Reid	Rockefeller	Simon
Robb	Sarbanes	Wellstone

NOT VOTING—1

Moynihan

So the conference report was agreed to.

Mr. GREGG. Mr. President, I move to reconsider the vote.

Mr. HOLLINGS. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

PARTIAL-BIRTH ABORTION BAN ACT

The PRESIDING OFFICER. Under the previous order, the Senate will now resume the consideration of H.R. 1833, which the clerk will now report.

The legislative clerk read as follows:

A bill (H.R. 1833) to amend title 18, United States Code, to ban partial-birth abortions.

The Senate resumed the consideration of the bill.

Pending:

Smith amendment No. 3080, to provide a life-of-the-mother exception.

Dole amendment No. 3081 (to amendment No. 3080), of a perfecting nature.

Pryor amendment No. 3082, to clarify certain provisions of law with respect to the approval and marketing of certain prescription drugs.

Boxer amendment No. 3083 (to amendment No. 3082), to clarify the application of certain provisions with respect to abortions where necessary to preserve the life or health of the woman.

Brown amendment No. 3085, to limit the ability of dead beat fathers and those who consent to the mother receiving a partial-birth abortion to collect relief.

AMENDMENT NO. 3083 TO AMENDMENT NO. 3082, AND AMENDMENT NO. 3081 TO AMENDMENT NO. 3080

The PRESIDING OFFICER. Under the previous order, there will now be 60 minutes equally divided for debate on amendments by Senators DOLE and BOXER.

The Senate will be in order.

Who seeks recognition?

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I ask the Senator from California for 5 minutes, when the Senate is in order.

Mrs. BOXER. Mr. President, if you will bring the Senate to order?

The PRESIDING OFFICER. The Senator from Massachusetts has asked for 5 minutes from the Senator from California.

Mrs. BOXER. Yes, as soon as the Senate is in order. I do not believe we should start the clock running until the Senate is in order. Mr. President, this is a very serious difficult debate. Members on both sides feel very strongly. I will be happy to yield 5 minutes to the Senator from Massachusetts when the Chair believes the Senate is in order.

The PRESIDING OFFICER. The Senator will begin debate when there is order.

The Senator from Massachusetts.

Mr. KENNEDY. Mr. President I yield myself 4 minutes and 15 second and ask to be notified at that time.

Mr. President, I oppose the pending bill and strongly support the Boxer amendment to protect the lives and health of women. I came away from the November 17 Judiciary Committee hearing more convinced than ever that this bill is an unwise, unconstitutional——

Mrs. BOXER. Mr. President, if I could ask the Senator to yield, the Senate is not in order.

The PRESIDING OFFICER. Will the Senators to the left of me take their conversations off the floor?

The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I oppose the pending bill to outlaw medically necessary abortions, and I strongly support the Boxer amendment to protect the lives and health of women.

The Senate began to debate H.R. 1833 last month, a mere 6 days after the bill had passed the House. At first, the bill's Senate sponsors even refused the reasonable request that hearings be held. But a strong bipartisan majority of the Senate rejected that unacceptable approach. The bill was committed to the Judiciary Committee for a hearing. But there was no committee markup and the Senate does not have the benefit of a committee report.

The haste with which this bill is being pushed through the Senate is unseemly. Obviously, its proponents don't want their proposal examined too closely. They'd rather have the Senate vote on emotion, not on the facts.

I attended the November 17 hearing, and I came away from it more convinced than ever that this bill is an unwise, unconstitutional, and dangerous proposal.

The hallmark of good legislation is clarity. But the November 17 hearing revealed that this bill is unacceptable vague. In criminal legislation like this, that's unconstitutional, and it's quite likely that the courts will throw out this bill under the void for vagueness doctrine.

The problem is obvious. The Judiciary Committee heard from a panel of medical experts who could not even agree among themselves on the medical meaning of the legislative language, or on which procedures might be banned. Dr. Courtland Robinson of Johns Hopkins University called the language ''vague, not medically substantiated, and just not medically correct . . . the name [partial-birth abortion] did not exist until someone who wanted to ban an abortion procedure made up this erroneous, inflammatory term.''

The bill's very vagueness itself threatens the lives and health of American women. In the absence of a clear definition of what is outlawed, doctors will decline to perform any abortion that a prosecutor or jury might later find objectionable.

Prof. Louis Michael Seidman of Georgetown Law Center testified: ''If I were a lawyer advising a physician who performed abortions, I would tell him to stop, because there is just no way to tell whether the procedure will [violate this law].''

Dr. Robinson, who has practiced medicine for over 40 years, expressed the fear that if doctors are unwilling to perform needed abortions, women will resort to the back-alley methods that were used before safe, legal abortions became available. He testified:

> In the 1950's in New York, I watched women die from abortions that were improperly done. By banning this technique, you would, in practice, ban most later abortions altogether by making them virtually unavailable. And that means that women will probably die. I know. I've seen it happen.

Despite the bill's apparently deliberate vagueness, the one activity it clearly bans is a procedure known as ''intact dilation and extraction'' or ''D&E'' surgery. There are perhaps 450 such operations performed in the United States each year, and they involve ''wanted pregnancies gone tragically awry,'' according to Dr. Mary Campbell of Planned Parenthood, who testified at the hearing. Dr. Campbell explained that when emergency conditions threaten the life or health of the pregnant woman, this procedure is safer than any other abortion method, such as induced labor or caesarean section.

Depending upon the position of the fetus in the womb, a woman is 14 times as likely to die from a C-section as from a D&E, and twice as likely to die from induced labor as from a D&E, according to Dr. Campbell. C-sections create an increased risk of rupture of the uterus in future pregnancies.

The bill's supporters ignore this compelling medical testimony and the scholarly articles that support it. They rely instead on a single quotation from a single doctor to the effect that 80 percent of these abortions he performs are ''elective.'' But proponents of the bill are grossly distorting what that doctor said. They never complete the quotation—the doctor stated that he is referring to abortions before the sixth month of pregnancy.

The Supreme Court has made plain that in the case of such pre-viability abortions, a woman may elect to terminate her pregnancy without the undue interference from the Government. After viability, of course, there are no elective abortions. As Dr. Campbell noted emphatically, ''third trimester abortion for healthy babies is not available in this country.* * * Occasionally, someone comes to see me who thinks she is 10 weeks pregnant; it turns out she is 32 weeks pregnant. I don't say, 'where can we get you a third-trimester abortion.' I say, 'You will be having a baby.' ''

The Judiciary Committee heard the facts about the D&E procedure from doctors. We also heard moving testimony from two women who needed and obtained this surgery to avoid serious health consequences.

Coreen Costello is a pro-life Republican. She learned that the fetus she

was carrying had ''a lethal neurological disorder. * * * Due to swelling, her head was already larger than that of a full-term baby. Natural birth or an induced labor were impossible.'' The D&E procedure, she said, ''greatly lowered the risk of my death. * * * There was no reason to risk leaving my children motherless if there was no hope of saving [my baby].''

Vicki Wilson testified about an equally tragic pregnancy. As she told the committee, ''approximately 2/3 of my daughter's brain had formed on the outside of her skull. * * * Because of the size of her anomaly, the doctors feared that my uterus would rupture in the birthing process, most likely rendering me sterile.'' She pleaded with the committee: ''There will be families in the future faced with this tragedy because prenatal testing is not infallible. I urge you, please don't take away the safest procedure available. This issue isn't about choice, it's about medical necessity.''

The bill's supporters obviously cannot deal with the force of this firsthand testimony. So what do they do? They now suggest that the surgical procedures that saved Coreen Costello and Viki Wilson were not ''partial-birth abortions.''

That devious retreat speaks volumes about the vagueness of this bill, and the uncertainty it is designed to create. Even its sponsors don't know what it means. But let there be absolutely no mistake. The procedure that these two witnesses underwent was an intact D&E. It was the procedure depicted on Senator SMITH's charts. It is the procedure that the bill's proponents say they object to. It is the procedure that saved the lives and health of Coreen Costello and Vicki Wilson. And now the bill's supporters pretend the bill wouldn't apply to those cases. If it doesn't apply to those cases, it will not apply to any cases.

These two brave women do not stand alone. Five other women submitted testimony for the record describing similar cases. Thousands of women owe their lives or their health to the availability of a surgical procedure that the U.S. Senate is on the verge of outlawing and sending any doctor to prison who performs it.

On its face, this bill is an unprecedented intrusion by Congress into the practice of medicine. Its passage would represent the first time in American history that Congress has outlawed a specific medical procedure and imposed criminal penalties on doctors for treating their patients. As Dr. Robinson told the Judiciary Committee: ''With all due respect, the Congress of the United States is not qualified to stand over my shoulder in the operating room and tell me how to treat my patients.''

This political excursion into the practice of medicine is plainly inappropriate. So why is it before the Senate today? The answer is simple. The right-to-life movement has brought this bill to Congress in the hope that its passage will advance their goal of discrediting Roe versus Wade and eventually outlawing all abortions. The bill's supporters in the House boasted of such a strategy. At least one witness at the committee hearing spoke frankly of this broader agenda. Helen Alvare of the Catholic Conference testified in support of the bill. She responded to questioning by Senator FEINGOLD that she absolutely favored criminal penalties for all abortion procedures. As she said, ''If abortion proponents are afraid that somehow this [bill] opens the public mind to considering abortion further, they are certainly right.''

That is why supporters of this bill do not mind its vagueness. They do not really want to imprison the doctors who perform this procedure. They want to intimidate all doctors into refusing to perform any abortions at all.

Before we head down that dangerous road, we should remember that Roe versus Wade and the subsequent Supreme Court decisions affirming a woman's right to choose are based squarely on the Constitution. The constitutional basis of the decision has been reaffirmed by the Supreme Court in case after case since 1973. In its decision in Planned Parenthood versus Danforth, the Supreme Court specifically invalidated a Missouri law that banned a particular abortion procedure. The Court held that the Missouri law might force ''a woman and her physician to terminate her pregnancy by methods more dangerous to her health than the method outlawed.''

This bill is a frontal assault on settled Supreme Court law. Basically, it asks the Supreme Court to overrule Roe versus Wade.

At the hearing, Professor Seidman of Georgetown Law Center identified a half dozen independent reasons why the bill is unconstitutional. The most disturbing of all the reasons is the bill's failure to permit abortions that are necessarily to preserve the life of the woman or to protect her from serious adverse health consequences.

The Boxer amendment would at least remedy this most glaring defect. It states clearly that the criminal prohibition in the bill will not apply in the case of pre-viability abortions, or in the case of abortions that in the medical judgment of the attending physician are necessary to preserve the life of the mother or avoid serious, adverse health consequences.

Every Member of the Senate who supports Roe versus Wade should support the Boxer amendment. So should every Member of the Senate who wants to protect the lives and health of American women.

In contrast, the Smith/Dole version of the exception is grossly inadequate. It fails to address the situation where an abortion is necessary to avoid serious adverse health consequences. The Boxer amendment protects both the life and the health of the woman. The Smith/Dole amendment protects only the woman's life.

Senator SMITH and Senator DOLE know how to write a genuine life-of-the-mother exception. The model is obvious—the long-standing Hyde amendment in Medicaid, which allows Medicaid to pay for abortions in cases where it is necessary to save the life of the mother.

But Senator SMITH and Senator DOLE don't want a real exception for the life of the mother. In fact, their language does not even protect a woman's life. It contains two gaping loopholes, and these loopholes make it meaningless.

First, the Smith/Dole amendment limits the types of life-threatening situations in which the exception applies. Only threats to a woman's life that arise from ''a physical disorder, illness or injury'' are covered. It does not cover the threat to a woman's life that may arise from the pregnancy itself, since pregnancy is not a ''physical disorder, illness or injury.'' Coreen Costello, for example, did not have an illness like cancer or diabetes that threatened her life. The threat to her life arose from her pregnancy itself, and would not be covered by the Smith/Dole exception.

Second, the Smith/Dole exception is conditioned on whether ''any other medical procedure would suffice'' to save the woman's life. This proviso is an outrageous example of second-guessing a doctor's judgment. Doctors who had literally saved a patient's life could find themselves in a Federal prison because a prosecutor and a jury concluded after the fact that the patient's life could also have been saved using a different medical procedure that offended Congress' sensibilities less.

What doctor would take that chance? None. The Smith/Dole exception is a sham. It provides no significant additional protection to doctors who want to save the life of the woman.

Few aspects of the lives of citizens are as sensitive and as deserving of privacy as the relationship between patients and their physicians. Several years ago, we debated a proposal to gag physicians and prevent them from counseling women about abortion. But this bill makes the gag rule debate pale by comparison. It puts the Federal Government—indeed, Federal law enforcement officers—directly into the doctor's office in the most intrusive way.

The procedure involved in this case is extremely rare. It involves tragic circumstances late in pregnancy where the mother's life or health is in danger. The Federal Government has no business intruding into these family decisions at all, and certainly not in so misguided a fashion.

The laws in 41 States already regulate post-viability abortions. The appropriations of medical practices is overseen by state and local health departments, medical societies, hospital ethical boards, and other organizations. The Federal criminal law is a preposterous means of regulating the highly personal, individual decisions

facing families with tragic pregnancies.

Coreen Costello told the Judiciary Committee: ''We are the families that ache to hold our babies, to raise them, to love and nurture them. We are the families who will forever have a hole in our hearts. We are the families that had to choose how our babies would die. Each one of you should be grateful that you and your families have not had to face such a choice. I pray that no one you love ever does. Please put a stop to this terrible bill.

I join Coreen Costello in urging the Senate to defeat this bill. The test for every male Senator in this Chamber is very simple—would you deny this procedure to your wife or daughter if it's needed to save her life or health? Would you send her doctor who performed it to jail?

This bill is medical malpractice. The Senate should stop practicing medicine without a license. This bill should be defeated.

The PRESIDING OFFICER. Who seeks recognition?

Mr. GRAMM addressed the Chair.

The PRESIDING OFFICER. The Senator from Texas.

Mr. GRAMM. Mr. President, I yield as much time as he might require to the distinguished Senator from Indiana, Senator COATS.

The PRESIDING OFFICER. The Senator from Indiana is recognized.

Mr. COATS. Mr. President, Americans have honest disagreements over the subject of abortion. Strong convictions often lead to strident rhetoric, at times straining the bounds of civil discourse. Labels and name calling too easily substitute for persuasion as a means of winning the hearts and minds of fellow citizens. Extremism and fanaticism are served up as daily fare, often being dismissively attached to those with strong pro-life views.

And yet there are times when strong words are necessary, when truth, raw and exposed, merits an apt label. There is only one issue at stake here: It is an affront to humanity and justice to kill a kicking infant with scissors as it emerges from its mother.

This legislation is not the expression of extremism. Only the procedure itself is extreme—extreme in its violence, extreme in its disregard for human life and dignity.

We have listened to the words of an eyewitness to this procedure. So we know what the procedure is. A prochoice nurse who assisted an abortionist in this procedure described the procedure. I do not like to describe the procedure on this floor. I do not like to read the procedure. But I know one thing. I cannot condone or support this procedure. And, if we are going to vote with a clear understanding of what it is we are dealing with, we need to understand the procedure.

I quote from this pro-choice nurse who assisted an abortionist in this procedure.

What I saw is branded on my mind forever . . . Dr. Haskell went in with forceps and grabbed the baby's legs and pulled them down into the birth canal. Then he delivered the baby's body and the arms—everything but the head. The doctor kept the head right inside the uterus. . . .

The baby's little fingers were clasping and unclasping, and his little feet were kicking. Then the doctor stuck the scissors in the back of his head, and the baby's arms jerked out, like a startled reaction, like a flinch, like a baby does when he thinks he is going to fall.

The Doctor opened up the scissors, stuck a high-powered suction tube into the opening, and sucked the baby's brains out. Now the baby went completely limp.

I was really completely unprepared for what I was seeing. I almost threw up as I watched Dr. Haskell doing these things.

Next, Dr. Haskell delivered the baby's head. He cut the umbilical cord and delivered the placenta. He threw the baby into a pan, along with the placenta and the instruments he had just used. I saw the baby move in the pan. I asked another nurse, and she said it was just ''reflexes.''

I had been a nurse for a long time, and I have seen a lot of death—people maimed in accidents, gunshot wounds, you name it. I have seen surgical procedures of every sort. But in all my professional years, I had never witnessed anything like this.

The woman wanted to see her baby, so they cleaned up the baby and put it in a blanked and handed it to her. She cried the whole time. She kept saying, ''I am so sorry, please forgive me.'' I was crying, too. I couldn't take it. That baby boy had the most perfect angelic face I think I have ever seen in my life.

The only possible way to defend this procedure is with evasion and misrepresentation.

It is said that this procedure is rare. But we are safely talking about hundreds of these abortions annually. And as a matter of unalienable human rights, it should not only be rare, it should be nonexistent.

I suggest, if we are talking about 1 abortion with this procedure rather than 600, the issue is exactly the same.

It is said that the child feels nothing. But we know that a mother's anesthesia does not eliminate her child's pain. And we know that a child killed in this procedure feels exactly what a preemie would feel if its doctors decided to kill it in its nursery.

It is said that this procedure is done to save the life of the mother. But we know that this procedure is not without substantial risk for the mother. And, in fact, its primary purpose is the convenience of the abortionist.

It is said that partial birth abortions are part of the mainstream of medicine. But we know that the AMA Council on Legislation stated that this practice is not a ''recognized medical technique'' and that the ''procedure is basically repulsive.''

I am quoting. The AMA Council on Legislation said that this procedure is ''basically repulsive.'' I think anyone who understands the procedure and knows the description of the procedure can come to no other conclusion.

It is said that only prolife fanatics support this legislation. But how could this possibly apply to Members of the House like PATRICK KENNEDY, SUSAN MOLINARI, and JOHN DINGELL? One prochoice Member of the House commented, ''It undermines the credibility of the pro-choice movement to be defending such an indefensible procedure.''

When we strip away all these arguments, we are left an uncomfortable truth: This procedure is not the practice of medicine, it is an act of violence.

It is hard to clearly confront reality in this matter, because clarity causes such anguish. But that reality is simple and terrible: The death of a child with the most perfect angelic face I think I have ever seen in my life. That face should haunt us and shame us as a society. It should cause us to grieve—but more than that, it should cause us to turn back from this path to barbarism.

Mr. President, I ask unanimous consent to have printed in the RECORD an article written by George Will called, ''Fanatics For 'Choice.' Partial-birth abortions, sonogram photos and 'the idea that the fetus means nothing.' ''

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

FANATICS FOR ''CHOICE''

(By George F. Will)

Americans are beginning to recoil against the fanaticism that has helped to produce this fact: more than a quarter of all American pregnancies are ended by abortions. Abundant media attention has been given to the extremism that has tainted the right-to-life movement. Now events are exposing the extraordinary moral evasions and callousness characteristic of fanaticism, prevalent in the abortion-rights lobby.

Begin with ''partial-birth abortions.'' Pro-abortion extremists object to that name, preferring ''intact dilation and evacuation,'' for the same reason the pro-abortion movement prefers to be called ''pro-choice.'' What is ''intact'' is a baby. During the debate that led to House passage of a ban on partial-birth abortions, the right-to-life movement was criticized for the sensationalism of its print advertisements featuring a Dayton nurse's description of such an abortion:

''The mother was six months pregnant. The baby's heartbeat was clearly visible on the ultrasound screen. The doctor went in with forceps and grabbed the baby's legs and pulled them down into the birth canal. Then he delivered the baby's body and the arms—everthing but the head. The doctor kept the baby's head just inside the uterus. The baby's little fingers were clasping and unclasping and his feet were kicking. Then the doctor stuck the scissors through the back of his head, and the baby's arms jerked out in a flinch, a startle reaction, like a baby does when he thinks that he might fall. The doctor opened up the scissors, stuck a high-powered suction tube into the opening and sucked the baby's brains out.''

