

But the legacy of debt for the 12 year period 1980-92 will not go away quickly and can be seen in three aspects of fiscal and budget policy.

First, net interest on the increase in the publicly held debt—accumulated during the 12 year period 1980-1992—is about \$180 billion or roughly the size of the annual deficit.

Second, even without a balanced budget amendment fiscal policy remains paralyzed—as long as we are running deficits of \$200 billion, for whatever reason, it is difficult to deliberately increase the deficit as an anti-inflationary measure. The public will just not accept that.

Third, the legacy of annual deficits of almost \$300 billion must be reduced gradually, so as not to depress the economy. Consequently, we will continue to add to the debt. By the end of the century the gross Federal debt will approach \$7 trillion.

But it can be done. Note once more. Spending on Government programs is less than taxes for the first time since the 1960s. If we keep at it, do more, the deficit could start declining in 5 years surely. The decline accelerates as smaller debt leads to lesser borrowing for interest which leads to smaller debt. But can we not do this on our own, of our own free will? I say to Senators that it won't happen otherwise. The Courts, to which all disputes under that misbegotten amendment will be referred, are not capable of making even remotely sensible decisions on fiscal policy.

Some 40 years ago, Guthrie Birkhead, professor, later dean of the Maxwell School of Citizenship and Government at Syracuse University, remarked that Americans are gadget-minded about government. The proposed balanced budget amendment is nothing if not a gadget. Allow me to offer a cautionary tale from New York history. On March 3, 1858, the New York Times reported from Albany that 86 State senators had presented a petition so brief and so explicit that it was given in its entirety:

The undersigned, citizens of the State, would respectfully represent: That owing to the great falling off of the Canal revenue, as well as the increasing drafts upon the State Treasury, and the large expenses of carrying on the several departments of the State Government, thereby swelling up the taxes; therefore, with the view of relieving the people from the large amount now unnecessarily expended to sustain the Executive and Legislative Departments, and to secure the *honest* and better administration thereof: your petitioners respectfully ask that your Honorable body pass an act for calling a Convention to so alter the Constitution as to abolish both the Executive and Legislative Departments, as they now exist, and to vest the powers and duties thereof on the President, Vice President, and Directors of the New York Central railroad Company.

The Times special correspondent, an early advocacy journalist, explained that the proposal, while intended as a joke, nonetheless conveyed a bitter satire, a satire which is deserved and just, such were the depredations of the ruling Democrats. The time would

come, he concluded, when "after long suffering" the people would rise and "retaliate."

They almost did and not long thereafter. Joke or not, the proposal passed the legislature, went on the ballot the next fall, and failed by only 6,360 votes.

The amendment failed, but retaliation came even so. The New York Democrats scarcely held office for the rest of the century. But retaliation has pursued us into the twentieth century, even to this time. The New York Democrats have controlled the New York State legislature for a total of 4 years in the whole of the twentieth century so far. Let Republicans beware. This amendment could pass.

Mr. HATCH. Mr. President, I see the distinguished Senator from Oklahoma is here. I am hoping that after he speaks, we will be able to close out the Senate for the day.

Mr. NICKLES. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. NICKLES. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. NICKLES. I ask unanimous consent to proceed as if in morning business.

The PRESIDING OFFICER. Without objection, it is so ordered.

FOSTER NOMINATION OBJECTION

Mr. NICKLES. Mr. President, over the last 9 days, a firestorm has erupted over President Clinton's announcement that he intends to nominate Dr. Henry W. Foster as the Surgeon General of the United States.

I believe that the President erred when he chose Dr. Foster as Surgeon General, and I believe the President should withdraw his nomination. I would also recommend to Dr. Foster that he withdraw his name from consideration.

Mr. President, much has been made about the fact that Dr. Foster, by his own admission, has performed abortions. President Clinton said yesterday when he was defending Dr. Foster that the only people who are fighting this nomination are people who oppose abortion. I believe the President is wrong.

Mr. President, I might mention that I do oppose abortion. I do not make any qualms about that. I do believe it is the deliberate taking of a human life, and I think it is a mistake to have as our Surgeon General a person who routinely performs abortions. To be named as Surgeon General, you are named as the Nation's No. 1 public health officer.

Some people say, should a person be totally disqualified because of that? I would not vote for him, but that does not mean that this body would not.

Likewise, I could not help but think of the reaction of many people in this body and what they would say if the medical researcher for American Tobacco Institute was appointed as Surgeon General. Smoking, like abortion, is legal, but I expect that there would be significant opposition because that is probably, again, not the right person to have as the Surgeon General.

Mr. President, my reason for speaking today and my reason for saying that the President should withdraw the nomination, is not just because Dr. Foster has performed a lot of abortions. It is because in this period of 9 days, there has been a real lack of candor from Dr. Foster. There has been a real misleading of the American people and the American Congress to the facts. I think that alone disqualifies him for this office.

The office of Surgeon General has been referred to as a bully pulpit, and it is. It is an office which gives the Surgeon General the ability to educate and to lead. And it is an office that, if one is going to educate and to lead by speaking, one has to have credibility. I think Dr. Foster has lost that credibility.

Mr. President, this morning's New York Times, in the lead editorial, calls on President Clinton to withdraw the Foster nomination. The editorial states:

Although Dr. Foster is a highly respected obstetrician, his lack of candor about his abortion record disqualifies him from serious consideration. Misleading statements by candidates for high position cannot be condoned.

The editorial concludes:

President Clinton promises to fight for his nominee and Dr. Foster pledges to stay the course. But this is a fight that neither the White House nor Congress really wants over a crippled candidacy. It is time to withdraw the nomination.

Mr. President, I ask unanimous consent to have the New York Times editorial printed in the RECORD at this point.

There being no objection, the article was ordered to be printed in the RECORD, as follows:

[From the New York Times, Feb. 10, 1995]

THE TAINTED FOSTER NOMINATION

The nomination of Dr. Henry Foster Jr. to be surgeon general has been so badly bungled, by the White House and by Dr. Foster himself, that there is little choice but to hope it dies quickly. Although Dr. Foster is a highly respected obstetrician, his lack of candor about his abortion record disqualifies him from serious consideration. Misleading statements by candidates for high position simply cannot be condoned.

Of course the chief blame for this debacle lies with the White House, which once again put forth in a nominee without adequately vetting the person's background or knowing the answers to potentially explosive questions. As a result, the Administration put out false information on the number of abortions performed by Dr. Foster. In this as in earlier episodes, White House bungling makes it difficult for President Clinton's natural allies to support him fully. The situation moves from difficult to impossible for

pro-choice Republicans like Senator Nancy Kassebaum of Kansas, who cannot reasonably be expected to take a political gamble amid such swirling incompetence.

That is a shame because Dr. Foster, based on his past record, is a good choice to succeed Dr. Joycelyn Elders, who was pushed from the job after her repeated intemperate language made her a target for conservative attacks. Dr. Foster, the acting director of Meharry Medical College in Tennessee, is deeply committed to delaying child-bearing among adolescents, one of the most pressing social issues confronting the nation. He developed a highly successful program, called "I Have a Future," in Nashville that was honored by President Bush as one of his "points of light."

During a 30-year practice Dr. Foster, like many obstetricians, performed a number of abortions. In doing so he was providing a legal, constitutionally protected medical service. If the latest numbers put forth are correct, he performed 39 surgical abortions during his 38-year medical career, a once-a-year rate that seems modest for a very busy practitioner serving a needy population. He was also the titular head of a federally sanctioned test of a potential abortion suppressor.

This record would in any case have probably inflamed America's anti-choice minority, which is fierce and well organized and has good friends in Congress. But since most Americans believe that women should retain the right to choose, Dr. Foster's nomination might well have been pushed through the Senate had his record been forthrightly presented. Instead both he and the Administration made it look as if there accounts were unreliable or designed to mask a more troubling history.

President Clinton promises to fight for his nominee and Dr. Foster pledges to stay the course. But this is a fight that neither the White House nor Congress really wants over a crippled candidacy. It is time to withdraw the nomination.

Mr. NICKLES. Mr. President, I do not often agree with the New York Times editorial page, but I think this editorial is correct. President Clinton should withdraw this nomination immediately because Dr. Foster has serious credibility problems.

The New York Times editorial says Dr. Foster is guilty of lack of candor in making misleading statements about his abortion record. They are correct.

In less than a week, he has given three different estimates on the number of abortions he has performed. Initially, he told the administration officials he had performed just one abortion. Then, last Friday, he issued a statement that said:

As a private practicing physician, I believed that I performed fewer than a dozen pregnancy terminations.

Mr. President, I ask unanimous consent that a statement by Dr. Henry Foster on February 3, 1995, be printed in the RECORD.

