were defeated:

(1) Senator Lieberman offered an amendment to require that the cost-benefit determination required by the bill not be judicially reviewable and to require that an agency's failure to conduct a particular requirement for cost-benefit analysis or risk assessment will not authorize a court to remand the rule unless the agency "entirely" fails to perform the analysis. The amendment was defeated 6–10. Voting in the affirmative were Senators Lieberman, Akaka (by proxy), Durbin, Torricelli (by proxy), Cleland (by proxy), and Edwards. Voting in the negative were Senators Roth (by proxy), Stevens (by proxy), Collins, Voinovich, Domenici (by proxy), Cochran (by proxy), Specter (by proxy), Gregg (by proxy), Levin, and Thompson.

(2) Senator Lieberman offered an amendment to require that public hearings in which scientific experts may be cross-examined would satisfy the bill's requirements for independent peer review of cost-benefit analyses and risk assessments. The amendment was defeated 6–10. Voting in the affirmative were Senators Lieberman, Akaka (by proxy), Durbin, Torricelli (by proxy), Cleland (by proxy), and Edwards. Voting in the negative were Senators Roth (by proxy), Stevens (by proxy), Collins, Voinovich, Domenici (by proxy), Cochran (by proxy), Specter (by proxy), Gregg (by proxy), Levin, and Thompson.

(3) Senator Durbin offered an amendment to exempt from the bill's cost-benefit and risk assessment requirements any rule or agency action to reduce the use of tobacco products by minors or protect the public from the health risks associated with tobacco products. The amendment was defeated 6–10. Voting in the affirmative were Senators Specter (by proxy), Lieberman, Akaka (by proxy), Durbin, Torricelli (by proxy), and Cleland (by proxy). Voting in the negative were Senators Roth (by proxy), Stevens (by proxy), Collins (by proxy), Voinovich, Domenici (by proxy), Cochran (by proxy), Gregg (by proxy), Levin, Edwards, and Thompson.

(4) Senator Lieberman, with Senator Akaka, offered an amendment to exempt any rules from the cost-benefit analysis and risk assessment requirements if the agency is not required to base the rule on the outcome of a risk assessment. The amendment was defeated 7–9. Voting in the affirmative were Senators Specter (by proxy), Lieberman, Akaka (by proxy), Durbin, Torricelli (by proxy), Cleland, and Edwards. Voting in the negative were Senators Roth (by proxy), Stevens (by proxy), Collins, Voinovich, Domenici (by proxy), Cochran (by proxy), Gregg, Levin, and Thompson.

(5) Senator Lieberman offered an amendment to require that the bill's risk assessment requirements would not apply to any programs for collecting and disseminating information. The amendment was defeated 7–9. Voting in the affirmative were Senators Specter (by proxy) Lieberman, Akaka (by proxy), Durbin, Torricelli, Cleland, and Edwards. Voting in the negative were Senators Roth

(by proxy), Stevens (by proxy), Collins, Voinovich, Domenici (by proxy), Cochran (by proxy), Gregg, Levin, and Thompson.

(6) Senator Cleland offered an amendment to exclude from a peer review panel any person who has, or is employed by an entity which has, a significant direct financial interest in the outcome of a rulemaking. Chairman Thompson noted that S. 746 specifically requires peer reviewers to be subject to current conflict of interest standards, and the amendment was defeated 6–9. Voting in the affirmative were Senators Lieberman, Akaka (by proxy), Durbin, Torricelli, Cleland, and Edwards. Voting in the negative were Senators Roth (by proxy), Stevens (by proxy), Collins, Voinovich, Domenici (by proxy), Cochran (by proxy), Gregg, Levin, and Thompson.

(7) Senator Torricelli offered an amendment to exempt from the bill's cost-benefit analysis and risk assessment requirements any rules relating to the protection of children's health, food safety, worker and workplace safety, environmental protection, firefighter safety, or civil rights. The amendment was defeated 6–10. Voting in the affirmative were Senators Specter (by proxy), Lieberman, Akaka (by proxy), Durbin (by proxy), Torricelli, and Cleland (by proxy). Voting in the negative were Senators Roth (by proxy), Stevens (by proxy), Collins, Voinovich, Domenici (by proxy), Cochran (by proxy), Gregg (by proxy), Levin, Edwards, and Thompson.

IV. ADMINISTRATION VIEWS

OMB Director Jacob Lew submitted a statement to the Committee dated April 21, 1999, expressing the Administration's views on S. 746. Director Lew noted that the Administration had offered suggestions concerning S. 981, that those concerns had been taken seriously by the sponsors, and that S. 746 includes changes suggested by the Administration. Director Lew stated that the Administration's view remains the same as in the July 15, 1998 letter to Senator Levin and Chairman Thompson and reiterated that "if S. 746 emerges from the Senate and House as you now propose, the President would sign it."

V. SECTION-BY-SECTION ANALYSIS

SECTION 1. SHORT TITLE

The name of this legislation is the "Regulatory Improvement Act of 1999".

SECTION 2. FINDINGS

Section 2 lays out eight basic findings by the Committee. These findings underscore both the strengths and limitations of regulatory analysis and review. The findings also reflect the experience and expertise of the Committee, as informed by scores of experts, government officials, and stakeholders in the regulatory process.⁵² These findings are as follows:

⁵²See, e.g., Letter of Baruch Fishoff, Professor of Social and Decision Sciences and Professor of Engineering and Public Policy, Carnegie Mellon University, to Chairman Fred Thompson, July 15, 1997, S. Hearing 105–535, at 294 ("The Findings are a remarkably succinct summary of what we have learned over the past 20 years regarding the role of analysis in regulation.

Continued

First, effective regulatory programs provide important benefits to the public, including improving the environment, worker safety, and public health. Regulatory programs also impose significant costs on the public, including individuals, businesses, and State, local, and tribal governments.

Second, improving the ability of Federal agencies to use scientific and economic analysis in developing regulations should yield increased benefits and more effective protections while minimizing costs.⁵³

Third, cost-benefit analysis and risk assessment are useful tools to better inform agencies in developing regulations, although they do not replace the need for good judgment and consideration of values.

Fourth, the evaluation of costs and benefits must involve the consideration of the relevant information, whether expressed in quantitative or qualitative terms, including factors such as social values, distributional effects, and equity.

Fifth, cost-benefit analysis and risk assessment should be presented with a clear statement of the analytical assumptions and uncertainties, including an explanation of what is known and not known and what the implications of alternative assumptions might be.

Sixth, the public has a right to know about the costs and benefits of regulations, the risks addressed, the risks reduced, and the quality of scientific and economic analysis used to support decisions. Such knowledge will promote the quality, integrity and responsiveness of agency actions.

Seventh, the Administrator of the Office of Information and Regulatory Affairs should oversee regulatory activities to raise the quality and consistency of cost-benefit analysis and risk assessment among all agencies.

Eighth, the Federal Government should develop a better understanding of the strengths, weaknesses, and uncertainties of cost-benefit analysis and risk assessment and conduct the research needed to improve these analytical tools.

This legislation is designed to elevate the use of modern decision-making tools, such as risk assessment and cost-benefit analysis, to make the regulatory process more transparent, more efficient and effective, and more accountable to the public.

SECTION 3. REGULATORY ANALYSIS

Section 3(a) substantially amends chapter 6 of title 5, United States Code. Section 3(a) creates two new subchapters. Subchapter II requires analysis of agency rules, including cost-benefit analysis, risk assessment, peer review, and guidelines, as well as a compara-

We would be much better off as a society were the wisdom in them more widely understood and accepted.”)

⁵³ See, e.g., Testimony of Paul R. Portney, President, Resources for the Future, before the Senate Committee on Governmental Affairs, September 12, 1997 (Under this legislation, “we might be able to shave off a chunk of the nearly \$300 billion OIRA estimates we spend each year on environmental, health and safety regulation . . . without compromising the benefits we get from regulations. . . . Even a cynical public ought to warm to a \$30 billion “free lunch” each year that does not compromise the quality of their environment or safety of their food and other products they consume each year.”); Testimony of John D. Graham, Director, Harvard Center for Risk Analysis, before the Senate Committee on Governmental Affairs, September 12, 1997.

tive risk analysis study. Subchapter III requires executive oversight of the rule making process.

Section 3(b) is a savings clause, stating that the current legislation does not limit any of the President's constitutional duties and authorities, including the authority to review regulatory actions not covered by this legislation.

Finally, section 3(c) provides the technical and conforming amendments necessary to reorganize chapter 6 into subchapters, including, for example, moving the Regulatory Flexibility Act to subchapter I of chapter 6.

In amending title 5, United States Code, the Committee-passed bill applies the definition of "agency" under section 551 to subchapters II and III of the bill—the regulatory analysis and executive oversight requirements. This definition includes the independent regulatory agencies within the scope of this legislation. Thus, the requirements to identify major rules and to perform cost-benefit analyses and risk assessments would apply not only to departments and other executive agencies, but also to the independent regulatory agencies, such as the Federal Energy Regulatory Commission, the Nuclear Regulatory Commission, and the Consumer Product Safety Commission.

This legislation also would require independent regulatory agencies, like all other Executive Branch agencies, to be subject to Presidential oversight for compliance with the requirements of this legislation. Such Presidential oversight includes the review of proposed and final major rules by OMB's Office of Information and Regulatory Affairs. Since 1981, OIRA's regulatory review authority under Presidential executive order (E.O. 12291, 12498, and 12866) has explicitly exempted independent regulatory agencies and made their participation in the regulatory review process voluntary. The Committee believes that the provisions of this legislation should apply to all Executive Branch agencies, including the independent regulatory agencies. The growing need for more efficient and effective government regulation, as well as for more coherent management of the Executive Branch, supports lowering some walls that have separated the independent agencies from other Executive Branch agencies.⁵⁴ Specific exemptions are provided within the definition of "rule" where this Committee or other authorizing Committees determined that there would not be significant benefits from regulatory analysis or OIRA review.

Section 3(a). In General

Section 3(a) creates new subchapters II and III in chapter 6, title 5, United States Code.

Subchapter II. Regulatory Analysis

Subchapter II establishes provisions for new definitions (sec. 621); applicability and effect (sec. 622); regulatory analysis (sec. 623); principles for risk assessments (sec. 624); peer review (sec.

⁵⁴ See, e.g., ACUS Recommendation 95-3: "Review of Existing Agency Regulations" (1995); Administrative Law Conference of the United States: Recommendation 88-9: "Presidential Review of Agency Rulemaking" (1988); American Bar Association, Commission on Law and the Economy, *Federal Regulation: Roads to Reform* (1979), at 108; American Bar Association, Administrative Law Report No. 110 (1986); Peter L. Strauss & Cass R. Sunstein, "The Role of the President and OMB in Informal Rulemaking," 38 Admin. L. Rev. 181, 205 (1986).

625); deadlines for rule making (sec. 626); judicial review (sec. 627); guidelines, interagency coordination, and research (sec. 628); and risk-based priorities study (sec. 629).

§ 621. Definitions

This section defines certain terms used in regulatory analysis. Many of these definitions are used not only in the new subchapter II, but also are referred to and incorporated into subchapter III.

(1) The term “Administrator” means the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget.

(2) The term “benefit” means the reasonably identifiable significant favorable effects, quantifiable and nonquantifiable, including social, health, safety, environmental, economic, and distributional effects, that are expected to result from implementation of, or compliance with, a rule.

The term “benefit” has broad meaning. Benefits are the favorable effects that are causally related to the rule. In other words, benefits are the improvements upon the status quo as a result of the rule. Federal agencies issue regulations to implement laws passed by Congress. As such, the value of a regulation is the extent to which it provides the public benefits envisioned by the underlying law. Regulations addressing health, safety, or environmental risks, for example, provide benefits from reducing risk, and the evaluation of those risk-reduction benefits would be based on the risk assessment performed under section 624 of this Act.

Benefits can be readily apparent, as in economic benefits obtained from hazardous material transportation rules or in the regained safety of a locality’s drinking water supply. Benefits also can be very broad, as in the growth of an economic sector or improved nation-wide employment rates. Finally, regulatory benefits can be significant but difficult to quantify, such as the value of increased visibility over the Grand Canyon.

This wide variety of possible benefits must be recognized in the rulemaking process. However, merely because benefits may be varied or difficult to quantify should not relieve agencies from identifying the specific benefits of a rule. The identification and evaluation of regulatory benefits should enable agencies to improve the effectiveness and efficiency of the regulatory process and to best serve the goals of the enabling statute.

As a part of this broad meaning of “benefit,” the Committee intends for agencies to consider direct as well as the indirect benefits. Many benefits can be clearly attributed to a regulatory action. Many, however, flow in more tangential ways. The Committee expects agencies to make a reasonably thorough effort at identifying and analyzing all significant benefits that flow from a regulatory action. At the same time, the Committee cautions agencies against speculative attribution of distant outcomes to a regulatory action.

The definition of benefits is not limited to favorable effects that can be quantified. They may include, for example, identifiable and significant but potentially nonquantifiable benefits, such as increased freedom of choice for consumers or enhanced opportunities for public enjoyment of the environment. In other words, benefits

that cannot be monetarily quantified, or even numerically measured, also should be considered and explained by the agency.

At the same time, the definition of benefits is limited to those that are “significant.” Benefits should be more than trivial or de minimis. The Committee does not anticipate that agencies will spend valuable resources trying to assess every small, remote benefit of a rule; during the cost-benefit analysis, only significant benefits need be addressed.

(3) The term “cost” means the reasonably identifiable significant adverse effects, quantifiable or nonquantifiable, including social, health, safety, environmental, economic, and distributional effects, that are expected to result from implementation of, or compliance with, a rule. The definition of “cost” parallels that of “benefit,” and the concerns expressed above regarding “benefit” apply equally here.

As in the case of “benefits,” the Committee intends to give broad meaning to the term “cost.” Agencies must be sensitive to all of the significant costs regulation can impose. While compliance costs often comprise a substantial portion of total costs, there are other costs of regulation. To name a few, these costs include adverse effects on health, safety or the environment; such adverse effects increase the net cost of a regulatory alternative. Costs also include adverse impacts on consumer choice, technological innovation, wages, productivity, economic growth, and lower employment. Again, agencies should eschew unreliable speculation about costs, as with benefits, but they should try to responsibly identify all “significant” costs imposed by a regulatory action. The concept of “cost” for cost-benefit analysis includes opportunity costs.⁵⁵ Accordingly, agencies should be more sophisticated in cost estimation than only summing up compliance costs.

Finally, agencies must identify and evaluate direct and indirect costs, as well as quantitative and nonquantitative costs. If a rule sets in motion a series of legally required actions that result in costs, even if those actions will be taken by entities other than the regulatory agency, the agency should consider such adverse effects as “costs” under this Act.⁵⁶

(4) The term “cost-benefit analysis” means an evaluation of the costs and benefits of a rule, quantified to the extent feasible and appropriate and otherwise qualitatively described, that is prepared in accordance with the requirements of this subchapter at the level of detail practical for reasoned decisionmaking on the matter in-

⁵⁵ As Paul Portney told the Committee:

[T]he sum total of out-of-pocket expenditures is not identical to “costs” as economists think of them for a benefit-cost analysis. [Costs] include the value of time that people must spend waiting in line for permits, car inspections, etc. It includes the adverse health effects they incur because of the time involved to bring a potentially effective new therapeutic drug to market. It includes the inconvenience they suffer when a product becomes less effective on account of a regulation, or disappears from the market altogether. None of these “costs” involves any out-of-pocket expenditure, but they must all be counted in any serious benefit-cost analysis.

Testimony of Paul R. Portney, Resources for the Future, before the Senate Committee on Governmental Affairs, February 8, 1995.

⁵⁶ For example, EPA recently issued a major rule under the Clean Air Act to reduce particulate matter and ozone and performed a cost-benefit analysis for the rule under Executive Order 12866. This rule would have required states to change their State Implementation Plans (“SIPs”) to satisfy the tighter standards. These SIP revisions would impose costs that are attributable to the EPA rule and such costs would be included in a cost-benefit analysis under this legislation.

volved, taking into consideration uncertainties, the significance and complexity of the decision, and the need to adequately inform the public. This definition includes the minimum essential features of cost-benefit analysis.

The Committee intends that the agencies use the best available techniques for these analyses and tailor the specificity and rigor of the analysis to the consequences of the decision to be made and the need to inform stakeholders and the public. This provides the agency with reasonable flexibility in the level of detail and rigor that should be employed. However, the Committee expects that the analysis will follow the essential requirements of this legislation.

(5) The term “Director” means the Director of the Office of Management and Budget, acting through the Administrator of the Office of Information and Regulatory Affairs. The reason for this definition is two-fold. First, the Committee expects the Director of OMB, not just the Administrator of OIRA, to be directly accountable for the prompt and effective implementation of this legislation. Second, the Committee at the same time intends to recognize the important role and responsibility of OIRA in the regulatory process. Since 1980, when the Committee passed the Paperwork Reduction Act, the Committee has viewed the Administrator of OIRA as an important partner in ensuring that the regulatory process is efficient, effective, and accountable. This legislation will further this critical role of OIRA.

(6) The term “flexible regulatory options” means regulatory options that permit flexibility to regulated persons in achieving the objective of the statute as addressed by the rule making, including market-based mechanisms, outcome-oriented performance-based standards, or other options that promote flexibility. The Committee believes that flexible regulatory options have the potential to be more efficient and effective than command-and-control regulation.

“Market-based mechanisms” include regulatory programs or requirements that impose legal accountability for achieving the regulatory objective on each regulated entity, afford maximum flexibility to each regulated entity in meeting mandatory regulatory objectives, and allow those regulated entities to respond freely to changes in pertinent economic conditions and circumstances without undermining the achievement of the program’s regulatory mandate or requiring a new rulemaking.

The Committee has heard testimony that some of our greatest regulatory successes have been achieved through market-based mechanisms.⁵⁷ One such example is the program for reducing na-

⁵⁷See, e.g., Statement of Paul R. Portney, President, Resources for the Future, before the Senate Committee on Governmental Affairs, September 12, 1997; Testimony of C. Boyden Gray, Partner, Wilmer, Cutler & Pickering and Chairman, Citizens for a Sound Economy, before the Senate Committee on Governmental Affairs, September 12, 1997; Testimony of Thomas F. Walton, Director of Economic Policy, General Motors Corporation, before the Senate Committee on Governmental Affairs, September 12, 1997; Testimony of Joseph Goffman, Senior Attorney, Environmental Defense Fund, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of Alan J. Krupnik, Senior Fellow, Resources for the Future, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of Jonathan B. Wiener, Associate Professor, Duke University School of Law and Duke University School of Environment, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of C. Boyden Gray, Partner, Wilmer, Cutler & Pickering and Chairman, Citizens for a Sound Economy, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of Carol M. Browner, Administrator, U.S. Environmental Protection Agency, before the Senate Committee on Governmental Affairs, March 8, 1995.

tionwide sulfur dioxide emissions, established under Title IV of the Clean Air Act. There, Congress imposed directly on sources of emissions explicit pollution reduction requirements. The sources were allowed to meet those requirements through any means they chose, including purchasing credits representing the performance of needed reductions by other sources. This program is achieving greater emissions reductions at a small fraction of the anticipated costs of command-and-control regulation and is far ahead of the statutory schedule.⁵⁸

“Performance-based standards” include requirements, expressed in terms of outcomes or goals instead of prescriptive command-and-control measures, that permit discretion and the use of market-based mechanisms in determining how best to meet specific requirements in particular circumstances. In contrast to command-and-control regulation, performance-based standards simply establish the ultimate regulatory goal and free regulated parties to meet or exceed that goal as they choose. Like market-based mechanisms, the Committee requires agencies to seriously consider performance-based standards because they have similar elements of flexibility, cost-effectiveness, and accountability.

(7) The term “major rule” is defined to include two categories of significant rules: economically significant and other significant rules designated by the Director of OMB.

The first category of “major rule” is defined in subsection 621(7)(A) as a rule that the relevant agency or the Director of OMB reasonably determines is likely to have an annual effect on the economy of \$100,000,000 or more in reasonably quantifiable costs.” To be classified as “major,” such a rule should be reasonably likely to have such an effect in any one year following its adoption.

The Committee’s decision to set the threshold for major rules at \$100 million follows the longstanding tradition under centralized executive review of rules. Since President Ford, every President has required by executive order the review of regulations which impose annual costs on the economy of \$100 million or more. The bill maintains the traditional \$100 million threshold because the Committee believes that it will not unduly increase the analytical burden of the agencies and that rules of such significance can benefit greatly from thorough analysis. All costs of a rule should be considered in determining whether a rule is “major” under subsection 621(7)(A).

Subsection 621(7)(B) provides a second prong to the major rule definition. This allows the President, through the OMB Director, to subject to cost-benefit analysis those rules which, while not imposing costs of \$100 million on the economy, still have a substantial impact. This category includes rules likely to adversely affect, in a material way, the economy, a sector of the economy (including small business), productivity, competition, jobs, the environment,

⁵⁸See Testimony of Joseph Goffman, Senior Attorney, Environmental Defense Fund, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of Alan J. Krupnik, Senior Fellow, Resources for the Future, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of Jonathan B. Weiner, Associate Professor, School of Law, Duke University, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of C. Boyden Gray, Partner, Wilmer, Cutler & Pickering and Chairman, Citizens for a Sound Economy, before the Senate Committee on Governmental Affairs, September 12, 1997.

public health or safety, or State, local or tribal governments, or communities.

Regulatory agencies and the OMB Director should be mindful of the disproportionate impact their actions can have on certain groups or sectors of the economy, even if the impact on the country as a whole is not substantial. This is particularly true of small business.⁵⁹ The Committee encourages the Director and the agencies to be sensitive to these concerns.

(8) The term “reasonable alternative” means a reasonable regulatory option that would achieve the objective of the statute as addressed by the rule making and that the agency has authority to adopt under the statute granting rule making authority, including flexible regulatory options.

Reasonable alternatives embrace the range of options that the agency has discretion to consider under the statute authorizing the rulemaking. The Committee included flexible regulatory options in the definition of “reasonable alternative” to encourage agencies to seek out such alternatives. The agency should consider the range of options authorized by the underlying statute to best achieve the objective being addressed by the rulemaking. “Reasonable alternatives” do not include alternatives prohibited by the statute authorizing the rule.

(9) The term “risk assessment” means the systematic, objective process of organizing hazard and exposure information and, based on a careful analysis of the weight of the scientific evidence, estimating the potential for specific harm to an exposed population, subpopulation, or natural resource including, to the extent feasible, a characterization of the distribution of risk as well as an analysis of uncertainties, variabilities, conflicting information, and inferences and assumptions.

Like the definition of “cost-benefit analysis,” the definition of “risk assessment” includes specific qualitative factors which the Committee views as minimum essential features of a risk assessment. Specifically, the risk assessment should be scientifically “objective”⁶⁰ and “based on a careful analysis of the weight of the scientific evidence.”⁶¹ Full consideration of the weight of the evidence often involves balancing positive and negative findings. The definition further requires that the risk estimate, to the extent feasible, must contain a characterization of the distribution of risk as well as an analysis of uncertainties, variabilities, conflicting information, and inferences and assumptions. The Committee believes that this type of information is necessary to get a complete and meaningful estimate of the risk.

⁵⁹ See Statement of Karen Kerrigan, President, Small Business Survival Committee, before the Senate Committee on Governmental Affairs, September 12, 1997 (citing Small Business Administration study showing that the annual regulatory cost per worker for companies with less than 20 employees is \$5,532).

⁶⁰ Agency risk assessments should be scientifically objective to the extent possible, neither minimizing nor exaggerating the nature and magnitude of the risks. Such risk assessments should be more transparent and credible, leading to less contentious risk management decisions. Such assessments should lead to a more risk-based regulatory system, offering the opportunity for greater overall protection with the available resources. See Testimony of John D. Graham before the Senate Committee on Governmental Affairs, September 12, 1997; Safe Drinking Water Act of 1996, Section 103, 42 U.S.C. § 300g-1(b)(3).

⁶¹ See Presidential/Congressional Commission on Risk Assessment and Risk Management, *Risk Assessment and Risk Management in Regulatory Decision-Making* (“Risk Commission Report”), Vol. 1, at 4, 23, 38.