To object to this as sensationalism is to say that discomforting truths should be suppressed. But increasingly the language of pro-abortion people betrays a flinching from facts. In a woman's story about her chemical abortion, published last year in Mother Jones magazine, she quotes her doctor as saying, ''By Sunday you won't see on the monitor what we call the heartbeat.'' ''What we call''? In partial-birth abortions the birth is kept (just barely) partial to preserve the legal fiction that a baby (what some pro-

abortion people call ''fetal material'') is not being killed. An abortionist has told The New York Times that some mothers find such abortions comforting because after the killing, the small body can be ''dressed and held'' so the (if pro-abortionists will pardon the expression) mother can ''say goodbye.'' The New York Times reports, ''Most of the doctors interviewed said they saw no moral difference between dismembering the fetus within the uterus and partially delivering it, intact, before killing it.'' Yes.

Opponents of a ban on partial-birth abortions say almost all such abortions are medically necessary. However, an abortionist at the Dayton clinic is quoted as saying 80 percent are elective. Opponents of a ban on such abortions assert that the baby is killed before the procedure, by the anesthesia given to the mother. (The baby ''undergoes demise,'' in the mincing words of Kate Michelman of the National Abortion and Reproductive Rights Action League. Does Michelman say herbicides cause the crab grass in her lawn to ''undergo demise''? Such Orwellian language is a sure sign of squeamishness.) However, the president of the American Society of Anesthesiologists says this ''misinformation'' has ''absolutely no basis in scientific fact'' and might endanger pregnant women's health by deterring them from receiving treatment that is safe.

Opponents of a ban say there are only about 600 such procedures a year. Let us suppose, as not everyone does, the number 600 is accurate concerning the more than 13,000 abortions performed after 21 weeks of gestation. Still, 600 is a lot. Think of two crashes of jumbo airliners. Opponents of the ban darkly warn that it would be the first step toward repeal of all abortion rights. Columnist John Leo of U.S. News & World Report says that is akin to the gun lobby's argument that a ban on assault weapons must lead to repeal of the Second Amendment.

In a prophecy born of hope, many pundits have been predicting that the right-to-life ''extremists'' would drastically divide the Republican Party. But 73 House Democrats voted to ban partial-birth abortions; only 15 Republicans opposed the ban. If the ban survives the Senate, President Clinton will probably veto it. The convention that nominated him refused to allow the Democratic governor of Pennsylvania, Bob Casey, who is pro-life, to speak. Pro-choice speakers addressed the 1992 Republican Convention. The two presidential candidates who hoped that a pro-choice stance would resonate among Republicans—Gov. Pete Wilson, Sen. Arlen Specter—have become the first two candidates to fold their tents.

In October in The New Republic, Naomi Wolf, a feminist and pro-choice writer, argued that by resorting to abortion rhetoric that recognizes neither life nor death, pro-choice people ''risk becoming precisely what our critics charge us with being: callous, selfish and casually destructive men and women who share a cheapened view of human life.'' Other consequences of a ''lexicon of dehumanization'' about the unborn are ''hardness of heart, lying and political failure.'' Wolf said that the ''fetus means nothing'' stance of the pro-choice movement is refuted by common current practices of parents-to-be who have framed sonogram photos and fetal heartbeat stethoscopes in their homes. Young upscale adults of childbearing age are a solidly pro-choice demographic group. But they enjoy watching their unborn babies on sonograms, responding to outside stimuli, and they read ''The Well Baby Book,'' which says: ''Increasing knowledge is increasing the awe and respect we have for the unborn baby and is causing us to regard the unborn baby as a real person long before birth . . .''

Wolf argued for keeping abortion legal but treating it as a matter of moral gravity because ''grief and respect are the proper tones for all discussions about choosing to endanger or destroy a manifestation of life.'' This temperate judgment drew from Jane Johnson, interim president of Planned Parenthood, a denunciation of the ''view that there are good and bad reasons for abortion.'' So, who now are the fanatics?

Mr. COATS. With that, Mr. President, I yield the floor.

The PRESIDING OFFICER. Who yields time?

Mrs. BOXER. Mr. President, I yield myself 2 minutes, and then I will yield directly to Senator SPECTER.

I wish to put a face to the women in this debate, so night after night as Senator SMITH and I have debated this issue, I have shown the faces of different families who have had to face this tragedy who are never shown on the posters that the other side has used during this debate. Those are the faces that I think are very, very crucial and very, very important.

This is Coreen Costello about whom Senator KENNEDY commented. This is a woman who describes herself as a pro-life Republican who underwent this procedure so she could live to see her other children grow.

Why on Earth would we in the Senate, knowing nothing about medicine, ban a procedure that some doctors testified before us at the Judiciary Committee saves lives like this and gives these children a mother.

I would say that as Senator COATS read the quote from the nurse, what he failed to say is she had worked for 3 days in this clinic in a temporary capacity. The fact is that her supervisor wrote the following, and I would place it in the RECORD:

Miss Pratt—

This nurse—

Absolutely could not have witnessed fetal movement as she describes. We do not train temporary nurses in second trimester dilation and extractions since it is highly technical and would not be performed by someone in a temporary capacity.

He also failed to mention that the American Nurses Association, which represents 2.2 million nurses, who learn to save lives, strongly opposes this legislation. They do not believe it is humane to deprive women such as Coreen Costello and their beautiful families of a chance to live. So we will be talking about that.

And now I would yield 4 minutes to the Senator from Pennsylvania, Mr. SPECTER.

The PRESIDING OFFICER. The Senator from Pennsylvania.

Mr. SPECTER. Mr. President, I thank the distinguished Senator from California.

Mr. President, I support both of the pending amendments, the amendment offered by the distinguished majority leader, Senator DOLE, and the amendment offered by the distinguished Senator from California, Mrs. BOXER.

I believe that the broader amendment, the Boxer amendment, is the preferable one because it articulates the basic constitutional standard which was setforth in Row v. Wade and upheld in Casey v. Planned Parenthood in 1992, an opinion written by three Justices appointed by Presidents Reagan and Bush.

When you talk about the life of the mother and the health of the mother, conditioning the health on ''serious adverse health consequences,'' that is the constitutionally protected doctrine. When you talk about the language of the Dole amendment, which I intend to support, it is not in the blanket terms of life of the mother as in the Hyde amendment or the traditional amendments which are offered on appropriations bills which make an exception for life of the mother but instead talks about ''saving the life of the mother whose life is endangered by a physical disorder, illness or injury, provided that no other medical procedure would suffice for that purpose.''

That language is hard to interpret at best, and I do believe would place substantial doubt in the minds of many doctors who would be called upon to try to figure out what it means.

This is a medical procedure which is chilling beyond any question, and we do at the present time have a line drawn as to when there is someone alive protected by the laws against homicide and infanticide and the constitutional protections which apply on the medical procedure of abortions.

We had only 1 day of hearings on this matter. The day we had was certainly preferable to having no hearings at all, but we were unable to get on relatively short notice, because we had a very limited time span, the doctors who were really familiar with these procedures. The fact is that those who are familiar were reluctant to step forward and offer medical judgments. But we heard very profound testimony from physicians who expressed the concern about having legislation in this field where it is very difficult to start to draw lines about what medical practices and what medical procedures ought to be.

There is so much to be said for the proposition that it is between the doctor and the patient as to what is necessary for the life of a mother, which is at least the most restrictive standard which ought to be adopted in clearcut terms and really is not by the amendment offered by the distinguished majority leader but really ought to be extended life of the mother or health of the mother which has been established by the constitutional parameters by the Supreme Court of the United States.

We have legislation which is very profound in its import, which had one limited hearing in the House, one limited hearing in the Senate, and which we will be legislating upon which will leave many, many open questions and many doubts on a very, very serious medical procedure.

So, at a minimum, Mr. President, I hope that the Boxer amendment would

be adopted as well as the Dole amendment.

The PRESIDING OFFICER. The 4 minutes yielded to the Senator from Pennsylvania have expired.

The Senator from New Hampshire.

Mr. SMITH. Mr. President, how much time is available on our side.

The PRESIDING OFFICER. There are 22 minutes, 14 seconds.

Mr. SMITH. And the other side?

The PRESIDING OFFICER. There are 19 minutes exactly.

Mr. SMITH. I will yield 5 minutes to the Senator from Texas, Mr. GRAMM.

The PRESIDING OFFICER. The Senator from Texas.

Mr. GRAMM. Mr. President, I wish to begin by congratulating our dear colleague from New Hampshire. First of all, I wish to congratulate him for his leadership on this issue. I wish to congratulate him for the way that he has handled the issue. I hope that we are successful today in ending this procedure which I believe no civilized society can condone.

This is not an issue that I had heard discussed before on the Senate floor until one day I came over to the floor to speak on another subject, and the distinguished Senator from New Hampshire was describing this procedure. Questions were raised as to whether someone might be offended by the description. I rose simply to make the point that if we are offended by the description of the procedure, surely we have to be offended by the fact that the procedure is occurring in America today.

I joined the distinguished Senator from New Hampshire as his original cosponsor when he introduced the bill. There were only two of us to begin with on the bill. That number has grown.

I do not know that I can add much to this debate. But let me try to sum up my feelings on the issue. The Dole amendment, which is now pending, removes any doubt about the fact that the life of the mother and any threat to the life of the mother is a defense for using this procedure. If the mother's life is in danger, this procedure can be used.

So the question really boils down to whether a civilized society can condone this procedure when the life of the mother is not at risk. And I submit this: We have heard the description. We have heard testimony of a nurse who witnessed this procedure first-hand. It really boils down to this. This procedure is almost always used with a late-term baby, which is generally viable outside the womb. And when the baby is 3 inches away from the full protection of the Constitution, the baby's life is terminated in a violent manner that I think is objectionable in a civilized society.

The question is, Are we going to stop it? I remind my colleagues, this is a vote about banning a procedure when the mother's life is not in danger. The child is delivered feet first, and when only the head of the child remains in the womb, its life is terminated—just 3 inches away from the full protection of the Constitution.

This amendment bans no other type of abortion. It simply bans this procedure, which I believe is offensive, and which I believe is unacceptable in a civilized society.

I hope our colleagues will vote for the Dole amendment because it formalizes what those of us who were for the Smith proposal to begin with understood, and that is, the life of the mother exception was included to begin with. This further clarifies it for someone who is concerned about that. And I think it is a legitimate concern, though I was satisfied with the original language. But with the Dole amendment adopted, I think we have a clear-cut choice. I hope our colleagues will vote for the Dole amendment, against the Boxer amendment, and then vote for the Smith proposal.

I think it is the right thing to do. I am very proud to associate myself with the distinguished Senator from New Hampshire on this issue. I reserve the remainder of our time.

Mrs. BOXER addressed the Chair.

The PRESIDING OFFICER. The Senator from California.

Mrs. BOXER. I plan to yield to the Senator from Maine, Senator SNOWE, in a moment.

I wanted to answer a couple points made by my friend from Texas. First, he did describe the usual life-of-the-mother exception, which we voted on many times in the Senate, which is usually the Hyde language. That is not the language in the Dole amendment. The language in the Dole amendment, although described as life-of-the-mother, relates to a woman with a pre-existing condition, not to situations that we are talking about where the woman's life is in danger due to the pregnancy itself.

So the only real life-of-the-mother exception is the Boxer amendment. But we will support both Dole and Boxer because under the Dole amendment two or three women may be saved a year. Under the Boxer amendment you will save more women like Coreen and others. So we would advise Senators to vote for both.

I want to say that I am very proud that we reached across the aisle here and the Boxer amendment is supported by Senator BROWN, Senator SPECTER, Senator SNOWE, and also on our side, Senators MURRAY, MOSELEY-BRAUN, and LAUTENBERG.

At this time I yield 4 minutes to the Senator from Maine, Senator SNOWE.

Ms. SNOWE. I thank the Senator for yielding.

Mr. President, Members of the Senate, I rise in support of the amendment that has been offered by my colleague from California, Senator BOXER. I think there is no question in light of the testimony that was presented to the Judiciary Committee during a hearing on this legislation, when many of us advocated that this legislation go to committee so that we would have a chance to hear first hand from those women who would be affected by this kind of legislation, that without a doubt this amendment becomes even more important, more crucial, more vital to women's health.

Twenty-two years ago the Supreme Court handed down the Roe versus Wade decision. It said that the woman's interest and decisions in reproductive matters should remain paramount. It also said the States could ban abortion in the last trimester. But they also had to include exceptions for when the life and health of the mother is in danger—let me repeat—as long as they allowed exceptions for cases in which a woman's life and health is endangered.

The Supreme Court has reaffirmed that decision time and time again. Forty-one States ban abortion in the last trimester, but they provide exceptions for the life and health of the mother, as is constitutionally required by the Roe versus Wade decision. That is what the Boxer amendment does. It upholds that decision providing for the life and health of the mother. The Supreme Court recognized, in its wisdom, that there would be certain limiting, exceptional, tragic circumstances that may require an abortion in the final trimester. That is a decision that has to be made between the doctor and his patient.

Without such an exception, without providing for life and health exceptions, innocent women are harmed. I have been somewhat amazed by some of the discussion that has taken place here on the floor. These are not casual decisions. These are not decisions that are made lightly. This procedure is not performed for sex selection.

These are tragic and compelling circumstances under which a woman has to make this decision. That was verified and reinforced by the testimony presented by so many women before the Judiciary Committee recently. It was compelling testimony. These are heart-wrenching decisions and very difficult ones. These are procedures that are rarely performed, seldom performed. But there are times in which they have to be performed to save the life of the mother or to prevent drastic consequences to her health. Those are the facts.

There have been 450 such procedures performed annually. They are so rare that they amount to 0.04 percent in the last trimester. Now we are talking about criminalizing a procedure that can save the life and the health of the mother. Now we are saying that political judgment will override medical judgment.

I cannot imagine that any doctor, under the language in this legislation, if this amendment is not accepted, would be willing to take an action that is the safest and the most appropriate course, given the criminal prosecution involved in this legislation, unless we

accept the Boxer amendment that provides for the exception in cases of life and health.

One doctor was quoted in the New York Times recently. He said, ''I don't want to make medical decisions based on congressional language. I don't want to be that vulnerable. It's not what I want for my patients.''

The PRESIDING OFFICER. The Senator's time has expired.

Mrs. BOXER. I yield the Senator an additional 60 seconds.

The PRESIDING OFFICER. The Senator is recognized for an additional 60 seconds.

Ms. SNOWE. Another doctor, Dr. Robinson, an OB-GYN at Johns Hopkins, testified before the Judiciary Committee:

> Telling a doctor that it is illegal for him or her to perform a procedure that is safest for a patient is tantamount to legislating malpractice.

So what we are doing under this legislation if we do not accept the Boxer amendment is saying to doctors, we want you to perform more dangerous, more traumatic procedures for the woman, even if it is against their best medical advice; for example, caesarean sections, that would require four times the risk of death as vaginal delivery. In fact, a woman is 14 times more likely to die from a caesarean section than from the procedure that this legislation seeks to outlaw.

Induced labor carries a potentially life-threatening risk and threatens the future fertility of women by potentially causing cervical lacerations and hysterectomies which leave women often unable to have children for the remainder of their lives.

As one professor said during the hearing, the only thing that this procedure does is to channel women from one less risky abortion procedure to another more risky abortion procedure. That is what we are doing here. He said that the Government does not have a legitimate interest in trying to discourage that.

I hope that we will not throw women's lives and women's health into limbo by rejecting this legislation. I hope that they support the Boxer amendment.

The PRESIDING OFFICER. The Senator from California.

Mrs. BOXER. Mr. President, I do not need time at this point.

The PRESIDING OFFICER. The Senator from New Hampshire.

Mr. SMITH. I yield 5 minutes to the Senator from Pennsylvania.

The PRESIDING OFFICER. The Senator from Pennsylvania.

Mr. SANTORUM. Mr. President, I thank the Senator from New Hampshire for yielding. I want to congratulate him on the work he has done. He has been here many, many days and many, many hours debating a very difficult, emotional issue.

I have been in the U.S. Senate and the House of Representatives now for 5 years. I have never spoken on the floor of either body on the issue of abortion. I never felt in my heart comfortable coming to the floor and talking about legislating the issue of abortion.

I thought, as do many folks who vote pro-life here, that the issue is one that we have to educate and we have to change hearts and we have to go out to the public and sensitize the public to the horrors of abortion in this country. I say that as someone who is pro-life, but I think there are people who are pro-choice who believe also that abortion is wrong, it should be minimized in this country. So I always felt uncomfortable talking about legislating abortion.

I have to say, I felt compelled to come up and talk about this. This is not about pro-life or pro-choice. This is about a horrific procedure that should shock the conscience of anyone who has heard how this procedure is done.

The Senator from Maine just said, ''Well, you are going to take folks and force them from one risky procedure to another risky procedure. That may be true, but this risky procedure shocks the conscience of anyone who has heard it described. This is so horrific. There is some sort of moral code in this country. To see a baby three-quarters born have scissors stuck in the back of their brain—where have we come as a country when we say, ''Well, we need a statute to prohibit that,''—this is wrong.

I do not even think we should be having debate about it. One of the problems I think many of us have who are pro-life, who are conservative is that we tend to argue facts and figures. I was ready to read you that of the two doctors who performed the majority of these abortions, half of the babies who were born were perfectly healthy. One doctor testified to that effect and nine of the flawed babies had cleft palate. Flawed babies.

We had Dr. Haskell, the other abortionist who does this, saying 80 percent of the abortions were purely elective abortions. So do not try to sell a bill of goods. Those are facts and figures.

I think what we have trouble with sometimes, as Republicans, is we put up charts, graphs, and numbers, and people just sort of glaze over. On the other side, they are much smarter. There is Senator BOXER with pictures of happy faces. There are no facts and figures.

There is no medical evidence to support that partial birth abortion is the right thing to do, this is the moral thing to do, that this is what our society should stand for. No, you put up pictures of happy, smiling faces. You pull at the heartstrings on the other side and hope that all the truth just gets pushed in the background.

There is an obvious truth here. There is an obvious truth here. You have a baby, not what they like to refer to as, ''an intact dilation and extraction.'' That is the way they describe this. An intact procedure. This intact thing is a baby, and it is three-quarters of the way delivered through the birth canal. It is not terminated, it is killed.

Whether you are for abortions or against abortions, you cannot be for doing this. It shocks the conscience of a society and should not—should not—be a procedure that is sanctioned by this body.

I yield back the remainder of my time.

Mrs. BOXER addressed the Chair.

The PRESIDING OFFICER. The Senator from California.

Mrs. BOXER. Mr. President, I yield myself 4 minutes, and I am glad the Senator from Pennsylvania is staying here because his remarks about this family are the most outrageous thing I have ever heard.

The reason this family is smiling is because Coreen Costello was pregnant with her daughter, Katherine Grace, and the dad's hand is on her stomach, and they are so excited about having this baby, their third child.

This is a woman who is pro-life who found out that Katherine Grace had a lethal neurological disorder and had been unable to move for 2 weeks.

Do you want facts? I will give you facts, sir.

The movements that Coreen had been feeling were not the healthy kicking of her baby. They were nothing more than bubbles in amniotic fluid which had puddled in her uterus rather than flowing through the baby. The baby had not been able to move for months—not her eyelids, not her tongue, nothing. The baby's chest cavity was unable to rise and fall to stretch her lungs to prepare them for air. Her lungs and her chest were left severely undeveloped, almost to the point of nonexistence. Her vital organs were atrophying.

The doctors told Coreen and her husband the baby was not going to survive, and they recommended terminating the pregnancy. She did not have an option. Her doctor told her if she did not use this procedure, which you will vote to outlaw today, she would probably not live.

So when you stand up here and you talk about happy faces and you try to demean the other side, you ought to know your facts and, sir——

Mr. SANTORUM. If the Senator from California will yield.

Mrs. BOXER. I have no time to yield on my time. I will be glad to yield on your time.

Mr. SANTORUM. Thirty seconds. You cannot have it both ways, Senator. You cannot have it both ways. You cannot have a life-of-the-mother exception, claim her life is in jeopardy and say our bill does not take care of that. If you are going to claim life-of-the-mother in her case, our bill covers that.