There being no objection, the statement was ordered to be printed in the RECORD, as follows:

PRESS RELEASE: STATEMENT BY DR. HENRY FOSTER, NOMINEE FOR U.S. SURGEON GENERAL, FEB. 3, 1995

My specialty in the practice of medicine is obstetrics/gynecology. I have personally delivered more than 10,000 babies in nearly 30 years of practice including my service in the military.

In that period of almost three decades as a private practicing physician, I believed that I performed fewer than a dozen pregnancy terminations. None were in out-patient settings; all were in hospitals and were primarily to save the lives of the women or because the women had been the victims of rape or incest.

I was also Chief of Service at two major teaching institutions where many physicians held hospital privileges. A wide variety of medical procedures and research was performed at both. To my knowledge, all were in accordance with the law and educational requirements.

I have dedicated my life's work to improving access to medical care and improving quality of life for women and children, a passion rooted in my early years of practice in the rural South. I have placed particular emphasis on prevention, especially in such areas as teen pregnancy, drug abuse and smoking cessation in children. In my work with teenagers, abstinence has always been stressed as my first priority.

Through my long affiliation with Planned Parenthood Federation of America, my personal goal has always been to provide education, counseling, preventive health care and contraceptive access to patients needing such services. If abortion is provided, my wish is that it be safe, legal and rare.

I am proud of my affiliation with Planned Parenthood just as I am of my affiliation with many other prestigious organizations such as the March of Dimes Foundation, the American Cancer Society, the Y.W.C.A. and my church.

Mr. NICKLES. Mr. President, on Wednesday, on ABC's "Nightline," Dr. Foster recanted an earlier estimate and provided a new estimate of the number of abortions he has performed.

Dr. Foster said:

I have worked at George W. Hubbard Hospital. At Meharry Medical College, all of my patient records and all of the operative logs from the time I went to Meharry in 1973 until tonight have revealed that I was listed as the physician of record on 39 of those cases, in 38 years of practice, in 22 years at Meharry.

Dr. Foster's statement on "Nightline" indicates he performed a grand total of 39 abortions in 38 years of medical practice, and all of those abortions were performed since 1973. But the Associated Press today reports that Dr. Foster performed an undetermined number of abortions prior to 1973, abortions that are not included in the 39 abortions he admitted on "Nightline" to having performed.

The article quotes Dr. Calvin Dowe, general practitioner and then a colleague of Dr. Foster at John A. Andrew Hospital in Tuskegee, AL, with William Hill, Dr. Foster's uncle, as saying Dr. Foster performed abortions in Alabama during the period from 1965 to 1973.

The article states:

Dowe and William Hill, Foster's uncle, said they do not know how many abortions he performed at Andrew Hospital, which closed in 1987. But both said Foster did only what was medically necessary.

The article also quotes Dr. Dowe as saying:

I don't see how any obstetrician has said he has never done an abortion. It's the nature of the business.

Mr. President, I ask unanimous consent to have printed in the RECORD the article I just referred to.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

[From the Associated Press, Feb. 10, 1995]

FOSTER WAS LONE OBSTETRICIAN FOR EAST ALABAMA'S BLACK WOMEN

(By Jay Reeves)

BIRMINGHAM, AL.—As the lone obstetrician at a black hospital during the days of racial segregation, Dr. Henry Foster was the only source of health care for thousands of poor, pregnant women in rural east Alabama.

Foster delivered hundreds of babies at John A. Andrew Hospital in Tuskegee from 1965 to 1973. When complications left him no other choice, he sometimes did abortions, a colleague and a relative say.

"Back then the medical treatment for Negroes was just deplorable," Dr. Calvin Dowe, a former colleague of Foster, recalled Thursday. "Hospitals in the surrounding areas didn't even consider them people."

While medical services were not segregated by law, Foster cared for almost every pregnant black woman in at least five counties.

Dowe, a general practitioner who is black, said he never referred women to Foster for abortions and did not know anyone who did. Women simply went to him because there was nowhere else to turn.

"Realistically, I don't see how any obstetrician can say he never has done an abortion. It's the nature of the business," Dowe said.

Abortions performed by Foster over his 38-year medical career have become a source of controversy since President Clinton nominated him to replace fired Surgeon General Joycelyn Elders. Foster, 61, initially acknowledged fewer than a dozen of the procedures but now says he did 39.

Dowe and William Hill, Foster's uncle, said they do not know how many abortions he performed at Andrew Hospital, which closed in 1987. But both said Foster did only what was medically necessary.

"He had to perform some for medical emergencies. He wasn't an abortion doctor," said Hill, 90, who still lives in Tuskegee.

Foster moved to Tuskegee in 1965 after completing his residency at Meharry Medical College in Nashville, Tenn. Dowe said the head of obstetrics at Andrew died about the same time, and Foster agreed to take over.

"With the training he had, he could have gone a lot of places. It was a form of mission work," Dowe said.

Foster was a member of a Baptist church in Tuskegee, and he took flying lessons under Charles A. Anderson, leader of the famed Tuskegee Airmen, an all-black squadron during World War II.

Foster also developed what became a national model for regional perinatal health systems. The White House was drawn to Foster by programs he started later in Nashville combatting teen-age pregnancy.

Mr. NICKLES. These statements by Dr. Foster's former colleague and Dr. Foster's uncle indicate he has done more than 39 abortions in his 38-year career.

Again, we are talking about credibility. They indicate that Dr. Foster misrepresented his abortion record three times in the last week, and we still do not know, despite three different estimates supplied by the nominee, how many abortions Dr. Foster has performed.

Mr. President, there is a record that was made on Friday, November 10, 1978, at the Federal Building in Seattle, WA, before the Department of Health, Education, and Welfare, Office of the Secretary, an ethics advisory board.

A list of participants included: Henry W. Foster, M.D., professor and chairman, department of obstetrics and gynecology, Meharry Medical College, Nashville, TN.

Mr. President, on page 180 of this record, under Dr. Foster's name, it says:

I have done a lot of amniocentesis and therapeutic abortions, probably near 700.

There is a lot in this transcript, Mr. President. There is a lot in this transcript, but this one line, Dr. Foster's words, "probably near 700." Initially from the White House we heard maybe the transcript was a forgery. Then we heard it probably was not this Dr. Foster; maybe it was a different Dr. Foster; maybe he was not there. I think they have recanted those statements and they said this probably is a legitimate transcript and it probably is the same person they nominated to be Surgeon General, but he did not say what the official transcript of the meeting says he said.

Again, credibility. Was it 1 or was it 12 or was it 39 or was it a lot more before 1973? So we do not know how many.

And, oh, yes, in his original comments he forgot that he was chief investigator of a drug, a suppository that would induce abortion that they gave to 60 people that he has written a report on, and I will include that for the RECORD as well. Out of the 60 pregnant women who participated in the study, 55 had their pregnancies aborted by the drug, and those abortions were not medically necessary. I think 58 of those who participated in the study were black women, ages 15 to 32; in 55 of the 60 cases, the drug successfully induced abortion; in 4 other cases, they had to go ahead and complete a surgical abortion procedure; and in one case, the mother changed her mind and carried the baby to term.

There are other things in this report. I am going to include this for the RECORD, not the entire report but I will include about 40 pages.

This transcript includes a discussion about research, trying to do research to determine whether the fetus has a disease called sickle cell anemia and whether or not they can detect that disease prenatally or find out whether the fetus is affected in time so there could be a therapeutic abortion; in other words, abort a fetus because it happens to have sickle cell anemia.

Mr. President, there are millions of Americans, I think it is estimated 2 or 3 million Americans who today have sickle cell anemia, and yet in this research proposal that they are talking to HEW about, they want to determine whether the fetus has sickle cell anemia so it would be in time to find out if the mother, I guess, would like to

have an abortion, a therapeutic abortion. Not very therapeutic for the fetus, I might mention.

It even goes on further, and I do not even like talking about this. It talks about research on human ova fertilized in a laboratory setting. Dr. Foster is saying, "Well, if we have spares that are not used for insemination, they could be used for research."

It happens to be against the law right now, but he was advocating they would use fertilized ovum for research. That bothers me. This is a report, this is a transcript of a hearing. Maybe a lot of us speak at hearings and we forget we are recorded. I do not know. But these are statements.

Mr. President, I would like to keep the CONGRESSIONAL RECORD very short, but this is a very controversial nominee and I think people are entitled to find out what the facts are. So I ask unanimous consent this portion of a copy of the ethics advisory board meeting dated November 10, 1978, be printed in the RECORD.