The Committee recognizes that risk assessment is a flexible process by which complex technical data are combined and analyzed to provide decision makers with useful information to make policy decisions. In some decision contexts, such as evaluating food additives, it is useful to distinguish four steps in the risk assessment: hazard identification, dose-response analysis (which together comprise “hazard assessment”), exposure assessment, and risk characterization. In other contexts, such as transportation safety, one or another of the first three steps may not be relevant. The Committee believes that the definition adopted by this legislation is sufficiently generic to apply to the wide variety of risks covered by this legislation. The Committee encourages advances in state-of-the-art risk assessment practices.

(10) The term “rule” has the same meaning as such term is defined in section 551(4) of title 5, United States Code, with a number of exclusions.

First, subparagraph (A) exempts from the definition of “rule” any rule that is exempt from notice and public comment procedures under section 553 of title 5 of the United States Code. These include: rules relating to a military or foreign affairs functions; interpretative rules; rules relating to grants, benefits, or loans; rules relating to agency management or personnel; and rules relating to the acquisition, management or disposal of federal property. In some cases, these rules could have a significant impact on the economy. Yet, the Committee decided to minimize the burdens on the agencies; where notice and comment pursuant to section 553 is not required, a cost-benefit analysis will not be required either.

However, the Committee cautions the agencies that any statement of general applicability that actually alters or creates rights or obligations of persons outside the agency is included in this definition. While informal agency guidance is encouraged, agencies should not attempt to evade the requirements of this legislation through mischaracterizations of such materials.

Subparagraph (B) excludes rules involving the internal revenue laws. The Committee was concerned that the enormous economic impact of such rules might make an overwhelming number of tax regulations major rules. While many IRS rules have a major economic impact or are otherwise significant, they have this impact because their goal is to raise revenue, pursuant to the explicit mandates of the underlying statute with little or no agency discretion.

Subparagraph (C) excludes rules of particular applicability that approve or prescribe for the future rates, wages, prices, services, corporate or financial structures, reorganizations, mergers, acquisitions, accounting practices, or disclosures bearing on any of the foregoing.

This exemption applies to rules “of particular applicability” as that phrase is understood in section 551(4) of title 5. These are rules which, while technically within the definition of “rule,” are more properly considered as licenses or orders because they apply only to a small group or a single individual. The Committee believes that such rules would not greatly benefit from the analytical requirements of this legislation because they are generally developed through complex and lengthy proceedings, which often involve sophisticated economic analysis.

Subparagraphs (D) and (E) exclude from the legislation's scope certain rules relating to monetary policy or to the safety or soundness of federally insured depository institutions.

Subparagraph (F) excludes certain rules relating to the integrity of the securities or commodities futures markets or to the protection of investors in those markets.

Subparagraph (G) excludes certain rules issued by the Federal Election Commission and the Federal Communications Commission.

Subparagraph (H) excludes certain rules required to be promulgated at least annually pursuant to statute. This exemption would include certain rules that establish, modify, open, close, or conduct a regulatory program for a commercial, recreational, or subsistence activity related to hunting, fishing, or camping.

Subparagraph (I) excludes certain rules or agency actions relating to the public debt or fiscal policy of the United States.

In all of these instances, the Committee believes that the analytic requirements of the legislation would not enhance the efficiency or effectiveness of these rules.

Subparagraph (J) exempts from "rule" a rule that authorizes or bars the introduction into or removal from commerce, or recognizes or cancels recognition of the marketable status, of a product under the Federal Food, Drug and Cosmetic Act.

(11) The term "substitution risk" means a reasonably identifiable significant risk to health, safety, or the environment expected to result from a regulatory option and does not include risks attributable to the effect of an option on the income of individuals. A regulatory option designed to decrease certain risks may sometimes actually increase other risks.⁶² A substitution risk is an unintended adverse consequence. The provisions of S. 746 are intended to focus greater attention on the possibility of such adverse consequences, including addressing the likelihood of their occurrence, estimating the nature and magnitude of their impacts, and systematically considering substitution risks as a part of sound regulatory policy-making. The agency should identify, describe, and evaluate any substitution risks in the regulatory analysis. The agency should integrate such risks in its analyses and in making the determinations required under Section 623(d).

By "significant," the Committee means that the effect of the substitution risk should be important. "Significant" does not refer to the magnitude of the increase in risk as the term "significant risk" is used or interpreted under various environmental, health, and safety statutes;⁶³ it refers to the relative relationship a risk may have to the effect of a rule. A risk need not have a likelihood of a particular level, such as one in ten thousand, to be significant. For a "significant increased risk" to qualify as a substitution risk, it need not be greater than the original risk reduction otherwise being achieved by the rule. By "expected to result," the Committee means that the substitution risk should not be implausible. The Committee does not intend that attenuated arguments that changes in lifestyle that could result from changes in income of in-

⁶²See John D. Graham & Jonathan Baert Wiener, *Risk vs. Risk: Tradeoffs in Protecting Health and the Environment*, Harv. Univ. Press (1995).

⁶³See Occupational Safety and Health Act 29, U.S.C. § 651.

dividuals potentially attributable to a regulatory option should be considered a substitution risk under this legislation.

§ 622. Applicability and effect

Section 622 clarifies the scope and effect of this legislation. Subsection 622(a) provides that this legislation applies to all “major rules” through the proposed and final rulemaking stages, except as provided in Subsection 623(f).

Subsection 622(b) clarifies that nothing in Subchapter II shall be construed to alter or modify: (1) the substantive standards otherwise applicable to a rulemaking under other statutes; (2) the range of regulatory options that an agency has the authority to adopt under the statute authorizing the agency to promulgate the rule, or deference otherwise accorded to the agency in construing such statute; or (3) any opportunity for judicial review made applicable under other statutes.

This so-called “savings clause” clarifies a few important points: First, this legislation is not intended to override existing statutory standards. The cost-benefit analysis, risk assessment, and cost-benefit determination required by this legislation do not supersede or override the substantive standards in the statute under which a rule is being issued. In other words, S. 746 does not contain a so-called “supermandate.” S. 746 also does not alter the range of regulatory options that an agency can consider or the deference otherwise accorded to the agency in construing the statute authorizing the rule.

Finally, subsection 622(b) clarifies that S. 746 does not alter or diminish any opportunities for judicial review available under other statutes. To the extent that another Federal statute provides an opportunity for judicial review of agency action, that opportunity for judicial review continues to apply. Section 622(b) preserves existing opportunities to secure judicial review and preserves the nature and scope of judicial review provided by any other Federal statutes.

§ 623. Regulatory analysis

A. Background

This section lays out the requirements for agencies to conduct regulatory analysis, including cost-benefit analysis, risk assessment, and substitution risk analysis when issuing proposed and final major rules. The Committee believes that better use of these important decisionmaking tools will lead to a significantly more efficient and effective regulatory process.

The Committee also recognizes that many of the problems with the regulatory process can be traced to the failure of agencies to consider all of the potential effects of their rules before promulgation. The cost-benefit analysis is intended to provide a framework for the agency to assess the impact of its rule on the economy and society as a whole. The concept of cost-benefit analysis has developed over the past several administrations to the point where some very sophisticated analyses have been prepared. The Committee intends that the analysis be used by agencies to consider alternative

regulatory approaches, to compare the benefits and costs of such approaches, and to produce better decisions.⁶⁴

A satisfactory cost-benefit analysis would enable the agency to make an informed judgment whether the benefits of the rule justify its costs, and whether the rule substantially achieves the statutory objectives in the most cost-effective manner, or with the greatest net benefits. This determination is based on the whole rulemaking record.

To fulfill its potential for improving the regulatory process, the preliminary cost-benefit analysis must be made public by the agency to allow comment and criticism by interested parties. As more information is submitted to support or rebut the analysis, it and the final rule will be improved. The preliminary cost-benefit analysis must be summarized in the notice of proposed rulemaking.

The bill requires the cost-benefit analysis to be developed by the agency during the development of the rule. The cost-benefit analysis must guide the agency decision-making process, not provide a post-hoc rationalization for a decision made before the analysis was prepared. Once completed, the final cost-benefit analysis must be made public with the statement of basis and purpose accompanying the rule. An executive summary of the analysis must be published with the proposed and final rules in the Federal Register. If the analysis is properly performed, it will provide an excellent brief in support of the agency's factual conclusions and policy choices. The cost-benefit analysis required by this legislation will help to identify questions clearly, to describe assumptions made, and then to clarify the rationale justifying the proposed action so it is open for public debate. An agency must have this information before it, along with other relevant information, in order to make an informed choice.⁶⁵

B. Framework for conducting cost-benefit analysis

The first step, outlined in subsection 623(a), is for agencies, before publishing a notice of proposed rulemaking, to determine whether the rule is or is not a major rule under subsection 621(7)(A)—that is, whether the rule is likely to have a gross annual effect on the economy of \$100,000,000 or more in reasonably quantifiable costs. If the rule does not fall within subsection 621(7)(A), then the agency must determine whether the rule is a major rule under subsection 621(7)(B).

If the agency does not determine a rule to be major, subsection 623(a)(2) allows the Director of OMB to exercise the same authority not later than 30 days after the close of the comment period for the rule. This provision is designed to ensure effective Executive Branch oversight of the requirements of the Act. A notice of any major rule determination shall be published in the Federal Register, as a part of the notice of proposed rulemaking where possible,

⁶⁴ When well used, cost-benefit analysis is a highly effective tool to increase the efficiency and effectiveness of regulation. See, e.g., Resources for the Future, *Economic Analysis at EPA* (Richard D. Morgenstern, ed. 1997); *The Greening of Industry: A Risk-Management Approach*, Harv. Univ. Press (John D. Graham & Jennifer Hartwell, eds. 1997). One EPA study found that “the return to society from improved environmental regulations is more than one thousand times EPA’s investment in cost-benefit analysis.” See, U.S. Environmental Protection Agency, “EPA’s Use of Cost-Benefit Analysis: 1981–1986” (Aug. 1987), at p. 5–2.

⁶⁵ See, e.g. Risk Commission Report, Vol. 1, pp. 29–36; Vol. 2, p. 93.

and such notice shall include a succinct explanation of the agency's or the Director's action.

Both the preliminary and final cost-benefit analysis should address in detail the issues presented by the regulation, including the need for the rule, the various alternative approaches (including the potential incremental costs and benefits of each), the legal basis for agency action, and an assessment of the benefits and costs of the proposed action. The analysis should provide an objective, critical, and impartial discussion of the regulatory problem and of the potential solutions.

Although basically parallel, the preliminary and final cost-benefit analyses differ in several important respects. In most instances, the quality of analysis and data relevant to the analysis will improve between the time a rule is first proposed and when it is finally issued. Later estimates typically apply better data sources more sophisticated analyses. This tends to improve the accuracy and reliability of estimates, often substantially. To a large degree, such additional information will be provided by peer review, public comments, or other material developed by the agency. Thus, the later analysis should generally be more complete. In addition, the final analysis should address significant comments submitted on the preliminary analysis. The preliminary cost-benefit and cost-effectiveness evaluations required by subsection 623(b)(2) will be followed by the formal determinations required by the final cost-benefit analysis. The final determinations, of course, should consider any additional data received by the agency since the publication of the preliminary cost-benefit analysis and risk assessments.

C. Content of the cost-benefit analysis

Subsection 623(b) requires the agency to place an initial regulatory analysis⁶⁶ in the file of a major rule and publish in the Federal Register a summary of such analysis. The agency then must provide an opportunity for interested persons to comment pursuant to section 553 of title 5, United States Code. This Subsection reflects the Committee's firm conviction that sound analysis of the benefits and costs of various alternative regulatory options before the rule is proposed is essential to reasoned decision making. An agency needs this information, along with other relevant information, to make the best regulatory choice.⁶⁷

According to subsection 623(b)(2), each initial regulatory analysis must contain three major items: (1) a cost-benefit analysis; (2) a risk assessment, if required; and (3) information on any substitution risks.

Under subsection 623(b)(2)(A), each initial cost-benefit analysis shall contain 5 major components:

- (i) An analysis of the benefits of the proposed rule;
- (ii) An analysis of the costs;
- (iii) An evaluation of the relationship of the incremental benefits of the proposed rule to its costs, taking into account the results of

⁶⁶ A regulatory analysis under this legislation encompasses a cost-benefit analysis, cost-benefit determinations, any risk assessment, and, if applicable, a substitution risk analysis.

⁶⁷ The Risk Commission Report emphasizes the importance of evaluating the costs and benefits of regulatory options before making a decision; this is an essential feature of the Commission's framework for environmental health risk management. See Vol 1, at 29–36; Vol. 2, at 93–101.

any risk assessment, including the determinations whether the identified benefits of the proposed rule justify its identified costs; whether the proposed rule is likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than other reasonable alternatives considered by the agency; and whether the rule adopts a flexible regulatory option.

(iv) An evaluation of the incremental benefits and costs of a reasonable number of reasonable alternatives reflecting the range options that would achieve the objectives of the statute as addressed by the rulemaking, including alternatives that require no government action; provide flexibility for small entities under the Regulatory Flexibility Act; provide flexibility for State, local or tribal agencies delegated to administer a Federal program; employ flexible regulatory options; and assure protection of sensitive subpopulations, or populations exposed to multiple and cumulative risks.

(v) A description of the scientific or economic evaluations or information on which the agency substantially relied in the cost-benefit analysis and risk assessment, and an explanation of how the agency reached the determinations under subsection (d).

In addition to the cost-benefit analysis, if the rule requires a risk assessment under section 624, that assessment must be incorporated into the regulatory analysis under subsection 623(b)(2)(B).

Finally, Subsection 623(b)(2)(C) requires the agency to identify and evaluate substitution risks. The analysis of substitution risks is an important part of the rational decisionmaking framework established by this legislation. The Committee believes that if an agency properly identifies and evaluates the potentially adverse health, safety, or environmental effects of a regulatory option, the agency will be best prepared to make a regulatory decision that accounts for such substitution risks. The Committee is concerned that government has not always been sensitive to substitution risks caused or exacerbated by certain regulatory actions.⁶⁸ The agency must explicitly identify a substitution risk, provided there is reasonably available scientific information on the risk, such as in the scientific literature or as provided during the public comment period. The phrase “reasonably available to the agency” connotes that the agency is expected to engage in an affirmative and reasonably thorough search for information on potential substitution risks, but the search does not have to be exhaustive.

1. Identification of the problem

Every cost-benefit analysis, whether preliminary or final, should begin with a discussion of the nature of the problem. The agency

⁶⁸Cass R. Sunstein, “Health-Health Tradeoffs,” 63 U. Chi. L. Rev. 1533 (1996). See also, John D. Graham & Jonathan Weiner, *Risk Versus Risk: Tradeoffs in Protecting Health and the Environment*, Harv. Univ. Press (1995). One example of the substitution risk problem is the asbestos scare in the early 1980s. Government scientists argued that asbestos exposure could cause thousands of deaths. Public alarm led Congress to pass a sweeping law that led cities and states to spend between \$15 and \$20 billion to remove asbestos from public buildings. But about three years later, EPA officials confirmed that asbestos removal had been a very costly mistake. Ripping out asbestos raised the risk to the public because asbestos fibers became airborne during removal. Removing the asbestos also delayed the opening of many schools and other buildings. See Gregg Easterbrook, *A Moment on the Earth: The Coming Age of Environmental Optimism*, 250–53 (1995); Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation*, 12–13 (1993).

should identify those persons that the underlying statute and the regulation is intended to benefit and discuss the nature of the harm that likely will occur if no action is taken. The analysis should identify the cause or causes of the problem and possible solutions.

The agencies should identify the statutory authority relied upon to promulgate the regulation. The agency should briefly explain why its proposals are within its statutory jurisdiction and are consistent with congressional intent. A similar analysis should be done for each significant alternative.

2. Benefits

The heart of a cost-benefit analysis is a review and discussion of the benefits and costs of the proposed rule and the reasonable alternatives considered by the agency, including an attempt to balance and compare those costs and benefits. Subsections 623(b)(2)(A)(i), (A)(iii), (A)(iv), and (d) require the agency to analyze and estimate the incremental benefits of a rule and its alternatives. Economists have noted that the valuation and calculation of benefits generally pose the greatest problem in preparing a cost-benefit analysis, although cost estimates also can be difficult. The benefits of regulation—particularly environmental, safety, and health standards—can be substantial, yet difficult to calculate. The Committee does not expect all cost-benefit analyses will assign numerical values to all projected benefits. The agencies should use a rule of reason. When some aspect of a benefit cannot be quantified, the agency should describe the benefit in detail, state what significance it attributes to the nonquantifiable aspects of the benefit, and explain the basis for its conclusion of this point. Those benefits that cannot be quantified should be described precisely and succinctly. If the agency provides a monetary or other quantitative estimate, the analysis should include the methodological justification. The ranges of predictions and margins of error also should be specified. The cost, benefit, or risk assessment information relied on by the agency, whether quantifiable or nonquantifiable, should be supported by material that would allow the public to assess the accuracy, reliability, and validity of such information.

The agency should bear in mind that, just as markets may not function perfectly, neither do regulatory programs. When considering the benefits of regulating, agencies should not compare imperfect markets or externalities with idealized, perfectly functioning regulatory programs. Recognizing these limitations, the agency should make a reasonable attempt to predict the real-world results of the rule in the cost-benefit analysis.

3. Costs

Subsections 623(b)(2)(A)(ii), (A)(iii), (A)(iv), and (d) make clear that the cost-benefit analysis should address several critical issues in assessing the costs of a regulation. The cost-benefit analysis should look beyond the immediate compliance costs of regulation and attempt to quantify, or at least identify, the significant direct and indirect costs and adverse effects which may result from the rule.

Agencies should estimate the total costs of compliance and opportunity costs. Agencies also should estimate costs to government units, including costs of compliance, administration, enforcement, or lost tax revenue.

It is conceivable that some agency actions could impose costs in the form of new risks to public health, safety, or the environment. These risks should be viewed as increasing the net cost of the regulatory alternative. Alternatively, reducing the compliance burden imposed on one group or sector of the economy may increase the burden on another; those costs also should be considered.

Agencies should consider lost benefits as a cost. Opportunity costs can be difficult to project but also can be among the most significant costs of regulation. The inefficient use of resources, and investment disincentives, can have a significant impact on the economy.

4. Alternatives

Subsection 623(b)(2)(A)(iv) requires the preliminary cost-benefit analysis to contain a brief description of alternatives that reflect the range of the agency's discretion for achieving the objective of the statute as addressed by the rulemaking. Agencies must consider alternatives proposed by the public, but they also should take the initiative to develop alternatives that could achieve the statutory objective as addressed by the rulemaking in a more cost-effective manner. In the past, agencies have sometimes adopted rules without seriously considering alternatives that could more effectively achieve the statutory goals in a less costly manner. This provision is intended to compel agencies to seek out and consider a "reasonable number" of such alternative approaches, particularly flexible options. The legislation focuses the agency's discussion on a "reasonable number" of alternatives so that agencies are not forced to engage in limitless or wasteful discussions of theoretical regulatory alternatives. At the same time, the Committee cautions the agencies against using this provision to justify ignoring compelling alternatives or using the cost-benefit analysis as a post-hoc rationalization for a pre-determined political decision.

Under this subsection, the agency should evaluate the incremental benefits and costs of a reasonable number of reasonable alternatives reflecting the range of the agency's discretion, including, where feasible,⁶⁹ alternatives that—(I) require no government action; (II) provide flexibility for small entities under the Regulatory Flexibility Act; (III) provide flexibility for State, local or tribal agencies delegated to administer a Federal program; and (IV) employ flexible regulatory options; and (V) assure protection of sensitive subpopulations, or populations exposed to multiple and cumulative risks.

Alternatives should be identified and considered to determine if such alternatives could reduce the net costs of the regulation. Alternative levels and methods of compliance may be appropriate. The alternative of having no regulation should be a starting point

⁶⁹The qualifier "where feasible" in Subsection 623(b)(2)(A)(iv) reflects the Committee's intent that the alternatives must be both legally feasible, as well as technically feasible.

in the analysis. There may be existing voluntary,⁷⁰ market, judicial, state, or local regulatory mechanisms that could adequately resolve the problem identified by the agency for action.

In recent years, agencies have developed a number of innovative regulatory techniques to make regulatory programs less costly and more effective. For example, performance-based standards can be used instead of design standards to reduce compliance cost while still meeting regulatory goals. Market-based mechanisms, such as the sale of marketable permits, have been used to reduce the costs of pollution control while meeting or exceeding regulatory goals.

While far from complete, a fundamental shift is taking place in the way federal regulators go about their business, a shift that this legislation is intended to encourage. In the past, agencies too often reached for a single tool, command-and-control regulation, relying on administrative sanctions imposed through formal enforcement procedures, to solve any regulatory problem that arose. Traditional regulation, while necessary and appropriate in some cases, can be time-consuming and costly to both stakeholders and governments, and can create disincentives to innovation. Command-and-control regulation is frequently less effective and more costly than more flexible approaches.

5. Analysis of Flexible Regulatory Options

The specific reference in section 623(d)(1)(A)(iii) to consider flexible regulatory options, such as market-based mechanisms and performance-based standards, reflects not only the Committee's belief in the importance of considering these options to design regulatory programs, but also the specific steps agencies must follow so that these options will be consistently considered when formulating major rules. When the agency is developing a major rule, subsection 623(d)(1)(A)(iii) requires the agency to determine whether the rule adopts a flexible regulatory option. Subsection 623(d)(2)(C) requires the agency to describe any flexible regulatory option considered by the agency and to explain why that option was not adopted. If agencies fulfill the requirement of setting forth the extent to which the designs of proposed regulatory programs incorporate flexible regulatory options, then each rulemaking process, as well as the record created therein, necessarily should reflect discussion and analysis of flexible regulatory options. Since the Committee believes that such alternatives have the potential to produce better performing and more cost-effective regulatory programs, then flexible regulatory options will be an important standard against which agency design efforts can be judged.

6. Scientific or Economic Evaluations or Information

Subsection 623(b)(2)(A)(v) has 2 major purposes. First, it promotes the public's right to know the key information underlying important regulatory decisions. Second, it helps protect against the use of invalid scientific or economic assumptions by requiring an agency to describe what information the agency relied on in mak-

⁷⁰Some agencies have successfully used voluntary programs, such as EPA's 33/50 Program, to achieve substantial reductions in pollution in a cost-effective, flexible manner. See Testimony of Carol M. Browner, Administrator, U.S. EPA, before the Senate Committee on Governmental Affairs, March 8, 1995.

ing its cost-benefit determinations under section 623(d), and to explain how that information supported the agency's conclusions. This requirement is intended to help ensure the accuracy and scientific validity of the data and studies upon which the agency relies.

7. Cost-Benefit Determinations

Subsections 623(b)(2)(A)(iii) and (iv) and 623(d) are the heart of the cost-benefit requirements of this legislation. They take the agencies one step beyond the descriptive exercises of other subsections. They serve the critical goals of promoting the public's right to know how and why agencies make important regulatory decisions; enhancing the quality of information underlying agency decisions; and increasing the accountability of government to the public it is there to serve.

Subsection 623(d) requires that, in the final cost-benefit analysis for a major rule, the agency must make a three-fold determination based on the whole rulemaking record: (1) whether the benefits of the rule justify its costs; (2) whether the rule will achieve the objective in a more cost-effective manner, or with greater net benefits, than the other alternatives before the agency; and (3) whether the rule adopts a flexible regulatory option. This requirement mirrors that in subsection 623(b)(2)(A)(iii) for the preliminary cost-benefit analysis issued in connection with the notice of proposed rule-making for a major rule.

In the first requirement, the choice of the word "justify" is an important one. It conveys two concepts: first, that precise quantification of costs and benefits is not mandated where it is not possible; second, that agencies may bring to bear certain judgmental factors to supplement their numerical analysis in making the required determination.

The second requirement, that the rule achieve the objective "in a more cost-effective manner, or with greater net benefits, than the other reasonable alternatives considered by the agency" also is not a purely quantitative exercise that focuses only on costs. The agency is not required to adopt the alternative with the lowest compliance costs where another alternative provides substantially greater benefits. The term "cost-effective" implies a balancing and weighing of not only the cost of each alternative considered, but also the differing degrees of effectiveness of each such alternative.⁷¹

The third requirement, discussed above, reflects the Committee's intent to promote flexible regulatory options. Such options hold great promise to be more efficient and effective than traditional command-and-control approaches.