If you are going to claim that she had alternative procedures, like a cesarean or other kinds of procedures where she could have had an alternative, you cannot argue both sides of the story, Senator. You have to argue the facts, just one side at a time.

Mrs. BOXER. Mr. President, if I may reclaim my time.

The PRESIDING OFFICER. The Senator from California has the floor.

Mrs. BOXER. Mr. President, I have read you the facts of the case. The doctor said her life might be in danger. The doctor said for sure she could suffer infertility. That is not excepted in your bill. As a matter of fact, sir, when your bill was written, there was no exception at all, and the exception that is now in your bill would not cover her particular case in any event because your exception only covers a preexisting condition. Therefore, the Boxer-Brown language is absolutely essential to cover this particular case.

I will give you more facts, I say to my friend from Pennsylvania. The American College of Obstetricians and Gynecologists represents 35,000 physicians. They opposes this bill. They think it is dangerous.

The American Nurses Association, representing 2.2 million nurses, oppose this bill. So those are just some of the facts.

Mr. President, I ask unanimous consent to add Senator MIKULSKI as a cosponsor of the Boxer-Brown amendment.

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

Mrs. BOXER. I yield the floor and reserve the remainder of my time.

The PRESIDING OFFICER. Who yields time?

Ms. MIKULSKI. Mr. President, I rise in opposition to H.R. 1833. I oppose it because it is a direct assault upon women's reproductive rights.

But let me first thank Senator SMITH for agreeing to support the motion which the Senate adopted on November 8. This motion called on the Judiciary Committee to hold a hearing on H.R. 1833, the so-called partial-birth abortion ban.

As my colleagues know, the committee held that hearing on November 17. I believe the hearing process was very important. The issues raised by this bill are complex and sensitive. It is vital they be thoroughly explored before the Senate votes on this legislation.

I believe both proponents and opponents of H.R. 1833 found the hearing most helpful. I think all would agree Senator HATCH conducted a fair and informative hearing. We heard from medical professionals, legal and constitutional experts, and from the women themselves who courageously shared their compelling and heartrending stories.

After reviewing all of the testimony, I am more convinced than ever that Congress should not pass the bill before us. I heard nothing to change my mind, and much to reinforce my deep concerns.

Let me tell you why I oppose this bill.

First, it intrudes on the doctor/patient relationship, by criminalizing a specific medical procedure.

Second, it is poorly drafted. The bill's vague language will have a chilling effect on physicians who provide abortions.

Third, it provides no exceptions for cases involving threats to the life and health of the woman.

Fourth, most significantly, it is a direct assault on Roe versus Wade. In my view, the bill is part of a concerted effort to ban all abortions.

I oppose this bill because it is a dangerous and unwarranted intrusion on the doctor/patient relationship. It has an impact far beyond the issue of abortion. For the first time, Congress would be deciding what medical procedures a doctor can and cannot provide. This bill substitutes political reasoning for medical judgment. Congress, not medical experts, would pass judgment on a medical procedure.

H.R. 1833 makes criminals of doctors, doing their best to serve the patient's needs, who perform the procedure banned by the bill. It makes criminals of doctors even when in their expert opinion, the procedure is medically necessary to save a woman's life or prevent serious, adverse consequences to her health.

At the November 17 hearing, medical experts had very different views on what the procedure involves, on what the medical alternatives would be, and on what is best to safeguard a woman's life and health. If they cannot agree on this medical issue, how can we expect to legislate in this area? This is reason enough why Congress should not intervene in decisions on medical procedure.

I oppose this bill because it provides no true exception for the life and health needs of the woman. At the hearing, very compelling testimony was offered by women who have faced the difficult decision to have a late term abortion to save their lives or their health. These were women who eagerly awaited the birth of their child.

Then a medical emergency occurred—one that threatened their lives or posed serious consequences to their health. Congress should not tell these women, and others who face this most tragic and personal of decisions, that they cannot have the medical procedure their physician recommends to save their life, or their health, or their ability to have a child in the future. Congress should not tell them that it knows better than their doctor what medical care they should be provided.

Senator SMITH has offered an amendment to provide an exception for cases where the woman's life is at risk. I have some concerns about this amendment. I fear it may not cover all situations where the life of the woman is threatened by continuing her pregnancy. And I am concerned that, under his amendment, the burden of proof will still be placed upon the physician. However, I will support his amendment. If it will save even a few women who need a late term abortion to save their lives, I cannot oppose it.

But I believe it is absolutely essential that we pass the amendment offered by Senator BOXER. Her amendment provides clear, direct language. It will enable physicians to use their expert medical judgment to act to preserve the life of the woman or to avert serious, adverse consequences to her health.

Senator BOXER'S amendment makes it clear that when a woman must choose abortion late in pregnancy, she must have access to the safest possible procedure. And, physicians, not Senators, should make that decision.

The Boxer amendment lets doctors be doctors. It trusts them to do what is right for their patients. It ensures that women's lives and health are not put at risk. I strongly urge my colleagues to vote for this essential amendment.

I oppose this bill because it is poorly drafted. It is filled with vague, nonmedical terminology. Much of the Judiciary Committee hearing was spent debating what the bill meant. Witnesses and committee members alike could not agree on such basic questions as: How is the procedure in question actually performed? What procedure is the bill describing at all? What does partial birth mean?

If Congress passes H.R. 1833, and it is signed into law, I guarantee you will open the door to endless litigation in an effort to sort out what the bill does and does not do.

The bill's vagueness creates a further problem, whether intentionally or not is unclear. This lack of clarity would have a chilling effect on abortion providers, who are trying to make the best decision for their patients. Physicians who are trying to do their duty to protect life or health, now will have to guess whether their decision might violate Federal law.

How many doctors will continue to perform this type of late term abortion, or any abortions at all, if faced with possible criminal or civil liability. There is already a tremendous shortage of abortion providers. The bill will make this shortage even greater. And, of course, that is part of the plan—to scare doctors from the field.

Doctors who provide abortion services already face death threats, firebombings, and harassment at work and home. Now they will have to look over their shoulder in fear of arrest. Who will be willing to provide abortion services in that climate? And who will pay the price? Women will pay the price, women trying to exercise their right to a legal medical procedure.

Finally, Mr. President, I oppose this bill because it is a direct assault on Roe versus Wade. In Roe and all its subsequent rulings, the Supreme Court has consistently upheld the right of doctors to perform late term abortions to protect life or health. The Court has allowed States to ban post-viability abortions, but only when an exception for life or health is provided.

The Court has maintained that a doctor's first duty is to the woman. Her

life and health must be the doctor's paramount concern. The doctor cannot trade off her life for the life of the fetus.

So, this bill, by ignoring the Court's requirement of a life and health exception is a direct challenge to Roe. And not the last challenge. Proponents of this bill have made clear they want to ban all abortions, one procedure at a time, one woman at a time.

If they succeed in passing this bill, what procedure will they target next? Which women will next be denied their right to choose? If we allow this bill to pass, even with the amendments which I hope will be adopted, Congress will have struck a major blow against reproductive rights.

Mr. President, the basic question is not what is decided, but who decides. And the answer is, women and their doctors should decide, not politicians. Women must have the right to make their own decisions on reproductive matters, in consultation with their physicians. That is what it means to be pro-choice, and that is why I will oppose this bill.

Mrs. MURRAY. Mr. President, let me just say at the outset that I think it is incredible that we are here today debating this bill. There are unfinished appropriations bills, and an unresolved Federal budget situation that demand our full attention. I believe the American people would prefer us to address the real issues of the day—issues that affect our hard-working families—and not this kind of divisive, inflammatory legislation.

Of course, the reality is that we are here and we are considering this so-called partial-birth abortion ban, and there are a few things that I want to say regarding the bill, and also to talk briefly about the amendment offered by my friend, Senator BOXER.

Mr. President, I have listened carefully to this debate and I am increasingly convinced that it is far from being a clear and narrowly defined piece of legislation, as the proponents of the bill keep claiming it to be. I find it to be a vaguely written and dangerous attempt to ban not just a single procedure. Rather, I see it as a way to instill fear and confusion in the doctors who perform abortions, and to deter them from performing a procedure that may help save a woman whose life is in danger.

It seems clear to me this bill is about families who are faced with a terrible tragedy, and it is about the doctors who must make an expert decision based on what they believe to be in the best interest of the mother. Frankly, this bill is about Congress muscling its way into the doctor's office. It is not only presumptuous, it is unprecedented and it is dangerous. We are proposing to criminalize doctors, and I want to caution each and every one of my colleagues to stop this legislation. Like Senator BOXER has said, this is a slippery slope we do not want to start down.

But, unfortunately, it looks like there are Senators who are intent on pressing on with this bill, and so we, at least, have to try and do what our colleagues in the House failed to do—to include an exception for cases to save the life and health of the mother. Mr. President. The Senator from New Hampshire has offered an amendment which he claims provides a life of the mother exception. Well, I will vote for his amendment, because it is at least a step in the right direction.

But let's be honest. The amendment makes no room for instances where, in the medical judgment of the attending physician, the procedure would be necessary to avert serious health consequences to the woman—consequences such as severe hemorrhaging or paralysis.

Only the Boxer amendment can be considered a true life exception. Only the Boxer amendment takes the health of women into account. Only the Boxer amendment sends the right message to the families of this Nation, to the women who are faced with an unimaginable tragedy. We hear, over and over again, graphic depictions of this procedure, but what of the vivid descriptions of the pain and torment these mothers have gone through? Of the horror of losing a much wanted child? Of the fear that she will never again have a chance to have a baby?

Is there anyone here who honestly believes these women are choosing to have a late-term abortion? This insinuation is an affront to the women of this Nation. The small number of women who have late-term abortions do so because their doctors have determined it to be medically necessary to save their lives and their health. End of story.

The Boxer amendment says: We respect you and will leave this difficult decision where it belongs—between you, your doctor, and your God. We think it is important to allow families to choose the procedure that is best for them, to best protect the health of the woman and to best safeguard her chances of being able to conceive again.

Without this amendment we send the women of this country the message: ''We don't care about you, we don't respect your or your doctors. The U.S. Congress and the Federal Government know best.

Well, I don't believe Congress know best. We should leave this difficult decision to the experts and to the families who are faced with this tragedy. Congress has no place telling doctors what procedures they can and cannot perform—we have never even considered getting involved in the lives of physicians, and we shouldn't start now. Not this way.

There is too much at stake, and I appeal to the common sense and humanity of each Member of this Chamber: If you must pass this reprehensible bill, at least vote to include this critical modification, and allow for exceptions in cases where women's health and lives are at stake.

Mr. LEVIN. Mr. President, the Supreme Court has held in Roe versus Wade and reaffirmed in Planned Parenthood versus Casey, that States can ban late-term abortions except when necessary to preserve a woman's life or health. Forty-one States have established postviability bans on abortion with exceptions to preserve a woman's life or health. Only one State has banned the intact D&E abortion procedure which is the apparent subject of the bill before the Senate and that ban is being challenged in the courts.

Forty-nine States have not banned this procedure. If the bill before the Senate becomes law, the Federal Government would dictate the regulation of abortion by banning a specific abortion procedure. This Federal ban in this bill would even apply to abortions performed previability, that is, in the second trimester and the bill does not contain the exception required by Roe, to preserve a woman's health.

Some physicians believe the intact D&E abortion procedure represents the safest late-term abortion option. Others disagree. Politicians are not equipped to make decisions banning specific medical procedures when the medical community itself cannot even reach agreement on these decisions. We should not be voting to criminalize a specific medical procedure when doctors themselves are divided on the matter.

If a physician is engaged in any inappropriate medical practice, the medical establishment has systems of peer and professional review in every State to deal with it. These systems of review include State medical boards and peer review on hospital review boards that police their membership. They should be the ones to ban a procedure if they determine it to be inappropriate.

But physicians and their review processes have not banned this procedure. In fact, the American College of Obstetricians and Gynecologists, an organization representing more than 35,000 physicians that specialize in this area of medicine, oppose the bill before us. It wrote, in a letter to majority leader DOLE, that:

> The College finds very disturbing that Congress would take any action that would supersede the medical judgment of trained physicians and criminalize medical procedures that may be necessary to save the life of a woman.

The American Medical Women's Association, Inc., representing 13,000 woman physicians, has also said of the bill:

> This legislation represents a serious impingement on the rights of physicians to determine appropriate medical management for individual patients.

In addition, the American Nurses Association, the only full-service professional organization representing the Nation's 2.2 million registered nurses through its 53 constituent associations, oppose the bill. Their letter states:

> It is the view of the American Nurses Association that this proposal would involve an

inappropriate intrusion of the federal government into a therapeutic decision that should be left in the hands of a pregnant woman and her health care provider.

I also received letters from physicians in Michigan familiar with this field of medicine opposing the proposed ban of the intact D&E abortion procedure. I ask unanimous consent to insert those letters in the RECORD.

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

[See exhibit 1.]

Mr. LEVIN. This bill would criminalize a so-called partial birth abortion which is defined by the bill as, ''an abortion in which the person performing the abortion partially vaginally delivers a living fetus before killing the fetus and completing the delivery.'' Senator HATCH referred to a statement by Dr. Haskell, a physician who has performed many intact D&E abortion procedures, that only about one-third of the fetuses he extracted using the procedure were dead.

My question is, in the one-third of the intact D&E abortion procedures he performed where the fetuses were dead, did Dr. Haskell know before beginning the procedure if those fetuses were dead? If he, and any other physicians in this situation, did not, they were taking a risk by beginning a procedure that could be a criminal act under the terms of this bill.

The Senator from New Hampshire and others have said that Coreen Costello's abortion was not a partial birth abortion, presumably because she said the ''fetus passed away peacefully in the womb.''

Did the physician know when he began the procedure whether the fetus was alive or dead? If a physician doesn't know for sure before beginning an abortion procedure whether the fetus is alive or dead, wouldn't the physician who starts down the path of performing the procedure be facing the possibility of criminal prosecution under the terms of this bill?

In addition, the physician who performed the intact D&E procedure on Mrs. Costello might not be sure when he began the procedure if the fetus would be alive or dead when extracted since there is a range of fetal response to the anesthesia administered in an intact D&E abortion, the procedure that Mrs. Costello underwent.

The performance of that procedure might then be considered an attempt at committing a crime even if the fetus turned out to be dead upon delivery. The procedure Mrs. Costello underwent thus could be covered by this bill and the physician that performed it subject to Federal criminal prosecution even if the fetus turned out to be dead when delivered.

While banning one abortion procedure, this bill leaves legal other abortion procedures which can be used in later-term pregnancies. Are those other procedures as safe for the mother? Are they any less destructive to the fetus? Why are the other procedures left legal when some have argued they are less safe for the mother, while this one procedure, which some physicians believe is the safest for the mother, is made criminal?

These other procedures that are left legal under this bill include inducing labor and delivery with drugs despite evidence of risk to the woman. A caesarean operation called a hysterotomy, which could result in severe bleeding, infection and even death for the woman, is also left legal, even in the third trimester to preserve the woman's life. Another procedure that would be left legal under this bill is called standard D&E which is performed in the second trimester and does not deliver the fetus intact, but removes the fetus from the uterus piece by piece.

In conclusion, the Supreme Court has held that States can ban late-term abortions except when necessary to protect a woman's life or health. Forty-one States have done that. But only one State has banned the intact D&E abortion procedure, and that ban is being challenged in the courts.

Forty-nine States have not acted to ban intact D&E. The medical profession's own self-regulating system has also not acted to ban intact D&E. The U.S. Senate is not equipped to make this technical medical decision.

The bill under consideration today would ban abortions using this procedure even in the second trimester and it does not allow for an exception required by Roe, to preserve a woman's health.

Finally, this bill establishes Federal criminal penalties for a specific abortion procedure which may be the safest alternative for the mother while permitting other abortion procedures that could be less safe for the mother. We should leave this issue to the medical profession and the State legislatures, where it is now and where it belongs.

EXHIBIT 1

THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS,
Washington, DC, November 6, 1995.

Hon. ROBERT DOLE,
Majority Leader,
Washington, DC.

DEAR MAJORITY LEADER DOLE: The American College of Obstetricians and Gynecologists (ACOG), an organization representing more than 35,000 physicians dedicated to improving women's health care, does not support HR 1833, the Partial-Birth Abortion Ban Act of 1995. The College finds very disturbing that Congress would take any action that would supersede the medical judgment of trained physicians and criminalize medical procedures that may be necessary to save the life of a woman. Moreover, in defining what medical procedures doctors may or may not perform, HR 1833 employs terminology that is not even recognized in the medical community—demonstrating why Congressional opinion should never be substituted for professional medical judgment.

Thank you for considering our views on this important matter.

Sincerely,

RALPH W. HALE, M.D.,
Executive Director.

AMERICAN MEDICAL WOMEN'S ASSOCIATION, INC.,
Alexandria, VA, November 5, 1995.

Hon. ——— ———,
U.S. Senate,
Washington, DC.

DEAR SENATOR ———: On behalf of the 13,000 women physician members of The American Medical Women's Association, I write to express AMWA's concern regarding Senate bill S. 939, ''The Partial-Birth Abortion Ban''.

It is the position of the American Medical Women's Association that this legislation represents a serious impingement on the rights of physicians to determine appropriate medical management for individual patients. AMWA recently passed resolution 15, which opposes federal legislation banning this or any other medical procedure determined to be of benefit to patients, at its annual House of Delegates Meeting.

AMWA urges the Senate to carefully consider the implications that its support of this legislation will have on the practice of medicine. We encourage the Senate to actively oppose S. 939 as legislation which unduly interferes with the physician-patient relationship.

Sincerely,

JEAN L. FOURCROY, MD, Ph.D.,
President.

———

AMERICAN NURSES ASSOCIATION,
Washington, DC, November 8, 1995.

Hon. CARL M. LEVIN,
U.S. Senate,
Washington, DC.

DEAR SENATOR LEVIN: I am writing to express the opposition of the American Nurses Association to H.R. 1833, the ''Partial-Birth Abortion Ban Act of 1995'', which is scheduled to be considered by the Senate this week. This legislation would impose Federal criminal penalties and provide for civil actions against health care providers who perform certain late-term abortions.

It is the view of the American Nurses Association that this proposal would involve an inappropriate intrusion of the federal government into a therapeutic decision that should be left in the hands of a pregnant woman and her health care provider. ANA has long supported freedom of choice and equitable access of all women to basic health services, including services related to reproductive health. This legislation would impose a significant barrier to those principles.

Furthermore, very few of those late-term abortions are performed each year and they are usually necessary either to protect the life of the mother or because of severe fetal abnormalities. It is inappropriate for Congress to mandate a course of action for a woman who is already faced with an intensely personal and difficult decision. This procedure can mean the difference between life and death for a woman.

The American Nurses Association is the only full-service professional organization representing the nation's 2.2 million Registered Nurses through its 53 constituent associations. ANA advances the nursing profession by fostering high standards of nursing practice, promoting the economic and general welfare of nurses in the workplace, projecting a positive and realistic view of nursing, and by lobbying the Congress and regulatory agencies on health care issues affecting nurses and the public.

The American Nurses Association respectfully urges you to vote against H.R. 1833 when it is brought before the Senate.

Sincerely,

GERI MARULLO, MSN, RN,
Executive Director.

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ROSEVILLE, MI, *December 7, 1995.*

Hon. CARL LEVIN,
Washington, DC.

DEAR SENATOR LEVIN: I am writing you with concerns about the S.B. 939, the D&X Abortion Procedure Ban. I am absolutely opposed to political intervention in the practice of medicine.

As a practicing OB–Gyn, I cannot begin to cite the ramifications of such a bill. If passed, it will prevent me from providing the best possible care for my patients in emergency situations. The D&X procedure is the safest option for many women faced with medical emergencies during pregnancy. It is done only in extreme situations, such as when a woman's life is in danger or when a fetus has severe abnormalities that are incompatible with life. This bill endangers the lives of women, who are already making heartwrenching decisions.