There being no objection, the transcript was ordered to be printed in the RECORD, as follows:

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, OFFICE OF THE SECRETARY, ETHICS ADVISORY BOARD, MEETING V, NOVEMBER 10, 1978

MEMBERS OF THE ETHICS ADVISORY BOARD

Gaither, James C., J.D., Chairman, Cooley, Godward, Castro, Huddleson and Tatum, San Francisco, California.

Hamburg, David A., M.D., Vice Chairman, President, Institute of Medicine, Washington, D.C.

Conway, Jack T., Senior Vice President, Government and Labor Movement Relations, United Way of America, Washington, D.C.

Foster, Henry W., M.D., Professor and Chairman, Department of Obstetrics and Gynecology, Meharry Medical College, Nashville, Tennessee.

Henderson, Donald A., M.D., Dean, The Johns Hopkins School of Hygiene and Public Health, Baltimore, Maryland.

Lazarus, Maurice, Chairman, Finance Committee, Federated Department Stores, Inc., Boston, Massachusetts.

McCormick, Richard A., S.T.D., Professor of Christian Ethics, Kennedy Institute for the Study of Reproduction and Bioethics, Washington, D.C.

Spellman, Mitchell W., M.D., Dean for Medical Services and Professor of Surgery, Harvard Medical School, Boston, Massachusetts.

Williams, Agnes N., LL.B., Potomac, Maryland.

Zwieback, Eugene M., M.D., Surgeon, Omaha, Nebraska.

STAFF MEMBERS

Dr. Charles McCarthy, Staff Director, EAB.

Ms. Barbara Mishkin, Deputy Staff Director, EAB.

Ms. Roberta Garfinkle, Assistant to EAB.

Mr. William Dommel, Special Assistant to Staff Director, EAB.

Mr. Philip Halpern, Special Counsel to Chairman, EAB.

EXCERPTS FROM HEARING

... given the risk benefit ratio and whatever—it would not be ethical and moral for the government to pay for that process.

Dr. LEIMAN. So long as we are leaving the conceptus out of the discussion, I think so.

Mr. GAITHER. Dr. Henderson, one last question.

Dr. HENDERSON. Just an observation. I wonder if we are really looking at proceeding on the assumption that there is no additional risk. As one looks at the whole field of medicine, almost any procedure one does, any drug one takes, there is some minimal additional risk. Acceptable minimal additional risk I think is the way we are really looking at this and to say there is probably no additional risk I think is probably not the way we can look at this. I think we must say minimally acceptable additional risk.

Mr. GAITHER. I think the acceptable is still at issue. But I think that the point is well taken.

Rabbi Leiman, thank you very much. We appreciate it.

Let's take a short break and figure out how we can get back to our schedule.

(Brief recess.)

Mr. GAITHER. Needless to say, we have fallen a bit behind schedule, and I would suggest that we postpone for the time being the legal discussion regarding in vitro fertilization, and proceed at this time to a consideration of the research application involving fetoscopy, submitted by the Charles Drew Postgraduate Medical School.

I would like to note at the outset that Dr. Spellman, formerly Dean at that medical school has asked that he be excused from the deliberation on this issue. I hope that you will stay with us and listen to it, but I understand your reluctance to become involved, and we will assume that you will not be involved in either the discussion or the decision on this issue.

Dr. HAMBURG. However, as a point of personal privilege, you may respond to insulting remarks. (Laughter.)

Mr. GAITHER. Mrs. Mishkin, we will let you describe the issue before us, and I would ask that you start by describing why the application is before us and what we are expected to do with it.

Ms. MISHKIN. The HEW regulations governing research involving the human fetus lay down certain conditions which must be met in order for an institutional review board to approve that research. If the institutional review board is not able to determine that all of the conditions have been met, and if it considers that the research nevertheless is important, it may refer that research proposal to this Board for review. And if the Board determines that the research should go on, it may recommend to the Secretary that he waive those parts of the regulations that the research proposal cannot meet.

Now, the proposal before the Board at this point is a proposal to perform fetoscopy on mothers who have elected to have abortions for reasons totally unrelated to the research, in order to discover and to document what the risk to mothers and fetuses might be from the procedure of fetoscopy. The purpose of developing the fetoscopy is to be able to diagnose prenatally certain conditions for which the parents are at risk. In this particular research proposal the focus is primarily on prenatal diagnosis of sickle cell disease.

Now, the reason that this proposal is before the Board is that it cannot meet or at least cannot clearly meet provisions of the HEW regulations set forth in sections 46.206(a), 46.207(a), and 46.208(a) which briefly, taken together, require that the activities in the research proposal be designed to meet the health needs of either the mother or the particular fetus involved, or, if that is not the case, that the procedures present no more than minimal risk to the fetus.

Now, the problem in this proposal is that it is not designed, as written, to provide therapy for the mother, nor is it designed to provide therapy for the fetus, because the purpose is to assess safety of a technique and to do it in mothers who have already elected to undergo abortion. So there is no question as to whether or not it is or not so-called therapeutic research. It clearly is not. Therefore, it does not meet that first condition.

It does not seem to meet the second condition because the risks, I think, must be considered undetermined. Although the HEW regulations do not define minimal risk, it is possible to go and look behind those regulations to the Commission's discussion of what they intended, because the regulations were an attempt by the Department fully to implement the Commission's recommendations on research involving the fetus.

So I am going to offer to you for your guidance what the Commission's intentions were when they made their recommendations to the Secretary. That does not mean that you must follow the Commission's intentions; it is only to elucidate for you somewhat what the Commission had in mind, because the regulations themselves give this Board no guidance. The only guidance in the regulations is to the institutional review boards.

Mr. GAITHER. Let me interrupt for just one second, because I think it is important that we understand the standards which we are to apply. I gather what you are saying is that this particular application is not therapeutic and not clearly within the category or at least so determined by the institutional review board, as involving no more than minimal risk.

Ms. MISHKIN. That is correct.

Mr. GAITHER. Therefore, it can only be funded if this Board determines that it is ethically acceptable? Is that the standard?

Ms. MISHKIN. Essentially, yes. If we recommend to the Secretary that he waive those provisions that we just mentioned because we feel the research is important and justified by the benefits to be obtained from the—the anticipated benefits.

Mr. GAITHER. So there is no particular standard other than for us to say to the Secretary whether or not we feel that he should go ahead despite that provision in the regulations?

Mr. HALPERN. Mr. Gaither, if I could be of help, if you look at subpart 5 under Tab I in our book, giving us the regulation, Section 46.211 provides some guidance as to the standard, at least which will guide the Secretary in his decision to accept our recommendation.

Ms. MISHKIN. At Tab I of your book, we have reproduced the applicable provisions of 45 CFR 46, and it simply says if this Board feels that the risk is justified by the sum of the benefit to the subject, which is not in question here, or the importance of the knowledge to be gained.

Mr. CONWAY. And you are referring us to 46.211?

Ms. MISHKIN. Yes.

Mr. HALPERN. In fact, it doesn't say that the Board should be guided by the risk benefit analysis, it says that the Board should consider whether waiver, which is what we are talking about, is appropriate in this particular instance. Then it says in making the decision the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such a modification or a waiver.

Mr. GAITHER. But it seems to me that it is important for us to note that .211 states that the Secretary can only waive, unlike the other situation before us, with our approval. So that is the question, whether we would approve a modification or waiver of these

regulations to permit this research to continue. And basically there are no specific standards imposed upon us. Is that correct?

Ms. MISHKIN. That is correct.

Mr. GAITHER. And what you are giving us is the background, now, for these particular regulations why the Commission suggested that a body such as ours be involved in the deliberations.

Ms. MISHKIN. And what the Commission coped with when it discussed the problem of research on fetuses to be aborted, and what standard might be appropriate in considering acceptable risk to fetuses about to be aborted or whose mothers intend to go through with an abortion. It was a very, very difficult problem for the Commission. Any of you who followed the Commission's activities in this area will know they spent a long time on this, and this was one of the areas in which there was not a full consensus among the Commission members.

First of all, let me say that this particular application underwent six reviews prior to coming before this Board. That included reviews by the appropriate IRB at the Drew Center; a review by the community board which is a separate community representative board at the Drew Center; review by the appropriate study section at HEW; review by a site visit team from study section, members ad hoc; review by the National Advisory Council under whose auspices this particular application came—if that is not six I have left one out, but they are all listed there anyway.

The staff of the Board then shipped the whole thing out to two additional people for independent reviews, and those have been mailed to you and are reproduced in your book. Dr. Haig Kazazian at Johns Hopkins University Hospital, and Dr. Dwayne Alexander at the National Institute of Child Health and Human Development.