The Committee is aware that there may be limits to quantifying certain benefits, as well as costs. However, this does not mean that agencies are free to act arbitrarily or in the absence of appropriate record support in making their determinations under subsections 623(b)(2)(A)(iii) and (iv) and 623(d). An agency's cost-benefit deter-

⁷¹ The concept of "cost-effectiveness" is fully consistent with providing protective and responsible regulatory standards. Cost-effectiveness does not require the smallest incremental ratio of cost to effectiveness when mutually exclusive alternatives are compared. See Hearing before the Senate Committee on Governmental Affairs, September 12, 1997, at 300-01 (Letter of John D. Graham, Harvard Center for Risk Analysis).

minations must be “reasonable.” By imposing this requirement of reasonableness, the Committee intends that the agency will engage in “reasoned decision making.” To satisfy this standard, an agency must explore a reasonable range of alternatives, apply clearly articulate and understandable criteria, and explain the reasons why it has reached the determinations required under subsections 623(b)(2)(A)(iii) & (iv) and 623(d).

The Committee realizes that in some cases it will not be possible or desirable to attempt to quantify all of the costs or benefits of a regulatory proposal or of the reasonable alternatives to it. Although nonquantifiable, such costs and benefits are not to be ignored; they must be described in the cost-benefit analysis, identified in as precise a manner as possible, and considered in making the determinations required by section 623(d). Such determinations need not be made primarily on a numerical or mathematical basis. The Committee has made clear that net benefits analysis under subsection 623(d) is not limited to quantifiable effects. This is consistent with the definitions of “benefit” and “cost.”

The Committee recognizes that regulations sometimes implement Congressional policy choices that are not consistent with efficiency criteria. For example, Congress may provide an economic incentive to create networks and infrastructure facilities available to Americans in both rural and urban areas. This policy choice may impose minor quantifiable costs on the entire population in order to provide significant nonquantifiable benefits to discrete populations and to ensure that the country benefits from truly national networks, infrastructure, services, and opportunities therefrom. The Committee does not intend that the provisions of this legislation, particularly the cost-benefit analysis requirements, override Congress’ policy choice.

Quantifiable costs and benefits should be made in the most appropriate units of measurement and specify the ranges of predictions and explain the margin of error involved in the quantification methods and in the estimates used.⁷² For example, a hypothetical cost-benefit analysis might describe one of the quantifiable benefits of a regulation as “cases of serious injury reduced.” The most precise estimate may be the prediction that actual benefits will be within a range of “ten to fifty cases annually” (this is the “range of prediction”). The probability that the number of cases reduced will actually be within this range may be eighty percent.

Reducing costs and benefits to common units of measurement can make the analytical and evaluative exercise more useful and understandable. Hence, efforts should be made to translate costs and benefits into monetary or other concrete terms where appropriate. For example, benefits that consist of reducing or controlling adverse effects on health or the environment could be described in the first instance by estimating, using the risk assessment procedures of this legislation, the degree to which the rule would reduce the risk that such effects would occur.

These requirements recognize that quantification of costs and benefits is far from an exact science. As stated elsewhere in this

⁷²See M. Granger Morgan & Max Herrion, *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*, Cambridge Univ. Press (1990).

Report, the Committee intends a reasonable analysis and comparison employing the degree of precision appropriate to each situation. The requirements also recognize that past regulatory analyses have not always adequately disclosed the imprecisions inherent in numerical estimates or the assumptions built into the methodologies used to arrive at them. The significant assumptions and uncertainties in the analysis should be prominently displayed, a requirement paralleling the directive in subsection 627(d) that the agency's cost-benefit determination be "reasonable."

Subsection 623(e) provides a practical mechanism to provide the public with better information about regulatory decisions. That information needs to be provided in a way that is understandable and accessible to the public. In the past, the critical information underlying rulemakings often has been buried in long, technical documents in large agency rulemaking files.⁷³ This does not serve the public's interest, nor does it serve the interests of Congress, stakeholders, or the President. In fact, it could inhibit communication among relevant decision makers inside and outside the agency, whether they be technical experts, legal counsel or policy makers. Subsection 623(e) addresses this problem by requiring a succinct executive summary of the regulatory analysis. The Committee intends that the executive summary be a useful tool to communicate the important information about the rulemaking to the public, stakeholders, Congress, the President, and the relevant decision makers. The minimal information to be provided includes: (1) the benefits and costs of the rule, and any determinations required under subsection 623(d); (2) the expected risk reduced and the key conclusions of any risk assessment; (3) the benefits and costs of reasonable alternatives; and (4) the key assumptions and scientific information upon which the agency relied. In addressing the key scientific information and assumptions, the agency should discuss significant uncertainties and the quality of the science or economics that is the basis of the regulatory analysis, including whether experts are divided over competing paradigms.

Subsection 623(f)(1) provides a limited exemption from compliance with the requirements of this legislation prior to issuance of the rule where: (1) the agency for good cause finds that conducting the analysis under this legislation before the rule becomes effective is impracticable or contrary to an important public interest; and (2) the agency publishes the rule in the Federal Register with such finding and a succinct explanation of the reasons for the finding.

⁷³ See Testimony of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, GAO, before the Senate Committee on Governmental Affairs, September 12, 1997; Statement of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, GAO, before the Senate Committee on Governmental Affairs, February 24, 1998; GAO, *Cost-Benefit Analysis Can Be Useful in Assessing Environmental Regulations, Despite Limitations*, GAO/RCED-84-62 (April 6, 1984) (recommending that regulatory analyses contain executive summaries that recognize all benefits and costs, including non-quantifiable; identify a range of values for benefits and costs subject to uncertainty, as well as sources of uncertainty; and compare all feasible alternatives); GAO, *Air Pollution: Information Contained in EPA's Regulatory Impact Analyses Can Be Made Clearer*, GAO/RCED-97-38 (April 1997) (finding deficiencies in EPA regulatory analyses and reiterating 1984 GAO recommendations). See also, GAO, *Regulatory Reform: Changes Made to Agencies' Rules Are Not Always Clearly Documented*, GAO/GGD-98-31 (Jan. 1998) (finding that selected federal agencies usually did not comply with requirements of E.O. 12866 to identify for the public "in a complete, clear, and simple manner" the substantive changes made to regulatory actions while under review at OMB's OIRA, and to identify the changes made at the suggestion or recommendation of OIRA).

The Committee merely intends to provide sufficient flexibility for agencies to respond to a true emergency when a rule must be promulgated without awaiting completion of the analysis. This exemption closely tracks the category of rules exempted from the notice and comment procedures of the Administrative Procedure Act, and the Committee does not expect this exemption to be used often.

Subsection 623(f)(2) requires that, if a major rule is adopted under subsection 623(f)(1) without prior compliance with the legislation, then the agency shall comply with this legislation as promptly as possible unless the OMB Director determines that compliance would be clearly unreasonable. This is a very narrow exception to avoid clearly unreasonable situations where a costly analysis would be required for a rule that would not be in effect when the analysis was completed.

Subsection 623(g) incorporates and extends the consultation requirements of Section 204 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. §1534). Agencies must develop, maintain and use effective processes and solicit meaningful and timely input of State, local and tribal governments (or their designated employees with authority to act on their behalf) into the development of any regulatory proposals that contain significant Federal intergovernmental mandates. Such processes and consultations shall be consistent with Section 204 of the Unfunded Mandates Reform Act and therefore shall be exempt from the Federal Advisory Committee Act. The Committee believes that federal agency consultation with State, local, and tribal governments before a decision is made will improve the quality, fairness, and responsiveness of federal regulations. In many respects, State, local, and tribal officials are closer to the public; they also are often burdened with unfunded mandates imposed by regulations or with implementing and enforcing them. The term “significant regulatory proposal” is substantially broader than the term “major rule,” which triggers the cost-benefit requirements of this legislation. Accordingly, the consultation requirements of this legislation apply to agency actions exempted from the cost-benefit requirements of this legislation.

Section 624. Risk assessment

Risk assessment is a widely recognized tool to structure information for regulatory decision making related to the environment, health and safety. The acceptance of risk assessment as a standard tool can be traced back to the seminal report issued by the National Academy of Sciences in 1983: *Risk Assessment in the Federal Government: Managing the Process*. The report presented a conceptually sound and logical approach that has been widely adopted by federal and state agencies to assess environmental, health, and safety risks.

Fifteen years after publication of the NAS risk report, there is general agreement that the risk assessment process needs to be refined. The process should be better understood and more accountable. Risk assessment can be most useful when those who rely on it to inform the risk management process understand the strengths and limitations of risk assessment, and use it accordingly. Decision makers should at least understand that the process must rely on assumptions and cannot completely be divorced from assessors’ val-

ues. Decision makers must understand what assumptions were used in the assessment in question, and what values they reflect; that the risk estimate is expressed as a range and distribution; and that variability is expressed to the degree that it is known, *i.e.*, how many and what kind of persons (*e.g.*, children) will likely be at significantly higher or lower risk than the hypothetical average individual. Risk managers must take all of those factors into account in making a decision, along with political, economic, and social factors extrinsic to the risk assessment.

In recent years, many studies have supported the use of risk assessment and recommended improvements to the process. In 1993, the Carnegie Commission on Science, Technology, and Government issued *Risk and the Environment: Improving Regulatory Decision Making*. In 1994, the NAS issued *Science and Judgment in Risk Assessment* to review and evaluate the risk assessment methods of EPA. In March 1995, the Harvard Center for Risk Analysis issued *Reform of Risk Regulation: Achieving More Protection at Less Cost*. The OSTP also issued a brief report entitled, "Science, Risk, and Public Policy." In 1997, the Presidential/Congressional Commission on Risk Assessment and Risk Management issued the report entitled, *Risk Assessment and Risk Management in Regulatory Decision-Making*. Many of the risk assessment provisions of this legislation are strongly supported by findings and recommendations of these and other reports.

Section 624 defines which agency actions must follow the basic principles in this legislation. Subsection (a)(1)(A) states that the risk assessment principles of this legislation apply to: (i) proposed and final major rules the primary purpose of which is to address health, safety, or environmental risk; and (ii) risk assessments not the basis of a rule making that the OMB Director reasonably anticipates are likely to have an annual effect on the economy of \$100 million or more in reasonably quantifiable costs and that the Director determines shall be subject to the requirements of Section 624.

The Committee recognizes that risk assessments are not necessary for rules that do not have the primary purpose to address health, safety or environmental risk. At the Committee hearing on S. 746, the concern was raised that S. 746 would require a risk assessment for Toxic Release Inventory ("TRI") reporting rules issued under the Emergency Planning and Community Right to Know Act. This law requires that covered entities report, not control, the levels of certain chemicals emitted from a facility. The primary purpose of such rules is not to address risks but to disclose information. At the Committee hearing and markup, Senators Levin and Thompson agree that S. 746 does not mandate a risk assessment for TRI rules.⁷⁴

The Committee also recognizes that some risk assessments can have a significant effect even though they are not associated with a major rule. Under Subsection (a)(1)(A)(ii), such "stand alone" risk assessments also would have to comply with the risk principles of S. 746 if the risk assessment is likely to have a \$100 million effect on the economy. This could occur, for example, where a risk assess-

⁷⁴ Hearing before the Senate Committee on Governmental Affairs, "S. 746, the Regulatory Improvement Act of 1999," April 21, 1999.

ment may establish the basis for significant regulatory actions at the Federal, state, or international level.

The Committee intends to promote the most advanced and scientifically valid techniques for performing the wide variety of risk assessments covered by this legislation. The Committee does not intend to deter agencies from using the forms of risk assessment appropriate to their respective regulatory decisions. It does intend that the methodology be credible and understandable, and its limitations be made known to the public.

Subsection (a)(1)(B) sets out two general principles for risk assessments. This first principle provides that a risk assessment shall be conducted in a manner that promotes rational and informed risk management decisions and informed public input into and understanding of the process. This recognizes that risk assessments play an important role as a tool for regulatory decision making, as well as for communicating information to the public about risks.

The second general principle provides that in determining the scope and level of analysis of a risk assessment, the significance and complexity of the decision must be considered as well as the need to inform the public adequately; the need for expedition; and the nature of the risk being assessed.⁷⁵ This provision acknowledges that some risk assessments need to be done with greater rigor than others. Differently stated, the level of effort required for a risk assessment depends on what is at stake. In some cases, very severe risks can be identified and managed with relatively simple risk assessments because the stakeholders agree that the danger is great enough that no further analysis is needed. Often, the risks requiring detailed analysis are those that are marginal on a cost-benefit scale: in these cases, credible, detailed analyses can be crucial to satisfying stakeholders. The Committee cautions the agencies against construing this provision as excusing noncompliance with the provisions of section 624 or other provisions of this legislation.

To avoid unnecessary duplication of effort, Subsection (a)(2) provides that an agency does not have to prepare a new risk assessment for a final rule where: (1) the final rule is substantially similar to the proposed rule with respect to the risk being addressed; (2) the risk assessment performed for the proposed rule is consistent with the provisions in Subchapter II; and (3) a new risk assessment is not necessary to address comments submitted during the comment period.

Subsection (b) requires each agency to “consider . . . all relevant, reliable and reasonably available scientific information” and to describe the basis for selecting that scientific information. This subsection promotes three basic principles. First, the agency must make a thorough search for relevant data. The agency should make

⁷⁵ See OSTP report, “Principles in Devising Risk Policy,” at 17 (“The level of effort should be commensurate with the severity of the risks and costs to society.”) The Risk Commission Report also supports this principle. See Vol. 2, at 63 (“Deciding to go forward with a risk assessment is a risk-management decision, and scaling the effort to the importance of the problem, with respect to scientific issues and regulatory impact, is crucial.”); Vol. 2, at 21 (“The level of detail considered in a risk assessment and included in the risk characterization should be commensurate with the problem’s importance, expected health or environmental impact, expected economic or social impact, urgency, and level of controversy, as well as with the expected impact and cost of protective measures.”).

a reasonable attempt to gather data from informed parties and may solicit information through the Federal Register. Second, the agency should assess whether the data are relevant and reliable. And third, if the data are relevant and reliable, the agency should consider and analyze all those data in the risk assessment. Data can be “reliable” if they are well understood and generally supported in the scientific community; come from well recognized, credible sources; or are of sufficient quality that the results could be reproduced.⁷⁶

The Committee understands that even reliable data will vary in quality, relevancy and applicability. The definition of “risk assessment” in Section 621(9) contemplates that an agency will use a careful analysis of the weight of the evidence to evaluate the information it has.⁷⁷ In considering the scientific information, the agencies should evaluate the data and apply the appropriate weight to them in the risk assessment.

Agencies make assumptions in conducting risk assessments to overcome a paucity of data or a lack of scientific understanding about such things as causality or basic biological mechanisms. As Subsection (b) establishes, the agency should consider all relevant, reliable and reasonably available data. If the agency concludes that information is not relevant or reliable, the agency should explain how and why it so concluded. When the agency needs to use assumptions in risk assessment, Subsection (c) sets out the appropriate treatment of the assumptions.

Subsection (c) does not dictate which assumptions an agency shall use. Rather, it requires the agency to disclose pertinent information about the significant assumptions so that anyone relying on the risk assessment can better evaluate the validity of the assumptions and their effect on the risk assessment. Accordingly, for a significant assumption, the agency must: (1) identify the scientific basis, and the policy basis (if any), as well as the extent to which the assumption is validated by or conflicts with empirical data; (2) explain the basis for choosing among possible assumptions and/or combining an assumption with other assumptions; and (3) describe reasonable alternative assumptions that would have had a significant effect on the results of the risk assessment, and those that were considered but not selected by the agency for use in the risk assessment.

Finally, Subsection (c)(2) establishes the agency’s obligation to update the assumptions it uses to reflect new data or new scientific understandings.⁷⁸ It requires the agency to revise its assumptions

⁷⁶See Risk Commission Report, Vol. 1, at 38 (“Because so many judgments must be based on limited information, it is critical that all reliable information be considered. Risk assessors and economists are responsible for providing decision-makers with the best technical information available or reasonably attainable, including evaluations of the weight of the evidence that supports different assumptions and conclusions.”)

⁷⁷The Risk Commission Report provides examples of the kinds of considerations entailed in making judgments on the basis of the weight of the scientific evidence in a toxicity study: quality of the toxicity study; appropriateness of the toxicity study methods; consistency of results across studies; biological plausibility of statistical associations; and similarity of results to responses and effects in humans. See Vol. 2, at 20.

⁷⁸The Committee supports the conclusions of Risk Commission Report, which states: “Agencies should continue to move away from the hypothetical . . . toward more realistic assumptions based on available scientific data.” Vol. 2, at iv. As *Science and Judgment in Risk Assessment* clearly acknowledges, “Over time, the choice of defaults should have decreasing impact on regulatory decision-making. As scientific knowledge increases, uncertainty diminishes. Better data

to incorporate all relevant and reliable scientific information as it becomes reasonably available. Subsection (c)(2) is intended to keep agency assumptions current. It is not intended to create a counter-productive and never-ending cycle of revisions. It is intended to promote credible and reliable risk assessments.

Subsection (d) requires that an agency provide notice to the public of a risk assessment, and the agency must solicit relevant and reliable data from the public. The agency must consider the data in conducting the risk assessment. The purpose is to make the process more transparent and accountable.⁷⁹

Subsection (e) mandates some of the basic contents of the document describing the risk assessment. This subsection and subsections (c) and (f) are critical to the transparency in the risk assessment. They will allow the public and agency decision makers to understand the full scope and dimensions of the problem that the agency is addressing. Subsection (e) sets out five pieces of information the agency risk assessment must disclose:

(1) *A description of the hazard of concern*—that is, the problem being addressed.

(2) *A description of the populations or natural resources that are the subject of the risk assessment.* Consistent with subsection (f), “populations” would include the population that could be exposed to the hazard and, as appropriate, highly exposed or sensitive subpopulations.

(3) *An explanation of the exposure scenarios used in the risk assessment, an estimate of the population or natural resource corresponding to each exposure scenario, and an estimate of the likelihood that the exposure scenario would actually occur.* The Committee is aware that the concept of “exposure” has been more associated with assessments of risks from pollutants or disease agents. However, the Committee believes that it also is applicable to risks from harmful events. For example, passengers in a car are exposed to passenger side airbag injuries; workers who work around electrical machinery are exposed to injuries from inadvertent start-ups during repairs; and vehicle passengers or downstream residents may be exposed to the potential harm from the collapse of a bridge. The Committee broadly interprets the term “exposure.”

(4) *A description of the nature and severity of the harm that could occur as a result of exposure to the hazard.* By “nature” the Committee means the type of adverse affect, such as disease, physical harm or ecosystem damage, that could be attributed to the hazard. By “severity” the Committee means the seriousness of the harm—not the likelihood—including whether the harm is reversible.

and increased understanding of biological mechanisms should enable risk assessments that are less dependent on default assumptions and more accurate as predictions of human risk.” (p. 90).

⁷⁹The Committee received comments on the need for a more transparent risk assessment process that would allow for greater public input. The Risk Commission Report strongly supports stakeholder (public) involvement at all stages of risk management. To avoid the politicization of risk assessments, however, the Commission noted that “stakeholders play an important role in providing information that should be used in risk assessments and in identifying specific health and ecological concerns” but should not participate directly in the risk assessment itself. See Vol. 2, at 21 (“Stakeholders play an important role in providing information that should be used in risk assessments and in identifying specific health and ecological concerns they would like to see addressed.”); *id.*, at 185.

(5) *A description of the major uncertainties in each component of the risk assessment and their influence on the results of the assessment.* This requirement will help inform the public and agency decision maker how certain the risk is. It also will help identify areas where additional research or data could significantly improve the quality and reliability of the risk assessment.⁸⁰

The final product of a risk assessment should be a set of numeric estimates which, along with the information required under Subsection (e), constitutes the risk characterization. Traditionally, agency regulatory decisions have been based on the estimate of the risk. Subsection (f) describes the form the risk estimate shall take. In the past, risk assessments resulted in risk estimates that were a single value, such as one-in-ten-thousand, or for some toxicological assessments, a “safe” dose or exposure level. The Committee believes that reliance on single point estimates may conceal important information from the public and the decision maker, such as the degree of uncertainty about the estimate, how different populations might be affected differently, or what policy judgments are embodied in the estimate. For example, to be protective, agencies routinely have used conservative assumptions where there were uncertainties or suspected variability in exposed individuals. The decision to be protective may well be the correct one, but embedding this important policy decision in the risk estimate (the “science”) is not transparent to the public or agency decision makers.⁸¹

The tools of probabilistic risk assessments are now sufficiently well-developed that agencies often can supply a multidimensional descriptive estimate of the risk—one that fully conveys both the range and likely distribution of the risk. The risk manager should have as complete a picture of the risk as possible, avoiding, for example, the simple presentation of a single-point risk estimate that could overstate or understate the true risk. Accordingly, Subsection (f) requires that “to the extent scientifically appropriate,” which should be typical, agencies must provide such estimates. Specifically, agencies are required to provide:

(1) *The estimate of risk as one or more reasonable ranges and, if feasible, probability distributions, reflecting variabilities and uncertainties.* By “reasonable” the Committee intends that the ranges and distributions convey a reasonably accurate picture of the risk, one that neither overstates nor understates the risk. The reasonable ranges and distributions would incor-

⁸⁰ In “Science, Risk and Public Policy,” OSTP emphasized the importance of describing the uncertainties inherent in risk assessments, stating “Variation in risk estimates also arises from choices of assumptions and methods to address and treat uncertainty in available scientific data. Risk assessors may develop different estimates of risk because they employ different (but equally justifiable) assumptions.” (p. 9).

⁸¹ See *Risk and the Environment: Improving Regulatory Decision Making*: “Regulatory agencies should report a range of risk estimates when assessing risk and communicating it to the public. How risk estimates, whether derived from an inventory or not, are conveyed to the public significantly affects the way citizens perceive those risks. Single-value risk estimates reported to the public do not provide an indication of the degree of uncertainty associated with the estimate. Such numbers do not convey the conservative nature of some risk estimates.” (p. 87); see also *Science and Judgment in Risk Assessment*: “EPA should make uncertainties explicit and present them as accurately and fully as is feasible and needed for risk management decision-making. To the greatest extent feasible, EPA should present quantitative, as opposed to qualitative, representations of uncertainty.” (p. 185).

porate all of the data and alternative assumptions used in the risk assessment. One of the underlying premises of this legislation is that more information leads to better decisions. Risk information should at least be presented as a range, but this bill reflects the preference that agencies should strive to obtain sufficient information to provide probability distributions. Such distributions, when accurately reflecting variability and uncertainty, give decision makers and the public a more complete picture of the risks. Accordingly, the bill requires the agency to provide a probability distribution where feasible. The reference to “one or more” ranges and distributions reflects that more than one distribution may be needed to demonstrate fundamental uncertainties or to provide specialized information for relevant subpopulations, as described in subsection (f)(2).

(2) *The central⁸² and high end estimates for each range and distribution and a description of the relevant exposure scenario for the potentially exposed population to which the range and distribution estimate applies.*⁸³ The Committee believes that the public and the agency decision maker will make more informed decisions if they know about the central and high-end estimates of each range and distribution and the exposure of particularly affected populations.

(3) *A description of qualitative factors that influenced the ranges, distribution and likelihood of the risk.* Such qualitative factors may include: choice of data sets; choice of extrapolation models; choice of statistical cutoff point for validity; choice of end point; choice of default assumptions, and so on. This paragraph promotes the core philosophy of this legislation—namely, that more information and greater transparency will improve the quality of agency decision making.