I find it very disturbing that the Senate would take any action that would overrule the judgment of trained physicians. As a physician, I and others like myself, would find it frightening that my government would prevent me from providing the best possible care for my patients. Please do not lot this happen.

Sincerely,

SAMUEL EDWIN, M.D.

DEPARTMENT OF DERMATOLOGY,
HENRY FORD HOSPITAL,
Detroit, MI, November 6, 1995.

Re Bills to limit physician abortion procedures.

Senator CARL LEVIN,
U.S. Senate,
Washington, DC.

DEAR SENATOR LEVIN: I am very upset to hear proposed legislation to make criminal various surgical procedures performed by physicians. I realize the legislation is being introduced as a method to limit abortion. However I am incensed that non-physicians are trying to limit the scope of medical practice, and make it criminal as well!

Personally I feel it is the woman's right to choose, and as men, we should not interfere. But as a physician it is a slippery slope for non-physicians to limit our practices especially for political means.

Please block this legislation!

Sincerely,

TOR SHWAYDER, M.D.,
Director, Pediatric Dermatology; Fellow, American Academies of Pediatrics & Dermatology.

Mr. FEINGOLD. Mr. President, I rise in opposition to H.R. 1833.

I do so because this legislation raises serious policy, legal and medical issues.

H.R. 1833 seeks to impose criminal sanctions upon physicians who perform certain types of late term abortions.

It is important, Mr. President, to understand that very few late term abortions take place in this country, under any circumstances. It is estimated that there are approximately 600 abortions annually performed in the third trimester of pregnancy, with about 450 done by what is called an intact D&E procedure. The procedure which would be banned under this legislation is a form of an intact D&E procedure. Late-term abortions take place under the most tragic of circumstances, where something has gone wrong with the pregnancy. Late-term abortions are physically difficult and emotionally devastating to the women involved and their families. Several women who were forced to have such an abortion testified at the Senate Judiciary Committee hearing about the pain and anguish they and their families had experienced.

This bill would place the Federal Government into the role of deciding what procedures a physician can or cannot use in performing a late-term abortion. It would substitute the judgment of Congress for the judgment of the individual physician performing an abortion.

I believe that such legislation is bad policy. The American people have repeatedly said that they want less government interference in their lives. This bill moves in exactly the wrong direction.

Since the beginning of the 104th Congress, there has been a great deal of rhetoric about how we need to restrain the Federal Government, about how the Federal Government has usurped the powers of State and local government entities, and about how the Federal Government has intervened in areas beyond its primary realm of responsibility. We have heard repeatedly that we need fewer Federal mandates and fewer Federal regulations.

Mr. President, let me say that I agree with a good deal of those sentiments. I believe that the Federal Government has gone too far in many areas. That is one reason why I voted against last year's Federal crime bill and this year's terrorism bill. In each instance, I saw examples of the Federal Government overzealously reaching into areas of law which have traditionally been within the jurisdiction of State and local law enforcement agencies.

I voted for the unfunded mandate legislation because I agree that the Federal Government needs to exercise restraint in forcing the States to comply with Federal mandates. I support many aspects of the regulatory reform drive because we do need greater flexibility and less Federal micromanagement in many areas.

But now, Mr. President, we are presented with legislation that places the Federal Government in the role of deciding what specific procedures a physician should use or not use when faced with a problem pregnancy and a woman's desire to terminate that pregnancy.

Mr. President, there are many reasons why this is a dangerous area for Federal Government intervention. One of the physicians said it well during the Judiciary Committee hearing on November 17. Dr. J. Courtland Robinson testified:

> Sometimes, as any doctor will tell you, you begin a surgical procedure expecting it to go one way, only to discover that the unique demands of the case require that you do something different. Telling a physician that it is illegal for him or her to adapt his or her surgical methods for the safety of the patient . . . flies in the face of standards for quality medical care.

Dr. Robinson also pointed out in his testimony that many physicians would not undertake a surgery at all if they were legally prohibited from completing it in the safest, most effective way, according to their professional judgment.

Mr. President, I want to reiterate that the measure under consideration would insert the Federal Government into one of the most intensely private and personal areas. This bill would have Congress override the decisions made by a woman and her physician in an area that literally involves life or death.

It is ironic that many of the same individuals who strongly challenged the ability of the Federal Government to handle comprehensive health care reform are among the foremost proponents of this effort to insert the Federal Government into a physician's decisions in the operating room.

For example, during last year's health care debate, the distinguished Senator from North Carolina (Mr. HELMS) asked:

> Do you want the Federal Government, the Government that operates your postal system to decide whether you should have an operation or not? With this kind of government intervention, what is left for the doctor and the patient to decide?

Yet, that is precisely the kind of intervention that is being proposed by this legislation. This measure says that a physician who determines that a specific procedure is necessary to protect the life or health of his or her patient may face a Federal criminal prosecution for exercising his professional judgment.

Mr. President, it is also important to note that the language of this bill is so vague that a number of physicians have indicated that they would simply stop performing late-term abortions rather than run the risk of criminal prosecution or endangering the life or health of their patient. Dr. Robinson told the committee:

> For many physicians, this law would amount to a ban on a D&E [procedure] entirely the law is so vague and based on erroneous assumptions, it would leave doctors wondering if they were open to prosecution or not each time they performed a late abortion. That means that by banning this technique, you would in practice ban most later abortions altogether by making them virtually unavailable. And that means that women will probably die.

Dr. Robinson, incidently, is a former Presbyterian missionary who has practiced medicine for more than 40 years. He described for the committee his exposure to the consequences of illegal abortions prior to the Roe decision. He testified that over a period of five years on the staff of a hospital in New York, he watched women die from abortions that were improperly performed. His concerns about the consequences of legislation that would make certain types of abortions illegal and deny women access to the safest abortion procedure for their individual circumstances were clearly an outgrowth of his familiarity with what happens when Government treads too

far into what should be a decision made by a woman and her physician.

Mr. President, that brings me to a second policy concern regarding this legislation. On its face, H.R. 1833 seeks to criminalize the performance of a particular type of abortion. Yet, Mr. President, there is little doubt that the purpose behind this legislation is to begin the process of curtailing and ultimately denying all access to legal abortion.

When pressed, many of the proponents of H.R. 1833 will admit the truth of this assertion.

One of the major House proponents, Congressman CHRIS SMITH (R. N.J.) stated in a November 9, 1995, USA Today article, '' We will begin to focus on the methods [of abortion] and declare them to be illegal.''

At the Judiciary Committee hearing on this measure, I asked one of the proponents, Helen Alvare, Director of Planning and Information, Secretariat for Pro-Life Activities of the National Conference of Catholic Bishops, whether all methods of abortion should be criminalized. The response I received was very clear. Ms. Alvare stated her view that ''every single kind of procedure that takes an unborn life'' should be outlawed.

Mr. President, I specifically asked whether that included nonsurgical forms of abortion, such as the use of a drug like RU–486 which leads to the termination of a pregnancy in the very early stages, the first few weeks. The answer was yes, and Ms. Alvare was very clear that she found the use of an abortifacient drug at the earliest stages of a pregnancy to be as objectionable as the procedure under discussion.

Mr. President, I think the record should also note that in the past there have been efforts to ban other methods of abortion which the proponents of this legislation now point to as remaining available should this ban be enacted into law. For example, in 1976, in Planned Parenthood versus Danforth, the Supreme Court struck down a Missouri statute which would have prohibited saline abortion procedures after the first 12 weeks of pregnancy.

It is clear that this legislation is part of a calculated plan to make abortion more difficult for women and their physicians. It is part of a calculated plan to limit and erode a woman's ability to exercise her constitutionally protected rights. We cannot lose sight of the fact that Dr. Robinson's memories of a time when abortion was illegal and women died from illegal abortions might become a reality again if these efforts are successful.

Mr. President, I want to focus now upon an important aspect of the Judiciary Committee hearings dealing with why this particular procedure might, in the judgment of a woman's attending physician, be the most appropriate in light of her individual circumstances.

Mr. President, throughout this debate, different physicians who testified at the Judiciary Committee hearing will be quoted as to their view regarding whether the procedure under discussion is more or less safe for a woman than other procedures, whether the procedure may be necessary in a particular situation to protect a woman's future ability to bear children, and precisely what the procedure is that would be banned under this legislation.

What occurred at the hearing, Mr. President, was a professional disagreement among members of the medical community on the efficacy and risks associated with various abortion procedures. That members of the medical community have different opinions on these issues is both understandable and expected.

It is also precisely the reason why trained physicians and their patients, not members of the Congress, should make the decisions about what course of treatment is appropriate in individual situations.

The ability to choose between alternative courses of medical treatment and the ability to choose between physicians who favor one procedure over another is something that we often take for granted.

Physicians who themselves do not choose to perform the type of procedure at issue have also made it clear that they do not believe Congress should be legislating in this area. In particular, Dr. Warren M. Hern of Boulder, Colorado, a physician who performs late-term abortions has been quoted by proponents of H.R. 1833 as having reservations about this particular procedure. However, in his testimony submitted to the Senate Judiciary Committee on November 17, 1995, he outlined the possible advantages of using the intact D&E procedure, including a reduction of the risk of perforation of the uterus and reducing the risk of embolism of cerebral tissue into the woman's blood stream. He concluded by stating:

> While I may choose a different method of performing a late abortion, I support the right of my medical colleagues to use whatever methods they deem appropriate to protect the woman's safety during this difficult procedure. It is simply not possible for others to second guess the surgeon's judgment in the operating room. That would be dangerous and unacceptable.

Mr. President, I am not sure that it is appropriate for Members of Congress to even try to resolve a matter that is the subject of debate between physicians as to whether there are situations where this procedure is preferable to another procedure. It is clear from the testimony at the Judiciary hearing that there are respectable differences of opinion in this area.

For example, Dr. Mary Campbell, medical director of Planned Parenthood of Washington, DC, testified there were a number of situations where alternative abortion procedures such as induction or cesarean section are considered less safe than an intact D&E procedure. For example, Dr. Campbell testified that ''a woman is twice as likely to die'' with an induction procedure, an alternative abortion procedure in a late-term pregnancy. She further testified that a cesarean section was another option, but that a woman was 14 times as likely to die with a Cesarean hysterotomy as with a D&E procedure.

Dr. Campbell outlined her views as to why the intact D&E procedure was preferable in certain cases. According to Dr. Campbell, the procedure requires less dilation of the cervix and thus markedly decreases the chances of cervical lacerations and cervical incompetence which can adversely affect future pregnancies. She also testified that the uterine scar, especially from the kind of vertical incision most often used in cesarean sections involving abnormal preterm fetuses, creates an increased risk of uterine rupture in future pregnancies.

Dr. Robinson testified with the same concerns about the risks posed by alternative procedures. In response to my question, Dr. Robinson testified that a vertical scar in the uterus resulting from such a cesarean was definitely an increased hazard when a woman has a subsequent pregnancy.

Included in the hearing record are letters from Dr. Elaine Carlson of Cedars-Sinai Medical Center in Los Angeles indicating that alternative procedures can cause a traumatic stretching of the cervix that then increases a woman's changes for infertility in the future and from Dr. George Henry of Denver, CO, indicating similar concerns. Dr. Henry, in a subsequent letter to me elaborated on the risks to both a woman's life and her future ability to bear children from a cesarean section type of surgical approach. ''Such a surgery,'' Dr. Henry wrote, ''exposes the patient herself to much greater medical risk immediately and also increases the need for repeat C- sections in future pregnancies as well as the risk of uterine rupture in future pregnancies because of the uterine scar—and even the potential loss of the uterus if emergency hysterectomy is required.''

Other witnesses, proponents of this legislation, disagreed and stated their view that the intact D&E procedure was more risky than the other procedures, and that there were no circumstances where they would consider this procedure necessary to protect the life or health of the woman.

Mr. President, what this debate told me is that there is room for disagreement between physicians about specific medical procedures; it is not for Congress to determine which side of this debate is right or wrong. These are medical questions which ought to be decided by medical professionals, not Members of Congress. Congress ought not to tie the hands of a physician trying to make the best decision for his or her patient. As Dr. Robinson testified, ''The physician needs to be able to decide, in consultation with the patient and based upon her specific physical

and emotional needs, what is the appropriate method. The practice of medicine by committee or legislature is not good for patients or for medicine in general.''

Mr. President, the reasons why Congress ought to stay out of this decisionmaking process was also eloquently made by several women who had made the difficult choice of choosing this procedure when a much wanted pregnancy has turned into a tragedy.

Coreen Costello testified:

It deeply saddens me that you are making a decision having never walked in our shoes. When families like ours are given this kind of tragic news, the last people we want to seek advise from are politicians. We talk to our doctors, lots of doctors. We talk to our families and other loved ones, and we ponder long and hard into the night with God.

Mr. President, we ought to heed those words. These decisions are private, personal decisions to be made by the families involved, guided by their physicians. The Federal Government ought to leave these decisions with the people involved.

Finally, Mr. President, let me briefly address the Constitutional issues raised by this legislation.

H.R. 1833, in my view, is fatally flawed because it fails to adequately provide protections for procedures necessary to preserve or protect a woman's life or health. Roe vs. Wade, and the cases that have followed including Casey, have made it clear that States have the authority to restrict and even ban abortions after fetal viability except where necessary to protect a woman's life or health. H.R. 1833 as originally proposed included an utterly inadequate provision allowing only an affirmative defense to be asserted by the physician that the procedure was necessary to protect a woman's life. In other words, a physician who performs this procedure in order to save a woman's life could be hauled into a Federal court and prosecuted for violating this statute. The physician would only be able to raise as a defense that the procedure was performed to save a woman's life. It is only after extensive debate that the proponents of H.R. 1833 proposed to change their language to provide an explicit exception from the statute's coverage for a procedure necessary to preserve a woman's life. However, the amendment they have offered contains limitations upon the life of the mother exception which also raise questions as to whether it comports with the standard set forth in Roe v. Wade.

Moreover, the proponents have failed to even acknowledge the requirement that an exception be provided where the procedure is necessary to protect a woman's health, including her future ability to bear children. The proponents argue that such an exception is unnecessary because alternative procedures are available. Those arguments fail to acknowledge the medical disagreement over whether such alternative procedures pose greater risks to the woman's health. The proponents of this legislation seem to take the view that even if an alternative procedure would result in a woman being unable to bear a child in the future, that is an adequate alternative.

Mr. President, I find this to be a particularly harsh judgement to be imposed upon families who have experienced the tragic end to a much-sought pregnancy. To tell a woman and her family that Congress will not allow her doctor to use a procedure which will allow her a greater chance to be able to have another pregnancy and bear a child in the future is cruel and unconscionable.

Mr. President, let me conclude by reiterating again that this legislation would insert the Federal Government into one of the most private, personal decisions a woman and her family and her physician must face. The American people have said time and again they want less Government intrusion into their lives, not more. This bill is in every way an inappropriate extension of power by the Federal Government into the lives of individual Americans at a very traumatic and emotion point. It ought to be rejected.

Mr. PELL. Mr. President. A month ago, the Senate chose to refer to the Senate Judiciary Committee a bill which would ban from use a medical procedure currently used to terminate late-term pregnancies. I supported that referral because it was unclear what all of the ramifications of such a ban were and the Senate deserved the opportunity to have a complete record upon which to make an informed decision regarding this complex and controversial issue.

Today, we have that record before us. I thank the members of the committee for their thorough and detailed work in exploring this difficult matter and based on that record, I have come to the conclusion that I will oppose this legislation.

I do so because I believe that the bill goes too far in its virtual ban of the use of this procedure, despite the fact that in many cases medical professionals believe that it is the safest means to terminate troubled and tragic late-term pregnancies. I believe that medical doctors, following the constitutional guidelines under which abortion is legal and following consultation with a woman and her family, should be able to choose the medical procedure he or she deems most appropriate to terminate a pregnancy without facing criminal or civil penalties. Indeed, criminalizing a medical procedure in the manner proposed in the bill would be the first such time we have done so in our country's history.

I do not come to this position lightly. I, and I believe virtually all Americans, am disturbed with the harsh realities that this issue forces our human conscience to acknowledge. In the end, however, I believe that it is not the place of Congress to interject itself in this manner into the tragic personal decisions that women and families must face. I do believe it should be a rarely used procedure and in that regard have been informed that there is no recollection of it being used in my State of Rhode Island. Indeed, there are only a handful of practices throughout the country that utilize it and the total number of cases amount to less than one-tenth of 1 percent of total abortions. I also believe that the heightened scrutiny that this procedure has received will reduce those occasions when it is used inappropriately. In the end, however, I believe that it should remain an option available to doctors when they deem it medically necessary in order to terminate a pregnancy.

By way of conclusion, I ask unanimous consent to have printed in the RECORD an article from the New York Times written by a woman who went through this procedure. I believe it eloquently makes the case that it would be wrong to enact the outright ban contained in this bill for this procedure and, accordingly, that this option should remain available to women and families of this country.

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

[From the New York Times, November 29, 1995]

GIVING UP MY BABY

(By Coreen Costello)

Those who want Congress to ban a controversial late-term abortion technique might think I would be an ally. I was raised in a conservative, religious family. My parents are Rush Limbaugh fans. I'm a Republican who always believed that abortion was wrong.

Then I had one.

It wasn't supposed to be that way. My little girl, Katherine Grace, was supposed to have been born in the summer. The births of my two other children had been easy, and my husband and I planned a home delivery.

But disaster struck in my seventh month. Ultrasound testing showed that something was terribly wrong with my baby. Because of a lethal neuromuscular disease, her body had stiffened up inside my uterus. She hadn't been able to move any part of her tiny self for at least two months. Her lungs had been unable to stretch to prepare them for air.

Our doctors told us that Katherine Grace could not survive, and that her condition made giving birth dangerous for me—possibly even life-threatening. Because she could not absorb amniotic fluid, it had gathered in my uterus to such dangerous levels that I weighed as much as if I were at full term.

I carried my daughter for two more agonizing weeks. If I couldn't save her life, how could I spare her pain? How could I make her passing peaceful and dignified? At first I wanted the doctors to induce labor, but they told me that Katherine was wedged so tightly in my pelvis that there was a good chance my uterus would rupture. We talked about a Caesarean section. But they said that this, too, would have been too dangerous for me.

Finally we confronted the painful reality: our only real option was to terminate the pregnancy. Geneticists at Cedars-Sinai Medical Center in Los Angeles referred us to a doctor who specialized in cases like ours. He knew how much pain we were going through, and said he would help us end Katherine's

pain in the way that would be safest for me and allow me to have more children.

That's just what happened. For two days, my cervix was dilated until the doctor could bring Katherine out without injuring me. Her heart was barely beating. As I was placed under anesthesia, it stopped. She simply went to sleep and did not wake up. The doctor then used a needle to remove fluid from the baby's head so she could fit through the cervix.

When it was over, they brought Katherine in to us. She was wrapped in a blanket. My husband and I held her and sobbed. She was absolutely beautiful. Giving her back was the hardest thing I've ever done.

After Katherine, I didn't think I would have more children. I couldn't imaging living with the worry for nine months, imagining all the things that could go wrong. But my doctor changed that. ''You're a great mother,'' he told me. ''If you want more kids, you should have them.'' I'm pregnant again, due in June.

I still have mixed feelings about abortion. But I have no mixed feelings about the bill, already passed by the House and being considered in the Senate, that would ban the surgical procedure I had, called intact dilation and evacuation. As I watched the Senate debate on C-Span this month, I was sick at heart. Senator after senator talked about the procedure I underwent as if they had seen one, and senator after senator got it wrong. Katherine was not cavalierly pulled halfway out and stabbed with scissors, as some senators described the process.

I had one of the safest, gentlest, most compassionate ways of ending a pregnancy that had no hope. I will probably never have to go through such an ordeal again. But other women, other families, will receive devastating news and have to make decisions like mine. Congress has no place in our tragedies.

Mr. SMITH. Mr. President, how much time do I have remaining?

The PRESIDING OFFICER (Mr. ABRAHAM). The Senator from New Hampshire has 12 minutes and 15 seconds remaining.