Dr. Kazazian has done fetoscopy himself; he no longer does so. Dr. Alexander has not done fetoscopy. He was a member of the staff of the Commission and he ran the amniocentesis collaborative research program, and is very familiar with questions of prenatal diagnosis, and the risks of various procedures associated with prenatal diagnosis.

All of the review boards and the individual reviewers have recommended approval of this research application based on the importance of being able to diagnose prenatally certain conditions which, up until now, have not been diagnosable through amniocentesis. Fetoscopy has been the only possible way to diagnose sickle cell disease, among other diseases, in fetuses prior to birth.

Now, there was one problem that we had in reviewing this particular proposal, and that was it was not entirely clear from the proposal, because we had conflicting statements—the site visit review said one thing, and the proposal said something else—as to whether or not the investigators planned to delay abortion for more than 24 hours after fetoscopy. The point of the research is to do the fetoscopy, monitor the women after fetoscopy, and look for complications as a result of fetoscopy. Complications include possible infection of the woman, possible bleeding of the fetus, and subsequent abortion prior to the induced abortion which is anticipated.

What is present in the research application is a plan to perform the fetoscopy, monitor the woman for 24 hours, and then go ahead with the abortion as planned. What is present in the site visit's review, however, is a plan to continue monitoring, if they are satisfied that a 24 hour delay poses no risk, to increase that delay step by step, until they reach, finally, a two-week delay during which they would monitor the woman for

two weeks following fetoscopy before going ahead with the abortion.

I called the principal investigator to find out what in fact was their intent, and he said that this does seem—that it is his intent to go incrementally if they are satisfied at any one stage as to the risk to mother and fetus, to go incrementally up to a two-week delay. This raises a very important concern that their subject population is women who are in their 16th to 20th week of gestation. A two-week delay in a woman who presents at 20 weeks would take that woman past 20 weeks gestation before her abortion, and this then would run into the possibility of a viable fetus being aborted, or of having a viable product of the abortion. This is one problem that the Commission was very much concerned about. That is why the staff recommendation on this particular proposal includes the provision that no abortion be postponed for reasons of this research that would then have to be performed after the 20th week of gestation. This is compatible with the regulations that no timing or methodological change be introduced for reasons of research that would add additional risk to the mother or the fetus. And surely the risk of having a viable product of abortion is an additional risk.

The current regulations note that viability is possible at 20 weeks, and that is why the staff recommends that no procedure be delayed beyond the 20th gestational week for purposes of this research.

Now, the whole thing was complicated by an article in the Washington Post that appeared on Saturday, November 4th, while we were in the process of preparing this memorandum of recommendations to you. That article indicates that a physician at the University of California at San Francisco believes he has developed a procedure to diagnose sickle cell disease through amniocentesis, thus avoiding the necessity to go to fetoscopy in order to diagnose sickle cell disease. These findings are supposed to have been in the most recent issue of the journal *Lancet*. We were unable to find whatever issue that was. It must not be out yet. If it is out it is not available in any of the libraries we had access to in Washington.

We tried very hard to call the investigator at the University of California at San Francisco, and we were unable to reach him. We do, however, have some further information on that. Dr. Alexander was able to reach Dr. Michael Kaback, who is Assistant Professor of Pediatrics and Medical Genetics at the University of California at Los Angeles, and who is familiar with the work of the investigators at San Francisco.

What I am going to give you now is my understanding of Dr. Alexander's understanding of Dr. Kaback's understanding of what they are doing in San Francisco. If all of that is clear, you will know how far we are removed from firsthand information. But nevertheless I will give it to you, because I think it is important.

It goes as follows: 85 percent of sickle cell carriers have an extra large piece of DNA on the gene that has the sickle cell trait. Now, this condition of having the extra large clump of DNA material is called polymorphism. Thus, it is possible assuming the test works as reported, to diagnose approximately two-thirds or more of sickle cell babies through amniocentesis and looking for this enlarged DNA clump.

Now, let me break that out for you. What they have to do if they identify both parents as carriers, they then look for this polymorphism, in other words, the extra clump of DNA in the parents. If those parents have that extra clump of DNA, that is, if they fall within the 85 percent of sickle cell carriers

who have that polymorphism, then it is possible to perform amniocentesis—yes?

Dr. FOSTER. I should clarify something at this point. You are using a medical term, and I am not sure—you are saying “carriers.” do you really mean carriers, or do you mean sickle cell disease?

Ms. MISHKIN. No, I mean carriers.

Dr. FOSTER. That is not a person with sickle cell disease.

Ms. MISHKIN. That is correct.

Dr. FOSTER. Okay.

Ms. MISHKIN. But again, this is my understanding from Dr. Alexander through Dr. Kaback. That is the best we can give you.

Dr. FOSTER. Go ahead and let me hear you out, then.

Ms. MISHKIN. My understanding is this is carriers.

Dr. FOSTER. Okay, go ahead. I will hear you out.

Ms. MISHKIN. So if both parents are carriers, either with or without the disease—

Dr. FOSTER. It is the previous I am concerned about.

Ms. MISHKIN. Right. If both parents are carriers and have this trait of the polymorphism, and it is possible to be a—15 percent of carriers do not show this trait. If they are among the 85 percent of carriers who show this trait, then through amniocentesis they can look for the segments in the fetus. If the fetus has two segments showing the polymorphi, that is a child with sickle cell disease. If the fetus has one segment that child is a carrier. If the fetus has no segments, that is a normal child.

Now, I went back and asked again whether that child could be one of the 15 percent that do not show the polymorphism, and the answer was that Dr. Alexander believes not. The answer is if they have done this whole procedure and the child does not carry that polymorphism, that child is not a carrier or a diseased child with respect to sickle cell.

Now, if either parent is not polymorphic, does not have this additional clump, is within that 15 percent of parents who are carriers but do not have this change of the DNA, then it is impossible to diagnose the sickle cell disease in the fetus through this amniocentesis procedure, and that would mean that for those parents the only way to diagnose the sickle cell disease in the fetus would be through fetoscopy, which brings us back to the Drew application.

Now, what all this means is there has been a shift in the risk benefit analysis that all of the reviewers performed on the Drew application, because when they looked at the Drew application fetoscopy was the only method for diagnosing sickle cell disease prenatally. Now it appears, although we do not have the documentation to give you, that it is possible in 85 percent of sickle cell carrier parents to diagnose the presence or absence of sickle cell disease by amniocentesis which is agreed to be a safer procedure than fetoscopy.

So your job is somewhat more difficult, but I don't think it is impossible. One is left with the question of whether it is appropriate for the investigators at Drew to do the research, to assess the risks of fetoscopy as a tool for prenatal diagnosis of sickle cell disease in their subject population, and the reason I am emphasizing this is that if it were the case that all sickle cell disease could be diagnosed prenatally through any other method, amniocentesis or any other, then the board would have to face the question of whether the subject population which the Drew Medical Center serves is an appropriate population to develop the methods of fetoscopy. Fetoscopy is useful for prenatal diagnosis of other disorders, but not disorders which are disorders of the black popu-

lation, which is the subject population which the Drew Center serves. So then one would have to question whether the black population is an appropriate subject population for developing fetoscopy if they are not going to be the population which will benefit from the development of that diagnostic tool.

In other words, one wants to have the population that will benefit from the research, participate as subjects and accept the risks of that research if possible.

Mr. HALPERN. Just related to this, are we not also in the position of asking whether or not we should remand this issue to Drew and the community that Drew serves for them to make the risk benefit analysis again, in light of this new data?

Ms. MISHKIN. Absolutely. That is a very viable option, and it certainly has a great deal of merit. I think one might reasonably ask for a total reassessment, by that IRB or by any number of other people, even including the study section that reviewed it, in the light of the new information. But I think we would want to get the actual information documented before we remanded it.

I don't know if this has been clear, and if you want more elucidation of the Commission's intent or of my understanding of the regulations, I would be glad to go forward with more.

Mr. GAITHER. Hank, would you say something about the science of this?

Dr. FOSTER. Yes, I am going to say something about the science and the sociology, if you will indulge me.

I heard of Kan's work just a few days ago, and I knew clearly like a shock wave that it was inevitably going to affect what we have to do, or what we recommended. But I want to say some things as we go through all of this deliberation, which may take me a few moments, but I really want to run through these steps that I have written down here. Some food for thought.

I just have one question. The genetic polymorphism that is necessary in the parents—is it required in both parents? In other words, you know, both parents may be carriers, but only one may show the polymorphism and the other may not. Is it a requirement for both parents? Do you recall?

Ms. MISHKIN. My understanding is that it is not going to be a reliable test through amniocentesis unless both parents show the polymorphism.

Dr. FOSTER. Now, the next question I have—and then I will make my comments—now, I read the research proposal, and I missed this delay. That bothers me a little bit, first. I have got to really clear that in my mind.