To help the public and the agency decision maker to better understand the nature and magnitude of the risks that are the subject of a risk assessment, Subsection (g) requires agencies to compare the risk to other risks “familiar to and routinely encountered by the general public.” The agency should disclose the critical features of the compared risks, including whether they are voluntary or involuntary, newly discovered or well understood, and reversible or irreversible.⁸⁴

Comparing risks in this manner helps the agency understand whether it is addressing the right problems in the most effective way. It also helps the public understand the dimensions of the risk and whether the agency is focusing its efforts on the right prob-

⁸²A “central estimate of risk” is: the mean or average of the distribution; or a number which contains multiple estimates of risk based on different assumptions, weighted by their relative plausibility; or any estimate judged to be most representative of the distribution. See, e.g., Charles A. Holloway, *Decision Making Under Uncertainty: Models and Choices* (1979), at 76, 214, 91–127; Theodore Colton, *Statistics in Medicine* (1974), at 28–31. The central estimate should neither understate nor overstate the risk, but rather, should provide the risk manager and the public with the expected risk. See *Science and Judgment in Risk Assessment*, at 170–75.

⁸³See EPA, Policy for Risk Characterization (March 21, 1995), at 2 (“Information should be presented on the range of exposures derived from exposure scenarios and on the use of multiple risk descriptors (e.g., central tendency, high-end of individual risk, population risk, important subgroups (if known) . . .”).

⁸⁴See, e.g., National Research Council, *Improving Risk Communication*, 165–79 (1989).

lems.⁸⁵ The Committee intended to underscore the public communication value of risk comparisons and therefore required that the comparison be familiar to and routinely encountered risks. The Committee expects the agencies to select appropriate comparisons that provide the best contextual information to the public.

§ 625. Peer review

This section specifies that agency heads must develop a systematic program for independent peer review of all risk assessments covered by S. 746 and of cost-benefit analyses conducted for major rules costing \$500 million or more.⁸⁶ Central to the peer review program should be review by an adequate number of individual experts from relevant scientific and technical disciplines, through formal or informal devices. Peer reviewers must be selected on the basis of their expertise in the sciences or economics relevant to the regulatory decision. The participants must be broadly representative of the scientific and technical views relevant to the decision at hand and independent⁸⁷ of the agency.⁸⁸

At the same time, the bill allows for a variety of approaches to peer review, including the use of informal methods. For example, the National Science Foundation (“NSF”) uses two principal methods for peer review of proposals, by mail and by panel. In its report to the National Science Board on the Merit Review System for FY 1997, the NSF reported that “In ‘mail only’ reviews, peers are sent proposals and asked to submit written comments to NSF by postal

⁸⁵ One of the key recommendations of the Commission Report was that the problems a regulation is intended to address should be placed in their “public health and ecological context.” Vol. 1, at 4. For example, in the environmental area the Report suggests four questions for an agency to ask and answer:

Is the population exposed to the same pollutant from other sources?

Is exposure to the pollutant also occurring from other environmental media?

Do other pollutants from the same sources pose additional risks to the population of concern?

How great a risk does the problem pose compared to other similar risks that the community?

Vol 1, at 9–10.

⁸⁶ Peer review is a widely endorsed component of risk assessment and cost-benefit analysis. See, e.g., Risk Commission Report, Vol 2, at 103 (“Peer review of economic and social science information should have as high a priority as peer review of health, ecological, and engineering information.”); National Research Council, *Valuing Health Risks, Costs, and Benefits for Environmental Decision Making* (1990), at 207 (“benefit-cost analysis should be subject to systematic, consistent, formal peer review”); American Enterprise Institute & Brookings Institution, *An Agenda for Regulatory Reform* (1997), at 13 (the president and Congress should adopt procedures to peer review regulatory analyses); John D. Graham, “Making Sense of Risk: An Agenda for Congress,” in *Risks, Costs, and Lives Saved* (Robert W. Hahn, ed. 1996); John D. Graham, *Harnessing Science for Environmental Regulation* (1991); Shelia Jasanoff, *The Fifth Branch: Science Advisors as Policymakers*, Harv. Univ. Press (1990). As stated in the OSTP *Principles in Devising Risk Policy*, “Appropriate scientific peer review and guidance are essential to the risk assessment process.” (p. 17). The Carnegie Commission Report also highlights the importance of external peer review. The report states, “A key element in setting risk-based priorities is science advice, both internal (within the agency) and external (through science advisory boards and other mechanisms). External science advisory boards serve a critically important function in providing regulatory agencies with expert advice on a range of issues.” (p. 90).

⁸⁷ Independence from the agency is not intended to preclude use of established advisory committees like the Science Advisory Board at EPA. The charter of EPA’s Science Advisory Board states that its objective is to provide “independent advice to EPA’s Administrator on the scientific and technical aspects of environmental problems and issues.” Its membership consists of persons from the private sector who serve for two year terms. No full time federal employee is permitted to be on the Science Advisory Board, although most members do serve as special government employees and are eligible by statute to be compensated for their services. Permanent advisory committees and the members of such committees, even though they serve as special government employees, are not intended to be precluded from serving as peer reviewers under S. 746.

⁸⁸ See Statement of Dr. Bruce Alberts, President of the National Academy of Sciences, in Response to Senator Levin’s Questions following February 24, 1998 Hearing on S. 981.

mail, facsimile, electronic mail, or through FastLane, NSF's Web-based system for electronic proposal submission and review." Many proposals peer reviewed by the National Science Foundation are done so using a combination of both mail and panel methods. The peer review requirements of S. 746 are intended to allow agencies to use peer review procedures that are commensurate with the significance and complexity of the subject matter.

The Committee considered in some depth how to draw the line with respect to possible conflicts of interest of peer reviewers. S. 981 as introduced provided specifically that persons with a financial conflict of interest in a rulemaking could serve as peer reviewers so long as the conflicts were disclosed to the agency. Many persons who commented on the bill were not satisfied with that approach as a universal requirement. After consulting with individuals with expertise on the practices and conflicts standards of leading agencies that use peer review widely, including the National Institutes of Health, the National Academy of Sciences, the National Science Foundation, and EPA, the Committee concluded that agencies themselves⁸⁹ can adequately address potential conflicts in a fair and impartial manner, which is their responsibility today. The Committee is not aware of any problems with the current conflict of interest standards being used by federal agencies with respect to peer review, and expects that agencies new to peer review under S. 746 will seek guidance from OMB, OSTP and agencies with expertise in the field.

S. 746 requires that agency peer review programs ensure that reviews are conducted on a timely basis and that they contain balanced presentations of all considerations, including minority reports and an agency response to all significant comments. In addition, adequate protection must be provided to ensure that confidential business information and trade secrets are protected.

Subsection (b)(2) requires the agency to respond in writing to all significant peer review comments. The agency response must be made available to the public and be part of the rulemaking record for purposes of judicial review of any final agency action.

Subsection (b)(3) provides that where the agency head and the OMB Director both determine that a cost-benefit analysis, risk assessment, or any component thereof, previously has been subjected to adequate peer review, they can exempt them from the peer review requirements.

Subsection (c) provides for a neutral referee who can attest to the independence and quality of the peer review. For each peer review under this section, the agency head shall include in the rulemaking record a statement by a Federal officer or employee who is not an employee of the rulemaking office or program: (1) whether the peer review participants reflect the independence and expertise required

⁸⁹For example, EPA's approach for addressing possible conflicts of interest is contained in EPA's recently issued Science Policy Council Handbook on peer review. It presents alternative approaches to identifying and resolving potential conflicts, depending upon the specific situation. The EPA handbook recognizes that "It is important that peer reviewers be selected for independence and scientific/technical expertise." U.S. Environmental Protection Agency, Science Policy Council Handbook, EPA 100-B-98-001 (Jan. 1998), at p. 45. Yet EPA also acknowledges that "experts with a *stake in the outcome*—and therefore a potential conflict—may be some of the most knowledgeable and up-to-date experts because they have concrete reasons to maintain their expertise. Such experts could be used provided the potential conflicts of interest are disclosed and the peer review panel or group being used as whole is balanced." *Id.*, at p. 48.

under subsection (b)(1)(A), and (2) whether the agency has adequately responded to the peer review comments as required under subsection (b)(2).

Subsection (d) provides that the formality of the peer review shall be commensurate with the significance and complexity of the subject matter.

Subsection (e) provides that the peer reviews required by this section shall not be subject to the Federal Advisory Committee Act. With the input of respected scientific and technical experts, the Committee determined that a FACA exemption would help expedite peer reviews as well as enhance their technical rigor. Peer review is not intended to provide policy advice or analysis to an agency, and it is not a political debate among interested parties.⁹⁰ Moreover, the Committee believes that the FACA exemption will reduce the potential rigidity, time, and expense of peer reviews.

Subsection (f) makes clear that statutorily created agency advisory boards may be considered “independent of the agency” under subsection 625(b)(1)(A)(ii). Subsection (g) clarifies that the status of a person as a contractor or grantee of the agency shall not by itself exclude such person from serving as a peer reviewer for such agency because of the requirement under subsection 625(b)(1)(A)(ii).

Finally, Subsection (h) makes clear that Section 625 does not mandate more than one peer review of the cost-benefit analysis or the risk assessment during a rule making. To the extent feasible, peer reviews under Section 625 shall occur prior to the notice of proposed rule making.

§ 626. Deadlines for rulemaking

For a 2-year period after the effective date of the legislation, this section extends certain rulemaking deadlines for up to six months to allow agencies time needed to comply with the analytical requirements of the legislation. The affected deadlines include statutory and judicial deadlines for rulemakings, as well as rulemaking deadlines that would create an obligation to regulate through individual adjudications. To avoid any constitutional concerns about extending judicial deadlines by legislation, subsection (b) authorizes and directs the United States to ask the relevant court to extend any deadlines imposed by the court.

The sole purpose of section 626 is to give agencies time to make a reasonable effort to faithfully fulfill the requirements of this legislation. The Committee understands that the legislation asks for better quality and greater openness in many analyses already done, and in some cases, creates new obligations. The Committee intends that agencies be given a reasonable opportunity to develop policies and procedures adequate to comply with the law. The Committee does not intend this grace period to be used otherwise to delay decisions or to compromise the implementation of legal requirements.

⁹⁰See, e.g., Statement of Dr. Bruce Alberts, President of the National Academy of Sciences, in Response to Senator Levin's Questions following February 24, 1998 Hearing on S. 981. As defined by EPA, “Peer review is a documented critical review of a specific agency major scientific and/or technical work product. . . . It is usually characterized by a one-time interaction or a limited number of interactions by independent peer reviewers.” EPA, Science Policy Council Handbook, at p. 10.

§ 627. *Judicial review*

Section 627 establishes the framework for judicial review of agency compliance with the regulatory analysis, risk assessment, and peer review requirements of this legislation. Specifically, Section 627 is addressed solely to judicial review of “[c]ompliance by an agency with the provisions of [Subchapter II].” To the extent that an agency action is being challenged on grounds other than alleged noncompliance with the provisions of Subchapter II, Section 627 would not apply.⁹¹

Subsection (a) sets three basic conditions for judicial review of agency compliance with the provisions of Subchapter II: The judicial review must occur—(1) in connection with review of final agency action; (2) in accordance with the provisions of Section 627; and (3) in accordance with the limitations on timing, venue, and scope of review imposed by the statute authorizing the review. In setting forth the third condition, the Committee recognizes that in some cases, the statute authorizing review may not impose any special limitations on timing, venue, or scope of review; in other cases, these matters may be addressed in several different statutes.

Subsection (b) governs the availability and standard of review of agency “major rule” determinations. An agency’s determination of whether a rule is a major rule—and thus subject to the regulatory analysis and risk assessment requirements of Subchapter II—is subject to review only in connection with review of the final agency action to which it applies. At that time, a court may set aside the agency’s determination of whether the rule is “major” only if it is shown to be arbitrary or capricious.

In close cases, the Committee would expect that the agency would err on the side of good analysis and avoid the risk of remand or invalidation of the rule. As a practical matter, the agency’s major rule determination will be consequential where the agency wrongly determines that a rule is not “major” and does not bother to perform the cost-benefit analysis, cost-benefit determination, risk assessment, or peer review that Subchapter II requires for “major rules.” In such a case, Section 627(e) would require the court to remand or invalidate the rule, unless the court found that such failure to perform the analysis or assessment, to make the determination, or to provide for peer review, was not prejudicial.

By contrast, if the agency incorrectly determines that a rule is “major,” the impact on the rule itself is not likely to be adverse—since a rule would not be remanded or invalidated just because an agency performed a cost-benefit analysis and risk assessment, made a cost-benefit determination, and provided for peer review in circumstances where such action was not statutorily mandated. After all, the Executive Branch is free to undertake such actions today even where not required to do so by statute. Indeed, that is the premise of a series of executive orders on regulatory analysis and review that dates back to the Carter Administration, that grew in the Reagan Administration, and that is currently embodied in Executive Order 12866.

⁹¹ This point is underscored by the savings clause in Section 622(b), which states: “Nothing in this subchapter shall be construed to alter or modify . . . any opportunity for judicial review made applicable under other statutes.”

Under subsection (c), a designation by the Director of OMB that a rule is a major rule—or the failure to make such a designation—is not subject to judicial review. If the Director has designated a rule as “major,” the requirements of Subchapter II that apply to major rules must be met. Conversely, if neither the Director nor the agency has designated a rule as “major,” and the rule does not fall within Subsection 621(7)(A), then the requirements of Subchapter II would not apply.

Subsection (d) provides that any cost-benefit analysis, cost-benefit determination, or risk assessment required under Subchapter II for a rule shall not be subject to judicial review separate from review of the final rule to which the analysis or assessment applies. Such a cost-benefit analysis, cost-benefit determination, or risk assessment, however, would be part of the rulemaking record, and if the final rule to which they apply is brought before a court for review, the court would have to consider the analysis, determination, and any assessment—to the extent relevant—in determining under the statute granting rule making authority whether the final rule is arbitrary, capricious, an abuse of discretion, or unsupported by substantial evidence.⁹²

Section 627(e) states that if an agency fails to perform the cost-benefit analysis, cost-benefit determination, or risk assessment, or to provide for peer review as required under Subchapter II, the court “may, giving due regard to prejudicial error, remand or invalidate the rule.” The adequacy of compliance with the specific requirements of the subchapter shall not otherwise be grounds for remanding or invalidating a rule under the subchapter. If the court allows the rule to take effect, the court shall order the agency to promptly perform such analysis, determination, or assessment or to provide for peer review. If an agency fails to perform the cost-benefit analysis, cost-benefit determination, risk assessment, or peer review, the court may, with due regard to the principle of prejudicial error, invalidate or remand the rule. In this respect, S. 746 expands the role of a reviewing court by directing that a rule may be invalidated in circumstances where it might not be invalidated under current law.

Under Section 627, an agency’s failure to comply with a specific requirement of S. 746 regarding how to perform a risk assessment or cost-benefit analysis would not, in and of itself, be grounds for invalidating a rule. That is, a rule could not be invalidated simply because a “how to” requirement of Section 623 (governing cost-benefit analyses) or 624 (governing risk assessments) was not met, unless the statute granting the rule making authority imposes such a requirement. At the same time, however, in determining whether the final rule is arbitrary or capricious, the court would be free to consider the effect that the agency’s failure to comply with any such requirement (*e.g.*, a failure to consider reliable and reasonably

⁹²The “substantial evidence” standard would apply in those cases where a “substantial evidence” standard of review is provided by the enabling statute—such as under the Occupational Safety and Health Act, 29 U.S.C. § 655(f), or the Toxic Substances Control Act, 15 U.S.C. § 2618(c)—or where it is required by the Administrative Procedure Act, 5 U.S.C. § 706(2)(E).

The phrase “under the statute granting the rule making authority” clarifies that a rule should not be set aside where the action alleged to be arbitrary, capricious, or an abuse of discretion involves a matter that cannot be relevant to promulgating the rule under the authorizing statute.

available scientific information) had on the rulemaking. In addition, of course, the cost-benefit and risk assessment information would be available to the court and could be considered in determining whether the final rule is arbitrary or capricious.

The following three scenarios illustrate how the judicial review provision of S. 746 is intended to operate.

Scenario (1): S. 746 requires an agency to identify and evaluate reasonably identifiable substitution risks. Suppose that during a rulemaking, a person submitted information to the agency on the possibility of a substitution risk and the agency ignored it. Could that person later argue in a lawsuit challenging the rule that the agency action in adopting the final rule is arbitrary or capricious simply because the agency violated a requirement of S. 746 when it failed to consider a legitimate substitution risk?

No. Failure to comply with a specific procedural requirement of S. 746 regarding how to perform a risk assessment or cost-benefit analysis would not, in and of itself, be grounds for invalidating a rule.

However, the person could argue that the agency's failure to consider the legitimate substitution risk had the effect of making the resulting rule arbitrary or capricious—whether or not that failure also violated a specific procedural requirement of S. 746. Such an argument is available today, and would continue to be available after S. 746 is enacted.⁹³

Scenario (2): S. 746 requires agencies, when doing a risk assessment, to consider “reliable and reasonably available scientific information.” If an agency fails to consider such information which we know the agency had access to through the public comment period, can a person argue that the rule should be remanded or invalidated just because the agency violated a specific procedural requirement of S. 746 when it failed to consider such information?

No. As indicated in Scenario (1), failure to comply with the procedural requirements of S. 746 regarding how to conduct a risk assessment is not independent grounds for remanding or invalidating a rule.

On the other hand, the fact that Congress directed agencies to follow this requirement is an indication that it is important to the development of a risk estimate on which a rational and well-informed rulemaking decision can be based. Depending on the circumstances of the particular case, a court today might conclude that a rule is arbitrary or capricious where it is based on a risk assessment that did not consider reliable and reasonably available scientific information. Nothing in S. 746 is intended to preclude a court from reaching the same result in the future. To the contrary, S. 746 specifically directs agencies to consider “reliable and reasonably available scientific information” in conducting risk assessments, so it does not prevent a court from finding a rule to be arbitrary or capricious when such information is ignored.

Scenario (3): S. 746 requires the agency to make a determination as to whether the benefits of the rule justify the costs. The agency

⁹³ In addition, of course, the failure to consider a substitution risk could be a ground for invalidating the rule if the statute granting the rule making authority requires that substitution risks be considered. See, e.g., the Safe Drinking Water Act of 1996, § 1412(b)(3)(C)(i), 42 U.S.C. § 300g-1(b)(3)(C)(i).

doesn't make that determination. Can a person challenge the rule for the failure of the agency to make that determination based on the requirement of S. 746?

Yes. The bill explicitly states that the failure to make the determination allows the court to remand or invalidate the rule.

As the foregoing scenarios illustrate, an agency's failure to comply with the specific procedural requirements of S. 746 regarding how to conduct a risk assessment or cost-benefit analysis would not, in and of itself, be grounds for invalidating a rule. That is, the rule could not be invalidated under section 627(d) simply because a procedure required by S. 746 had been violated. At the same time, the court could consider the content of the cost-benefit analysis and risk assessment, any omissions in such analyses (such as those discussed in the above scenarios), or the arbitrary treatment of the content of those analyses, in determining whether the final rule is arbitrary or capricious. This is true under current law and would continue to be true once S. 746 is enacted.

In addition, if an agency fails to perform a required cost-benefit analysis or risk assessment, does not make a cost-benefit determination, or does not provide for peer review, a court could remand or invalidate the rule. In this respect, S. 746 changes the role of a reviewing court by providing that a rule be remanded or invalidated in circumstances where it might not be remanded or invalidated under current law.

In sum, in determining whether a rule is arbitrary or capricious, a court would remain free under S. 746—as it is under current law—to consider both what the agency did do, as reflected in the cost-benefit analysis and risk assessment, and what it did not do, such as failing to consider relevant, reliable, and reasonably available scientific information. But, with the exception of cases covered by Section 627(e)—where remand or invalidation of the rule is allowed—a court would not remand or invalidate a rule solely on the ground that the agency had not complied with a specific procedure of S. 746.

§ 628. Guidelines, interagency coordination, and research

Subsection 628(a)(1) requires the Director of the Office of Management and Budget, in consultation with the Council of Economic Advisors, the Director of the Office of Science and Technology Policy, and relevant agency heads, to develop and issue uniform guidelines to implement the cost-benefit analysis, risk assessment, and peer review requirements of this legislation. Such guidelines should embody, and expand upon, principles required by this legislation. The OMB Director is responsible for overseeing the implementation of these guidelines, and periodically revising them as appropriate and as warranted by advances in risk analysis, cost-benefit analysis, and related fields.

No later than 18 months after issuance of those uniform guidelines, each agency subject to section 624 is required to adopt detailed guidelines under subsection 628(a)(2) for risk assessments as required by section 624. Such guidelines shall be consistent with the uniform guidelines issued under subsection 628(a)(1). The Committee expects each agency to revise these risk assessment guide-

lines as appropriate and as warranted by advances in science and risk assessment methodology.

Subsection (a)(3) requires that all guidelines developed under subsection (a) must be developed following notice and public comment. OMB and the agencies are expected to make diligent efforts to solicit input from all informed parties. Agencies are not required, however to develop the guidelines through the legislative rule-making process. The Committee was concerned that the APA rule-making process may be too rigid and time-consuming for the expeditious development and updating of risk assessment guidelines. Accordingly, Subsection (a)(3) makes clear that the development, issuance, and publication of risk assessment and risk characterization guidelines developed under this section are subject only to limited judicial review under section 706(1) of title 5. The Committee expects the agencies to develop and maintain state-of-the-art guidelines.

Subsection (b) is designed to improve the conduct, application, and practice of cost-benefit analysis and risk assessment across all relevant agencies. Subsection (b)(1) requires the OMB Director, in consultation with the Council of Economic Advisors and the Director of the Office of Science and Technology Policy, to oversee periodic evaluations of the manner in which agencies are conducting cost-benefit analyses and risk assessments. Such a survey will allow for a determination of the scope and adequacy of cost-benefit analysis and risk assessment practices of the federal agencies. It also will promote the injection of new scientific and technical advances into the analytical practices of the agencies.

Subsections (b)(3) and (b)(4) require OMB to establish with CEA and OSTP appropriate interagency mechanisms to promote coordination between agencies and to ensure consistent use of state-of-the-art cost-benefit and risk assessment practices.

Subsection (c)(1) requires OMB, in consultation with the agencies, CEA, and OSTP, to develop and periodically evaluate a strategy to meet agency needs for research and training in cost-benefit analysis and risk assessment. This strategy should address the need for research on modeling, the development of generic data, use of assumptions, the identification and quantification of uncertainty and variability, and other areas. OMB also should identify long-term needs to adequately train individuals in risk assessment techniques.

Subsection (c)(2) requires the OMB, in consultation with OSTP, to enter a contract with an accredited scientific institution, to conduct research to: (1) develop a common basis to assist risk communication related to both carcinogens and non-carcinogens; and (2) develop methods to appropriately incorporate risk assessments into related cost-benefit analyses.⁹⁴ The OMB shall enter into the contract no later than 6 months after enactment of section 628, and the results of the research shall be submitted to OMB and to Congress no later than 24 months after the date of enactment.

⁹⁴ See Risk Commission Report, Vol 2, at 43, 99.

§ 629. *Risk-based priorities study*

The Committee believes that setting risk-based priorities offers an excellent opportunity to promote better allocation of resources of both the government and the private sector to increase the protection of human health, safety and the environment. The importance of such a risk-based approach has been advocated in numerous studies and publications,⁹⁵ as well as in testimony before the Governmental Affairs Committee.⁹⁶ The Committee believes that the tool of comparative risk analysis can help us find ways to make our health, safety and environmental protection dollars go farther and provide greater overall protection, saving even more lives than the current system.⁹⁷ As the blue-ribbon Carnegie Commission panel noted in its report, *Risk and the Environment: Improving Regulatory Decision Making*, “The economic burden of regulation is so great and the time and money available to address the many genuine environmental and health threats so limited, that hard resource allocation choices are imperative.” (p. 118).

The 1995 National Academy of Public Administration (“NAPA”) report to Congress, entitled *Setting Priorities, Getting Results*, recommends that the Environmental Protection Agency use comparative risk analysis to identify priorities and use the budget process to allocate resources to the agency’s priorities. The NAPA study commends EPA for having pioneered risk prioritization studies and comparative risk analyses. However, the report states that during the budgetary process, EPA did not push for shifts in resources to the higher-priority programs. The report recommends that Congress “could enact specific legislation that would require risk-ranking reports every two to three years. Congress should use the information when it passes environmental statutes or reviews EPA’s budget proposals.” (p. 49).