Mr. SMITH. Mr. President, I hope my colleagues are listening carefully at this stage of the debate, because we are down now to where we are about to vote on two very important amendments related to this bill.

Senator BOXER has taken the time to go through two very compelling cases, very tragic cases. Both of those women testified before the Judiciary Committee, and that was heart-rending testimony.

I viewed the testimony. I have read it. There is only one problem, and I have said it, Senator DEWINE has said it and others have said it: These women did not have partial-birth abortions. I will repeat, these women did not have partial-birth abortions. Coreen Costello and Viki Wilson did not have partial-birth abortions. Senator BOXER knows that, and both of the young women know that. A partial-birth abortion specifically is killing a child who is 90 percent born through the birth canal by the use of the catheter and the scissors.

Now, let me read from the testimony of Coreen Costello:

When I was put under anesthesia, Katherine's heart stopped. She was able to pass away peacefully inside my womb, which was the most comfortable place for her to be. When I awoke a few hours later, she was brought to us. She was beautiful. She was not missing any part of her brain. She had not been stabbed in the head with scissors. She looked peaceful.

Mr. President, that is my point.

Mr. SANTORUM. If the Senator will yield, that picture is not factual, right? That picture is not factual, is it?

Mr. SMITH. The Senator is correct.

Mrs. BOXER. Will the Senator yield to me on my own time?

Mr. SMITH. Yes.

Mrs. BOXER. I will place in the RECORD a letter from these women, and I will read it later, which completely makes the statement that this particular procedure that they underwent is, in fact, the procedure that would be outlawed. And, in fact, the doctor that was vilified in this debate—by name, Dr. McMahon—and was summoned before the House committee is the doctor that performed the intact dilation and evacuation procedure. These women are completely upset, and here is a quote from the first sentence:

We are shocked and outraged—

This is to Senator SMITH.

—at attempts by you and other Members of the Senate to dismiss our significance as witnesses against the partial-birth abortion ban.

I have to tell you Senators, you can fight this and you may well have the votes. But do not demean these women. I have to say, Viki Wilson, who you said yesterday did not have this procedure, had Dr. McMahon as a doctor. She is a registered nurse. Her husband is a physician in an emergency room. They both know this bill. They say what Viki underwent is exactly what is described in the bill.

So if we are going to have an argument every time I bring out another family, and you are going to say they are excepted, are we going to write legislation like that?

I reserve the remainder of my time.

Mr. SMITH. Reclaiming my time, Mr. President, when you look out the window and it is raining, and the person sitting next to you says it is not raining—I mean, you can argue this, but facts are facts. I am not demeaning the testimony of Viki Wilson or Coreen Costello. They were very, very moving stories. This Senator was very moved by those stories. But they are not partial-birth abortions.

This Senator's bill, and all the amendments we are talking about on the bill, does not stop the procedure that Viki Wilson and Coreen Costello had.

I will now repeat and read verbatim from the testimony of Viki Wilson. Please listen carefully and make your own judgment.

Viki Wilson said:

My daughter died with dignity inside my womb. She was not stabbed in the back of the head with scissors. No one dragged her out half alive and killed her. We would never have allowed that.

Mr. SANTORUM. If the Senator will yield. So the second picture the Senator from California has up there is also not factual, is that true?

Mr. SMITH. It is a fact that that is the family, but it is not a fact that they had a partial-birth abortion.

Mr. SANTORUM. So we are going to continue to throw pictures up, and that is how we are going to deal with facts.

Mr. SMITH. Yes. This bill is very clear and specific, and it outlines this procedure in the birth canal. That is all this allows. I say that in sincerity to the Senator because I know he feels very strongly. I must say to him, that is the fact.

Why Senators would come down here and testify to things that are not accurate, you will have to ask them. Listen, here is the exact language of my bill:

The term partial-birth abortion means an abortion in which the person performing the abortion partially, vaginally delivers a living fetus before killing the fetus and completing the delivery.

When I read the testimony of the two women, both of them said their child died in their womb peacefully. Now, dying in womb peacefully—does that say ''an abortion in which the person performing the abortion partially, vaginally delivers a living fetus before killing the fetus and completing the delivery''? That is what this bill stops. That is all it stops. That is all it says. That is exactly what it says.

I say to my colleagues, no matter how you feel on the issue, please, at least accept facts as being facts. This is the floor of the U.S. Senate. We have an obligation to tell the truth. That is not the truth, what Senator BOXER is saying. Whether it is meant to be or thought to be is another issue. But it is not fact. I know what my bill says. That is what it says. I just read it to you.

How much time is remaining?

The PRESIDING OFFICER. Six minutes thirty seconds.

Mr. SMITH. I yield 2 minutes to myself and ask to be notified when the 2 minutes are up.

Let me just say that this Dole-Smith amendment provides a life-of-the-mother exception. We had an affirmative defense in the bill. Members came to me and said, ''We want it a little more clarified.'' I said, ''Fine,'' and we clarified it because I think Senators sincerely had a concern about that—even though there have been no witnesses to testify that the mother's life was ever a problem. Let me just say that this applies to any situation in which a pregnant woman's life is physically threatened by any pregnancy, complication, or other disorder, and a partial-birth abortion is the only means by which her life can be saved. That is the life-of-the-mother exception. It is very clear. There is no question about it.

If we go to the Boxer partial-birth abortion on demand amendment, it allows partial-birth abortions on demand throughout the full 9 months of the pregnancy. If a woman has any health

problem that she so indicates, then any child could be aborted for any reason. That is a fact.

We voted on this before on the floor of the Senate, and we voted it down. I hope that we will vote it down now and have a true life-of-the-mother exception, as we have tried to do.

I remember in the debate when the Senator from California, and others, made a big case here on the floor to please have the life-of-the-mother exception, have it clarified. We have done that. In fact, I voted to send the bill back to committee to have time to do that and to hear the testimony of the witnesses.

I will conclude on this point, Mr. President. We had no doctors who performed partial-birth abortions testifying and no women who had them testifying. So I am not sure what the committee hearing produced.

Thank you, Mr. President.

Mrs. BOXER. Mr. President, how much time remains on my side?

The PRESIDING OFFICER. Seven minutes, 30 seconds.

Mrs. BOXER. I ask that I be notified when I have used 3 minutes.

Mr. President, I will tell you, this debate is one of the most fascinating I have ever been in. I will hold up picture after picture of people who know that this bill applies to the procedure they had, and my colleague, who thinks he might perhaps be a doctor, and his friends think that, in fact, they do not know what they are doing because they are U.S. Senators. After all, they know more than the families that went through this what happened. Again, here is the letter I read part of, dated December 7—and that is today. This was raised yesterday as a red herring, that these people that I held up did not know what they were talking about.

These women and families wrote us. Seven of them said this, and I will quote—this is to Senator SMITH:

We are shocked and outraged by attempts by you to dismiss our significance as witnesses against the partial-birth abortion bill.

Then they say:

Your rhetoric vilifies our physician, Dr. McMahon, who is the Nation's leading developer and practitioner of this technique for third-trimester abortions, and you claim simultaneously that we did not undergo the procedure in question. But we definitely had intact dilation and evacuation procedures, and it is definite that no doctor who wants to stay out of prison will perform that procedure, or any surgery that remotely resembles it, if your bill is passed.

They write this:

If your bill passes, families with tragedies like ours will have added misery and pain because the surgical procedure that helped us will be unavailable. Please stop pushing this awful bill and please stop pretending that we are irrelevant.

Of course, Senators will continue to say that these people, religious families, loving families, simply do not know what they are talking about and do not know what was done to the body of their incredibly important family member.

Now, this is Viki Wilson. She testified to the Judiciary Committee as follows. These are facts, facts from her mouth.

I am a practicing Catholic and I couldn't help but believe that God had some reason for giving us such a burden, and then I found out about this legislation. I knew then and there that Abigail's life had special meaning.

I think God knew I would be strong enough to come here and tell you my story, to try to stop this legislation from passing and causing incredible devastation for other families like ours, because there will be other families in our situation, because prenatal testing is not infallible and I urge you please do not take away the safest method known.

The PRESIDING OFFICER. There are 4 minutes 30 seconds remaining.

Mrs. BOXER. I will take an additional 30 seconds, and I will retain the time for my colleague from New Jersey.

Coreen Costello says, ''I hope you can put aside your political differences, your positions on abortion, your party affiliation''—this is a picture of Coreen—''and just try to remember us. We are the ones who know. We are the families that ache to hold our babies, to love them, to nurture them. We are the families who will forever have a hole in our hearts.''

I say to any Senator that tries to demean these families and tell them they do not know what went on in these families should think again. We were elected to be Senators, not doctors, and not God.

I retain the remainder of my time.

Mr. SMITH. Mr. President, how much time remains?

The PRESIDING OFFICER. Four minutes twenty-two seconds.

Mr. SMITH. I yield myself 3 minutes 22 seconds.

Mr. President, it is very frustrating. Again, I will just repeat for emphasis for those, I hope, who are listening to the debate: Viki Wilson in her testimony not only indicated that she did not have a partial-birth abortion, she said she would not have one. So these are not partial-birth abortions. But again I will not continue to debate it.

Any reasonable person, hopefully, who is watching the debate would understand the definition is very clear. A partial-birth abortion is when a child is killed in the birth canal. These two women in the horrible circumstances they went through lost their children in the womb. This amendment would not prevent what happened to them.

Since I have been accused of not being a doctor, which is a fair accusation, let me offer into the RECORD a sample of the 200 unsolicited letters from ob-gyn's from all over America. I ask unanimous consent that all of these be printed in the RECORD after this debate.

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

(See exhibit No. 1.)

Mr. SMITH. I will quote from a letter from a Dr. Dorothy Czarnecki, an ob-gyn from Philadelphia. She says:

DEAR SENATOR SMITH: I appreciate your efforts on behalf of the ''partial-birth abortion'' controversy. In no way are these done only on abnormal infants. This is just another brutal way to destroy life. This procedure is not necessary to protect the life or health of women in this country.

Another one from Dr. Lauri Scott, M.D., assistant professor of maternal-fetal medicine in Dallas, TX.

I am a specialist in maternal-fetal medicine and on faculty in the Department of Obstetrics and Gynecology at the University of Texas, Southwestern Medical Center. It is the nature of my specialty that I deal with high-risk pregnancies and would be the consultant called to deal with issues regarding the ''life-of-the-mother.''

I can tell you unequivocally there is no maternal medical reason for ''late-term abortions.'' In situations where the life of the mother is at stake, we simply deliver the infants and the baby takes its chances in the nursery.

''DEAR SENATOR SMITH,'' Mary Davenport, Oakland, CA:

I am writing to you in support of the partial-birth abortion bill. There is no medical indication for this procedure, and the performance of this operation is totally in opposition to 2,000 years of Hippocratic medical ethics. Please do your best to eliminate this procedure. It is not done in any other nation of the world.

Margaret Nordell, M.D., caring for women of all ages, Minot, ND:

I am a member of the DakotaCare Physicians Association. I believe that this procedure is unnecessary to protect either the life or health of women in this country.

Dr. Karin Shinn, Coney Island Hospital:

DEAR SENATOR SMITH: I am a practicing obgyn on the staff of Coney Island Hospital. It is my professional opinion that the partial-birth abortion procedure is very dangerous and absolutely unnecessary to protect either the life or the health of the women in America.

Letter after letter after letter, Mr. President, all over the country. To say that somehow the U.S. Senator who stands here on the floor, quoting from doctors about a medical procedure, to taking the ''slam'' that somehow we cannot vote for something or talk about something because we are not doctors—we send troops into Bosnia, that will happen. And I assure you that every Senator who votes to send them there has never served in combat and probably never been there. That is for sure. We vote on Medicare and we vote on Medicaid and not everybody here is a senior citizen.

The argument is absolutely ludicrous and frankly insulting. I hope my colleagues will defeat the Boxer amendment and support the Smith-Dole amendment.

EXHIBIT 1

PHILADELPHIA, PA,
November 28, 1995.

Hon. ROBERT SMITH,
U.S. Senate,
Washington, DC.

DEAR SENATOR SMITH: I appreciate your efforts on behalf of the ''partial birth abortion'' controversy. In no way are these done only on abnormal infants. This is just another brutal way to destroy life. This procedure is not necessary to protect the life or health of women in this country.

Thank you again and keep up the fight to protect our children.

Sincerely,

DOROTHY CZARNECKI, M.D.

DALLAS, TX,
November 7, 1995.

Re late term abortions.

Hon. ROBERT SMITH,
U.S. Senator, Washington, DC.

DEAR SENATOR SMITH: I am a specialist in Maternal-Fetal Medicine and on faculty in the Department of Obstetrics and Gynecology at the University of Texas Southwestern Medical Center. It is the nature of my specialty that I deal with high risk pregnancies, and thus would be the consultant called to deal with issues regarding ''the life of the mother''. Prenatal diagnosis is also part of my specialty, and I am the one who breaks the news of fetal abnormalities and helps to plan how best to manage the rest of the pregnancy.

I can tell you unequivocally that there is no maternal medical indication for ''late term abortions.'' In situations where the life of the mother is at stake, we simply deliver the infant and the baby takes its chances in the nursery. In our nursery, 50% of the infants born at 24 weeks gestation will survive, most without significant problems. Prior to 24 weeks we recognize that the baby will generally die due to extreme prematurity, but we perform no procedures to ensure its death; there is no medical reason for this when the concern is with the life of the mother. ''Late term abortions'' are no safer, and may be more dangerous for the mother, than simple induction of labor.

The only reason for a ''late term abortion'' is to ensure that the late second trimester and third trimester fetus is born dead. The only possible medical indication would be a situation in which the fetus has abnormalities incompatible life. However, in most of these situations, the infant would die shortly after birth anyway and terminating the pregnancy in the late 2nd or 3rd trimester carries the same complications as allowing the pregnancy to go to term and end naturally.

This procedure has no place in modern obstetrics and only serves to destroy lives that might otherwise survive. I suspect that the women who made such tragic decisions for medical reasons chose this procedure without truly informed consent or full knowledge of their options. It should never be performed as an elective procedure. Please support legislation banning this procedure.

Sincerely,

L. LAURIE SCOTT, M.D.,
Assistant Professor,
Maternal-Fetal Medicine.

OAKLAND, CA,
December 1, 1995.

DEAR SENATOR SMITH: I am writing to you in support of the partial birth abortion bill. There is NO medical indication for this procedure, and the performance of this operation is totally in opposition to 2000 years of Hippocratic medical ethics. Please do your best to eliminate this procedure. It is not done in any other nation of the world.

Sincerely yours,

MARY L. DAVENPORT, M.D.

MINOT, ND,
November 28, 1995.

Senator ROBERT SMITH,
U.S. Senate,
Washington, DC.

DEAR MR. SMITH: I, Margaret Nordell, a medical doctor of obstetrics and gynecology am supporting Senator Robert Smith in the ban against ''partial birth abortion''. I am a member of the DakotaCare Physicians Association. I believe that this procedure is unnecessary to protect either the life or the health of women in this country.

Sincerely,

MARGARET NORDELL, M.D.

CONEY ISLAND HOSPITAL,
DEPARTMENT OF OBGYN,
Brooklyn, NY, November 26, 1995.

Hon. ROBERT SMITH,
U.S. Senate,
Washington, DC.

DEAR SENATOR SMITH: I am a practicing OBGYN on the staff of Coney Island Hospital in Brooklyn, New York. It is my professional opinion that the partial birth abortion procedure is very dangerous and absolutely unnecessary to protect either the life or the health of women in America. Therefore, I whole heartedly support the partial birth abortion ban bill to be passed and become officially law. Thank you.

Sincerely,

KARIN E. SHINN, D.O.,
Assistant attending.

The PRESIDING OFFICER. The Senator from California has 3 minutes 52 seconds.

Mrs. BOXER. I yield 2 minutes to the Senator from New Jersey.

Mr. LAUTENBERG. Mr. President, first, let me commend my colleague from California for speaking so forthrightly about an issue that does not belong in the kind of debate that we have heard from the other side from the proponents of this amendment.

Strangely enough, and I speak now as a father and a grandfather, as a father of four. We lost a couple because of health problems with my wife, and every one of those pregnancies that was lost was a terrible experience for us.

When my youngest daughter lost a fetus, lost a pregnancy that was in its 7th month because the baby was entangled in the cord, it was very painful, very painful. We did not know whether we had a healthy baby or not, but we were torn by this experience, to have her go to the hospital, spend 8 hours in labor to deliver the fetus.

The interesting thing to me, Mr. President, is I have not heard one woman speak for that side. It is the men who speak on what women ought to do, tell them how to conduct their lives, tell them what to do with their bodies, describe the pain that they will never feel. It is quite interesting. They want to tell everybody what the moral right is.

I just heard one of our Senators say something that to me is so preposterous. He says those who will vote to send troops to Bosnia will never serve in combat. Who is he that knows all this information? What a silly thing to say. It is the same thing we are talking about here.

What this is is license for the Government to participate in the operating room when a doctor does a procedure, when a doctor decides to perform a procedure that the woman carrying the fetus wants to have done because she feels that it is essential or the doctor feels it is essential for her health.

These abortions, these procedures are rarely done when someone was making that choice simply to rid themselves of that pregnancy.

This is a sad day, I think, Mr. President.

Mr. President, the bill before us is extremely dangerous and I strongly oppose it.

This bill is poorly titled for many reasons. It would more appropriately be called The Big Government Intrusion into the Doctor-Patient Relationship Act.

Under this bill, we will literally have FBI agents snooping around examining rooms. Let me repeat this. This legislation authorizes the FBI to go wandering around doctors' offices looking at patients and what doctors are doing to them.

Furthermore, this bill does not include a life and health of the mother exemption.

This bill will send a chilling signal to doctors in this country. And they will leave the practice of reproductive health care in droves.

And women could die in waiting rooms while doctors are on the phone, consulting with defense and constitutional lawyers, about what they can or cannot do to treat their patients.

Mr. President, one reason I am opposing this bill is because I believe doctors and patients can make proper decisions about which health care treatment is most appropriate.

Mr. President, one of the most extreme elements of this bill is its failure to include an exception to deal with situations in which the life or health of the mother is at risk. The pending Boxer amendment seeks to make this bill a little less extreme. The Boxer amendment would create a real health and life-of-the-mother exception.

Under the bill, as originally presented, if a doctor thought it likely that a woman would become permanently disabled if she carried a fetus to term, the doctor would still be prohibited from performing this procedure. Can you imagine that? A doctor would have to feel certain that carrying a fetus to term would endanger the life of the mother in order to do what is medically required for treatment.

Otherwise, the doctor could not perform this procedure even though the woman could suffer severe, permanent health damage without the procedure.

Mr. President, this bill will affect real people. Real women and families who have had to go through this procedure.

One such woman is Viki Wilson, a nurse, who 18 months ago was expecting her first child. Early tests showed the child to be normal but an 8-month ultrasound revealed that the fetus had a fatal condition—two thirds of the brain had formed outside the skull.

Carrying the pregnancy to term would have imperiled Viki's life and health. In consultation with her doctor, Viki and her husband Bill made the heartbreaking decision to undergo this procedure. This bill would make this practice illegal.

Mr. President, I would like to quote Viki at this point. She stated ''I strongly believe that this decision should be left within the intimacy of the family unit.''

So do I Mr. President.

While this bill is really extreme, the Boxer amendment would make it a little less extreme. At a minimum, we ought to adopt the amendment, which would establish a meaningful exception in cases where the life and health of the mother is at stake.

I urge my colleagues to adopt the Boxer amendment and I yield the floor.

The PRESIDING OFFICER. The time of the Senator has expired.

Mr. LAUTENBERG. I yield the floor and hope that my colleagues will support the amendment that is proposed by Senator BOXER.

Mrs. BOXER. Mr. President, I retain the remainder of my time.

The PRESIDING OFFICER. The Senator has no other time.

Mrs. BOXER. I thought I saved some time.

The PRESIDING OFFICER. They have no time.