I have done a lot of amniocentesis and therapeutic abortions, probably near 700. As I read the protocol, the patient would be brought in the hospital, and that would be a 24 hour delay, which was not inordinate, based on the information that we have. It is very reasonable. But the clinical part, catheter is introduced into the amniotic cavity, and that is the time when the fetus is studied, the blood vessels, and the sample is taken. Then the fetoscope is withdrawn, but the catheter is left in place, which is quite acceptable. In fact, this is one of the techniques we use for continuous prostaglandin infusion.

But there gets to be a real question with regard to infection after a 24 hour period with an indwelling connection to the outside. I missed the entire reviewer's section about some extension beyond 24 hours, and if there is an extension of observation beyond 24 hours, does it involve the catheter being in place? This would be critical in my mind.

Dr. MCCARTHY. Yes, it certainly does.

Dr. FOSTER. I think that is something that really needs to be addressed in terms of the details of the research.

Ms. MISHKIN. I am frankly bothered by anything coming as far as to the Ethics Advisory Board through all those reviews without this being quite clear. It was in the site visit review, and it was because of the ambiguity that I called the principal investigator.

Now, Dwayne Alexander was working on the application in front of him, and so he really addressed only the 24 hour delay. But because of the ambiguities I did call, and the investigators do intend to go to two weeks. I think it might not be inappropriate for the Board to make some strong statement about wanting to be clear on what the procedures proposed are here.

Mr. LAZARUS. I wasn't clear either on the consent procedures.

Dr. FOSTER. That doesn't come through. But the one thing I do want to say, and then I will get to the other points I want to make about what all of the implications of fetoscopy are as I see it. I do think a longer observational period is an acceptable research modality provided safeguards are there. We have already talked about extending beyond the 20 weeks. That can be controlled for fairly well with ultrasonography for establishing fetal age, and a few other things. But I think you might want to consider the observation period without the catheter in place, because repeated amniocentesis has proven to be relatively safe in terms—the danger is in leaving a conduit for bacterial migration.

So what I am really saying is I can see the investigators making a justification for an observation period of longer than 24 hours, but I find it a little difficult at this point to see that justification with an indwelling catheter in beyond this point.

And now I think the things we need to be concerned about irrespective of what we ultimately recommend in terms of going back or whatever. There was very, very strong community support for this proposal. Anyone who read the type of support, and the rather incisive and critical questions, I thought, that the community asked in regard to many of the social and medical implications. I think it is keen that we remember that there have been so many charges of disregard for ethic makeups of our research, genocide and all the issues, if this is an indigenous decision by a community, I think we need to give that great respect, because it is a justification for us to say this is a decision that you made. If we say to the community no, we shouldn't do this, the community in a sense has a right to say you are willing to impose certain things on us externally that we feel are an abridgment, but here when we see something clearly directing us, you deny it. So that is something that has to be considered strongly in terms of sociology.

I think another thing that is very important from what I know about this—Drew has been one of the few centers that had federal support prior to the moratorium in 1973, I believe, involving aborted fetal subjects on the research, has gone through the steps of animal experiments. They have used the ovine model very well with sheep and I think we certainly have to give that some accord. They have gone through all the steps prior to using humans.

Now, the implications of Kan's work I don't need to go over. You have made that very clear. So I will move on to my fourth point.

Mitch Spellman makes this point a lot, and it is a good point. There is a basis for basic research with regard to doing fetoscopy, irrespective of Kan's work. There

is a basic need. Now, I am going to go slowly and really try to make this point.

Kan's approach right now is the acceptable one. It is a reaction. It is an after-the-fact approach. It gives us an option simply to abort a defective pregnancy. Basic research will afford us a much broader and brighter horizon, might I add. And that is the possibility of diagnosing the defective fetus and then preventing the development of sickle cell disease in that fetus.

Now, I will try and paint a picture. In utero, for all of us normally, there is a different set of protein in two of the chains of our hemoglobin in early fetal life. The normal hemoglobin molecule has four chains, two upper alpha chains, which are proteins in a set sequence, and two lower, somewhat larger, beta chains in a set sequence.

The only difference between one who has sickle cell hemoglobin and a normal person is out of 184 amino acids in one of those chains, and that is in set sequence, there is an exchange of valine for glutamic acid, in the sixth position from the end. One of 184 chains. That is the only difference. But because of this change in the chain, certain physical and chemical defects, as you may call them, are imparted into the hemoglobin. It makes it less stable. Its ability to hold and release oxygen is affected. The stability of the red cell membrane is affected. It changes its pattern of migration in an electrical field. This is how we do our hemoglobin electrophoresis.

Back to in utero, none of us has these beta chains when we are developing. We have another chain called a gamma chain, and that gamma chain is provided for through a mechanism which we yet do not fully understand, and this is where our basic research should continue. There are repressor genes and activator genes. Rarely, through chance, some people who were destined to have sickle cell disease never develop it. But they continue to make the gamma chains which make fetal hemoglobin throughout life, even in the postnatal period. And these people have absolutely no trouble. That is the ideal situation for the sickle cell person, is to be able to find that mechanism that will prevent the turning on of the activator genes from going from gamma chains to defective beta chains. So there is a clear need for this kind of research in spite of the work by Kahn and his group.

It is at this basic step where not only will we be able to diagnose the child destined to have sickle cell disease, but indeed, to prevent it. So I think that alone justifies continuation of this basic research approach.

Lastly—well, that includes—I wanted to say something about the basic science of the molecule. So there is a real horizon out there that has to be untapped, and that is the ability to diagnose the abnormal hemoglobin but not by default to get rid of the fetus. That is the thinking that if you want to prevent forest fires, cut down all the trees. I want to take a different approach. I want to see can we afford this fetus that was destined to be one thing, that our basic research will continue to allow us to do something about it.

So I just wanted these thoughts to be in the back of our minds, particularly in light of Kan's recent work as to the obsolescence of this continued basic research approach.

Ms. MISHKIN. Is the research to develop that therapy now ready for pursuing through fetoscopy now, or does one have to wait for more development in animals and other methods before you actually go to fetuses in utero?

Dr. FOSTER. I think I understand your question, Barbara. Are you saying is our technique to such a point that we can go ahead with just the technique of amniocentesis?

Ms. MISHKIN. No, I am asking whether one would endorse the Drew application today on the basis of the need to develop the prenatal therapy, or are we not yet there with respect to the therapy, with the animal work and so forth?

Dr. FOSTER. I think the animal work has been done. I think that has been satisfied.

Ms. MISHKIN. There is one other thing I forgot to mention on the risk benefit analysis, and that is the concern about using fetuses to be aborted. There is not much direction in the HEW regulations on this matter, but the Commission came down to a guideline that may or may not be useful for you, but I think it has some merit. That is, they felt that it was ethically acceptable to perform procedures on a fetus to be aborted if one would feel ready to perform those procedures on a fetus intended to go to term.

In other words, if one had done all of the animal work, including primate work, which they have done in this case, and if they were unable to do it on fetuses to be aborted to further assess the risk, if they would be willing then to go forward therapeutically with it on fetuses going to term. That condition has been met in this case, because there are apparently several groups who are performing amniocentesis on fetuses intended to go to term.

Father MCCORMICK. Fetoscopy, you mean?

Ms. MISHKIN. In fetoscopy, yes.

Mr. GAITHER. In somebody's judgment.

Ms. MISHKIN. I mean the condition of its being performed on fetuses going to term has been met, and the question is whether or not that meets your feeling of acceptability for performing the procedure on fetuses to be aborted. But this procedure is being performed on fetuses going to term.

Mr. GAITHER. Can I just ask for some clarification, first? One, what are the purposes of this particular protocol? Is it particularly experience and safety, or does it get into the basic research questions that Dr. Foster was mentioning?

Ms. MISHKIN. My understanding of the protocol is that it is to assess the risks of infection, of bleeding, of premature abortion, and so forth, that are attendant with fetoscopy. Now, Dr. Alexander also sees an additional benefit, which is developing the competence of the investigators to perform the procedure prior to trying to do it on fetuses going to term. That also is included. That is not the primary purpose of the application as written. The application is to determine with somewhat better certainty the risks involved to mother and fetus.

Dr. FOSTER. And a part of that is improving the technique. It is not basically designed to go into a specific basic research question. As I understand it, it is what Barbara says, to assess the safety and to improve the technique. That is going to evolve from that. And that is one of the reasons I feel they are asking for a somewhat longer observation period, because if you do the procedure and then proceed directly to the termination, you would deny some of the longer term effects, delayed bleeding and the like.