The purpose of the analyses required by this section is to provide Congress and the President with the information to make more informed choices. The Committee anticipates that, among other things, these analyses will be useful for identifying unaddressed risks, risks borne disproportionately by a segment of the population, and research needs. This will provide better information for deciding where to focus regulatory efforts and agency resources. Finally, conducted through an open process, these analyses are likely

⁹⁵See, e.g., J. Clarence Davies & Jan Mazurek, *Pollution Control in the United States*, Resources for the Future (1998), at 101–22; Cass R. Sunstein, “Health-Health Tradeoffs,” U. Chi. L. Rev. 1533 (1996); Resources for the Future, *Comparing Environmental Risks* (J. Clarence Davies, ed. 1996); John D. Graham, “Making Sense of Risk: An Agenda for Congress,” in *Risks, Costs and Lives Saved*, (Robert W. Hahn, ed. 1996); National Academy of Public Administration, *Setting Priorities, Getting Results* (April 1995); Harvard Center for Risk Analysis, *Reform of Risk Regulation: Achieving More Protection at Less Cost* (March 1995); Carnegie Commission on Science, Technology, and Government, *Risk and Environment: Improving Regulatory Decision-making*, Washington, D.C. (June 1993); Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation*, Harv. Univ. Press (1993).

⁹⁶See, e.g., Testimony of John D. Graham, Director, Harvard Center for Risk Analysis, before the Senate Committee on Governmental Affairs, September 12, 1997.

⁹⁷The need for a national comparative risk analysis was one of the chief recommendations of the Report of the Harvard Group on Risk Management Reform entitled, *Reform of Risk Regulation: Achieving More Protection at Less Cost* (March 1995). The Harvard report states that the purpose of such an analysis would be “to learn how diverse risks should be compared, how ordinary citizens should participate in risk ranking, what inherent limitations to the process might be, and how guidelines can be developed to govern a broad-based process of risk-based priority setting in the federal government.” (p. 27).

to enhance public debate about these choices and ultimately create greater public confidence in government policy.

The comparative risk study should compare significant risks to human health, safety or the environment and make recommendations on setting priorities to reduce them. The comparison is limited to “significant” risks, and the study should examine which of those risks are the most serious and most amenable to cost-effective reduction.

Section 629 furthers the use of comparative risk analysis to inform planning and budgetary decision making. To begin, it calls for contracting with an accredited scientific institution to conduct a study with three components. The first and most important component is a comparative risk analysis, which is a process to systematically estimate, compare, and rank the size and severity of risks to provide a common basis for evaluating strategies for reducing or preventing those risks.⁹⁸

Since the purpose is to assist the Federal government in evaluating how to use its resources effectively to address the most serious problems, to the extent feasible, the comparison should include all such risks that are, or could reasonably be, addressed by the various agencies and programs whose purpose is to protect human health and safety or the environment, including natural resources. Comparative risk analysis is not purely a scientific undertaking. The Committee believes that, while hard data will form the underpinnings of the analysis, public values must also be incorporated when assessing the relative seriousness of the risks and when setting priorities. Scientific data alone cannot tell us which risks should be addressed first, for example: neurological damage, heart disease, or birth defects; a plane crash or cancer. The comparative risk analysis should be conducted in a way that enables public values to be ascertained and considered. This will require public input into the comparative risk analysis. Nevertheless, when the analysis is completed, it should be clear to the public and policy makers which part of the risk comparison reflects science and which part reflects values.

The second component is a study of methodologies for using comparative risk analysis to compare dissimilar risks to further development and use of this tool. Because comparative risk analysis is still a relatively new science, particularly when used to compare dissimilar risks, sub section (a)(2) requires that, even while the comparative risk analysis is being conducted, a study be done to improve the methods and use of comparative risk analysis. The Committee anticipates that this study will draw on the analyses already conducted by numerous states. The results of this part of the study should also facilitate risk comparisons required by Section 624(g).

The third component of the study is a set of recommendations on the use of comparative risk analysis for setting priorities. These recommendations should provide sufficient guidance to enable the President, the agency heads, and Congress to evaluate how to bet-

⁹⁸See OSTP report, *Science, Risk, and Public Policy*. The report defines policy trade-offs, and stakeholder concerns. The goal is to conduct a broad examination of governmental policies and expenditures to reduce risk. (p. 11).

ter allocate resources across agencies and among programs to achieve the most cost-effective risk prevention and reduction.

To assure its credibility, the study must be conducted by an accredited body selected by the Director of OMB in consultation with the Office of Science and Technology Policy. Subsection (b) requires that the study provide an opportunity for public comment and public participation. For the comparative risk analysis to be reliable and credible, the Committee thinks it is important that the study be conducted through an open process, utilizing expertise in appropriate fields, such as toxicology, biology, engineering, medicine, industrial hygiene and environmental effects. The Committee also recognizes that experts in the relevant social sciences may be needed to help incorporate public values into the process. The analysis should be conducted consistent with the risk assessment principles in Section 624. The methodologies and scientific determinations made in the analysis are to be subjected to external peer review, in compliance with Section 625, and made available for public comment. The results of the comparative risk analysis under subsection 629(a)(1) should be presented in a manner that distinguishes between the scientific conclusions and any policy or value judgments embodied in the comparisons.⁹⁹

The study must be completed within three years following enactment of this section. Within one year thereafter, agencies are to use the results of the study to inform the agencies in the development of their budgets and strategic plans and performance plans under the Government Performance and Results Act, which should provide an excellent framework for achieving more cost-effective risk reduction.

Finally, to implement any lessons learned from the exercise, Subsection 629(d) directs the President to recommend legislative changes to assist in setting priorities so that the federal government can “more effectively and efficiently” reduce risks to human health, safety, or the environment. The Committee views this report to Congress as an important element in setting the federal government’s priorities so that we can achieve the greatest degree of protection for health, safety and the environment with our resources. Congress needs this information to evaluate its agenda.

Subchapter III. Executive Oversight

This subchapter establishes in law the responsibility of the President to supervise the regulatory process of the federal agencies. Such responsibility includes coordinating agency regulatory policies and procedures, including those required by this legislation; developing a process for the review of rules; and developing and overseeing an annual government-wide regulatory planning process.

⁹⁹The Carnegie Commission report, *Risk and the Environment*, recommends that agencies “experiment with different mechanisms for integrating societal values into the process of setting risk-based regulatory priorities.” (p. 89). The report states that value choices should not be made covertly by unaccountable “experts.” The report offers that “One possibility is for the experts to make explicit, to the extent possible, all value judgments and their relative weights in the ranking process.” (p. 89).

The 1995 NAPA report supports the Carnegie Commission recommendation: “Because comparing risks is a value-laden process as well as a technical challenge, EPA should conduct its comparative risk analyses as policy exercises with the active engagement of the public or its representatives. Doing so would provide legitimate results that would become a base for agency priorities and budget proposals.” (p. 49).

Oversight of the federal regulatory process by the President, including review of proposed rules by an office designated by the President, has been in effect in one form or another for about twenty years. Since 1981, it has been conducted in a centralized process by OMB through the Office of Information and Regulatory Affairs under Executive Order Nos. 12291, 12498, and, most recently, 12866. The bill recognizes that centralized regulatory review has become an integral part of the Federal regulatory process and provides an important double-check on the work of the regulatory agencies in the effort to achieve cost-effective regulations. The Committee is mindful that in the past, presidents have argued against regulatory review legislation because of potential inroads on presidential prerogatives. The Committee believes, however, that placing a regulatory review mandate into this legislation will help put to rest arguments about the fundamental nature or need for effective and transparent regulatory review. Nonetheless, respectful of separation of powers, the Committee has placed into statute only a general framework of executive oversight, with basic guidelines for regulatory review and public disclosure. This allows the President the flexibility to craft the details and scope of any regulatory review scheme, consistent with the requirements of this legislation.

Subchapter III has four sections: Section 631, definitions; Section 632, presidential regulatory review; Section 633, public disclosure of information; and Section 634, judicial review.

Section 631 provides several definitions for Subchapter III. First, it applies the same definitions in Section 551 of current law and Section 621 of the bill to the provisions in Subchapter III. The section also defines the term “regulatory action” to include advance notice of proposed rulemaking, notice of proposed rulemaking, and final rulemaking, including interim final rulemaking. These are the activities for which the Director of OMB, acting through the OIRA Administrator, is responsible to review and coordinate under this subchapter.

Subsection 632(a) makes clear that Subchapter III applies to all proposed and final major rules, including interim direct and interim final rules, and to all other rules designated by the President, acting through the Director, for review.

Subsection 632(b) requires the President to establish a process for such review and coordination and requires that the day-to-day responsibility for that reside in the Director of OMB, acting through the Administrator of OIRA. Section 632(c) enumerates specific activities that the Director/Administrator is required to carry out, namely: the development and oversight of uniform regulatory policies and procedures throughout the federal government, including those by which each agency shall comply with the requirements of chapter 6; the development of policies and procedures for the review of rulemakings or regulatory actions by the Director/Administrator; and the development and oversight of an annual government-wide regulatory planning process. The planning process in 632(c)(3) is to include:

A summary of and schedule for the promulgation of major rules.

Agency specific schedules for the review of existing rules required under section 610 of title 5, United States Code, and under other authorities.

A summary of regulatory review actions undertaken in the prior year.

A list of major rules promulgated in the prior year for which an agency could not make the determinations that the benefits of a rule justify the costs under section 623(d) of this Act.

An identification of significant agency noncompliance with Chapter 6 of title 5, United States Code, in the prior year.

Recommendations for improving compliance with this chapter and increasing the efficiency and effectiveness of the regulatory process.

Section 632(d)(1) states that the OMB review of regulatory actions should be conducted as expeditiously as practicable and should be limited to no more than 90 calendar days. Under subsection (d)(2), the review may be extended by either the Administrator of OIRA or at the request of the rulemaking agency to the Administrator, and such extension must be published promptly in the Federal Register.

Section 633 mandates important disclosure requirements for the OMB review process. This has been an area of particular concern to the Committee for almost 20 years, beginning with President Reagan's issuance of E.O. 12291. Many in Congress were concerned about guaranteeing the openness of the regulatory review process to instill public confidence and equal access in such review. The Committee held numerous hearings over the years on OMB's review process, culminating in an agreement in 1986 with then OIRA Administrator, Wendy Gramm, over basic disclosure procedures specifically identified in a Memorandum to all agencies and made available to the public. This debate reemerged in connection with oversight of the Council on Competitiveness in 1991–92 and consideration of legislation to require disclosure in regulatory review. In 1996, Senator Thompson, then Chairman of the Subcommittee on Financial Management and Accountability, conducted oversight on President Clinton's E.O. 12866 on regulatory review. That oversight, and related GAO investigations, showed that agencies were not complying with the disclosure requirements of E.O. 12866.¹⁰⁰

The disclosure procedures in the 1986 Gramm memo were included in E.O. 12866 when it was issued in 1993. Also included in E.O. 12866 was the additional requirement that the public be informed on an ongoing basis as to the status of regulatory actions undergoing review (a requirement never resolved in the 1986 Gramm memo). Section 633 would codify those disclosure procedures developed and agreed to over time. Generically, Subsection 633(a) requires the Director of OMB, acting through the OIRA Administrator, to establish procedures for public and agency access to information concerning the review of regulatory actions. Specifi-

¹⁰⁰ See GAO, *Regulatory Reform: Changes Made to Agencies' Rules Are Not Always Clearly Documented*, GAO/GGD-98-31 (Jan. 1998); Hearing before the Senate Committee on Governmental Affairs, Subcommittee on Financial Management and Accountability, "Oversight of Regulatory Review Activities of the Office of Information and Regulatory Affairs," 104th Cong., 2d Sess. (Sept. 25, 1996).

cally it requires that certain elements must be included in such procedures. These are:

Disclosure to the public on an ongoing basis of information regarding the status of regulatory actions undergoing review.

Disclosure to the public no later than publication of a regulatory action of—(1) all written correspondence relating to the substance of a regulatory action (including the drafts of proposed and final rules and the associated analyses) between the OIRA Administrator or employees of the Administrator and the regulatory agency; (2) all written correspondence relating to the substance of a regulatory action between the Administrator and employees of the Administrator and any person not employed by the executive branch of the Federal Government; and (3) a list identifying the dates, names of individuals involved, and subject matter discussed in significant meetings and telephone conversations relating to the substance of a regulatory action between the OIRA Administrator or employees of the Administrator and any person not employed by the Executive Branch.

Disclosure to the regulatory agency, on a timely basis of—(1) all written correspondence relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government; and (2) a list identifying the dates, names of individuals involved, and subject matter discussed in significant meetings and telephone conversations, relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the Executive Branch.

Subsection 633(b) requires the rulemaking agency, before publication of any proposed or final rule, to include in the rulemaking record the following—

A document identifying in a complete, clear, and simple manner, the substantive changes between the draft submitted to the Administrator for review and the rule subsequently announced.

A document identifying and describing those substantive changes in the rule that were made as a result of the regulatory review and a statement if the Administrator suggested or recommended no changes.

All written correspondence relating to the substance of a regulatory action between the Administrator and the agency during the review of the rule, including drafts of all proposals and associated analyses.

Finally, Subsection 633(c) requires that a representative of the agency submitting the regulatory action shall be invited to any meeting relating to the substance of a regulatory action under review between the Administrator or employees of the Administrator and any person not employed by the Executive Branch.

Section 634 states the exercise of the authority granted under this Subchapter by the President, the OMB Director, or the OIRA Administrator shall not be subject to judicial review.

Section 3(b). Presidential authority

Section 3(b) provides that nothing in this Act shall limit the exercise by the President of the authority and responsibility that the President otherwise possesses under the Constitution and other laws of the United States with respect to regulatory policies, procedures, and programs of departments, agencies, and offices. The President retains the authority to extend regulatory analysis and review requirements beyond those established in this Act.

Section 3(c). Technical and conforming amendments

Section 3(c) provides the technical and conforming amendments to Chapter 6 of title 5, United States Code. Up to this point, Chapter 6 consisted of the Regulatory Flexibility Act. With this legislation, Chapter 6 is substantially amended to create Subchapter I, which includes the regulatory flexibility analysis. It also creates two new subchapters: Subchapter II—Regulatory Analysis—and Subchapter III—Executive Oversight.

SECTION 4. COMPLIANCE WITH THE UNFUNDED MANDATES REFORM
ACT OF 1995

To avoid duplicative cost-benefit analyses under the Unfunded Mandates Reform Act of 1995, Section 4 states that compliance with the cost-benefit provisions of the Regulatory Improvement Act constitutes compliance with the cost-benefit provisions applicable to the private sector in sections 202, 205(a)(2) and 208 of UMRA (2 U.S.C. §§ 1532, 1535(a) and 1538).

SECTION 5. REPORT TO CONGRESS

Section 5 requires that by February 5, 2002, the President, acting through the Director of the Office of Management and Budget, shall prepare and submit to Congress an accounting statement and report containing an estimate of the total annual incremental benefits and costs of complying with the provisions of subchapter II of the Regulatory Improvement Act for each agency.

SECTION 6. EFFECTIVE DATE

Except as otherwise provided in this legislation, this Act shall take effect 180 days after the date of the enactment of this Act, but shall not apply to any agency rule for which a notice of proposed rule making is published on or before 60 days before the date of enactment of this Act.

VI. REGULATORY IMPACT STATEMENT

Pursuant to paragraph 11(b), rule XXVI of the Standing Rules of the Senate, the Committee, after due consideration, concludes that S. 746 will have a significant regulatory impact.

VII. CBO COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 9, 1999.

Hon. FRED THOMPSON,
Chairman, Committee on Governmental Affairs,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 746, the Regulatory Improvement Act of 1999.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is John R. Righter.

Sincerely,

BARRY B. ANDERSON
(For Dan L. Crippen, Director).

S. 746—Regulatory Improvement Act of 1999

Summary—CBO estimates that implementing S. 746 would, on average, cost about \$6 million a year, assuming appropriation of the necessary amounts. Enacting the bill would not affect direct spending or receipts; therefore, pay-as-you-go procedures would not apply. The bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on the budgets of state, local, or tribal governments.

S. 746 would amend chapter 6 of title 5, U.S. Code, to require federal agencies to complete specific studies, including cost-benefit analyses and risk assessments, as part of the regulatory analysis performed before certain major rules are issued. The bill would define a major rule as a regulatory action expected to result in an annual impact on the economy of \$100 million or more in costs, or a rule designated as major by the Office of Management and Budget (OMB). The bill will exempt many rules from the new requirements, however, and would primarily apply to those agencies that issue major rules governing health, safety, and the environment. In cases where an agency issues a rule that is expected to have an annual impact on the economy of \$500 million or more in costs, the legislation would require that the agency submit the rule for peer review. For major rules covered by S. 746, agency compliance with the bill's regulatory analysis provisions would be subject to limited judicial review.

CBO expects that implementing S. 746 would have a small impact on the federal government's cost to perform regulatory analyses because the bill would: (1) codify much of existing practice, (2) generally not apply to so-called minor rules, (3) exempt most major rules from its review, and (4) allow agencies to opt out of its requirements in certain situations. Based on our review of the number and type of major rules issued in fiscal years 1997 and 1998 and on past costs of regulatory analyses, CBO estimates that, subject to appropriation of the necessary amounts, implementing S. 746 would increase the government's costs to perform regulatory analyses by around \$5 million annually. Such costs would result from the additional documentation and analyses required by S. 746

and from requiring that independent agencies perform cost-benefit analyses for certain major rules.

In addition, the bill would require the Office of Information and Regulatory Affairs (OIRA) within OMB to write regulations, periodically evaluate training needs at agencies that perform regulatory analyses, contract for a pair of studies, submit an accounting statement to the Congress that contains an estimate of agencies' incremental costs in complying with the bill's regulatory analysis provisions, and review applicable major rules issued by independent agencies. The legislation also would direct agencies that regulate health, safety, and the environment to devise detailed guidelines for performing risk-assessment analyses. CBO estimates that implementing these administrative requirements would cost federal agencies an average of less than \$1 million a year over the 2000–2004 period.

Under some circumstances, S. 746 could result in additional costs to federal agencies beyond those in this estimate. OMB could require that agencies perform risk assessments according to the bill's detailed procedures for agency actions, other than major rules, that it anticipates could have an annual effect on the economy of \$100 million or more in costs. CBO assumes however, that the bill's procedures for conducting risk assessments would be applied only in the case of major rules. If OMB required agencies to apply the bill's risk assessment procedures to other agency actions that include an assessment of risk, the additional costs would likely be significant. The estimate also does include costs that might be incurred as the result of additional judicial review because CBO has no basis for predicting how many regulatory actions might be challenged under this bill.

Estimated cost to the Federal Government—CBO estimates implementing S. 746 would increase the costs of regulatory analysis at agencies that issue major rules government health, safety, and the environment, as well as increase federal reporting and administrative costs. In total, implementing the bill would require appropriations of about \$6 million a year over the next five years.

Regulatory Analysis

Much of the regulatory analysis and review that would be required by S. 746 is already required by Executive Order 12866 ("Regulatory Planning and Review") and the accompanying best practices for performing economic analyses of significant regulatory actions ("Economic Analysis of Federal Regulations Under Executive Order 12866"), as well as title II of UMRA.

In addition, the bill would exempt many federal regulatory actions from its requirements, including rules that apply to regulate: (1) military or foreign affairs, (2) federal agency management or personnel, (3) public property, loans, grants, benefits, or contracts, (4) governmental receipts, (5) certain commerce activities, including wages and prices, mergers and acquisitions, and accounting practices, (6) securities trading, (7) monetary and federal fiscal policy, (8) banking, and (9) the removal or introduction of products under the Federal Food, Drug, and Cosmetic Act.

In addition, the bill would exempt certain regulations of the Federal Election Commission and the Federal Communications Com-

mission (FCC) and any rule that an agency must issue at least annually. Based on a review of the summaries provided by the General Accounting Office (GAO) of approximately 115 major rules issued by agencies during fiscal years 1997 and 1998 (GAO's list, which is required by Public Law 104-121, does not include all major rules issued over the two years), CBO estimates that at least two-thirds of major rules would be exempt from the bill's requirements.

In addition to the specified exemptions, agencies could exempt rules from the bill's provisions where the more detailed reviews are either not practical or contrary to an important public interest. In such cases, the bill would direct the agency to comply with its provisions as soon as possible after adopting the rule, unless OMB determines that such compliance would be unreasonable.

CBO expects that enacting S. 746 would have a small impact on the cost to perform regulatory analyses for agencies that issue major rules governing health, safety, and the environment, such as the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration, and the Departments of Health and Human Services, Energy, Transportation, and Agriculture, as well as certain independent agencies that are excluded from the requirements of Executive Order 12866.

Based on our review of the type and number of major rules issued during fiscal years 1997 and 1998, we expect the bill's provisions would apply to about 20 rules a year, although the volume of regulatory activity can fluctuate depending on the demands on regulatory agencies. On average, we expect that the EPA would issue about one-third of the major rules covered by S. 746.

In 1997, CBO published a paper that examined the costs of 85 regulatory impact analyses (RIAs) conducted by selected agencies (*Regulatory Impact Analysis: Costs at Selected Agencies and Implications for the Legislative Process*, March 1997). The cost of these RIAs ranged from \$14,000 to \$6 million, with the time required to complete them ranging from six weeks to more than 12 years. (Because the paper did not attempt to obtain a representative sample of RIAs, it does not indicate the cost of a typical or average RIA.) Based on our review of the number and type of rules that would likely be affected by the provisions of S. 7246, the bill's requirements for conducting regulatory analyses, and our analysis of the costs of RIAs, CBO estimates that implementing S. 746 would, on average, increase regulatory analysis costs for agencies that issue rules governing health, safety, and the environment by around \$5 million a year. That estimated increase would cover the costs for health, safety, and environmental agencies to conduct additional analyses, including assessments of comparative risks and analysis of substitution risks, as well as to provide additional documentation of the agencies' assumptions, models, findings, public comments, and conclusions. On average, we estimate that the provisions of S. 746 would add a few hundred thousand dollars to the cost of such rules, although the amount per rule could vary greatly.

Independent agencies, which currently are not required to prepare a cost-benefit analyses for major rules, would also need to begin preparing such analyses for a handful of rules each year. This requirement would predominantly affect the FCC, although it

also would occasionally affect rules issued by the Nuclear Regulatory Commission (NRC). While implementing the cost-benefit analysis provisions of S. 746 would increase regulatory costs at both agencies, particularly the FCC, both the FCC and NRC are authorized to collect fees to offset the cost of their regulatory programs. Thus, CBO estimates that implementing S. 746 would result in no significant net budgetary effect for independent agencies.

Finally, S. 746 would require that agencies submit for peer review any cost-benefit analysis or risk assessment developed for a rule that is covered by the bill's provisions and is reasonably expected to have an annual impact on the economy of \$500 million or more in costs. The bill would require that the peer review panel represent all points of view and that agencies respond in writing to all significant comments from peer review. With the concurrence of OMB, an agency could certify that a cost-benefit analysis or risk assessment has received adequate peer review outside of the bill's procedures. Based on our review of GAO's summaries of major rules for fiscal years 1997 and 1998, the bill's requirement for peer review would appear to have applied to only four of those rules—all issued by EPA, which already submits its rules for formal peer review. Although the provisions would, at times, apply to rules issued by other agencies, most or all of which do not currently submit their rules for peer review, CBO expects that implementing this provision would result in only a negligible increase in the annual cost for agencies to issue major rules.

Reporting, Oversight, and Implementation

S. 746 would impose several reporting and oversight requirements, which would be performed mostly by OIRA. Specifically, the bill would require that OIRA:

- (1) issue guidelines for cost-benefit analyses, risk assessments, and peer reviews and periodically evaluate agency efforts in implementing these guidelines;
- (2) develop a strategy to meet agency needs for research and training in performing regulatory-impact analyses;
- (3) contract with accredited scientific institutions to study the use of risk assessments and comparative-risk analysis in performing regulatory analyses;
- (4) prepare and submit to the Congress by February 5, 2002, an estimate of the total annual incremental costs and administrative benefits for each agency of complying with the bill's provisions; and
- (5) review the regulatory analyses of certain major rules issued by independent agencies.