Mrs. BOXER. How much time do I have remaining?

The PRESIDING OFFICER. The Senator has 1 minute.

Mrs. BOXER. Mr. President, this has been a tough debate so far. We have gone through it for 3 days. Maybe this is the 4th day, Senator SMITH.

I have to say, it is emotional. Why is it emotional? Because what we are doing impacts real people. We have seen these families night after night. We have seen charts of part of a woman's body, as if she had no face. I have to say to my colleagues, if they really think about it, if their daughter came to them and said, ''Dad, I have been told the most horrible news. If I do not terminate this pregnancy, even though it is so late term, I could die. I could be infertile. And the only procedure is this procedure,'' I really do believe, if Senators are honest, male or female, they would fall to their knees and pray to God and go ahead and have that procedure.

Why would we want to risk that woman's life? Please vote ''yes'' for Dole and ''yes'' for Boxer-Brown.

VOTE ON AMENDMENT NO. 3081

The PRESIDING OFFICER. The question now occurs on amendment No. 3081, offered by the majority leader, Mr. DOLE.

The yeas and nays have been ordered. The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. FORD. I announce that the Senator from New York [Mr. MOYNIHAN] is necessarily absent.

The PRESIDING OFFICER. Are there any other Senators in the Chamber who desire to vote?

The result was announced—yeas 98, nays 0, as follows:

[Rollcall Vote No. 592 Leg.]

YEAS—98

Abraham	Feingold	Lott
Akaka	Feinstein	Lugar
Ashcroft	Ford	Mack
Baucus	Frist	McCain
Bennett	Glenn	McConnell
Biden	Gorton	Mikulski
Bingaman	Graham	Moseley-Braun
Bond	Gramm	Murkowski
Boxer	Grams	Murray
Bradley	Grassley	Nickles
Breaux	Gregg	Nunn
Brown	Harkin	Pell
Bryan	Hatch	Pressler
Bumpers	Hatfield	Pryor
Burns	Heflin	Reid
Byrd	Helms	Robb
Campbell	Hollings	Rockefeller
Chafee	Hutchison	Roth
Coats	Inhofe	Santorum
Cochran	Inouye	Sarbanes
Cohen	Jeffords	Shelby
Conrad	Johnston	Simon
Coverdell	Kassebaum	Simpson
Craig	Kempthorne	Smith
D'Amato	Kennedy	Snowe
Daschle	Kerrey	Specter
DeWine	Kerry	Stevens
Dodd	Kohl	Thomas
Dole	Kyl	Thompson
Domenici	Lautenberg	Thurmond
Dorgan	Leahy	Warner
Exon	Levin	Wellstone
Faircloth	Lieberman	

NOT VOTING—1

Moynihan

So the amendment (No. 3081) was agreed to.

Mr. COHEN. Mr. President, I move to reconsider the vote.

Mr. GRAMM. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. Under the previous order, the underlying amendment, No. 3080, as amended, is agreed to.

VOTE ON AMENDMENT NO. 3080

The PRESIDING OFFICER. The question now is on agreeing to amendment No. 3083 offered by the Senator from California. The yeas and nays have been ordered. The clerk will call the roll.

The legislative clerk called the roll.

Mr. FORD. I announce that the Senator from New York [Mr. MOYNIHAN] is necessarily absent.

The PRESIDING OFFICER (Mr. BENNETT). Are there any other Senators in the Chamber who desire to vote?

The result was announced—yeas 47, nays 51, as follows:

[Rollcall Vote No. 593 Leg.]

YEAS—47

Akaka	Feingold	Lieberman
Baucus	Feinstein	Mikulski
Biden	Glenn	Moseley-Braun
Bingaman	Graham	Murray
Boxer	Harkin	Nunn
Bradley	Hollings	Pell
Brown	Inouye	Pryor
Bryan	Jeffords	Robb
Bumpers	Kassebaum	Rockefeller
Byrd	Kennedy	Sarbanes
Campbell	Kerrey	Simon
Chafee	Kerry	Simpson
Cohen	Kohl	Snowe
Daschle	Lautenberg	Specter
Dodd	Leahy	Wellstone
Dorgan	Levin	

NAYS—51

Abraham	Bennett	Breaux
Ashcroft	Bond	Burns
Coats	Grams	McCain
Cochran	Grassley	McConnell
Conrad	Gregg	Murkowski
Coverdell	Hatch	Nickles
Craig	Hatfield	Pressler
D'Amato	Heflin	Reid
DeWine	Helms	Roth
Dole	Hutchison	Santorum
Domenici	Inhofe	Shelby
Exon	Johnston	Smith
Faircloth	Kempthorne	Stevens
Ford	Kyl	Thomas
Frist	Lott	Thompson
Gorton	Lugar	Thurmond
Gramm	Mack	Warner

NOT VOTING—1

Moynihan

So the amendment (No. 3083) was rejected.

Mr. SMITH. Mr. President, I move to reconsider the vote.

Mr. DOLE. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. Under the previous order, the Senator from New Hampshire is recognized.

AMENDMENT NO. 3088 TO AMENDMENT NO. 3082

(Purpose: To express the sense of the Senate that the Senate should, through the Committee on the Judiciary, conduct hearings to investigate the effect of the new patent provisions of title 35, United States Code, (as amended by the Uruguay Round Agreements Act) on the approval of generic drugs)

Mr. SMITH. Mr. President, I send a second-degree amendment to the desk and ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from New Hampshire [Mr. SMITH], for Mr. DEWINE and Mr. DODD, proposes an amendment numbered 3088 to amendment No. 3082.

Mr. SMITH. Mr. President, I ask unanimous consent that reading of the amendment be dispensed with.

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

The amendment is as follows:

Beginning on page 1, line 3, strike ''**APPROVAL**'' and all that follows through line 22 on page 3 and insert the following: ''**SENSE OF THE SENATE.**

''It is the sense of the Senate that the Senate should, through the Committee on the Judiciary, conduct hearings to investigate the effect of the new patent provisions of title 35, United States Code (as amended by subtitle C of title V of the Uruguay Round Agreements Act (Public Law 103-465; 108 Stat. 4982)), on the approval of generic drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).''.

Mr. SMITH. Mr. President, I will try to explain the amendment.

First, I yield to the majority leader.

SCHEDULE

Mr. DOLE. Mr. President, I have been asked to indicate what may be in store for the rest of the evening. It is not certain that these are all the amendments, but we have an amendment by Senator BINGAMAN on shutting down the Government; an amendment by Senator FEINSTEIN which, as I understand it, is similar to the Boxer amendment just disposed of; a Brown amendment on deadbeat dads; then we have

the pending amendment of Senator PRYOR, which Senator SMITH will second-degree. There may be additional amendments. I think it is safe to say there will be votes well into the evening.

I yield the floor.

Mr. CHAFEE. I wonder if the majority leader has any indication, if this is disposed of this evening, what would happen tomorrow?

Mr. DOLE. We have a cloture vote scheduled on the constitutional amendment on the desecration of the flag. That could be resolved if we get an agreement on State Department reorganization. If we do that, then we can vitiate the vote on cloture and probably have debate only tomorrow on the flag amendment, but no final disposition.

Mr. JOHNSTON. Does the majority leader expect we will have a small window where we might get home to get a bite to eat?

Mr. DOLE. How close are you?

Mr. JOHNSTON. About 20, 25 minutes.

Mr. DOLE. You are not going to New Orleans, are you? I think we may have a vote in the next few minutes, and then we can probably arrange at least an hour.

Mr. JOHNSTON. I thank the majority leader.

The PRESIDING OFFICER. The Senator from New Hampshire is recognized.

Mr. SMITH. Mr. President, let me just say, for the benefit of my colleagues, I am not going to prolong the debate on this second-degree amendment. I know Senator PRYOR has some comments and Senator DEWINE wants to speak. I do not know of any others. But if others are going to speak, hopefully, they will come to the floor and we can expedite this matter as quickly as possible.

This amendment requires hearings on the relationship between GATT patent laws and the FDA Hatch-Waxman law relating to prescription drugs. At the outset, let me say I would have preferred not to have this bill, become a Christmas tree for nongermane amendments. It was hopeful that we would not have nongermane amendments. But the underlying Pryor amendment dealing with pharmaceutical products, GATT, and patent protections has nothing to do with partial-birth abortion. However, I recognize the right my colleague has to offer such an amendment, and I respect that. I hope that we will not spend a lot of time on this and delay this bill. We saw the same tactic a few weeks ago, and it seems to me that maybe there is some reluctance to face the issue at hand.

Mr. President, this second-degree amendment calls for hearings in the Judiciary Committee to look into this issue. I say to my colleague from Arkansas that it is an important issue and deserves a hearing, and I recognize that. I recognize that the Senator has a legitimate interest in this. I hope that it will not delay a vote on the bill, as other Senators have expressed interest to me—or have asked me whether or not there would be a vote tonight on final passage of the partial-birth bill. I am prepared to do that at any time. I do not know specifically of other amendments, but you never know.

If this second-degree amendment fails or if any other Senators are going to try to load the bill up, we will have to be offering second-degree amendments on all kinds of things from sex selection to Down's syndrome, and Lord knows what. Let's hope we do not get into all that.

Hopefully, Mr. President, why don't we just vote and move on and see where the votes fall on this bill.

If we want to talk about patent protections, come to the hearing and testify about patent protections. Then when the Senate is ready to vote on that, when we can come down and debate it.

It is a very complicated issue, patents and trade. I don't think it ought to go through the Senate in a hurry without having an opportunity to hear from both sides. The Senator from Arkansas voted a couple weeks ago to have a hearing on partial-birth abortion, and we did. I was not originally in favor of it, I admit, but we did have the hearing.

I did reconsider my views and allowed it to be sent to the committee. I hope the Senator from Arkansas will do the same.

I urge my colleagues if there is a vote to vote for the Smith amendment so we can have a full hearing under this issue of patent protection. I yield the floor.

Mrs. BOXER. Before my colleague from Arkansas speaks on this particular subject which he has been such a leader on, I wanted to make a comment that President Clinton has long believed that it is important to protect the life and the health of a mother, of a woman.

We know he will, in fact, veto this bill because the Senate now voted this down. A very close vote. I want to thank my colleagues who stood with Senator BROWN, with me, and with those who feel so strongly about this, that we must put a woman's face on this debate.

I am very moved by the vote that we had. It sends a very strong signal to the President of the United States: That 47 Senators, notwithstanding incredible organized phone banks, et cetera, stood up for the life and the health of the women in this country. I am proud that you stood with me. I am proud that you stood with women.

I want to particularly thank in that context every one of my colleagues that spoke on this. Senator MOSELEY-BRAUN spoke so eloquently yesterday and she made the point that the women of America will have to wake up to what is happening to their rights. She did that in the most beautiful fashion. I urge everyone to read the RECORD, because this assault on a woman's right to choose has begun in earnest.

When people do go to the polls they will have to decide where they stand. Could they stand with a Government that wants to get right into the hospital room with your family, right into your bedroom with your family, or do they believe that the families in our country with their God and with their conscience can make those kind of decisions?

I am very moved by the vote that we had. I will certainly vote against the final passage of this bill. Senator FEINSTEIN will be offering us an excellent substitute which basically restates the law of the land that says in the late term of a pregnancy the States control what happens in these late-term abortions.

I think everyone was very surprised by this vote. I was moved by the vote. I hope colleagues will vote ''no'' on final passage, since there is no exception for the life of the mother. The Senate voted for a partial exception, and therefore it makes it a very, I think, weak bill, and the President has said he would veto it. I applaud that.

I yield the floor.

Mr. PRYOR. Mr. President, I thank the Chair for recognizing me. Mr. President, the day before yesterday I introduced an amendment on behalf of myself and my very good friend from Rhode Island, Senator CHAFEE, and our good friend from Colorado, Senator BROWN.

Mr. President, I ask unanimous consent that Senator Robert BYRD of West Virginia be added as an original cosponsor of this amendment.

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

Mr. PRYOR. Mr. President, what we are seeing here tonight on the second-degree amendment, and I say this in all due respect to my colleagues who have offered this second-degree amendment to this principal amendment, this is merely an attempt to kill the Pryor-Chafee-Brown-Byrd amendment. That is it, pure and simple.

First, it is a sense-of-the-Senate resolution which all of us know in this body has no force of law. It has no real meaning. It has no traction, as we say around here. Beyond that, it does not require any Committee to hold any hearing at any specific time.

It merely says that the Judiciary Committee would conduct hearings to investigate the effect of the new patent provisions of title 35 U.S. code as amending subtitle C. of title 5 of the Uruguay Round agreements.

Mr. President, this amendment would probably end up in the wastebasket. There is no date certain for a hearing. Additionally, the amendment sends instructions for a hearing, under this sense-of-the-Senate amendment, to the Judiciary Committee. It would not be sent to the Labor Committee that has jurisdiction over food and drug issues. It is being sent to the Judiciary Committee of the U.S. Senate.

Once again, there is no date certain for when a hearing might be held on

the effect of the proposal that we are discussing this evening in the U.S. Senate.

Make no mistake, what this amendment is all about is an attempt to kill the Pryor-Chafee-Brown-Byrd amendment. It is a tactic to delay. It is a motion to protect one of the greatest windfalls that we have ever created in the history of our entire Government.

Now, Mr. President, I have several things I want to say during the course of this debate. I see my very good colleague, Senator CHAFEE, my colleague on the Finance Committee, who has been so loyal as a friend and as a supporter in trying to close this loophole that we created when we did not conform the food, drug and cosmetic law to the GATT treaty and its provisions.

Mr. President, I also see my friend from Colorado, Senator BROWN, an original cosponsor of our amendment.

Mr. President, expecting that my colleagues might have something to say on this issue, for the moment I yield the floor and I reserve the opportunity to address this issue further.

Mr. CHAFEE. Mr. President, I want to take a moment to discuss the pending amendment. This is really a very simple issue.

Under the Uruguay Round the nations agreed to boost protection of patents significantly. This was an historic step. Indeed, this was the first time that in these multilateral trade agreements such as this, the GATT, we became involved with so-called intellectual property.

In order to implement the provisions of the commitment to increase the protection for patents, the Congress changed the U.S. patent law from 17 years from approval to 20 years from filing date. This was a change to conform with GATT.

To be fair to existing patent holders, Congress gave those existing patent holders the option of taking the longer term. As a result, those holding patents as of June 1985 received an extension of up to 3 years.

However, granting this extension affected generic drug manufacturers who had been preparing to go to market after the original patents expired. To be fair to them, too, Congress made a compromise: manufacturers who had already made a substantial investment preparing to go into the market, would be allowed to proceed—but they would be required to pay a royalty to the holder of the patents. This was a carefully worked out compromise.

This transition was made available to all manufacturers, not just generic manufacturers of drugs. There are generic manufacturers of blue jeans and every other patent. Wherever there is a patent involved someone is waiting for the patent to expire and then come forward with their own product.

The product is called a generic product—not just a generic drug, but generic blue jeans, or whatever it might be. However, Congress made an error. It is not the first error Congress has ever made, but it was a costly one. We failed to consider a conforming amendment to the patent provisions of the Food, Drug and Cosmetic Act, which Senator PRYOR previously alluded to.

The consequence of this oversight is that one group of generic manufacturers—in other words, those coming on with a substitute product—had been denied the benefits of this transition provision. These were the generic pharmaceutical manufacturers. So, while the manufacturers, that is the manufacturers who had the patent of these branded pharmaceutical products, got an extra 3 years, the generic drug manufacturers were cut out altogether from transition remedies—from doing anything.

This oversight, if left uncorrected, I must say, is a wonderful windfall for the pharmaceutical manufacturers who are protected by it, who got this windfall which was never planned for. This windfall is in the area of billions of dollars—not millions, but billions. So, quite understandably, they are very enthusiastic to prevent anything from happening around here, to prevent the Pryor amendment from going into effect. Obviously, others can give illustrations of this.

What will be the effect of the passage of the Chafee-Brown-Pryor-Byrd amendment? First, it will level the playing field by making the GATT transition provision available to generic drug manufacturers like it is to generic blue jeans manufacturers, or whoever it might be. This is what we intended. Second, it will stop the unintended, and therefore unfair, windfall. And, third, it will save consumers, insurers, and, I might say, the Government—because the Government will benefit greatly from getting their Medicaid prescription drugs at a far lower price than otherwise would be true.

There are two counterpoints that opponents of this will make. Some have warned that this amendment would negate or otherwise affect the hard-won gains that came about through GATT and the intellectual property protections. That is a red herring. The STR, the Special Trade Representative, has assured us that our amendment will not in any way interfere with the GATT intellectual property protection rights. In fact, the USTR supports this amendment, for they say the conforming amendment—namely, the Pryor effort—should have been included in the GATT bill but was overlooked inadvertently.

Now, as to the argument that our amendment would upset the delicate balance of the Hatch-Waxman Act, that also is a red herring. This is not about Hatch-Waxman; this is about GATT. Officials of the Food and Drug Administration have assured us that our amendment absolutely would not disturb the so-called Hatch-Waxman Act. Let me say, if this were interfering with GATT in some way, the intellectual property provisions, I would not be for this amendment.

This is what we might call a ''good Government'' amendment. It seeks to close a loophole which was unintentionally created. We made a mistake, and now we are trying to correct it. Does it have any support outside of those of us here? Certainly a broad coalition of senior citizens and consumer groups support it. Furthermore, it is the right thing to do. Occasionally we do the right thing around here.

I certainly hope that this amendment of the Senator from Utah, to send this back, and the Senator from New Hampshire, would not prevail. I hope it will not prevail because, if it does prevail, that does in the Pryor effort here.

Could I ask the Senator from Arkansas, does this amendment provide for a date that the hearing must be completed?

Mr. PRYOR. Mr. President, I respond to my colleague from Rhode Island, there is absolutely no date set forth in the sense-of-the-Senate resolution to require the Judiciary Committee, or any other committee of the Senate, to hold a hearing. It is totally open ended. Again, there is no date specified in the sense-of-the-Senate resolution.

Mr. CHAFEE. I have a question for the distinguished Senator from New Hampshire. He mentioned the sending of his bill back to committee for a study. I guess the Senator from New Hampshire supported that in the end, reluctantly.

My question is this: Did that amendment, that sent the Senator's bill back to committee, have a date at which the committee must report back? As I recall, it did. I may be mistaken.

Mr. SMITH. I believe it was 17 days, I say to my colleague, Senator CHAFEE. But I need to check that.

Mr. CHAFEE. I certainly would abide by whatever the Senator says, and if he wishes to correct it later, that is fine. But, as I recall, when that was sent, Senator SMITH's bill which came up here, say, a month ago, when that was sent back to committee, that was sent back with a time limit to it, a definite period. Whether it was 17 days or 3 weeks or whatever it was, I am not sure. But I remember, to the best of my recollection, there was a time certain. Yet, in this case, the Senator from New Hampshire, in his amendment, has not provided for a date certain. What does the Senator from Arkansas suggest on that? Would this be more palatable if there was a time limit?

Mr. PRYOR. Let me respond, Mr. President, to my friend from Rhode Island once again. It would certainly be more palatable if we had an imminent date for the Judiciary Committee to hold such a hearing. But, to be honest, I do not think a Judiciary Committee hearing is going to give us any more facts than we know today. We pretty well have the facts. Those facts are that the Congress made an mistake. We created an error in the GATT legislation. We opened a loophole, and now we have an opportunity to fix it.

As the Senator from Rhode Island just stated, this is really a very, very

simple matter. It becomes dramatic because of all the dollars involved: All the dollars that appeared unexpectedly in a windfall that goes to a small handful of drug companies that had no idea a year ago that this windfall would occur and that these billions of dollars would basically be falling out of the trees into their bank accounts.

So I say, even if there were a day certain, we are about to leave for Christmas. If we even set a day certain of 10 days from now, perhaps the Senate and the House will not even be in session. We do not know when we are coming back in session next year. So I say once again, this is an attempt to kill the original Pryor-Chafee-Brown-Byrd amendment.