Mr. GAITHER. Two further points of clarification, and then I will open the discussion. The work that is presently going on at Yale and the University of California, has that been subjected to these regulations and approved, the distinction being that it was therapeutic, that is, regarded to be of benefit to a possible child, and that is why it is different, or not? Do you know what the status is?

Ms. MISHKIN. I am not entirely clear. My understanding is probably not with respect to the Yale group, because I do not think that is funded by HEW. I believe that is the information we got from Jerry Mahoney just

recently. But as you know, the regulations are somewhat ambiguous with respect to whether or not research conducted at an institution but not funded by HEW must be reviewed by the IRB, and also subject to the same review standards. So it is a somewhat unclear point with respect to the Yale group.

Dr. MCCARTHY. It is perfectly clear that the Yale group felt obliged under Section 474(b) of the Public Health Service Act to have Dr. Mahoney's research involving fetoscopy reviewed by the IRB. They also made the interpretation, which I think is a reasonable one, although not the only possible one—they made the interpretation that they need not review according to HEW standards. And in fact, there is some question in my mind as to whether Dr. Mahoney's work would have been acceptable under HEW standards, because I think they regard this as more than minimal risk—not a great deal more, but somewhat more than minimal risk. Therefore, if they had followed our standards, his work would have had to come to the Board. Because it is not funded by HEW, they decided they could make that decision and they have made it and are carrying out that work.

Mr. GAITHER. There would not have been a distinction based on their work being therapeutic and this work not, because of the abortion?

Dr. MCCARTHY. No. As I understand it, initially they—and I am not quite sure at what phase they are in. They have planned a series of steps, the later stages of which they intend to be therapeutic. As I understand it, they are still in the diagnostic phase of those steps, but I believe their approval goes all the way to—assuming all the other stages are carried out with no untoward events—they intend to go all the way to applying fetoscopy to therapeutic interventions to try to assist fetuses that are in one way or another abnormal.

Mr. GAITHER. Mr. Lazarus?

Mr. LAZARUS. I think one of the key issues in this request is the problem of risk and how it is presented to the patient. Barbara says in her note that the risk presented by research cannot be characterized as minimal. Rather, it should be considered undetermined. And yet, the patient consent states that "I have been advised that these risks are minimal to me and to my fetus."

I think that one of the items that must be clarified is the whole consent procedure, and the nature of the risk must be spelled out a lot more consistently than they are spelled out under the present consent procedure that has been presented by Drew.

Ms. MISHKIN. I think one of the problems is that minimal risk, as I pointed out, is not defined in the HEW regulations, and in the Commission's report and its deliberations, that was a problem in two areas. At one point they indicate—and they indicate more strongly in subsequent reports—that risk which has not yet been determined should not be classified as minimal, but should remain under the categorization of undetermined.

On the other hand, there were some Commissioners although not all of them—there was a difference of opinion on this point, as to whether when you are talking about a fetus to be aborted, one can consider risk of abortion as a minimal risk to that fetus, whereas one would not consider risk of abortion a minimal risk to a fetus intended to go to term. This was one of the very difficult points where there was a lack of consensus among the Commission members.

So I think that when the IRB and the various people who reviewed the Drew application determined that it was minimal risk, that was not a clearly unacceptable determination. It was simply their interpretation,

given very little guidance from the Department as to how to assess and categorize that risk.

Mr. LAZARUS. It would seem to me, though, that a patient's consent is very important with the nature of the risk, which is undetermined. It should be very carefully spelled out.

Mr. GAITHER. Particularly when one is conducting the research for the purpose of finding out how risky the procedure is.

Mr. LAZARUS. Right.

Mr. HALPERN. Underlining the illogic of the word "minimal" where you are saying we don't know what it means, well, the problem is it is in our HEW regulations, and if in fact the risk is minimal as the patient is told, it wouldn't be here.

Ms. MISHKIN. That is right. It would not be before this Board if the risk were minimal. Then the IRB could have approved the project by themselves, although there is another provision that would need a waiver, so it probably would come here anyway. That is, the regulations currently provide that there be no change in timing or procedure of an abortion for research purposes that would add any additional risk, and that provision does not say "that would add more than minimal risk," but that "would add any additional risk." So it might have had to come here even so.

Dr. MCCARTHY. But the determination, the very point that Mr. Lazarus made, was picked up in the Office for Protection from Research Risks, which refused to—even though it had been reviewed by all of the subsidiary bodies—refused to go ahead and fund until and unless it has been approved by this Board.

So it is that very point: If you are doing research to assess risk, it does not seem possible then to prejudice the outcome by calling it minimal. It may turn out to be minimal, but there is no justification for the research if you already know it is minimal.

Mr. LAZARUS. And you are getting your consents under a false clause.

Dr. MCCARTHY. Yes, and I think the Office for Protection from Research Risks was correct in making the judgment that it should come before this Board to comply with HEW regs.

Mr. GAITHER. Yes, Dr. Henderson?

Dr. HENDERSON. Let me just carry that a little further. One of the important criteria here is that the research is important and justified. I think this is what is indicated. Clearly we have got investigators who are very competent people and they have obviously proceeded step by step in reaching the point they have.

I guess there are a couple of things in my own mind that are rather unclear. There are two centers where the work is being done now, Toronto and New Haven, where the risks now appear to be rather small. I think this is perhaps where the statement is that it is probably a minimal risk, that experienced people following along with two other centers, and doing what I interpret or what I understand is the same procedure that they are doing in New Haven and Toronto.

The question I guess I have, then is is it necessary to fund yet a third center? Should HEW fund a third center to be doing this? What are the advantages?

The initial point here, as they say, initially it is limited to an assessment of the safety. I find that fully justified to go—initially one is doing a study to assess the safety. But then I ask what is the ultimate objective, because we want research which is important and justified. What is it leading to? Obviously there is an objective here.

I believe, as I interpret it, that they would hope to be defining sickle cell disease. Now, I think in talking with you earlier, the ques-

tion is can you identify either the sickle cell trait or sickle cell disease before 30 weeks? Can you define it at this period in time?

Perhaps we are talking about, as you mentioned earlier, longer term basic research, which requires this technique to be used. Is it enough to say that it is important that we do longer term basic research employing this technique without defining what is that basic long term research, and are we at the point now to approve of this sort of application which is based on safety, for some sort of ill-defined subsequent future, when in fact we are supposed to be judging this that the research is important and justified.

Now, it is obvious that there are a lot of very good people who have looked at this, and I am asking the questions, I would say, out of ignorance, because I found some contradictions here which I am having trouble with.

Father MCCARTHY. Do you want to respond to that, because I have got a different point I want to raise.

Dr. FOSTER. Well, yes. I tried to make some of them and I will try again. I think there are quite a number of justifications, Don, for continuing. One of the biggest reasons—I think the assumption is not completely correct that this work is being done at the other centers. I don't think there is anywhere the proportionate interest in sickle cell disease at either other center, nor is there the particular population base in either other center to be able to address this effectively.

Even if Kan's work proves to be what it is purported to be, based on what Ms. Mishkin has said, we are still left with 15 percent of a large population that is at great need, as you are probably aware. About eight percent of the blacks in this country harbor the sickle cell trait, and that is 2.5 million people, and 15 percent of that is a large part of the population.

So I think there is still in our current state of the art to continue to try and be able to diagnose sickle hemoglobinopathies prior to the 30th week. I think there may be ways that we can do it. As yet we can't do it very reliably.

So I think the justification for continuing this work is clearly there. The justification may not be as strong as it was, but I certainly think it is within the realm of acceptability. This is what I personally feel.

Let me say one other question while I have the microphone. Let me address one other question regarding therapy versus research. I have not seen the research proposals that John Hobbins had at Yale, or what Kan has done at USC. But I do know that a lot of their fetoscopy work was therapeutic. The work on thalassemia was clearly therapeutic. It was done for the same reasons that we do amniocentesis, to decide whether or not the pregnancy should continue, and to provide a therapeutic abortion. In fact, I know much of that.

Hobbins' most recent article, which I believe was December of last year where he had, as I recall, about six or seven patients with sickle cell disease which he was working with. These were all therapeutic. He had tried to make a determination as to what type of hemoglobinopathy, whether it would be homozygous or heterozygous around the 22nd week, and the results were just inconclusive. His conclusion at the end of the article was that at this point we still can't do it. But that was clearly done to be therapeutic. Had he felt that he could have made the determination, he would have offered therapeutic abortion. So I do know that some of the work has been therapeutic.

Dr. MCCARTHY. That is correct. I should amend what I said. I think what Mahoney is doing is now tending to move into the pre-

ventive therapy and not—so I would like to amend what I said before about therapy, because it was clearly for the purpose of giving parents the option of a therapeutic abortion. But now they hope to move into preventive therapy, which is the sense in which I was using "therapeutic."