The bill would require that the results of the research on risk assessments be forwarded to OMB and the Congress within two years of enactment and that the results of the research on comparative-risk analyses be forwarded within three years. In addition, the bill would require agencies that issue health, safety, and environmental regulations to adopt within 18 months detailed guidelines for performing risk assessments as part of their regulatory impact analyses. In total, CBO estimates that the bill's reporting, oversight, and implementation requirements would cost agencies an average of less than \$1 million a year over the 2000–2004 period.

Such costs would be about \$1 million for each of the next three years, but would fall below \$500,000 in subsequent years.

Pay-as-you-go considerations—None.

Intergovernmental and private-sector impact—S. 746 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on the budgets of state, local, or tribal governments.

Estimate prepared by—John R. Righter.

Estimate approved by—Paul N. Van de Water, Assistant Director for Budget Analysis.

VIII. MINORITY VIEWS

We understand that the goal of our colleagues in crafting S. 746 is to improve the regulatory process. We appreciate the efforts that the sponsors of this bill have made, including a number of changes in response to some of the concerns that we and others expressed about this legislation in the last Congress. The sponsors and we share the goal of protecting the health and safety and environment of Americans through effective and efficient regulation, but how to accomplish this goal is where there are differences.

S. 746 would require Federal agencies issuing major rules to take a number of new, complex, and time-consuming analytic and procedural steps and would authorize more judicial review. We oppose this bill because of our concerns that the consequences of this kind of omnibus regulatory reform legislation will be to threaten the ability of our health and safety, environmental, and consumer protection agencies to act in a timely and decisive manner to protect us, our children, and the natural resources we all cherish.

As elected representatives, we have an obligation to the people we serve to protect them from harm, and that includes protecting people from breathing polluted air, drinking poisonous water, eating contaminated food, working under hazardous conditions, exposing children to unsafe toys, and becoming victims of consumer fraud. Americans depend on regulatory agencies to prevent harm before it occurs. As we have evaluated and heard testimony on S. 746 and predecessor legislation in recent years, the risks to these protections of trying to achieve regulatory reform through one-size-fits-all requirements has become increasingly evident.

Witnesses testified that the highly prescriptive requirements for risk assessment, cost-benefit analysis, net benefit determinations, and peer review could further delay what is already a slow process of establishing needed public protections.¹ For example, the bill would require agencies to conduct time-consuming risk assessments even where Congress has decided that regulatory standards should be based on available technology rather than on estimates of risk. We also heard concerns that new avenues for judicial review may create significant new opportunities for opponents of public protections to challenge them in court. The provisions on peer

¹ Our laws provide a host of procedural protections to make certain that all individuals have an opportunity to participate in the rule making process and then to challenge decisions that they believe are wrong in federal court. Guaranteeing that all citizens have these procedural due process rights with respect to rule making makes the process of issuing regulations a lengthy one. It is, therefore, rare that citizens object that a health or safety agency has acted with too much speed on their behalf. On the contrary, citizens often complain that agencies do not act rapidly enough. Sue Doneth, the mother of hepatitis A victim, and Nancy Donley, whose child died from eating an E. Coli contaminated hamburger, spoke eloquently to the Committee on this point. (This testimony was presented at hearing on S. 981 in the 105th Congress, which was a predecessor bill to S. 746.) So did Dr. Franklin Mirer, Director of the Health and Safety Department of the United Automobile, Aerospace & Agricultural Implement Workers of America, who testified that he current standard setting process at OSHA to protect workers from chemical exposure is stalled and failing to protect workers.

review and on OMB review of agency regulations would make the regulatory process less fair and transparent than it is now. And perhaps most troubling, witnesses explained that the emphasis on cost-benefit analysis and net benefits, coupled with new opportunities for judicial review, could lead agency officials to choose regulatory alternatives that are less protective of the public. We believe that the combined effect of these new hurdles will actually make it more difficult for the environmental, health, safety, and consumer agencies to establish the protections Americans want.

These are not just abstract concerns. The Committee has heard about a number of specific examples where S. 746 would adversely affect programs to establish protective regulation—illustrating how this bill would be the wrong kind of regulatory reform. Some of these examples will be discussed below. We have also heard a wide array of environmental organizations, public health groups, and other public interest organizations and labor unions express very serious concerns about the harmful consequences of this legislation.

We offered a number of amendments at Committee markup to try to fix some of the problems that we identified. Unfortunately, except for an amendment requiring a report on the cost of the legislation to agencies, none of the amendments was adopted. When this legislation comes before the entire Senate, we will try again to fix the problems that have been identified by offering a number of amendments.

Furthermore, in considering across-the-board regulatory reform legislation such as S. 746, which would impose new analytic and procedural requirements on regulatory agencies across-the-board, we must also recognize that there will surely be unforeseen consequences. As far as we know, neither the proponents of this legislation nor anyone else has produced a law-by-law analysis showing how this bill would affect individual programs—whether involving the environment, worker safety and health, highway and aviation safety, food safety, protection of nursing home residents, nuclear safety, civil rights including rights of individuals with a disability, and all the other areas where we rely on regulation to protect the public. We are therefore concerned about the unforeseen consequences—the problems that we may not learn about until some months or years after the legislation has passed, when the resulting harm to our efforts to establish essential regulatory protections will become manifest.

For these reasons we oppose S. 746.

THERE IS A BETTER WAY TO IMPROVE REGULATIONS

We would all agree on the importance of adopting and enforcing health and safety and consumer protections in an equitable, efficient, and fact-based way, that is as open to as much public understanding and participation as possible. Such improvements might be called “regulatory reform.” But we have concluded that the better way to enact such regulatory reform is targeted and in the framework of specific regulatory statutes, not in an across-the-board omnibus bill such as S. 746.

Statute-by-statute reform does not create problems of over-inclusiveness, as does omnibus legislation like S. 746. And it works. The 1996 Safe Drinking Water Act Amendments is an outstanding ex-

ample of regulatory reform legislation that was very targeted and dealt with the problems unique to drinking water quality. The Congress carefully considered how risk assessment and cost-benefit analysis could make the statute more effective and incorporated those principles, based on the overall objectives and operation of that law. For example, an issue unique to the Safe Drinking Water Act is the different capacities of large and small water systems. As a result, the law specifically tailored the Environmental Protection Agency's authority to use cost-benefit analysis based on differences in these systems. We are concerned that such refinement and targeting will be missed in this type of broad government-wide proposal.

In another example of specifically tailored regulatory reform legislation from the 104th Congress, we also passed and the President signed the 1996 Food Quality Protection Act. In the enactment of this legislation, like the Safe Drinking Water Act Amendments, negotiations led to bipartisan agreements for tailored provisions to increase future cost-effectiveness, while giving EPA flexibility to address high-priority risks. The Accountable Pipeline Safety and Partnership Act of 1996 is yet another example of legislation that included narrowly targeted regulatory reform provisions. Such refinement and targeting is impossible in across-the-board regulatory reform legislation like S. 746, and serious unintended consequences may result.

Although the statute-by-statute approach may be more time-consuming and difficult in the short-run than an omnibus bill, the result is well worth it. The Environment and Public Works Committee spent three years on the reauthorization process for the Safe Drinking Water Act, listening to all views on how this law was or was not working, but the bill passed the Senate unanimously with the support of virtually every interested group. The Food Quality Protection Act also passed the Senate by a wide margin. The importance of that type of consensus cannot be overstated. Among other advantages, it makes everyone want to work to implement effectively a law that they supported and have a stake in.

By contrast, there is no consensus with respect to S. 746. As we noted, the bill is opposed by a wide array of environmental, public-health, and other public-interest and labor organizations. The testimony of one Committee witness, Patricia Kenworthy on behalf of the National Environmental Trust, indicates just how far from consensus we are. Ms. Kenworthy testified: "it is our belief that this legislation will result in extensive delays in the time it takes for regulatory decisions to be made and will thus undermine federal agencies' ability to protect public health, worker safety and the environment." In a similar vein, Dr. Frank Mirer of the UAW testified: "Now our members are asking why legislation is being considered to make it even more difficult to get new protections against hazards that put their lives, limbs and health in danger."

In addition to the statute-by-statute approach, in recent years Congress passed and President Clinton signed a number of more targeted regulatory reform bills to address some of the concerns raised by the business community and state and local governments about the regulatory process. The Unfunded Mandates Reform Act of 1995 includes provisions for cost-benefit analysis of major rules.

The Paperwork Reduction Act, which was designed, in part, to assure that Federal regulations requiring the collection of information will minimize the burden on respondents and maximize the usefulness to agencies, was reauthorized in 1995, including specific requirements for paperwork reduction. The Small Business Regulatory Enforcement Fairness Act (SBREFA), passed in 1996, combines several new laws intended to ease regulatory burdens on small businesses. Under this legislation, agencies must write regulations so that those affected can more easily understand them and know how to comply, and must establish programs to provide for the reduction and, in some circumstances, for the waiver of penalties for violation of requirements by a small entity. SBREFA also provides for enhanced judicial review for regulations affecting small businesses and provides for Congressional review of agency rule-making whereby Congress acknowledges and assumes more responsibility for the rules that agencies issue. Finally, in 1996, 1997, and 1998, Congress passed regulatory accounting measures requiring OMB to submit a report on the costs and benefits of regulations.

The Clinton Administration has also undertaken a number of initiatives to improve the Federal regulatory system. In 1993, President Clinton issued Executive Order No. 12866 setting forth a regulatory philosophy that, consistent with existing law, regulations should be issued only where necessary and be based on a full assessment of costs and benefits of reasonable alternatives. This Executive Order is a powerful tool for OMB to ensure that agencies' regulations both protect public health and make good economic sense, but the Order does not add new judicial hurdles for agencies to overcome. The Administration has also undertaken to improve programs at every regulatory agency as part of the National Partnership for Reinventing Government. EPA, for example, has reported that it established stronger partnerships, especially with States; provided for greater public access to environmental information; gave more attention to compliance assistance to help businesses and communities meet their environmental responsibilities; used more flexible, tailored approaches to solving environmental problems; and substantially reduced regulatory paperwork.

Proponents of S. 746 have referred to assertions in GAO reports that some of these new requirements are not being implemented as effectively as they could be. We do not know whether GAO is correct in these conclusions—and we will not know until this Committee takes the appropriate next step, which is to conduct oversight hearings to determine how these laws are working, where the gaps, if any, may be, and whether more needs to be done. Let us try to make the laws work that we just passed in the last several years, rather than throwing up our hands and imposing yet another set of overlapping requirements on our environmental and public health and safety agencies.

SPECIFIC CONCERNS WITH S. 746

In addition to our general concerns about the unforeseen consequences arising from omnibus, across-the-board regulatory reform legislation, we also have particular concerns about specific provisions of S. 746.

1. *Judicial review*

Throughout the years of debate on regulatory reform, many have expressed their opposition to creating new grounds for litigation. We fully support the thorough judicial review that the Administrative Procedure Act (APA) provides for all rules. Under the APA, an agency's decision will be set aside if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Courts find that an agency has passed these tests if the agency's analyses, assessment and responses to comments have provided the court with a reasoned discussion of choices the agency has made and a sufficient explanation of the reasons for those choices so that the court can conclude that the agency had a reasonable basis for making its decision. Any relevant risk assessment or cost-benefit analysis that is prepared must be sufficient to withstand this APA test.

- a. Judicial review of the bill's cost-benefit tests create new opportunities and arguments for regulated interests to overturn safeguards in court, and create incentives for agencies to choose less protective options.*

S. 746 imposes new, more burdensome hurdles that the agency must overcome, beyond what is required under present law. We are particularly concerned that the judicial review allowed by S. 746 could create new opportunities and arguments for overturning regulations and could result in agencies' selecting rules that are less protective of the public than those the agencies would have selected without the bill. S. 746 would do this, first, by mandating that agencies must justify their decisions using the specific cost-benefit terminology set forth in the bill, and then by placing those agency justifications before the reviewing courts—thereby providing new substantive arguments that regulated interests could use in challenging the agency's decision as arbitrary and capricious. In particular, S. 746 would first require the agency to publish a determination of: (1) whether the agency's rule is likely to provide "benefits that justify the costs," (2) whether the rule is likely to achieve its objectives in "a more cost-effective manner" or with "greater net benefits" than alternatives, and (3) whether the rule "adopts a flexible regulatory option." If any answer is no, the agency head must: (4) explain why. The bill then requires that each of these determinations and explanations by the agency must go into the record for judicial review. By requiring the agency to make determinations about whether these demanding new tests are satisfied, and then by making the agency's determinations subject to judicial review, S. 746 raises our concern about unintended consequences: a competent lawyer representing opponents of the regulation will frequently be able to find some basis for arguing that the agency's conclusions about whether the "benefits justify the costs," and whether the selected rule is "more cost-effective" or achieves "greater net benefits" was arbitrary and capricious. We fear that courts may allow these complex cost-benefit determinations, as well as the bill's cost-benefit terminology, to be injected into the argument about whether the rule is arbitrary and capricious, thereby encouraging new substantive arguments for challenging an agency's rule.

For example, suppose EPA were setting a standard for reducing pollution from hazardous industrial waste, and must choose be-

tween a less-stringent standard and a more-stringent standard. Typically, all of the costs, but only some of the benefits, would be quantifiable. Let's say, in our example, that the most significant benefit—avoiding reproductive problems causing birth defects in children—cannot be fully quantified, so that the more stringent standard has lower net quantifiable benefits than the less stringent standard. The law now generally instructs EPA to develop hazardous-waste standards “as may be necessary to protect human health and the environment.” Therefore, under current law, if EPA selected the more stringent alternative, the debate before a reviewing court would focus on whether it was arbitrary or capricious for the agency to decide that the standard yielding greater reduction in reproductive problems and birth defects is “necessary to protect human health and the environment.”

If S. 746 were enacted, however, EPA would be required to state the agency's determination whether benefits of the more stringent standard justify costs, and whether the standard is “more cost-effective” or has “greater net benefits” than the alternative, and the agency would also have to explain any decision to adopt a rule that did not pass these tests. Then the bill instructs that all of these determinations and explanations by the agency shall be part of the rule making record for the court to consider in deciding whether the rule is arbitrary and capricious. S. 746 might thereby direct the court's attention away from whether the agency's decision satisfies the standards of applicable environmental law, and towards evaluating the agency's determinations and explanations mandated by the economics-based requirements of the bill. Thus, a court case that under today's law would focus on the mandate to adopt standards “as necessary to protect human health and the environment” could be transformed into a debate on whether it was reasonable for the agency to conclude that “greater net benefits” are achieved when the nonquantifiable health and social values are balanced against the economic costs of the selected regulatory standard.

We do not believe that the law should grant regulated entities new opportunities to challenge an EPA decision as being arbitrary and capricious, by finding fault with the agency's determination that the chosen standard is “more cost-effective” or would achieve “greater net benefits” than alternatives, or by arguing that it was unreasonable for the agency to select a standard that does not pass these new tests. In essence, the court would be second-guessing whether the agency, for example, was “correct” in the quantifiable and nonquantifiable value it assigned to avoiding birth defects in children and whether the agency properly balanced that value against economic costs to ascertain the “net benefits” or the “cost-effectiveness” of the rule. Current environmental law does not require the agency to determine whether those tests are satisfied, and we see no reason to provide litigants with new opportunities and arguments for overturning good rules. We oppose giving courts the ability to be the arbiters of fundamental value decisions such as the value of avoiding birth defects in children, or the value of preserving a child's IQ, or the value of seeing a clear Grand Canyon. But this is what could occur under S. 746.

We also oppose creating incentives for agencies to avoid judicial challenge by adopting less protection for these values. Again, this

is what could occur under S. 746, and is another concern raised by the judicial review provisions of S. 746—another unintended consequence. The agencies may choose a less protective option in order to avoid the risks of a court fight. This could lead to regulations that will be unnecessarily weakened, resulting in potential dangers to the public and less protection of the environment.² As Dr. Mirer testified on behalf of the UAW, the bill would, in the OSHA context, “shift the balance in standard setting decisions from worker protection to industry costs.”

b. Courts might overturn rules if the agency has not performed the required analyses to the letter of the statute.

We are also concerned that this bill may authorize the courts to overturn a rule if the agency fails to perform some particular requirement in the bill regarding cost-benefit analysis and risk assessment. This problem is most evident when the language of S. 746 is compared to provisions considered by the Committee in prior Congresses. Judicial review language in the Glenn/Chafee proposal from the 104th Congress, and proposed by the Administration in a letter on March 6, 1998 from former Director of OMB Franklin Raines to the Chairman of this Committee, allowed for judicial remand only if the agency “entirely fails to perform” the required cost-benefit analysis or risk assessment. Earlier Glenn-Chafee language, introduced in S. 1001 from the 104th Congress, and incorporated into S. 291 as reported in that Congress by this Committee, provided for remand only if the required analysis was “wholly omitted.”

S. 746 dropped the phrases “entirely fails to perform” and “wholly omitted” used in these earlier proposals and instead authorizes judicial remand if the agency “fails to perform” a cost-benefit analysis or risk assessment. Both the terms “cost-benefit analysis” and “risk assessment” are defined in the bill in considerable detail, and an opponent of an agency’s regulation could therefore argue that the agency failed to perform the “cost-benefit analysis” or “risk assessment” based on a failure to perform any one of the numerous requirements in the bill. One of the Committee witnesses, David Vladeck, a lawyer with extensive experience arguing cases in front of courts of appeals, testified that: “courts are likely to measure whether an agency has ‘performed’ these analyses against the yardsticks established in the statute. If the agency has not followed the statute to the letter, a court might well rule that it has not ‘performed’ the required analysis and set aside the rule on that basis alone.”

² One of the ironies of this bill is that it could actually discourage use of voluntary, incentive-based programs, despite the sponsors’ clear intention to encourage these programs. One of the Committee witnesses in hearings last Congress on a predecessor bill to S. 746, Karen Florini of the Environmental Defense Fund, testified that the cost-effectiveness or net benefits test, combined with judicial review, may actually discourage the use of information-based and incentive-oriented approaches such as the very popular Right-to-Know laws. She testified: It’s typically difficult to predict just how, and to what extent, incentives will lead to a particular outcome because, by definition, compliance isn’t mandatory. But if you can only generally describe the benefits, how can you do a ‘net benefits’ or ‘cost-effectiveness’ determination with enough specificity to withstand attacks by lawyers seeking to derail the rule?” Testimony of Karen Florini, Senior Attorney, Environmental Defense Fund, before the Senate Committee on Governmental Affairs on February 24, 1998, in Hearing on S. 981, 105th Cong., 2nd Sess., S. Hrg. 105–486, at page 131.

Senator Lieberman offered an amendment at markup to make clear that the bill would not give rise to these new bases for overturning an agency's rule. The amendment would have made changes in the judicial review provision of the bill like the Glenn/Chafee judicial review language recommended by the Administration in the March 6, 1998, letter from former OMB Director Raines to the Chairman of this Committee. Unfortunately, the amendment was rejected. The sponsors contend that their intent is to have limited judicial review.³ We therefore remain troubled by their rejection of an amendment that would express their intent clearly in the text of the bill.

2. Peer review

We strongly support a process for ensuring that the agencies' approaches to risk assessment are vetted on a regular basis with those who are the best in their field and willing to devote the time to such a review. But we are concerned that this bill does not achieve such a goal and instead will result in burdensome new processes for peer review without any benefits and without appropriate safeguards of fairness and due process. The reaction to this legislation of many scientists we have heard from has been strongly negative.⁴

a. For proposed Occupational Safety and Health standards (and other rules thoroughly vetted through public hearing processes), the peer review required by S. 746 would superimpose yet another time-consuming, burdensome, and completely unnecessary process.

S. 746 would impose new requirements for "peer review" applicable to all risk assessments required by the bill and to cost-benefit analyses of those major rules having a large (\$500 million) annual effect on the economy. We are concerned, first, about the interaction of this peer review requirement with other established approaches that may not currently be called peer review, but that serve to provide a similar type of review—another example where unintended consequences emerge when we start looking at how this bill would apply to individual agencies and programs. The pur-

³ "The [cost-benefit] analysis and [risk] assessment are included in the rulemaking record, but there is no judicial review of the content of those items or the procedural steps followed or not followed by the agency in developing the analysis or assessment. Only the total failure to actually do the cost-benefit analysis or risk assessment would allow the court to remand the rule to the agency." Statement of Senator Levin upon introducing S. 746, Congressional Record, page S3482, March 25, 1999 (emphasis added).

⁴ For example, in a letter to the sponsors of S. 981 in the 105th Congress, a group of scientists, including representatives from across the country, concluded that the legislation, "particularly the provisions governing participation on peer review panels, takes a peculiar and even damaging approach to science." Letter to Senators Levin and Thompson, signed by 74 scientists, physicians, and public health professionals, dated March 3, 1998. Most of the problems in S. 981 identified by these scientists remain in S. 746, including: (1) that the peer review requirements are redundant and wasteful, since the science and the risk assessments underlying major regulations are already being vetted routinely by intra-agency review panels and independent scientific bodies; (2) that the agency's own experts are excluded from participating on peer review panels, yet employees of the regulated industry may participate, as long as the federal agency's procedures permit it; (3) that a requirement in predecessor bills that the membership of panels be "balanced" has been dropped from the legislation; and (4) that panel deliberations could take place "behind closed doors" and review is made exempt from the Federal Advisory Committee Act, which guarantees public scrutiny and participation in established advisory committees. The letter also criticized S. 981 because university researchers might be disqualified from participating on panels because of research grants received in that university, but S. 746 has been fixed to make clear that grantees are not disqualified.

pose of peer review in S. 746 is to create an opportunity for individual experts from relevant scientific and technical disciplines to provide their expert advice to the agency. However, such an opportunity is already built into the hearing process that the Labor Department must follow in adopting or amending OSHA standards.

We heard testimony about the OSHA procedures from Dr. Franklin E. Mirer, Director of the Health and Safety Department of the UAW. Under current law and procedure, proposed OSHA standards must be presented in a public hearing if any affected party requests a hearing. The agency must present evidence supporting the proposed standard including the health risks, control measures, cost analyses and other details. Scientific experts, unions, employers, and individual employees also are allowed to testify. Any participant in the rule making proceeding may ask questions of the others, and OSHA staff may ask questions as well. This OSHA process, which is mandated by statute and agency regulation, fulfills the same function as “peer review,” and the OSHA procedures are better in some ways than those in S. 746, because the hearing follows public notice and is open and on the record. To require the agency to conduct an additional round of peer review to meet the specifics of the bill would further delay a rule making process that already takes a very long time. Dr. Mirer testified that “the extra peer review step mandated by the legislation takes extra time and extra OSHA and stakeholder resources, which could be better spent addressing additional hazards.”

Senator Lieberman offered an amendment at markup to establish that the OSHA hearing procedure and similar procedures under other laws would be recognized under the bill as satisfying the peer review requirements. We were disappointed that the amendment was not accepted.

b. Peer review under S. 746 lacks necessary protections of due process, fairness, and transparency.

In arguing against Senator Lieberman’s amendment at markup, proponents of S. 746 argued that the OSHA hearing comes too late in the process because, for peer review to have its desired effect, it must occur before the proposed rule is published when agency staff positions remain amenable to influence. But this argument actually shows how the OSHA hearing procedure is preferable. Unlike the hearing, peer review as required by S. 746 is actually contrary to the principles of due process and public participation established under the Administrative Procedure Act. The OSHA hearing occurs only after public notice, is open to the public, and is fully on the public record. Under the APA, it is at this stage, after public notice, that interested parties are to submit their comments and evidence to the agency, and the agency is then legally obligated to consider these comments and evidence in deciding whether and how to modify the original proposal. All interested parties—both the regulated industry and the people to be protected by the regulation—receive the notice at the same time and have the same opportunity to submit their views and information.

By contrast, S. 746 calls for peer review before the public is even notified of the agency’s proposed rule, and authorizes the peer review to occur without public announcement and including rep-

representatives of the regulated industry. Although we are convinced that the sponsors of S. 746 advocate this kind of peer review in a good-faith effort to improve regulations, we are concerned that the peer review requirements in the bill would actually foster suspicion that some interested parties may get unfair access and influence in the rule making; and we believe it is understandable that Dr. Mirer, on behalf of the UAW, testified that: "Quite frankly, this extra step is just one more foothold for interests who simply want no change and whose only goal is to stop any new regulation."