Mr. CHAFEE. I would ask the Senator from Arkansas another question. It seems to me that this is an odd provision, in that it is referred to the Judiciary Committee, yet the jurisdiction of the Food and Drug Administration is in the Labor Committee.

Mr. PRYOR. The Senator is absolutely correct.

Mr. CHAFEE. So, why is this being sent to the Judiciary Committee?

Mr. PRYOR. I believe the distinguished Senator from New Hampshire is the author of this amendment. Perhaps he could advise us as to why the amendment is being sent to the Judiciary Committee.

Mr. SMITH. The Senator from New Hampshire is not the sponsor of the amendment. The Senator from New Hampshire offered the amendment.

Mr. HATCH. If the Senator will yield, I will be happy to answer that. I will be happy to answer that. It is because it involves a hallowed and important element in the history of this country and in the world, and that is patents. We happen to handle patents. It involves intellectual property. It also involves an international intellectual property agreement which we better be careful of here, because there are a lot countries out there that do not honor intellectual property.

There are a lot of countries out there that do not believe in patents. Or, if they do not believe in patent terms—if, after a multiyear negotiated agreement in international relations, intricate, negotiated every line of that agreement—it is bunk to say that this was a mistake. We then retrench on patent terms the first time out of the blocks when we have gone all over the world talking about intellectual property, respect for intellectual property, and for other countries to treat American products fairly. And right out of the blocks we say we have to do away with that, you send a message that we are going to wreck the world window on the rest of our lives. We have taken years to get to this point.

I am going to have a lot to say on why there are two sides to this thing, and that it is more important to uphold the international treaty, uphold the international patent protection, than it is to demagogue on this particular issue.

I will make my points afterwards. But the reason it is sent to the Judiciary Committee is because it involves the most important aspects of the patent law and intellectual property law. That is what is involved here.

Mr. CHAFEE. Mr. President, first of all, if it involves treaties, then, of course, it goes to the Finance Committee. The last place in the world it should go is the Judiciary Committee.

Mr. HATCH. Not if it involves patents.

Mr. CHAFEE. If you want time, you can have time after I finish.

We have a letter from Mickey Kantor, U.S. Trade Representative, September 25, 1995:

> The extension of the section 1534(c)—that is what we are doing here to pharmaceutical property products—would not undermine ongoing U.S. efforts to seek high levels of intellectual property protection around the world.

So there is no problem here with patents. That does not have anything to do with it. The fact of the matter is that this reference, if indeed it should be made—I do not think it should—but if it should, it should go to one of two places: The Finance Committee, which deals with trade, or the Labor Committee, which deals with FDA. I would be far happier to see it go there than to the place suggested.

Mr. PRYOR. Mr. President, if the Senator from Rhode Island will yield—then I want to hear, and I know we all do, our friend from Colorado, Senator BROWN—I'd like to ask if in the history of the Judiciary Committee has that committee held hearings on the Food, Drug and Cosmetic Act? That committee does not have jurisdiction over this act, yet that is where we are about to dump this issue.

The second point I would like to raise is my friend from Utah, Senator HATCH, has talked about, ''Oh, this is relating to patents. We have to protect these patent rights.'' That seems ironic, since on June 7, 1995 the United States Patent Office ruled—the Patent Office ruled, Mr. President—that they determined the expiration dates of the patents in question. They are in force on June 8, 1995 and, therefore, are entered into the greater of the term of 20 years from their relevant filing days, or 17 years from grant. In other words, they held in our favor. The Patent Office held in our favor that the generics could in fact come in and compete with the brand-name companies. Of course, the brand-name companies with all of their high-powered lawyers, money, et cetera, moved on to the courts. And because the courts interpreted literally our mistake as being the intent of Congress, and I must say that I think they made a mistake, Glaxo and other major pharmaceutical companies won out.

I would like to make one more point, and then I am going to sit down for a spell.

The PRESIDING OFFICER. The Senator from Rhode Island controls the floor.

Mr. CHAFEE. I would certainly like to hear the Senator make that explanation, if he might.

Mr. PRYOR. I would like to just say, if we allow this situation to persist and refuse to close this loophole, let us for a moment look at what is going to happen to one pharmaceutical company that has inherited this windfall. Let us look at Glaxo. They make Zantac. Here is some Zantac. It cost $170 a bottle. You can go over to Canada, by the way, and buy this for about $70 a bottle. Or, if in our country we had the competition for Zantac on the shelves today, as we should have occurred earlier this week, it would cost about half of what this $170 bottle of Zantac cost.

But, if we go forward, let us say even for an additional 30 days and allow this windfall to continue, or let us say just to Christmas day—and Christmas day is just a few days away, Mr. President—Glaxo is going to make another $115 million. If we hold a hearing in the Judiciary Committee, say next November, and then keep this thing in effect, maybe until 1996, a year from Christmas and do not correct it until a year from this Christmas, this one company—because of our mistake and because of our refusal to correct that mistake—will have made an extra $2.328 billion.

Do we want our patent law in this country to be based upon an error, to be based on a mistake that we made, and refuse to correct? I do not think so, Mr. President.

I look forward to hearing some of the comments from other colleagues who feel, I believe, as strongly about this issue as I do.

Mr. CHAFEE. Mr. President, I would like to ask the Senator from Arkansas one more question. I understand that these substantial amounts will be made by the companies that they would not otherwise make, if we corrected this. My question is: But, if we correct it sometime in the future, then is there a refund in some type that occurs? Does it undo itself, or everything is just prospective?

Mr. PRYOR. The way that I understand the law, I say to my friend, if a generic company has been out there and has made what we call a substantial investment where they are ready to come into the market at the end of the 17-year patent protection period, then the generic would be allowed to go on the shelves, to go on the market, to be advertised, to be marketed, selling for one-half of what the brand name sells these drugs for today. At that time a royalty for this time that was unexpired—like for 600 additional days for Glaxo and Zantac—a royalty would be paid even to the Glaxo company by the competing generic drug company. The amount of that royalty would be established in a court of law, and there is a system whereby that amount would be established.

I think that is the question the Senator from Rhode Island is asking.

Mr. CHAFEE. I understand that. But now my question is: But, let us assume

that this is referred back to this committee—the wrong committee, as it turns out, but nonetheless it is referred back—nothing happens, and finally let us say in March we straighten out the law, then retroactively is there some compensation that takes place?

Mr. PRYOR. Mr. President, I apologize to my friend from Rhode Island. I did not understand his original question. I do now.

In other words, if we were to correct this, even in March or April, whenever, and admit we made a mistake, which we did and we all agree that we did, then the company gets to keep all of that money. There is no refund. The Medicaid programs have continued to pay the highest price for these drugs. The Veterans Administration has continued to pay the highest price for these drugs. The consumers get no rebate. The consumers get no relief. The only benefit accrues to a very few drug companies that we failed to include in the coverage of the new law in the GATT treaty. They get to keep all of these excess profits. And that is what this fight is all about. Every time, every day that these drug companies get to keep this amount of money, these exorbitant profits, this windfall, it comes out of the pocketbooks of the consumer, the veterans, the Medicaid programs, and every citizen of this land.

Mr. CHAFEE. I thank the Senator. I thank the Chair.

Mr. BROWN addressed the Chair.

The PRESIDING OFFICER. The Senator from Colorado.

Mr. BROWN. Mr. President, I appreciate the thought. I wish to assure my good friend from Ohio that I will not be long.

I hope Members, as they vote on this, will consider a couple of points. I don't think these are in dispute. If they are, I know my good friends will correct me. But I think every Member ought to be aware that this amendment is very important and would have a significant impact on the Treasury of the United States. The estimates are that this will save the taxpayers in the neighborhood of $150 million. It may be more than that, but CBO has come forward with that figure. So one of the things Members ought to think about is the dramatic, significant increase in revenue and reduction of the deficit that this amendment can have if it is passed.

Second, many Members may have read the Newark Star Ledger's editorial of October 26. Let me quote it:

> Thanks to a gigantic loophole resulting in the GATT, consumers may wind up paying as much as $6 billion more for higher priced brand name drugs.

Mr. President, I do not know if the $6 billion figure is correct or not. That is an estimate by the paper. I must say my own estimate is less than that. But there is no question this is big, big, big money, and it comes right out of the pockets of the consumers of this country.

So the two things that I think are really without question here are first that the amendment offered by the distinguished Senator from Arkansas is a friend of the taxpayers of this country. It has a significant impact in a positive way on reducing the deficit.

Second, this amendment is very much a friend of the consumers in this country. It saves the consumers of this country literally billions of dollars. Is it the $6 billion the Newark paper talked about? My guess is it is less than that. But it is a huge amount. If you are concerned about the consumers of this country, you ought to be in favor of it.

Two other points have been raised, and I think they merit addressing. One is, is this fair? Is it fair to adjust the rules? Well, let us take a look at it. When the patent for this medicine was granted, it extended 17 years from the time of filing. Is that diminished in any way if this amendment passes? The answer is no. The answer is absolutely no. The drug company gets exactly what they thought they were getting when they filed for the patent. They do not lose in any way. They get exactly what they were offered at the time they developed the product, at the time they marketed the product, at the time they put the factory together to produce the product. Nothing has changed.

What do they lose? They lose the windfall that came from the treaty.

If you are on the subject of what is fair, let us ask ourselves, what if you were a different firm? What if you were a firm that was aware of the drug and aware of the law and got geared up to produce a competitive product in reliance on the laws of this Nation, and the laws of this Nation said the exclusivity ends after 17 years.

For this particular drug, there are competing companies. There are companies that relied on the law. There are companies that made investments. They put together a plant to produce this, and they geared up to produce it and sell it on the market. If you are concerned about fairness, you should not be concerned about Glaxo. They got exactly what they invested for. You ought to be concerned about the companies, honest people who invested in facilities and plants and processes in reliance on our law and had the product taken away from them after they made that big investment. Now, if you are concerned about fairness, you ought to be in favor of the amendment, not against it.

Last, Mr. President, let me simply add one other thing that I think is important. It has been suggested on this floor by a number of people that doing this somehow will be inconsistent with our treaties under GATT, and the very distinguished chairman of the Judiciary Committee has just pointed out what a great investment we have in intellectual property. He is absolutely right.

I might say, Mr. President, from my point of view, if you were going to send this to a committee, I would think the Judiciary Committee would be a great committee. It has some of the brightest, most able Members, and the most modest, too, in the Senate. But the point is this should not go to committee at all. The point is if you send it to the committee, what you do is you cost consumers hundreds of millions of dollars just by the delay, and you cost the taxpayers some money, too.

I think the last point that deserves addressing is this one. Are we doing something, with the Pryor amendment are we doing something that violates the GATT treaty? We do have—and I acknowledge it—a vested interest in making sure that treaty is honored.

For that point I wish to draw Members' attention to some information. It is the treaty itself. I know a lot of Members did not get a chance to read it, and having tried to read it myself I understand why. But there are some interesting things you find out. I wish to read you the precise words of the agreement itself because it relates specifically to this point. And I am talking about part VII. This is under article 70. The title is: ''Protection of Existing Subject Matter.'' In paragraph 4, there are the following words:

> . . . or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide—

By ''Member'' they are referring to a country—

> for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.

Mr. President, the treaty itself anticipates exactly this kind of legislation. Let me repeat it. This amendment in no way is at odds with the treaty. It in no way violates the treaty. As a matter of fact, the exact words of the treaty anticipate this very action.

Now, to suggest that we somehow are jeopardizing our intellectual property rights by taking this action, I do not believe conforms with either the spirit of the treaty or the precise words of the treaty. The reality is if someone has made a substantial investment relying on our current law, we have a right under the treaty, in specific terms, to do this.

Mr. President, there are two editorials at this point I would like to enter into the RECORD because they make the point very well. One is by the Des Moines Register and the other is by the Washington Post. I ask unanimous consent that they be printed in the RECORD.

There being no objection, the editorials were ordered to be printed in the RECORD, as follows:

[From the Des Moines Register, Nov. 27, 1995]

A COSTLY OVERSIGHT—FINE PRINT IN GATT LAW COULD COST ZANTAC USERS MILLIONS

The nation's prescription drug makers are at war again, with a $1 billion-plus purse

going to the winner. If the brand-name drug manufacturers win, the losers will include the millions of Americans who suffer from ulcers or heartburn, and take the drug Zantac regularly to combat the problem. It's going to cost each of them about $1,600.

Zantac is made by Glaxo Wellcome, the biggest in the business.

Here's what started the current war:

When a new prescription drug hits the market, generic drug manufacturers await the patent expiration so they can enter the market with the same drug. They offer it for sale without the brand name, usually at a fraction of the brand-name price.

The new international GATT treaty signed by the United States and 122 other countries sets the life of a patent at 20 years from the date of application. Former U.S. law provided patent protection for pharmaceuticals for 17 years from the date of approval. Because the difference could have a significant impact on the number of years a firm could market its patented drug without competition. Congress made special provisions for drugs under patent at the time GATT was approved last summer.

But when the legal beagles got done reading all the fine print, it turned out that Zantac was granted a 19-month extension of its patent life—and it is such a hugely popular drug that that translates into a multimillion-dollar windfall.

Generic drug makers call the windfall a congressional oversight, and estimate the difference is worth $2.2 billion to Glaxo, because the generics can't enter the market for 19 more months. Glaxo counters that Congress made no mistake, that the extension was part of the compromise with generics. It won't wash. Nothing in the GATT treaty was intended to further enrich the happy handful of brand-name drug makers who hold lucrative patents—or to penalize the users of the drugs.

A month's supply of Zantac ordinarily sells for around $115; the generic price—meaning the same drug without the Zantac label—would be around $35, the generic makers contend. Unless Congress changes the wording of the law regarding transition to GATT provisions, Zantac users will pay the difference for 19 months longer.

Some generic drug manufacturers had already spent a bundle preparing to enter the market before the GATT treaty took effect. They lose. So do taxpayers, who pay for Medicaid prescriptions. The Generic Drug Equity Coalition estimates that the higher cost of Zantac and some other drugs affected by the mistake (such as Capoten, for high blood pressure) will cost Iowa Medicaid $3.5 million. Further, say the generic drug makers, it will tack another $1.2 million onto the cost of health-insurance premiums for Iowa state employees.

Glaxo's political-action committee has doubled its contributions to Congress in recent months. Glaxo wants the mistake to stay in the law. Generic drug manufacturers want it out.

So should ulcer sufferers. So should taxpayers. So should Congress.

[From the Washington Post, Dec. 4, 1995]

THE ZANTAC WINDFALL

All for lack of a technical conforming clause in a trade bill, full patent protection for a drug called Zantac will run 19 months beyond its original expiration date. Zantac, used to treat ulcers, is the world's most widely prescribed drug, and its sales in this country run to more than $2 billion a year. The patent extension postpones the date at which generic products can begin to compete with it and pull the price down. That provides a great windfall to Zantac's maker, Glaxo Wellcome Inc.

It's a cast study in legislation and high-powered lobbying. When Congress enacted the big Uruguay Round trade bill a year ago, it changed the terms of American patents to a new worldwide standard. The effect was to lengthen existing patents, usually by a year or two. But Congress had heard from companies that were counting on the expiration of competitors' patents. It responded by writing into the trade bill a transitional provision. Any company that had already invested in facilities to manufacture a knock-off, it said, could pay a royalty to the patent-holder and go into production on the patent's original expiration date.

But Congress neglected to add a clause amending a crucial paragraph in the drug laws. The result is that the transitional clause now applies to every industry but drugs. That set off a huge lobbying and public relations war with the generic manufacturers enlisting the support of consumers' organizations and Glaxo Wellcome invoking the sacred inviolability of an American patent.

Mickey Kantor, the president's trade representative, who managed the trade bill for the administration, says that the omission was an error, pure and simple. But it has created a rich benefit for one company in particular. A small band of senators led by David Pryor (D–Ark.) has been trying to right this by enacting the missing clause, but so far it hasn't got far. Glaxo Wellcome and the other defenders of drug patents are winning. Other drugs are also involved, incidentally, although Zantac is by far the most important in financial terms.

Drug prices are a particularly sensitive area of health economics because Medicare does not, in most cases, cover drugs. The money spent on Zantac is only a small fraction of the $80 billion a year that Americans spend on all prescription drugs. Especially for the elderly, the cost of drugs can be a terrifying burden. That makes it doubly difficult to understand why the Senate refuses to do anything about a windfall that, as far as the administration is concerned, is based on nothing more than an error of omission.

Mr. BROWN. Mr. President, let me simply conclude this way. If you are concerned about the taxpayers, you ought to like the Pryor amendment because the CBO says it brings us in $150 million, or saves it. If you are concerned about the consumers of this country, you ought to be in favor of the Pryor amendment because it is going to save them $6 billion, if you believe some estimates, or a little less if you believe my estimate.

If you are concerned about fairness, you ought to be in favor of the Pryor amendment because people have invested money in plant and process and production capability to comply with our laws and they are simply out by this windfall.

Last, Mr. President, if you are concerned about the integrity of our protection of intellectual property, you ought to be for the Pryor amendment because this is precisely and exactly what the treaty anticipated.

I yield the floor.

Mr. BRYAN. Mr. President, I have come to the Senate floor a number of times to talk about prescription drug pricing, and to support Senator PRYOR's efforts to control the costs of drugs. Today I am pleased to cosponsor Senator PRYOR's amendment to correct the GATT treaty loophole that creates a windfall profit for certain prescription drug companies.

The GATT treaty, voted on by Congress, included two important provisions that affected every product, company, and industry in the country. One, provided that all patents would be extended from 17 to 20 years; an additional 3 years of protection. Two, provided that a generic company, in any industry, would be permitted to go to the marketplace and compete on the 17-year expiration date, if the generic company had made a substantial investment, and was willing to pay a royalty.

An unintended loophole was created, however, when the prescription drug industry was accidently excluded from the generic competition provision. The loophole means that prescription drug companies have a 3 year longer patent period, without any competition during that time extension from generic companies. This loophole has created a multimillion dollar windfall for certain drug companies that must be corrected.

Seniors use prescription drugs more than any other age group. For them, this loophole means they will pay higher drug prices for 3 years because of a mistake. Without the ability of generic drug companies to compete, drug prices will remain artificially high during that 3-year period. There is no reason why seniors should suffer because of an unintended mistake that can be corrected today.

What drugs are involved here? More than 100 drugs would be protected from generic drug competition. The world's best-selling ulcer drug, Zantac, would cost twice as much as it should because of the loophole. The hypertension drug, Capoten, will cost 40 percent more than it should because of the loophole. Additionally such drugs as Mevacor for lowering cholesterol, Prilosec for ulcers, and Diflucan, an antifungal agent are affected.

This loophole will also affect the drug prices paid by the Medicaid Program. Medicaid already faces deep cuts in its funding. If this loophole is not corrected, Medicaid will be forced to pay higher drug prices during the 3-year period, further straining its ability to provide medical care for the most vulnerable in our country.

Veterans will also suffer as the Veterans Affairs Administration will be forced to pay higher drug prices. People using public health services will also be affected. The bottomline is that taxpayers will pay more for the drugs used by these programs than they should, because competitive generic alternatives will not be available.

There is no reason to allow some prescription drug companies an unintended windfall profit to the detriment of all Americans who depend on drugs for their continued health. Seniors, veterans, and the most vulnerable in our country particularly deserve our protection from unnecessarily high

drug prices. I hope my colleagues will see this loophole for the mistake it is, and support this amendment to correct it.

Ms. MOSELEY-BRAUN. Mr. President, I would like to take this opportunity to express my support for the Dodd-DeWine amendment. This amendment would require the Judiciary Committee to hold hearings on the GATT patent extension provisions. The GATT issue is a complex one and requires full disclosure. The Pryor amendment has no place on the partial birth abortion bill. Hearings are appropriate and, in my opinion, critical to ensure that the members of this body fully understand the issue and the implications of any action to modify the GATT agreement.