Mr. GAITHER. Is there an answer to Dr. Henderson's question, though? Do we know whether this technique will enable the researcher to determine the presence of the sickle cell disease?

Dr. FOSTER. We never know that until we do the research. I mean, no, I don't think we know it beforehand.

Mr. GAITHER. I think that is kind of a fundamental point here, because implicit in all of these papers, it seems to me, is precisely that, that this technique will enable the discovery of whether or not the disease is present. The question is whether it can be safely done. Now, if that is wrong, my whole reading of all of these papers is very much mistaken. I think it is a very fundamental point.

Either we are dealing with something that we know can help, and the question is whether it is safe, or we are dealing with something that we don't know much about.

Dr. HENDERSON. I am puzzled by your statement that the sickle cell trait is not identifiable before the 30th week. This is what is concerning me at the moment. And if it isn't identifiable before the 30th week, because you do have fetal hemoglobin present, I am not quite sure where this technique leads. I think this is information which we do have a reasonable body of knowledge on, do we not?

Dr. FOSTER. I don't know. The only thing that I do know is that the struggle has been to try and be able to diagnose sickle cell—homozygous sickle cell disease at a point at which therapeutic abortion could be offered. Right now we don't have that capability, and it was my understanding that one of the thrusts of this research proposal was to help to try and find that capability.

I would certainly think that this is an issue that again could be raised with the team, the basic research team who conducted the site visit. I think that these might be some issues that Jim and the staff might wish to bring up.

Mr. HALPERN. Dr. Henderson, it might be helpful.

Mr. NICKLES. Mr. President, we have the nominee saying a week ago Friday he performed less than 12 abortions. On the "Nightline" show, Dr. Foster said he did 39. Now we have the AP report saying that other physicians said he did many more than that in the years prior.

We have a transcript of a meeting where he said he did about 700 amniocentesis and therapeutic abortions. There are a lot of inconsistencies.

Again, I say, this nominee should be withdrawn or he should withdraw himself because of these inconsistencies, because I think there has been a deliberate attempt to mislead Congress.

Finally, I will say a couple of other things. Dr. Foster's credibility has been called into question, not only because of his inconsistent statements about abortion, but also because of other public statements. For example, during the same "Nightline" appearance, Dr. Foster said,

We have a responsibility in training residents to maintain our accreditation, a very

difficult job. I maintained an accredited residency program for 17 years.

But as today's Washington Times reports, the obstetrics residency program at Meharry Medical College lost accreditation in May 1990 when Dr. Foster was department chairman.

I watched a tape of that program, and I heard him say he maintained accreditation for 17 years. He kind of forgot to say that it lost accreditation when he was department chairman. Maybe he just forgot to say that. I do not know why it lost accreditation. I have heard, but I am not even going to mention that. I am not even faulting him for that. I am just saying his record before the public is misleading because he lost accreditation in that program. As a matter of fact, that accreditation, according to this article, has not been recovered, meaning Meharry Medical College cannot place students in hospital residency programs in obstetrics.

I ask unanimous consent to print the Washington Times article in the RECORD.

There being no objection, the article was ordered to be printed in the RECORD, as follows:

[From the Washington Times, Feb. 10, 1995]
MED SCHOOL FALTERED WITH FOSTER AT HELM
(By Paul Bedard)

The obstetrics and gynecology residency program at Meharry Medical College in Nashville, Tenn., permanently lost its accreditation when surgeon general nominee Henry W. Foster Jr. ran the department—countering his characterization that he kept it operational.

Senate critics of President Clinton's nominee said Dr. Foster misled them on his administration of the department and the college and said it was another example of the gynecologist hiding his record, especially on the number of abortions he has performed.

"He is not being straightforward with the American people and the administration is trying to cover up," said Sen. Dan Coats, Indiana Republican.

Mr. Coats and other Senate Republicans joined Sen. Don Nickles, Oklahoma Republican, in calling on Mr. Clinton to withdraw the nomination because of the differing accounts by Dr. Foster and the White House on the number of abortions he has done in a 37-year medical career.

The growing chorus of GOP voices demanding the withdrawal muted the support for Dr. Foster stated yesterday by six Senate Democrats.

Meanwhile, White House officials vented their frustration with Dr. Foster's inability to settle on a concrete figure on the number of abortions he has performed.

On the same "Nightline" show Wednesday night, the 61-year-old former Planned Parenthood board director said he had done 39 abortions since 1973, but he didn't address his eight-year stint as chief of obstetrics and gynecology at John A. Andrew Memorial Hospital at Tuskegee University in Alabama.

Asked if the White House was satisfied with Dr. Foster's answer that he had performed 39 abortions, White House spokesman Michael McCurry said: "No, we're not satisfied. We will continue to work with Dr. Foster. Many of the records he described last night are only available to him because he's the only person that can request those records."

Dr. Foster had previously said he performed one, then "fewer than a dozen" abor-

tions. He also headed a study on an abortion pill that led to 55 more abortions. And he has disavowed an official government transcript in which he indicates he may have done hundreds more abortions.

Officials at historically black Meharry said that Dr. Foster's obstetrics-gynecology residency program lost accreditation in May 1990 and the withdrawal took place a year later—after Dr. Foster had been promoted to the dean of medicine and vice president of health services.

Several efforts to restore the accreditation have failed. Without accreditation, medical schools can't place students in hospital residency programs, according to the American Medical Association.

Meharry spokeswoman Martha Robinson said the program failed because there weren't enough patients to sustain a residency internship. "It was clearly a numbers problem. It wasn't a quality issue," she said.

Dr. Edward R. Hill, who was vice chairman of Dr. Foster's program from 1982 until it ended in 1991, explained that black patients chose suburban hospitals in the late 1980's. "We lost a very significant market share among the poor who now had a ticket, Medicaid, to more affluent areas," he said in an interview.

But a prominent Nashville doctor familiar with the program and Dr. Foster said the University of Arkansas-trained physician was a poor administrator.

"He's a great idea guy but not with following through or getting the job done," said the doctor, who requested anonymity.

Senate Republicans and a White House team are studying Dr. Foster's management at Meharry, which twice received government financial bailouts while Dr. Foster was associated with the school.

"One day after he goes on 'Nightline' to brag about running his department we learn it crashed on his watch and he failed to get it accredited. He has a very deep credibility problem," said an aide with the Senate Republican Conference.

Mr. Nickles said that termination of the obstetrics-gynecology program clashed with the impression Dr. Foster left "Nightline" viewers with when he explained the reason for accepting a grant to do a study on an abortion pill in the early 1980s.

On that show, Dr. Foster said, "We have a responsibility in training residents to maintain our accreditation. It's a very difficult job. I maintained an accredited residency program for 17 years [1973 to 1990]. We have a responsibility to teach all residents how to manage the complications of abortion."

Dr. Foster's changing stories on the number of abortions he did along with concerns about his management of the Meharry obstetrics-gynecology program sparked moves by Republicans to kill the nomination. Dr. Foster is to replace outspoken former Surgeon General Joycelyn Elders, fired for controversial statements on child masturbation and sexual conduct.

"In the wake of Dr. Joycelyn Elders' discordant and failed tenure, I believe that America deserves to have a surgeon general capable of inspiring Americans on a broad range of public health issues. Plainly, Dr. Henry Foster's background and the White House's mishandling of his nomination renders him incapable of achieving that goal," said Sen. Phil Gramm, Texas Republican.

"As a result, I intend to strenuously oppose the confirmation of Dr. Foster to become surgeon general of the United States," he said.

Mr. Coats, a member of the Labor and Human Resources Committee, which will vote on the Foster nomination said, "There is a litmus test here and it is not abortion. It's the truth."

Liberal groups supporting Dr. Foster have charged that the "radical right" is using the Foster nomination to push its anti-abortion agenda.

But Mr. Coats said that Dr. Foster simply hasn't told the truth about his past. "You make the same accident three or four times and you begin to wonder if it's an accident."

After watching the nominee get hit for eight straight days, Senate Democrats finally began to rally behind Mr. Clinton's choice. The president also used a press conference with German Chancellor Helmut Kohl to speak in favor of Dr. Foster.

"I think he's a good man, I think he'll be a good surgeon general, and I think that that ought to be the issue," he said.

The president also joined with Dr. Elders in bashing Dr. Foster's opponents as ardent anti-abortion radicals.

"Now, I know that those who believe that we should abolish the right to choose and make conduct which is now legal criminal will try to seize upon this nomination to negate the work of a man's life and define him in cardboard-cutout terms, but I think that is wrong," he said.

Sen. Frank Lautenberg, New Jersey Democrat, said, "This is a vendetta, this is a witch hunt."