Furthermore, the requirement in the bill that the peer review panel be independent of the agency could also diminish the quality of the panel. The federal government has some of the best scientists in the world and there is no reason to exclude a scientist working in one office from serving on the peer review panel reviewing a risk assessment done by another office. Former OMB Director Raines pointed out in his March 6, 1998 letter to the Chairman of this Committee, that the independence requirement could mean that in some highly specialized areas, such as nuclear safety, good peer review would become virtually impossible.

On the other hand, the bill provides no assurance that a person with a direct financial interest in the outcome of the rulemaking or employed by an entity with a direct financial interest in the outcome of the rulemaking will not be allowed to serve on a peer review panel. This raises serious concerns about potential conflicts of interest.

Supporters of S. 746 have asserted that decisions about conflicts of interest are best left to agencies. But agencies cannot always be relied upon to avoid conflicts of interest undermining the integrity of peer review. For example, Senator Lieberman described to the Committee his experience in a Senate investigation relating to pesticides where there were allegations that people on the peer review panels, including some experts from the academic world, were nonetheless also doing work for the regulated industries.⁵ Furthermore, the Majority Report gives no assurance that all agencies have any conflict-of-interest rules, but offers merely the "expectation" that agencies new to peer review will seek guidance from their more experienced sister-agencies.

Senator Cleland offered an amendment at markup designed to address some of these concerns by excluding participation in peer review by individuals with a direct and substantial conflict of interest. We were disappointed and puzzled that the sponsors did not accept this amendment.⁶ Furthermore, the bill provides no safeguards to counteract the potentially corrosive effects of conflicts of interest in the peer review panel. The bill does not require that conflicts be disclosed or that panel meetings be announced and

⁵ Hearing on S 981, 105th Cong., 1st Sess., S. Hrg. 105-335, Sept. 12, 1977, at page 18.

⁶ The sponsor's argument in response to Senator Cleland's amendment was puzzling. They quoted from EPA's Peer Review Handbook, which states that sometimes experts with a "stake in the outcome—and therefore a potential conflict" may be used for peer review because they may be the most knowledgeable and up-to-date. However, Senator Cleland's amendment did not exclude those with a "potential conflict," such as EPA may use in peer review; his amendment would exclude those with a "direct" and "significant" conflict of interest. This limitation in the proposed amendment is similar to the limitation in this EPA Handbook, which states that in some cases "the conflict may be so direct and substantial as to rule out a particular expert." EPA Peer Review Handbook, prepared by the EPA Science Policy Council, page 48 (January 1998).

opened to the public or that the membership of panels be balanced.⁷

In fact, S. 746 would actually make some peer review less transparent and balanced than it is under present law. Peer review carried out by formal and established advisory committees such as the EPA Science Advisory Board is now subject to the Federal Advisory Committee Act (FACA), which requires that panel membership be balanced and that meetings be announced and open to the public. However, if S. 746 were enacted, even peer review conducted by established advisory committees would become exempt from these existing guarantees of fairness and openness.

3. Risk assessments; over-broad and time-consuming analytic requirements generally

S. 746 would require the agency to conduct a risk assessment for each proposed and final major rule “the primary purpose of which is to address health, safety, or environmental risk.” In addition, the Director of OMB would have authority to impose the prescriptive requirements of the bill on any agency risk assessment anticipated to have an annual effect on the economy of \$100 million, even if the risk assessment is not part of a rulemaking.

In the all-too-common situation where adequate scientific data are not available, the requirements of S. 746 are ambiguous. It is unclear whether the risk assessment provisions direct the agency to base its decision on whatever data are available or to collect additional data. This uncertainty presents the agency and its scientists with a Hobson’s choice. If they rely on available data, they put the rule in jeopardy of judicial challenge by regulated interests who will argue that the agency failed to collect sufficient data to perform a risk assessment meeting the minimum requirements of S. 746. However, the only way to limit this risk of judicial remand is to delay the rule while additional data are collected, even if the new data are not essential to making any critical regulatory or policy decision. These serious consequences are described in a recent report from the Congressional Research Service (CRS), which concludes: “Such uncertainty [in S. 746, as ordered to be reported,] is likely to lead to legal challenge.”⁸

⁷The Glenn/Chafee regulatory reform proposal from the 104th Congress and S. 981 as introduced in the 105th Congress required that peer review panels be “balanced.” However, this requirement was dropped from S. 981 as reported by this Committee in the 105th Congress and, now, from S. 746. Instead, S. 746 requires that the peer review must “contain a balanced presentation of all considerations,” but does not require that the membership on the panel be balanced.

⁸The CRS report states:

“Some proposals attempt to ensure scientific objectivity by mandating it. For example, S. 746, as ordered to be reported, would require scientists to consider ‘all relevant’ and ‘all reliable’ scientific data and to perform an ‘objective’ assessment ‘based on the weight of the scientific evidence.’ However, the effect of these legislated mandates on agency behavior is unpredictable due to the variety of circumstances surrounding risk assessments and the legal consequences of EPA actions. For example, the validity of the ‘weight-of-the-(scientific)-evidence’ approach in practice depends on the quality and comprehensiveness (or representativeness) of the data. Therefore, a legal requirement to rely on the approach may be interpreted by scientists as a directive either to base decisions on *available* data even if data are inadequate and misleading, or to collect additional data to meet minimum data requirements, even if the aspect of the risk assessment for which data are unavailable is unimportant to the risk analysis as a whole or to significant regulatory or policy decisions. Such uncertainty is likely to lead to legal challenges.”

CRS Issue Brief, “The Role of Risk Analysis and Risk Management in Environmental Protection” (Order Code IB94036, updated June 9, 1999), at page CRS-3.

- a. The risk assessment provisions of S. 746 would impose burdensome requirements even where those requirements cannot enhance the rule*

In those circumstances where Congress has already mandated that the regulatory agency must base its standard on best available performance practices rather than on an assessment of risk, it makes no sense to require the agency to conduct an expensive, complex, and time-consuming risk assessment before the standards can be proposed and adopted. This is a particularly good demonstration of why one-size-fits-all regulatory reform may unduly delay critical public protections, and why it is better to craft targeted reforms appropriate in the framework of particular regulatory statutes.

In its comments on S. 981 in the last Congress, the Administration proposed to exclude from the coverage of the risk-assessment requirements those major rules that are not premised on the outcome of a risk assessment. (These comments were presented in the March 6, 1998 letter from former OMB Director Franklin Raines to the Chairman of this Committee.) The examples offered in the letter are the technology-based standards that EPA is required to adopt for toxic air pollutants and water pollutants.

Let us consider first the example of air toxics regulation. When amending the Clean Air Act in 1990, Congress recognized that toxic air pollution was not being adequately controlled. Literally thousands of pollution sources were releasing chemicals into the air that were known or suspected causes of cancer, birth defects, or other serious health problems. Many of these sources were without controls (despite the availability of cost-effective technology to control the pollution), partly because it took too long for the agency to research and analyze the nature and extent of the risks. Instead, Congress decided there was already enough evidence of risk to justify regulating a list of particularly harmful chemicals and instructed EPA to set standards for sources of those chemicals based on existing technologies, to reflect the “maximum achievable control technology” (MACT).⁹ A second phase of controls, based on risk, are to be established, only if necessary, eight years after the MACT standards are required. Congress made a similar decision in the Clean Water Act, which requires EPA to set technology-based standards for water pollutants.

We worry that if S. 746 applied to the air toxics or water pollutant programs, EPA could be required to delay issuing technology-based standards until the agency conducted risk assessments on the potential for harm posed by each pollutant B despite Congress’s intent to the contrary. We believe that Congress should not pass omnibus reform legislation that would effectively overturn earlier decisions enacted by Congress to require agencies to develop standards without further consideration of the risk posed by each pollutant. At markup, Senators Lieberman and Akaka proposed an amendment to exempt an agency from the risk-assessment requirements insofar as Congress has not authorized the agency to take

⁹ In preparing the MACT standards, the agency is to consider costs, non-air quality health and environmental impacts, and energy requirements. See Section 112(d)(2) of the Clean Air Act, 42 U.S.C. § 7412(d)(2).

risk into account in developing a regulation. Again, we were disappointed that this amendment was not adopted.

In arguing against the amendment, a sponsor of S. 746 proposed that risk assessments should be required, even if not useful to the agency preparing the regulations, because the assessments will provide useful information to Congress and the public. However, in situations where Congress decided that the agency should issue standards to reduce toxic emissions without evaluating the potential for harm posed by those toxic emissions, we would oppose holding those public-health standards hostage while the agency prepares risk assessments that are irrelevant to the agency's decision and would result in considerable delay. We believe it is inappropriate for this Committee, on the record before us, to use this legislation to effect wholesale changes in the approach enacted by prior Congresses for regulating air toxics or water pollutants. The current air toxics provisions, for example, were adopted after many years of debate. Yet this Committee has not held a single hearing on whether EPA's technology-based standards are working. If, on this record, Members of the Committee believe that further evaluation of the potential for harm posed by toxic emissions would be valuable not to the agency developing the rules, but to Congress for legislative purposes or to the public, then let us consider commissioning the necessary research in some way that does not delay the issuance of the essential public-health regulations.

Another example of the harm that could result from over-broad requirements in S. 746 involves right-to-know laws. At the hearing on S. 746, Senators Durbin and Lieberman asked whether the listing of toxic chemicals under the Emergency Planning and Community Right-to-Know law should be delayed while complex risk assessments and cost-benefit analyses are conducted. The purpose of this law is to provide information about toxic chemicals and releases to local communities and to encourage voluntary actions by companies to reduce releases of these chemicals, and the law has been successful.

The sponsors of S. 746 responded (as noted in the Majority Report) that right-to-know regulations are not covered by the risk assessment requirements. This seems a highly debatable point, so Senator Lieberman proposed an amendment at markup to clarify that the risk assessment requirements would not cover community right-to-know or similar programs that address risks to health, safety, and the environment by requiring the collection, reporting, and dissemination of information. This amendment would have exempted the community right-to-know law, OSHA's worker right-to-know requirements, and other environmental and consumer protection programs that require reporting, disclosure, and dissemination of information about health and safety risks and precautions. For example, a number of programs require labeling of commercial products to provide consumers accurate information about risks and precautions they can take.

Unfortunately, this amendment was not adopted. The debate on the right-to-know law again points to the fundamental problems with across-the-board regulatory reform; we simply do not, and cannot, now know the unintended consequences if S. 746 were enacted.

- b. Application of S. 746 to “stand-alone” risk assessments could be used to delay scientific research and analysis important to protecting public health and the environment and could engender legal challenge to future regulations based on that analysis.*

The risk assessment requirements of S. 746 apply not only to a rule, but also to a “stand-alone” risk assessment, provided the OMB Director “reasonably anticipates” that the risk assessment “is likely to have an annual effect on the economy of \$100,000,000 or more in reasonably quantifiable costs.” We fear this provision could be used to significantly delay important scientific research and analysis needed to protect human health and the environment.¹⁰

Moreover, S. 746 imposes no deadline for the OMB Director to determine whether a “stand-alone” risk assessment is subject to the bill. A Director might assert that he has the authority to require a Federal regulatory agency or research institute to comply with the bill’s specifications and procedures even after a risk assessment is well underway or is even completed. Finally, if regulations are eventually promulgated based on an earlier risk assessment that the OMB Director determined was subject to the bill, opponents of the regulations could attempt to use the judicial review provisions of S. 746 in seeking to have the regulations overturned. These provisions of S. 746 are a prescription for disruption and delay of research, analysis, and regulatory actions by our public health, safety, and environmental agencies.

Additional concerns about the risk assessment provisions were expressed in the March 6, 1998 letter from former OMB Director Franklin Raines, which criticized these provisions for being too specifically tailored to analysis of cancer risks, and thus ill-suited to evaluation of other kinds of risks such as environmental and natural resource protection, worker safety, or airworthiness. No changes were made in S. 746 to respond to these concerns.

- c. S. 746 does not just provide “information”; it will also move agencies towards less protective decisions and will delay critical rules.*

In response to some of our concerns about risk assessments and other analytic requirements of the bill, proponents contend that the required analyses are simply designed to provide “information.” However, this response is not reassuring, for several reasons. First, the combination of mandated judicial review and the new complex regulatory requirements will move agencies towards making decisions that are less protective of public health, the environment, wildlife, and consumers. This is a substantive outcome about how protective our laws will be, not simply a requirement to provide information. Furthermore, other Congresses determined in the context of specific laws, in areas such as clean air, clean water, and wildlife protection, that some of the analysis required in this bill

¹⁰ The Majority Report adds to our concern by stating that the Director might apply the legislation where a risk assessment “may establish the basis for significant regulatory action at the Federal, state, or international level.” If this requires our Federal regulatory agencies and research institutes to demonstrate that their risk assessments are not likely to be the basis for regulatory actions aggregating \$100 million in annual effect at some future date anywhere in the world, the legislation could be made applicable to many “stand-alone” risk assessments each year.

should not be done. Congress determined, in some instances, that the agencies already had enough information on which to proceed, or that delay was too risky to public health and the environment, or that the delay resulting from requiring the analyses (such as risk assessment) had actually proved counter-productive to Congress's goals, or that the analyses were fundamentally incompatible with the basic guarantees provided by this nation (among other reasons). Senator Torricelli highlighted this last concern at markup by demonstrating the fundamental inappropriateness of applying cost-benefit analysis to civil rights protections. Thus, to impose the analytical requirements of this legislation can both affect the substantive outcome of a rulemaking and impose undue delay, in some instances in direct contradiction of decisions made by prior Congresses.

Proponents of S. 746 also respond to our concerns about delay by referring to testimony of one witness, Dr. Lester Crawford, expressing his opinion that the bill would have sped up, rather than delayed, issuance of food-safety regulations including the U.S. Department of Agriculture's 1996 meat and Poultry Hazard Analysis Critical Control Point (HACCP) rule. He observed that agencies' proposed regulatory actions were often held up during review within the executive departments or at OMB by arguments over such matters as cost-benefit analysis, risk assessment, and judicial review; and he expressed his opinion that requiring these matters to be addressed early would actually accelerate the development of useful regulations. However, we believe it is far more likely that the highly prescriptive requirements for regulatory analysis in S. 746, enforceable by judicial review, will create even more grist for controversy during administrative review and will encourage and empower cautious reviewers to return even well-analyzed regulatory proposals to the agency for yet more complete analysis. Our view is shared by a number of public health experts and consumer representatives who have been active participants in rule making to assure food safety. For example, on June 9, 1998, in response to similar comments by Dr. Crawford regarding S. 981 (a predecessor bill in the 105th Congress), the American Public Health Association (APHA) wrote to each Senator: "Food safety regulations are a prime example of regulations that could be substantially delayed under S. 981."¹¹

4. TRANSPARENCY AND ACCOUNTABILITY IN OMB REVIEW OF AGENCY REGULATIONS

Vice President Quayle's Council on Competitiveness in the 1980's was accused of bottling up regulations from agencies such as EPA and of providing an off-the-record mechanism by which outside in-

¹¹ Likewise, on May 19, 1999, the APHA, the Consumer Federation of America, the Consumers Union, and the United Food and Commercial Workers, among others, sent a letter to all Senators in opposition to S. 746, stating: "The bill's mandates would also delay the agencies' [FDA and USDA] already slow regulatory process." Furthermore, in a June 24, 1998 letter to all Senators, Nancy Donley, President of S.T.O.P.—Safe Tables Our Priority, wrote: "S.T.O.P. was and is actively involved in USDA rulemaking and implementation for meat and poultry regulations. . . . [U]nder S. 981's prescription, common sense and practical science would not have been enough. The 2½ year meat and poultry HACCP rulemaking process would have been further delayed."

terests could impose pressure on agencies without public scrutiny. This Committee was in the forefront of opposing these abuses.

President Clinton, upon taking office in 1993, sought to end these abuses by issuing Executive Order 12866. This executive order guaranteed that regulations could not be bottled up by OMB indefinitely, and it established a number of procedural guarantees to avoid off-the-record pressure on the agencies.

Some supporters of S. 746 have said that it only codifies this executive order. However, the bill actually differs from the executive order in a number of important ways. Perhaps most significantly, the implementation of the executive order's requirements is not subject to judicial review, the executive order does not require risk assessment, and it does not require peer review.

Furthermore, specifically in the area of regulatory-review procedures, S. 746 includes some of the guarantees established in E.O. 12866, but omits or cuts back on several of the most important ones:

The executive order provides that OMB may only review a regulation for 90 days, subject to a single 30-day extension. S. 981 as introduced in the last Congress contained the same provisions. However, the language was modified in the version of S. 981 reported by this Committee and in S. 746 so that OMB may unilaterally extend the review period indefinitely.

The executive order requires OMB to provide a written explanation for all regulations that OMB returns to the agency. (In fact, this requirement has been in place since it was established in a 1986 memorandum by former OIRA Administrator Wendy Gramm.) A similar requirement was included in S. 981 as introduced and reported by this Committee last Congress—yet it has now been dropped from S. 746.

Under the executive order, OMB must log and disclose to the agency all “substantive” oral communications, such as meetings and telephone conversations, relating to the regulation under review. (Indeed, OMB has been committed to disclosing to the agency “all oral communications” since the 1986 memorandum by former OIRA Administrator Gramm.) A requirement to log and disclose all “substantive” oral communications was included in S. 981 as introduced and reported by this Committee last Congress. However, in S. 746 the logging requirement has now been weakened, so that OMB may decline to log a substantive communication if OMB deems it to be not “significant.”

The logging requirement in S. 746 applies only to communications with OMB's Office of Information and Regulatory Analysis. If OMB assigned regulatory review responsibilities to any other office, the requirements to log correspondence and communications could be circumvented.

Under the executive order, if OMB decides to declare that an agency's proposed regulatory action is a major rule subject to regulatory review, it must do so at an early stage, when the disruption to the agency's rulemaking process will be relatively limited. Specifically, if an agency decides that its proposed regulatory action is not a major rule, that decision will stand unless overruled by OMB within 10 days after receiving the agen-

cy's list of planned regulatory actions. By contrast, S. 746 would allow OMB to declare that a proposed action is a major rule as late as 30 days after the end of the comment period for the rule—giving OMB the power to force the agency to go back and prepare a cost-benefit analysis and risk assessment at that stage, when disruption to the agency's rulemaking process will be far greater.

We are concerned that these provisions would allow a future Administration to depart from the procedures in E.O. 12866 and to restore the abuses of Vice President Quayle's Council on Competitiveness. Specifically, an Administration could bottle up rules in endless review, could return rules to the agency without explanation, and could use regulatory review as a back-channel conduit for opponents of regulations to communicate their views off the record.

Senators Lieberman and Edwards advocated amendments at the markup to rectify some of these problems in the bill. The sponsors did express a willingness to consider these concerns further, but we were disappointed that the amendments were not accepted.

One final point—we are concerned that the bill and the Majority Report may skew the cost-benefit analysis by including costs that are speculative and often inflated. For example, the Majority Report states that agencies should include both compliance costs and “opportunity costs” of the regulation. This concept of “opportunity costs” could lead to very speculative cost estimates, including, for example, forecasts of how a business project not even in existence might have worked out had the government regulations not been issued. Projections of opportunity costs could also require time-consuming and extensive information-gathering and analyses of financial and business data collected from companies by the government, which some might view as intrusive. Difficult confidentiality issues and claims might also arise in the context of collecting and analyzing information on opportunity costs, resulting in potentially more litigation. Moreover, the Majority Report fails to acknowledge many of the uncertainties associated with estimating compliance costs. For example, industries often adopt advanced or innovative control measures that significantly bring down costs, but are not anticipated at the time of the rulemaking.¹²

* * * * *

In conclusion, we do not question that the sponsors of S. 746 seek to improve the regulatory process through this bill. But we disagree that this result has been achieved. We are concerned that the consequences of this legislation will be to threaten the ability of our health and safety, environmental, and consumer protection agencies to act in a timely and decisive manner, and we therefore oppose this bill.

JOSEPH LIEBERMAN.
DANIEL K. AKAKA.
DICK DURBIN.
ROBERT TORRICELLI.
JOHN EDWARDS.

¹² In a 1995 study, the Congressional Office of Technology Assessment reviewed seven major OSHA regulatory programs and found that in no case had regulated companies spent significantly more than OSHA had predicted, and in five to seven they had spent less.

IX. CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 746 as reported are shown as follows (existing law proposed to be omitted is enclosed in brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

UNITED STATES CODE

TITLE 5—GOVERNMENT ORGANIZATION AND EMPLOYEES

PART I—THE AGENCIES GENERALLY

<i>Chapter</i>	<i>Sec.</i>
1. Organization	101
* * * *	
7. Judicial Review	701
8. Congressional Review of Agency Rulemaking	801
9. Executive Reorganization	901

CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS

[Sec.
[601. Definitions.
[602. Regulatory agenda.
[603. Initial regulatory flexibility analysis.
[604. Final regulatory flexibility analysis.
[605. Avoidance of duplicative or unnecessary analyses.
[606. Effect on other law.
[607. Preparation of analyses.
[608. Procedure for waiver or delay of completion.
[609. Procedures for gathering comments.
[610. Periodic review of rules.
[611. Judicial review.
[612. Reports and intervention rights.]

CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS

Subchapter I—Analysis of Regulatory Flexibility

<i>Sec.</i>
<i>601. Definitions.</i>
<i>602. Regulatory agenda.</i>
<i>603. Initial regulatory flexibility analysis.</i>
<i>604. Final regulatory flexibility analysis.</i>
<i>605. Avoidance of duplicative or unnecessary analyses.</i>
<i>606. Effect on other law.</i>
<i>607. Preparation of analysis.</i>
<i>608. Procedure for waiver or delay of completion.</i>
<i>609. Procedures for gathering comments.</i>
<i>610. Periodic review of rules.</i>

611. *Judicial review.*
 612. *Reports and intervention rights.*

Subchapter II—Regulatory Analysis

621. *Definitions.*
 622. *Applicability and effect.*
 623. *Regulatory analysis.*
 624. *Principles for risk assessments.*
 625. *Peer review.*
 626. *Deadlines for rule making.*
 627. *Judicial review.*
 628. *Guidelines, interagency coordination, and research.*
 629. *Risk based priorities study.*

Subchapter III—Executive Oversight

631. *Definitions.*
 632. *Presidential regulatory review.*
 633. *Public disclosure of information.*
 634. *Judicial review.*

Subchapter I—Analysis of Regulatory Flexibility

§ 601. Definitions

For purposes of this chapter—

* * * * *

Subchapter II—Regulatory Analysis.