A day after giving Dr. Foster a 50-50 chance of winning approval by the Senate, Sen. Barbara Mikulski, Maryland Democrat, said: "Unfortunately, the White House did not do the best job in putting doctor Foster's nomination forward. Maybe that's the way the White House does such things."

Mr. NICKLES. Mr. President, Dr. Foster became dean of Meharry Medical College later in 1990. The following year, according to the June 26, 1991, edition of USA Today, two other residency programs at Meharry also lost accreditation—pediatrics and surgery. So while he was dean of the medical school, they lost pediatrics and surgery accreditation.

I ask unanimous consent to print the USA Today article in the RECORD.

There being no objection, the article was ordered to be printed in the RECORD, as follows:

[From USA Today, June 26, 1991]

PROGNOSIS: POOR—MED SCHOOL'S CRITICAL
ROLE IS IN PERIL

(By Mark Mayfield)

For 115 years, Meharry Medical College has trained more black doctors than any other school in the nation, earning a reputation for excellence.

But now Meharry's doctors are facing their toughest case: the school itself.

Lack of patients at Meharry's modern, 12-story training hospital is jeopardizing the school's medical residency programs.

And that means trouble for the national health-care system because Meharry is a top provider of doctors for low-income rural areas and medically starved inner cities.

"If the Meharrys and other minority medical schools slide into a crisis situation, it will have a serious long-term impact on health care in low-income areas around the country," says Thomas W. Chapman, president of Greater Southeast Community Hospital in Washington, D.C.

"They play a critical role in continuing to sustain a appropriate levels of health care in low-income communities."

This week, Meharry's obstetrics-gynecology residency program loses its accreditation; residents in pediatrics must transfer to a New York hospital to finish their training.

The same problem cost Meharry its surgical training program.

"When you don't have enough patients, you don't have enough cases and not enough experience for your residents," says Dr. Washington Hill, Meharry's chairman of obstetrics and gynecology.

Loss of the school's teaching hospital programs could limit its ability to attract minorities to medical careers.

"When Meharry has a serious problem, that obviously has an impact on the opportunity of black students to go to medical school," says David Denton of the Southern Regional Education Board, which has just completed a study of minority medical student education.

"In absolute terms, if you don't have residency programs in pediatrics or obstetrics-gynecology, two primary health-care fields, * * * it affects the whole teaching atmosphere of a medical school."

But Denton says the school's overall quality isn't a problem.

"People shouldn't confuse the residency problems with the quality of teaching at Meharry. It has been very effective in getting its graduates licensed," he says.

Nearly 40% of the nation's practicing black doctors and dentists are Meharry graduates. Most of them work where doctors are needed the most—poor urban areas and under-served rural towns.

"Our graduates are working in inner cities, in New York, in downtown Detroit, here in downtown Nashville," Hill says. "Nobody wants to practice in inner cities. But our graduates do."

Meharry also has produced four of every 10 black faculty members in the nation's 126 medical schools.

Until the 1970s, Meharry and Howard University School of Medicine in Washington, D.C., trained nearly 80% of the nation's black doctors. But with desegregation of what were once all-white schools, just 20% of the nation's black doctors now graduate from any one of the four black medical schools.

Nevertheless, under 7% of all first-year medical students nationally are black, so educators say Meharry gives opportunity to those who would not otherwise have it. More than 50 of the 80 first-year students enrolled at Meharry this year were accepted nowhere else.

"We take kids knowing they bring (academic) baggage," says Dr. Henry Foster, Meharry's medical school dean. "We know they can catch up. It's not how they enter that counts, it's how they exit. We'll put our graduates up against anybody."

Administrators and students cite a "cultural sensitivity" that graduates may not get elsewhere, based partly on the school being located in a poor, mostly black section of north Nashville.

"Being here is like being in the giant arms of a loving mother," says fourth-year student Andi Coleman, 28, of Greenville, Miss. "Meharry * * * sends its students out to take care of the poor, of the homeless. There is a warmth here you don't find in other programs."

Says Dr. David Satcher, Meharry's president: "African-Americans face a chronic health problem when you look at life-expectancy rates, infant mortality, death rates from treatable health problems. Meharry is not just a black institution. It's the leading hospital for the care of the poor and indigent. In all of our history, we have been involved with people who are disproportionately poor."

Meharry's patient shortage stems from a combination of politics, tough competition for patients in one of the nation's best medi-

cally served cities and financial woes inherent to black colleges.

Nashville, with 510,000 residents, has one of the highest per-capita number of hospital beds: 6,000 in 17 hospitals. It is home to the largest private hospital corporation in the nation, HCA, and Vanderbilt University Medical Center, which employs 10,000 people.

To solve Meharry's residency problem, administrators have proposed merging two hospitals—Meharry-Hubbard, where most patients are black, and Metro General, a dilapidated downtown hospital where most patients are white.

Meharry-Hubbard, with 235 beds, rarely has more than 100 patients at a time. "We have a relatively modern, empty plant," says Dr. Rupert Francis, chairman of family and preventive medicine. "We have to get patients back."

The 200-bed Metro General also rarely has more than half its beds filled.

A merger "will benefit people who are using a very antiquated facility, and it will provide more patients in which to train medical students," Hill says.

Among those supporting the merge is Vanderbilt, which now provides most of the doctors at Metro General.

But Nashville's Metro Board of Hospitals, in a 4-2 vote, rejected the merger in February, citing economic reasons.

"Some of us call (the vote) racism. The more dignified way is to call it Southern politics," Francis says.

Meharry administrators are confident they'll get the merger and re-establish accreditation for residency programs.

"Every hospital located in a low-income community is having a problem," Satcher says. "If you're in that business, you take a beating. You're punished for your commitment. We'll struggle to hold on, until one's ability to pay does not control access to health care in this country."

Says Dr. Tim Holcomb, a white Meharry resident in family medicine: "We have an emphasis on care for the poor. If I went to a big-city type of residency, I'd see sniffles and colds. Here, I see people who haven't seen a doctor in 20 years. I have absolutely no regrets coming here."

Mr. NICKLES. Mr. President, in my opinion, this raises further questions concerning Dr. Foster's credibility. On "Nightline," he presented himself as someone who had maintained accreditation at Meharry obstetrics residency program. He neglected to mention that he was department chairman when that accreditation was lost.

In my opinion, this nomination should not go forward. Some people say, "Let's wait until we have a hearing and get all the facts out." But these are statements that came from Dr. Foster himself. This statement came from Dr. Foster himself before a committee. It directly contradicts the statement he made on "Nightline." The "Nightline" statement directly contradicts a statement that he made and gave to the press, which I inserted in the RECORD, that he gave a week ago. Dr. Foster's statements are totally inconsistent. They have been misleading. His statement about the accreditation of Meharry was misleading.

So, Mr. President, I do reluctantly—I do not do this often—but reluctantly, I urge Dr. Foster to withdraw his name from consideration or urge the President to withdraw his name from con-

sideration to be the next U.S. Surgeon General.

Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. DASCHLE. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

SENATOR WILLIAM FULBRIGHT

Mr. DASCHLE. Mr. President, the British poet John Donne said that "every person's death diminishes us." That is certainly true, and it is especially true today, for yesterday America and, indeed, the world said goodbye to a man whose death diminishes us all, Senator William Fulbright.

He served in the Senate for 30 years. He served with distinction. Some in this Chamber had the privilege of working with him. But whether or not we knew Senator Fulbright personally, we were all touched by him. Our Nation and our world are better for him having passed through it.

Senator Fulbright understood that the most powerful deterrent to war is not bombs, not some mysterious shield we might try in vain to erect, but simply understanding.

The cornerstone of his legacy, the Fulbright scholars program, has created more than 200,000 ambassadors for peace and for progress throughout the world. These are bright young men and women who have traveled from America to study in 130 nations as well as men and women from around the globe who have come here to our Nation to learn. Our world is safer for the work of these Fulbright scholars and for the vision of the man who made their studies possible.

He was a son of Arkansas, but his influence was felt throughout the world, and it will be, I suspect, for generations to come.

Today, as we remember Senator Fulbright, it is easy to feel diminished by his passing. But let us also remember how enlarged we are by his life. As we struggle to find America's place in the post-cold war world, let us remember the lesson Senator Fulbright taught us about the formidable power of understanding. Let us also remember that America has a responsibility to be not only a military leader in this world, but a moral leader as well. And we must never shrink from either role.

William Fulbright, the "Chairman," as he was fondly known, was a diplomat, an idealist with a strong heart, an uncommon vision, a dogged fighter for what he believed was right. He was unafraid to stand against public opinion when his conscience told him he must.