§ 621. Definitions

For purposes of this subchapter the definitions under section 551 shall apply and—

(1) the term “Administrator” means the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget;

(2) the term “benefit” means the reasonably identifiable significant favorable effects, quantifiable and nonquantifiable, including social, health, safety, environmental, economic, and distributional effects, that are expected to result from implementation of, or compliance with, a rule;

(3) the term “cost” means the reasonably identifiable significant adverse effects, quantifiable and nonquantifiable, including social, health, safety, environmental, economic, and distributional effects, that are expected to result from implementation of, or compliance with, a rule;

(4) the term “cost-benefit analysis” means an evaluation of the costs and benefits of a rule, quantified to the extent feasible and appropriate and otherwise qualitatively described, that is prepared in accordance with the requirements of this subchapter at the level of detail appropriate and practicable for reasoned decisionmaking on the matter involved, taking into consideration uncertainties, the significance and complexity of the decision, and the need to adequately inform the public;

(5) the term “Director” means the Director of the Office of Management and Budget, acting through the Administrator of the Office of Information and Regulatory Affairs;

(6) the term “flexible regulatory options” means regulatory options that permit flexibility to regulated persons in achieving the objective of the statute as addressed by the rule making, including regulatory options that use market-based mechanisms, outcome oriented performance-based standards, or other options that promote flexibility;

(7) the term “major rule” means a rule that—

(A) the agency proposing the rule or the Director reasonably determines is likely to have an annual effect on the economy of \$100,000,000 or more in reasonably quantifiable costs; or

(B) is otherwise designated a major rule by the Director on the ground that the rule is likely to adversely affect, in a material way, the economy, a sector of the economy, including small business, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments, or communities;

(8) the term “reasonable alternative” means a reasonable regulatory option that would achieve the objective of the statute as addressed by the rule making and that the agency has authority to adopt under the statute granting rule making authority, including flexible regulatory options;

(9) the term “risk assessment” means the systematic, objective process of organizing hazard and exposure information, based on a careful analysis of the weight of the scientific evidence, to estimate the potential for specific harm to an exposed population, subpopulation, or natural resource including, to the extent feasible, a characterization of the distribution of risk as well as an analysis of uncertainties, variabilities, conflicting information, and inferences and assumptions;

(10) the term “rule” has the same meaning as in section 551(4), and shall not include—

(A) a rule exempt from notice and public comment procedure under section 553;

(B) a rule that involves the internal revenue laws of the United States, or the assessment or collection of taxes, duties, or other debts, revenue, or receipts;

(C) a rule of particular applicability that approves or prescribes for the future rates, wages, prices, services, corporate or financial structures, reorganizations, mergers, acquisitions, accounting practices, or disclosures bearing on any of the foregoing;

(D) a rule relating to monetary policy proposed or promulgated by the Board of Governors of the Federal Reserve System or by the Federal Open Market Committee;

(E) a rule relating to the operations, safety, or soundness of federally insured depository institutions or any affiliate of such an institution (as defined in section 2(k) of the Bank Holding Company Act of 1956 (12 U.S.C. 1841(k)); credit unions; the Federal Home Loan Banks; government-sponsored housing enterprises; a Farm Credit System Institution; foreign banks, and their branches, agencies, commercial lending companies or representative offices that operate in the United States and any affiliate of such foreign

banks (as those terms are defined in the International Banking Act of 1978 (12 U.S.C. 3101)); or a rule relating to the payments system or the protection of deposit insurance funds or Farm Credit Insurance Fund;

(F) a rule relating to the integrity of the securities or commodities futures markets or to the protection of investors in those markets;

(G) a rule issued by the Federal Election Commission or a rule issued by the Federal Communications Commission under sections 312(a)(7) and 315 of the Communications Act of 1934 (47 U.S.C. 312(a)(7) and 315);

(H) a rule required to be promulgated at least annually pursuant to statute;

(I) a rule or agency action relating to the public debt or fiscal policy of the United States; or

(J) a rule or agency action that authorizes or bars the introduction into or removal from commerce, or recognizes or cancels recognition of the marketable status, of a product under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.); and

(11) the term “substitution risk”—

(A) means a reasonably identifiable significant increased risk to health, safety, or the environment expected to result from a regulatory option; and

(B) shall not include risks attributable to the effect of an option on the income of individuals.

§ 622. Applicability and effect

(a) Except as provided in section 623(f), this subchapter shall apply to all proposed and final major rules.

(b) Nothing in this subchapter shall be construed to alter or modify—

(1) the substantive standards applicable to a rule making under other statutes;

(2) (A) the range of regulatory options that an agency has the authority to adopt under the statute authorizing the agency to promulgate the rule; or

(B) the deference otherwise accorded to the agency in construing such statute; or

(3) any opportunity for judicial review made applicable under other statutes.

§ 623. Regulatory analysis

(a)(1) Before publishing a notice of a proposed rule making for any rule, each agency shall determine whether the rule is or is not a major rule covered by this subchapter.

(2) The Director may designate any rule to be a major rule under section 621(7)(B), if the Director—

(A) makes such designation no later than 30 days after the close of the comment period for the rule; and

(B) publishes such designation in the Federal Register, together with a succinct statement of the basis for the designation, within 30 days after such designation.

(b)(1)(A) When an agency publishes a notice of proposed rule making for a major rule, the agency shall prepare and place in the rule making file an initial regulatory analysis, and shall include a summary of such analysis consistent with subsection (e) in the notice of proposed rule making.

(B)(i) When the Director has published a designation that a rule is a major rule after the publication of the notice of proposed rule making for the rule, the agency shall promptly prepare and place in the rule making file an initial regulatory analysis for the rule and shall publish in the Federal Register a summary of such analysis consistent with subsection (e).

(ii) Following the issuance of an initial regulatory analysis under clause (i), the agency shall give interested persons an opportunity to comment under section 553 in the same manner as if the initial regulatory analysis had been issued with the notice of proposed rule making.

(2) Each initial regulatory analysis shall contain—

(A) a cost-benefit analysis of the proposed rule that shall contain—

(i) an analysis of the benefits of the proposed rule, including any benefits that cannot be quantified, and an explanation of how the agency anticipates that such benefits will be achieved by the proposed rule, including a description of the persons or classes of persons likely to receive such benefits;

(ii) an analysis of the costs of the proposed rule, including any costs that cannot be quantified, and an explanation of how the agency anticipates that such costs will result from the proposed rule, including a description of the persons or classes of persons likely to bear such costs;

(iii) an evaluation of the relationship of the benefits of the proposed rule to its costs, including the determinations required under subsection (d), taking into account the results of any risk assessment;

(iv) an evaluation of the benefits and costs of a reasonable number of reasonable alternatives reflecting the range of regulatory options that would achieve the objective of the statute as addressed by the rule making, including, where feasible, alternatives that—

(I) require no government action or utilize voluntary programs;

(II) provide flexibility for small entities under subchapter I and for State, local, or tribal government agencies delegated to administer a Federal program;

(III) employ flexible regulatory options; and

(IV) assure protection of sensitive subpopulations, or populations exposed to multiple and cumulative risks; and

(V) a description of the scientific or economic evaluations or information upon which the agency substantially relied in the cost-benefit analysis and risk assessment required under this subchapter, and an explanation of how the agency reached the determinations under subsection (d);

(B) if required, the risk assessment in accordance with section 624; and

(C) when scientific information on substitution risks to health, safety, or the environment is reasonably available to the agency, an identification and evaluation of such risks.

(c)(1) When the agency publishes a final major rule, the agency shall prepare and place in the rule making file a final regulatory analysis.

(2) Each final regulatory analysis shall address each of the requirements for the initial regulatory analysis under subsection (b)(2), revised to reflect—

(A) any material changes made to the proposed rule by the agency after publication of the notice of proposed rule making;

(B) any material changes made to the cost-benefit analysis or risk assessment; and

(C) agency consideration of significant comments received regarding the proposed rule and the initial regulatory analysis, including regulatory review communications under subchapter IV.

(d)(1)(A) The agency shall include in the statement of basis and purpose for a proposed or final major rule a reasonable determination, based upon the rule making record considered as a whole—

(i) whether the rule is likely to provide benefits that justify the costs of the rule;

(ii) whether the rule is likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than the other reasonable alternatives considered by the agency; and

(iii) whether the rule adopts a flexible regulatory option.

(B) Consistent with section 621 (2) and (3), net benefits analysis shall not be construed to be limited to quantifiable effects.

(2) If the agency head determines that the rule is not likely to provide benefits that justify the costs of the rule or is not likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than the other reasonable alternatives considered by the agency, the agency head shall—

(A) explain the reasons for selecting the rule notwithstanding such determination, including identifying any statutory provision that required the agency to select such rule;

(B) describe any reasonable alternative considered by the agency that would be likely to provide benefits that justify the costs of the rule and be likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than the alternative selected by the agency; and

(C) describe any flexible regulatory option considered by the agency and explain why that option was not adopted by the agency if that option was not adopted.

(e) Each agency shall include an executive summary of the regulatory analysis, including any risk assessment, in the regulatory analysis and in the statement of basis and purpose for the proposed and final major rule. Such executive summary shall include a succinct presentation of—

(1) the benefits and costs expected to result from the rule and any determinations required under subsection (d);

(2) if applicable, the risk addressed by the rule and the results of any risk assessment;

(3) the benefits and costs of reasonable alternatives considered by the agency; and

(4) the key assumptions and scientific or economic information upon which the agency relied.

(f)(1) A major rule may be adopted without prior compliance with this subchapter if—

(A) the agency for good cause finds that conducting the regulatory analysis under this subchapter before the rule becomes effective is impracticable or contrary to an important public interest; and

(B) the agency publishes the rule in the *Federal Register* with such finding and a succinct explanation of the reasons for the finding.

(2) If a major rule is adopted under paragraph (1), the agency shall comply with this subchapter as promptly as possible unless the Director determines that compliance would be clearly unreasonable.

(g) Each agency shall develop an effective process to permit elected officers of State, local, and tribal governments (or their designated employees with authority to act on their behalf) to provide meaningful and timely input in the development of regulatory proposals that contain significant Federal intergovernmental mandates. The process developed under this subsection shall be consistent with section 204 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1534).

(h) Not later than February 5, 2002, the Director of the Office of Management and Budget shall prepare and submit to Congress an accounting statement and report containing an estimate of the total annual incremental administrative benefits and incremental costs of complying with the provisions of this subchapter for each agency.

§ 624. Principles for risk assessments

(a)(1)(A) Subject to paragraph (2), each agency shall design and conduct risk assessments in accordance with this subchapter for—

(i) each proposed and final major rule the primary purpose of which is to address health, safety, or environmental risk; or

(ii) any risk assessment that is not the basis of a rule making that the Director—

(I) reasonably anticipates is likely to have an annual effect on the economy of \$100,000,000 or more in reasonably quantifiable costs; and

(II) determines shall be subject to the requirements of this section.

(B)(i) Risk assessments conducted under this subchapter shall be conducted in a manner that promotes rational and informed risk management decisions and informed public input into and understanding of the process of making agency decisions.

(ii) The scope and level of analysis of such a risk assessment shall be commensurate with the significance and complexity of the decision and the need to adequately inform the public, consistent with any need for expedition, and designed for the nature of the risk being assessed.

(2) *If a risk assessment under this subchapter is otherwise required by this section, but the agency determines that—*

(A) a final rule subject to this subchapter is substantially similar to the proposed rule with respect to the risk being addressed;

(B) a risk assessment for the proposed rule has been carried out in a manner consistent with this subchapter; and

(C) a new risk assessment for the final rule is not required in order to respond to comments received during the period for comment on the proposed rule,

the agency may publish such determination along with the final rule in lieu of preparing a new risk assessment for the final rule.

(b) Each agency shall consider in each risk assessment all relevant, reliable, and reasonably available scientific information and shall describe the basis for selecting such scientific information.

(c)(1) When a risk assessment involves a choice of assumptions, the agency shall, with respect to significant assumptions—

(A) identify the assumption and its scientific and policy basis, including the extent to which the assumption has been validated by, or conflicts with, empirical data;

(B) explain the basis for any choices among assumptions and, where applicable, the basis for combining multiple assumptions; and

(C) describe reasonable alternative assumptions that—

(i) would have had a significant effect on the results of the risk assessment; and

(ii) were considered but not selected by the agency for use in the risk assessment.

(2) Significant assumptions used in a risk assessment shall incorporate all reasonably available, relevant and reliable scientific information.

(d) The agency shall inform the public when the agency is conducting a risk assessment subject to this section and, to the extent practicable, shall solicit relevant and reliable data from the public. The agency shall consider such data in conducting the risk assessment.

(e) Each risk assessment under this subchapter shall include, as appropriate, each of the following:

(1) A description of the hazard of concern.

(2) A description of the populations or natural resources that are the subject of the risk assessment.

(3) An explanation of the exposure scenarios used in the risk assessment, including an estimate of the corresponding population or natural resource at risk and the likelihood of such exposure scenarios.

(4) A description of the nature and severity of the harm that could reasonably occur as a result of exposure to the hazard.

(5) A description of the major uncertainties in each component of the risk assessment and their influence on the results of the assessment.

(f) To the extent scientifically appropriate, each agency shall—

(1) express the estimate of risk as 1 or more reasonable ranges and, if feasible, probability distributions that reflects variabilities, uncertainties, and lack of data in the analysis;

(2) provide the ranges and distributions of risks, including central and high end estimates of the risks, and their corresponding exposure scenarios for the potentially exposed population and, as appropriate, for more highly exposed or sensitive subpopulations; and

(3) describe the qualitative factors influencing the ranges, distributions, and likelihood of possible risks.

(g) When scientific information that permits relevant comparisons of risk is reasonably available, each agency shall use the information to place the nature and magnitude of a risk to health, safety, or the environment being analyzed in relationship to other reasonably comparable risks familiar to and routinely encountered by the general public. Such comparisons should consider relevant distinctions among risks, such as the voluntary or involuntary nature of risks, well understood or newly discovered risks, and reversible or irreversible risks.

§ 625. Peer review

(a) Each agency shall provide for an independent peer review in accordance with this section of—

(1) a cost-benefit analysis of a major rule that the agency or Director reasonably anticipates is likely to have an annual effect on the economy of \$500,000,000 in reasonably quantifiable costs; and

(2) a risk assessment required by this subchapter.

(b)(1) Peer review required under subsection (a) shall—

(A) be conducted through panels, expert bodies, or other formal or informal devices that are broadly representative and involve participants—

(i) with expertise relevant to the sciences, or analyses involved in the regulatory decisions; and

(ii) who are independent of the agency;

(B) be governed by agency standards and practices governing conflicts of interest of nongovernmental agency advisors;

(C) provide for the timely completion of the peer review including meeting agency deadlines;

(D) contain a balanced presentation of all considerations, including minority reports and an agency response to all significant peer review comments; and

(E) provide adequate protections for confidential business information and trade secrets, including requiring panel members or participants to enter into confidentiality agreements.

(2) Each agency shall provide a written response to all significant peer review comments. All peer review comments and any responses shall be made—

(A) available to the public; and

(B) part of the rule making record for purposes of judicial review of any final agency action.

(3) If the head of an agency, with the concurrence of the Director, publishes a determination in the rule making file that a cost-benefit analysis or risk assessment, or any component thereof, has been previously subjected to adequate peer review, no further peer review shall be required under this section for such analysis, assessment, or component.

(c) *For each peer review conducted by an agency under this section, the agency head shall include in the rule making record a statement by a Federal officer or employee who is not an employee of the agency rule making office or program—*

(1) whether the peer review participants reflect the independence and expertise required under subsection (b)(1)(A); and

(2) whether the agency has adequately responded to the peer review comments as required under subsection (b)(2).

(d) *The formality of the peer review conducted under this section shall be commensurate with the significance and complexity of the subject matter.*

(e) *The peer review required by this section shall not be subject to the Federal Advisory Committee Act (5 U.S.C. App.).*

(f) *A member of an agency advisory board (or comparable organization) established by statute shall be considered independent of the agency for purposes of subsection (b)(1)(A)(ii).*

(g) *The status of a person as a contractor or grantee of the agency conducting the peer review shall not, in and of itself, exclude such person from serving as a peer reviewer for such agency because of the requirement of subsection (b)(1)(A)(ii).*

(h) *Nothing in this section shall require more than one peer review of a cost-benefit analysis or a risk assessment during a rule making. A peer review required by this section shall occur to the extent feasible before the notice of proposed rule making.*

§ 626. Deadlines for rule making

(a) *All statutory deadlines that require an agency to propose or promulgate any major rule during the 2-year period beginning on the effective date of this section shall be suspended until the earlier of—*

(1) the date on which the requirements of this subchapter are satisfied; or

(2) the date occurring 180 days after the date of the applicable deadline.

(b) *In any proceeding involving a deadline imposed by a court of the United States that requires an agency to propose or promulgate any major rule during the 2-year period beginning on the effective date of this section, the United States shall request, and the court may grant, an extension of such deadline until the earlier of—*

(1) the date on which the requirements of this subchapter are satisfied; or

(2) the date occurring 180 days after the date of the applicable deadline.

(c) *In any case in which the failure to promulgate a major rule by a deadline occurring during the 2-year period beginning on the effective date of this section would create an obligation to regulate through individual adjudications, the deadline shall be suspended until the earlier of—*

(1) the date on which the requirements of this subchapter are satisfied; or

(2) the date occurring 180 days after the date of the applicable deadline.

§627. Judicial review

(a) *Compliance by an agency with the provisions of this subchapter shall be subject to judicial review only—*

(1) in connection with review of final agency action;

(2) in accordance with this section; and

(3) in accordance with the limitations on timing, venue, and scope of review imposed by the statute authorizing judicial review.

(b) Any determination of an agency whether a rule is a major rule under section 621(7)(A) shall be set aside by a reviewing court only upon a showing that the determination is arbitrary or capricious.

(c) Any designation by the Director that a rule is a major rule under section 621(7), or any failure to make such designation, shall not be subject to judicial review.

(d) The cost-benefit analysis, cost-benefit determination under section 623(d), and any risk assessment required under this subchapter shall not be subject to judicial review separate from review of the final rule to which such analysis or assessment applies. The cost-benefit analysis, cost-benefit determination under section 623(d), and any risk assessment shall be part of the rule making record and shall be considered by a court to the extent relevant, only in determining under the statute granting the rule making authority whether the final rule is arbitrary, capricious, an abuse of discretion, or is unsupported by substantial evidence where that standard is otherwise provided by law.

(e) If an agency fails to perform the cost-benefit analysis, cost-benefit determination, or risk assessment, or to provide for peer review, a court may, giving due regard to prejudicial error, remand or invalidate the rule. The adequacy of compliance with the specific requirements of this subchapter shall not otherwise be grounds for remanding or invalidating a rule under this subchapter. If the court allows the rule to take effect, the court shall order the agency to promptly perform such analysis, determination, or assessment or provide for such peer review.

§628. Guidelines, interagency coordination, and research

(a)(1) Not later than 270 days after the date of enactment of this section, the Director, in consultation with the Council of Economic Advisors, the Director of the Office of Science and Technology Policy, and relevant agency heads, shall issue guidelines for cost-benefit analyses, risk assessments, and peer reviews as required by this subchapter. The Director shall oversee and periodically revise such guidelines as appropriate.

(2) As soon as practicable and no later than 18 months after issuance of the guidelines required under paragraph (1), each agency subject to section 624 shall adopt detailed guidelines for risk assessments as required by this subchapter. Such guidelines shall be consistent with the guidelines issued under paragraph (1). Each agency shall periodically revise such agency guidelines as appropriate.

(3) The guidelines under this subsection shall be developed following notice and public comment. The development and issuance of the guidelines shall not be subject to judicial review, except in accordance with section 706(1).

(b) To promote the use of cost-benefit analysis and risk assessment in a consistent manner and to identify agency research and training needs, the Director, in consultation with the Council of Economic Advisors and the Director of the Office of Science and Technology Policy, shall—

(1) oversee periodic evaluations of Federal agency cost-benefit analysis and risk assessment;

(2) provide advice and recommendations to the President and Congress to improve agency use of cost-benefit analysis and risk assessment;

(3) utilize appropriate interagency mechanisms to improve the consistency and quality of cost-benefit analysis and risk assessment among Federal agencies; and

(4) utilize appropriate mechanisms between Federal and State agencies to improve cooperation in the development and application of cost-benefit analysis and risk assessment.

(c)(1) The Director, in consultation with the head of each agency, the Council of Economic Advisors, and the Director of the Office of Science and Technology Policy, shall periodically evaluate and develop a strategy to meet agency needs for research and training in cost-benefit analysis and risk assessment, including research on modeling, the development of generic data, use of assumptions and the identification and quantification of uncertainty and variability.

(2)(A) Not later than 180 days after the date of enactment of this section, the Director, in consultation with the Director of the Office of Science and Technology Policy, shall enter a contract with an accredited scientific institution to conduct research to—

(i) develop a common basis to assist risk communication related to both carcinogens and noncarcinogens; and

(ii) develop methods to appropriately incorporate risk assessments into related cost-benefit analyses.

(B) Not later than 2 years after the date of enactment of this section, the results of the research conducted under this paragraph shall be submitted to the Director and Congress.

§ 629. Risk based priorities study

(a) Not later than 1 year after the date of enactment of this section, the Director, in consultation with the Director of the Office of Science and Technology Policy, shall enter into a contract with an accredited scientific institution to conduct a study that provides—

(1) a systematic comparison of the extent and severity of significant risks to human health, safety, or the environment (hereafter referred to as a comparative risk analysis);

(2) a study of methodologies for using comparative risk analysis to compare dissimilar risks to human health, safety, or the environment, including development of a common basis to assist comparative risk analysis related to both carcinogens and noncarcinogens; and

(3) recommendations on the use of comparative risk analysis in setting priorities for the reduction of risks to human health, safety, or the environment.

(b) The Director shall ensure that the study required under subsection (a) is—

(1) conducted through an open process providing peer review consistent with section 625 and opportunities for public comment and participation; and

(2) not later than 3 years after the date of enactment of this section, completed and submitted to Congress and the President.

(c) Not later than 4 years after the date of enactment of this section, each relevant agency shall, as appropriate, use the results of the study required under subsection (a) to inform the agency in the preparation of the agency's annual budget and strategic plan and performance plan under section 306 of this title and sections 1115, 1116, 1117, 1118, and 1119 of title 31.

(d) Not later than 5 years after the date of enactment of this section, and periodically thereafter, the President shall submit a report to Congress recommending legislative changes to assist in setting priorities to more effectively and efficiently reduce risks to human health, safety, or the environment.

Subchapter III—Executive Oversight

§631. Definitions

For purposes of this subchapter—

(1) the definitions under sections 551 and 621 shall apply; and

(2) the term “regulatory action” means any one of the following:

(A) Advance notice of proposed rule making.

(B) Notice of proposed rule making.

(C) Final rule making, including interim final rule making.

§632. Presidential regulatory review

(a) This subchapter shall apply to all proposed and final major rules and to any other rules designated by the President for review.

(b) The President shall establish a process for the review and coordination of Federal agency regulatory actions. Such process shall be the responsibility of the Director.

(c) For the purpose of carrying out subsection (b), the Director shall—

(1) develop and oversee uniform regulatory policies and procedures, including those by which each agency shall comply with the requirements of this chapter;

(2) develop policies and procedures for the review of regulatory actions by the Director; and

(3) develop and oversee an annual government-wide regulatory planning process that shall include review of planned significant regulatory actions and publication of—

(A) a summary of and schedule for promulgation of planned agency major rules;

(B) agency specific schedules for review of existing rules, including under section 610;

(C) a summary of regulatory review actions undertaken in the prior year;

(D) a list of major rules promulgated in the prior year for which an agency could not make the determinations that the benefits of a rule justify the costs under section 623(d);

(E) identification of significant agency noncompliance with this chapter in the prior year; and

(F) recommendations for improving compliance with this chapter and increasing the efficiency and effectiveness of the regulatory process.

(d)(1) The review established under subsection (b) shall be conducted as expeditiously as practicable and shall be limited to no more than 90 days.

(2) A review may be extended longer than the 90-day period referred to under paragraph (1) by the Director or at the request of the rule making agency to the Director. Notice of such extension shall be published promptly in the Federal Register.

§ 633. Public disclosure of information

(a) The Director, in carrying out the provisions of section 632, shall establish procedures to provide public and agency access to information concerning review of regulatory actions under this subchapter, including—

(1) disclosure to the public on an ongoing basis of information regarding the status of regulatory actions undergoing review;

(2) disclosure to the public, not later than publication of a regulatory action, of “

(A) all written correspondence relating to the substance of a regulatory action, including drafts of all proposals and associated analyses, between the Administrator or employees of the Administrator and the regulatory agency;

(B) all written correspondence relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government; and

(C) a list identifying the dates, names of individuals involved, and subject matter discussed in significant meetings and telephone conversations relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government; and

(3) disclosure to the regulatory agency, on a timely basis, of—

(A) all written correspondence relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government; and

(B) a list identifying the dates, names of individuals involved, and subject matter discussed in significant meetings and telephone conversations, relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government.

(b) Before the publication of any proposed or final rule, the agency shall include in the rule making record—

(1) a document identifying in a complete, clear, and simple manner, the substantive changes between the draft submitted to the Administrator for review and the rule subsequently published;

(2) a document identifying and describing those substantive changes in the rule that were made as a result of the regulatory review and a statement if the Administrator suggested or recommended no changes; and

(3) all written correspondence relating to the substance of a regulatory action between the Administrator and the agency during the review of the rule, including drafts of all proposals and associated analyses.

(c) In any meeting relating to the substance of a regulatory action under review between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government, a representative of the agency submitting the regulatory action shall be invited.

§634. Judicial review

The exercise of the authority granted under this subchapter by the President, the Director, or the Administrator shall not be subject to judicial review in any manner.