The Pryor amendment would modify the current General Agreement on Tariffs and Trade [GATT] as it applies to patent protections for pharmaceutical products. This amendment, which was voted down in the Finance Committee, has been portrayed as a technical correction to the General Agreement on Tariffs and Trade [GATT] agreement. It is not. This amendment opens up an international agreement on trade to resolve a domestic intra-industry dispute. It is shortsighted, counterproductive and will impede the availability of life saving drugs and therapies for all of us.

Before, I discuss substantively the issue at hand, I would like to state unequivocally that I firmly believe that all persons who are sick should have access to affordable, comprehensive health care services. In 1992, I campaigned on the issue of health care reform and I remain firmly committed to that goal. My views on the GATT patent extension issue are in no way inconsistent with my support for reform. In fact, I believe present attempts to undo and reopen GATT could have an adverse impact on the development of state of the art medicines and treatments, which in turn deny all of us the benefit of advances in medical science.

At question, is a provision, in the newly adopted agreement, that provides additional patent protection to pharmaceutical products. GATT provides 20 year patent protection to all products and industries covered by the agreement—there are over 1 million patent holders in the United States who will receive extended patent protection. This change, which extends U.S. patent protection from the current 17 years from the date the patent is granted to 20 years from the date of filing, conforms U.S. patent law to the international standards agreed to under GATT. The agreement, including the patent provisions, was overwhelmingly approved by Congress last November. The Pryor amendment would repeal the patent extension provisions as they apply to pharmaceutical products. Some of my colleagues believe this amendment is needed because they believe the patent extension provisions were a mistake and that an inadvertent windfall to a handful of pharmaceutical companies was created. I do not believe this assertion is fair or accurate.

The GATT law was very clear. The implementing legislation provided that, in certain circumstances, individuals or organizations that had relied on the shorter expiration term could use the patented technology during the extension period, although they must pay a royalty to the patent holder to do so. Section 102 of the GATT, however, states that ''Nothing in this Act shall be construed . . . to amend or modify any law of the United States . . . unless specifically provided for in this Act.'' GATT changed many areas of patent law, but it did not change current Federal law that prohibits the FDA from granting approval for the manufacture of generic drugs until the patent term on the original product has expired. On May 25, the FDA ruled that nothing in the GATT explicitly overrules this provision and on November 1, the court of appeals for the Federal circuit also upheld the patent extension provisions in GATT.

The actions by the FDA and the Federal circuit court of appeals underscore the purpose of the GATT treaty which is to make trade laws more uniform and consistent. Uniformity is needed to prevent countries from passing laws that are favorable to their own domestic companies; 110 countries worked for over 7 years to complete negotiations on GATT. The intellectual property issues were among the most contentious. The essential goal of patent protections are to allow companies and individuals to invest freely and securely in the development of important and needed products. If companies are provided exclusive protection over an innovation, they are more likely to invest the necessary resources into developing a safe and effective product. This kind of market stability and security are vital with respect to pharmaceutical products, which require enormous R & D resources. Achieving better protection of intellectual property was a major victory for the United States as U.S. manufactured products, trademarks, and services are increasingly counterfeited abroad. The agreement is final and cannot be renegotiated without putting these hard fought, and hard won, protections at risk.

The patent language in GATT gives the United States greater assurance that innovations that originate here will not be pirated by foreign firms. The benefits of the provisions cannot be overstated. First, it will provide American companies the economic and intellectual security needed to develop safe and effective new products; second, it will ensure stability in the U.S. pharmaceutical market. This will not only stabilize the U.S. market, but also protect U.S. jobs. Third, it will ensure research and investment by U.S. companies on products that are needed to treat fatal disease. To change this international agreement now, because of an intra-industry dispute, invites retaliation from other countries eager to undo our gains.

One of my main concerns is that if the United States is seen as hesitant about implementing this part of the new GATT, a number of countries that have been reluctant to prevent their firms from pirating United States products would have the excuse they need to go slow in implementing the agreement, or to avoid implementing it at all. That would result in the destabilization of the U.S. market, a loss of U.S. exports and U.S. jobs, have a letter here, that I would like to place in the RECORD from Sir Leon Brittan, Vice President of the European Commission, that comments on a proposed changes to the patent extension provisions in GATT. Brittan states that ''this threat causes serious concern to the European research-based pharmaceutical industry and to the Commission, and it seems to be in contradiction with the long-standing U.S. policy of providing strong protection for research-based, intellectual property right both home and abroad.'' Brittan also notes that changes to the GATT law in the area of patent extension will set back hard-won improvements in universally agreed upon patent protections.

Finally, I would like to return to my first concern—consumer interest. On average it takes 12 years and $360 million to bring a new drug to market. Research-based, pharmaceutical firms spend nearly $18 billion annually on research and development. This emphasis on R&D has produced treatments not only for common conditions and ailments, but also for life-threatening diseases. The United States invests more than any other nation on research. I have received numerous letters from patient groups that are very concerned that modifications to GATT will adversely impact research and development, particularly on orphan diseases for which there is little or no ability to recoup the up-front, financial investment. At the close of my statement I will insert several of these letters for the RECORD. We must continue to increase our investment if we are to discover cures and effective treatments for diseases that continue to plague millions of Americans like AIDS, Alzheimers, Parkinson's disease, and cancer.

Some have maintained that repealing the patent-extension provisions, as they apply to pharmaceutical products, is appropriate, because it would make available cheaper versions of a limited number of name-brand drugs a few months earlier than they would otherwise be available. I believe there is a more compelling issue regarding the balance of trade and the larger consumer interest. Increased patent protection ensures that research and development will continue in, not only, the medical field, but also in all areas of innovation. This country leads the world in research and innovation; it

contributes to the public good both here and abroad, and every American benefits from our leadership. Changes to the GATT agreement that seek to repeal patent extensions for only one class of innovations are, in my opinion, shortsighted. Such changes will decrease private sector revenues for research and development, compromise U.S. leadership on intellectual property protection, and adversely impact the competitiveness of U.S. companies in relation to their foreign counterparts.

The competitiveness of U.S. industries is of great concern to me since I became a Member of this body 3 years ago. This is because of the inextricable linkage between competitive industries and the growth and maintenance of U.S. jobs. This is why I supported legislation such as NAFTA, GATT, product liability reform. I have given careful consideration to all of the these issues. I am convinced that these measures will increase the ability of U.S. industries to compete and lead to a more viable job market. The patent-extension issue is a complex one, and I believe, any action by Congress to modify the GATT agreement should only be undertaken after a thoughtful and thorough review of the long-term implications of such action. It is for these reasons that I must oppose the Pryor amendment.

I ask unanimous consent that the letters referred to earlier be printed in the RECORD.

There being no objection, the letters were ordered to be printed in the RECORD, as follows:

UNITED PATIENTS' ASSOCIATION
FOR PULMONARY HYPERTENSION, INC.,
Speedway, IN.

Hon. CAROL MOSELEY-BRAUN,
Hart Senate Office Building,
U.S. Senate,
Washington, DC.

DEAR SENATOR MOSELEY-BRAUN: I'm writing to you on behalf of 400–500 Americans who suffer from a very rare and very deadly disease known as Primary Pulmonary Hypertension (PPH). Until recently, the best hope for long-term survival from PPH was through a lung or heart/lung transplant. However, today, thanks to research which dates back to the 1970's, a new drug was recently approved to treat PPH which not only is extending these patients' lives but is allowing them to live full, active and productive lives.

I have learned that some generic companies are now trying to change the law so that they can gain financially by bringing their products to market before the patents on the pioneering companies' products expire. I can attest to the value that research-based companies bring to patients as a result of strong patent protection, and I urge you to oppose these efforts.

While I appreciate the cost savings that generic drugs can offer in the short term, I also know that innovative new therapies for complex, life-threatening diseases will come only from research-based pharmaceutical companies. When it comes to serving patients suffering from deadly orphan diseases like PPH, it is the research-based companies that give us hope.

Glaxo Wellcome recently received approval to market the first medicine that will significantly extend the life, greatly improve the quality of life, and help avoid complex, risky surgery for people suffering from PPH. I know of no generic drug company that would commit the millions of dollars or many, many years of research to discover or develop such a medicine, and it is unlikely that they will ever produce a generic version for a patient population so small. There are many other similar patient populations who depend on the research-based companies to bring these new medicines to market.

The purpose of the General Agreement on Tariffs and Trade (GATT) was to strengthen intellectual property law around the world and bring U.S. intellectual property law into compliance with other industrialized countries. If the GATT resulted in longer patent protection for a few medicines—all of which already face competition from other therapies—that in my view is a benefit for our society.

Our patients have experienced the direct benefits of the tremendous investments that the pharmaceutical industry has made in research and development. Research-based companies need and deserve the incentives provided by strong intellectual property protection. Please do nothing to weaken them.

Sincerely,

JUDITH SIMPSON,
R.N., Ed. S., President, UPAPH.

FIBROSIS FOUNDATION,
Bethesda, MD, November 8, 1995.

Hon. CAROL MOSELEY-BRAUN,
U.S. Senate, Hart Senate Office Building,
Washington, DC.

DEAR SENATOR MOSELEY-BRAUN: I understand Senators Pryor and Chafee are attempting to amend the Hatch-Waxman Act to eliminate extensions for existing pharmaceutical patents granted by GATT. I urge you not to vote for that amendment, but instead to protect existing legislation that preserves incentives for research and development.

As President and Chief Executive Officer of the Cystic Fibrosis Foundation, I have personally witnessed the great suffering endured by patients and their families in their fight against cystic fibrosis (CF). There are 30,000 young individuals in this country with CF, a fatal genetic disease; more than 900 live in Illinois. I have also witnessed how, for many patients, modern medicines have brought hope, relief from suffering, and even a return to health—a miracle made possible by biomedical research.

By rewarding ingenuity and encouraging innovation, patent protection makes possible the investment of hundreds of millions of dollars and years of time and effort in medical research, all the while with no guarantee of success. Because of the discoveries born of these investments, the patients we come in contact with every day benefit through saved lives and improved quality of life. Our health care system benefits from a reduction in the overall cost of care.

While we certainly support patient access to lower cost treatments for disease, that short-term benefit pales if it comes at the long-term expense of finding cures to life-threatening illnesses. The current law governing pharmaceutical patents is fair and in the long-term best interest of patients.

On behalf of those patients who still await a cure or effective treatment to alleviate their suffering, I again urge you not to undercut the patent protection that underlies America's best hope for new and better answers to disease.

Sincerely,

ROBERT J. BEALL,
President and Chief Executive Officer.

NATIONAL KIDNEY ASSOCIATION,
Evanston, IL, November 22, 1995.

Hon. CAROL MOSELEY-BRAUN,
Senate Hart Office Building,
Washington, DC.

DEAR SENATOR MOSELEY-BRAUN: I am writing you as both a constituent, and as the President of the National Kidney Cancer Association. Thank you for your recent vote in support of the enforcement of the General Agreement on Tariffs and Trade (GATT) provision regarding drug patents.

Your action will allow significant pharmaceutical research to continue on numerous diseases, including kidney cancer. As you may be aware, kidney cancer afflicts thousands of individuals each year and at the present time, no cure exists for this disease.

Our greatest hope for a cure is innovative pharmaceutical and biotechnology products, derived from private sector efforts. To find this cure, millions of dollars will have to be spent. It is imperative that Congress provide steadfast support for scientific discovery and strong patent protection for new drugs and therapies. My view is that this new GATT law will encourage further investment in research and development, and make new medicines possible. This new law gives hope to millions around the world, including kidney cancer patients, who currently have no options.

I applaud your courage in opposing efforts to weaken the GATT patent provisions. Keep up the important battle to support research and development of new drugs. Thank you for your determination and insightful leadership.

Sincerely,

EUGENE P. SCHONFELD,
President and Chief Executive Officer.

THE NATIONAL ORGANIZATION ON
FETAL ALCOHOL SYNDROME,
Washington, DC, November 8, 1995.

Hon. CAROL MOSELEY-BRAUN,
Hart Senate Office Building,
Washington, DC.

DEAR SENATOR MOSELEY-BRAUN: It has come to my attention that, through an effort by Senator Pryor, Congress is considering changes to existing law that would chip away at patent protections in the United States, and possibly around the world. I ask you to reject that effort.

This nation has sought to protect and foster innovation since its very beginnings, primarily through our system of patent protections. Most recently, as a result of the General Agreements on Tariffs and Trade, the U.S. changed its patent terms to bring them in line with international standards. Yet Congress is now considering weakening that agreement.

As a member of the National Organization on Fetal Alcohol Syndrome, I find that possibility very disturbing. Patients afflicted with disease book to biomedical research, especially research taking place in America's pharmaceutical industry, for new and better treatments to restore them to health. But this country's huge investments in research and development cannot be maintained without the assurance of strong patent protection, not only in the U.S., but also in other markets around the world.

If Congress begins chipping away at patent protection in the U.S., it begins chipping away at the foundations of a system that has made this country Number One in the world in the discovery of new medicines. It also begins to undermine patent protection standards around the world. And it begins the process of deflating the hopes of millions of patients in this country who depend on medical research to find a cure.

Please, cast your vote in favor of innovation, and against any effort to undermine

patent protection in this or any other country around the world.

Sincerely,

PATTI MUNTER,
President.

ALLIANCE FOR AGING RESEARCH
Washington, DC, November 9, 1995.

Hon. CAROL MOSELEY-BRAUN,
U.S. Senate, Washington, DC.

DEAR SENATOR MOSELEY-BRAUN: It has come to my attention that, in connection with a proposal sponsored by Senator David Pryor, Congress is considering changes to existing patent law that would erode patent protection in the United States. I am pleased to see that you are opposed to that effort.

America has always sought to protect and foster innovation primarily through our system of patent protection and patent-term restoration. Recently in accordance with its multilateral obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights negotiated during the Uruguay Round of GATT, Congress amended the Patent Code to harmonize its provisions with international standards. As a result, patent terms for certain eligible products—in all industries—were extended. Under the Pryor proposal, however, Congress would weaken our implementation of GATT patent provisions.

As the Executive Director of the Alliance for Aging Research, I am concerned by any proposal that would have such as effect. Patent rights are the cornerstone of America's biomedical research enterprise. Patents provide a critical incentive for all companies, particularly pioneer pharmaceutical manufacturers, to conduct ground breaking biomedical research. Patients and their physicians depend upon access to the fruits of biomedical research—access which can only occur if there are adequate incentives for the research to be conducted in the first place. Congress cannot expect the private sector to continue making high-risk investments in research and development if there is no assurance of strong patient protection (and if there is no assurance that the United States will meet its multilateral obligations to provide such protection).

This is a particularly critical issue for the aging Americans represented by the Alliance. Clearly, the curtailment of biomedical R&D will lead to a downturn in the rate at which biomedical innovations will become available to the public. New incentives for research and innovation such as those provided by GATT must be maintained. Otherwise, Congress will erode the foundations of a system that has made America the leader in the discovery of new medicines.

I thank you for supporting innovation and research for new treatments that will benefit America's elderly.

Best regards,

DANIEL PERRY,
Executive Director.

GATT AND PRESCRIPTION DRUGS

Mr. LEAHY. Mr. President, I have worked for many years with Senator PRYOR on trying to keep prescription drugs affordable for Americans. High prices for prescription drugs force some elderly and low-income Vermonters to choose between buying food or fuel for heat and paying for their medication.

In this continuing effort, I am very pleased to join Senator PRYOR as a cosponsor of S. 1277, the Prescription Drug Equity Act of 1995. This bill corrects a loophole in the GATT Treaty that gives a handful of drug companies as much as a $6 billion windfall at the expense of seniors, the poor and all consumers. This bill would allow generic drug companies to sell some of the world's most frequently prescribed drugs at half the cost that they are available at today.

Here is an opportunity for the Congress to lower out-of-pocket health care costs. It is an opportunity that comes at a time when Congress is discussing multibillion dollar cuts in Medicare and Medicaid that will increase health care costs for seniors and low-income Americans.

Today, seniors who rely on Medicare for their health insurance do not receive assistance for the cost of prescription drugs. Even if a senior also has private health insurance, there is no guarantee that it will cover prescription drug bills. Seniors on fixed incomes depend on money saving generic drugs.

Seniors need the savings on prescription drugs now more than ever. So do the over 40 million Americans with no health insurance whatsoever.

Prescription drugs and the research devoted to developing new drugs are vital to meet the health care needs of many Americans. While the manufacturers that take risks and invest in the development of new drugs have a right to a return on their research investment, we must not allow prohibitive costs to jeopardize consumer access to these drugs. There must be a balance.

If the GATT loophole is closed, Medicaid will save $150 million over 5 years and consumers will save up to $2 billion. In my home State of Vermont alone, the savings in Medicaid are estimated to be almost $1 million. And, Vermont consumers are expected to save as much as $6.8 million in prescription drug costs.

Opponents of the Pryor legislation argue that it will prevent drug companies from conducting research and development on new drugs. Under the Pryor legislation, however, these companies still would have had more than the full 17 year protection they expected to have when they introduced their products, to gain a return on their research investment. In addition, drug companies will continue to receive royalties from the generic companies who market competing prescription drug products.

Drug firms pocket almost $6 million each day that the GATT loophole is in effect. These companies will go to no end to protect their windfall. They have launched a multimillion dollar effort to lobby Congress. They even went as far as misrepresenting a statement by former Surgeon General, C. Everett Koop, by portraying him as a strong supporter of their billion dollar windfall.

We in Congress have a responsibility to protect consumers against these drug company giants. I urge my colleagues to support the Prescription Drug Equity Act of 1995 and pass this legislation as soon as possible.

Mr. GRASSLEY. Mr. President, I would like to say a few words about the amendment offered by my colleague, for though it is well intentioned, it does have important potential adverse effects on our international trade agreements.

This legislation would deny innovator pharmaceutical products the full statutory term of patent protection that was provided under GATT and the Uruguay Round Agreements Act [URAA]. There is a requirement in the GATT Intellectual Property Agreement [TRIPS], found in article 70:2, that WTO members provide TRIPS level patent protection for existing subject matter on the date of application of the agreement for the country in question. This requirement will greatly benefit U.S. industries across a broad range of intellectual property elements; not just those industries concerned about pharmaceutical patents. It is in the U.S. interest that countries with weak patent protection provide the shortest possible transition periods. This is the clear objective of the TRIPS agreement and, in particular, article 70:2.

To meet this key objective of the TRIPS agreement, I believe the FDA interpretation of the Hatch/Waxman Act must prevail. Article 70:2 was specifically inserted in the TRIPS agreement to prevent WTO members from delaying the application of the stronger protection found in the TRIPS agreement to existing patents, most of which we can safely say will be held by U.S. rightholders.

I strongly believe that U.S. commercial interests in WTO countries that currently provide weak protection will be dealt a severe blow should this amendment pass. We need look no further than Argentina, whose patent protection laws are bad and getting worse, as an example of what might happen if the United States pursues a policy that minimizes GATT mandated improvements in patent rights. And there are other countries whose patent regimes offer no protection to the makers of patented pharmaceutical products, costing billions of dollars that would otherwise go into research for new breakthrough drugs.

I should also point out that the courts have had a chance to render judgment on this issue, and they have upheld the current interpretation of the Hatch-Waxman Act that this amendment would overturn. So I urge my colleagues to vote against this amendment and for the motion to send this to the Judiciary Committee.

Mr. BYRD. Mr. President, the Pryor amendment would correct an unintended loophole created in the legislation implementing the General Agreement on Tariffs and Trade [GATT]. This loophole will cost consumers billions and give a windfall profit to certain drug companies. Congress must take the responsible course of action and correct its mistake by passing the Pryor amendment. Omissions and errors are more likely to happen when large, complex bills are taken up under

limited time constraints. Such is the case with GATT, which was considered under fast track procedure and was rushed through Congress. I believe this is an ill-advised way to conduct Senate business. It is the responsibility of the Congress to correct its unintended oversights and omissions.

How did this loophole come about? When Congress enacted the Uruguay Round Agreements Act [URAA], the legislation implementing the General Agreement on Tariffs and Trade [GATT], which I opposed, it extended all patent terms from 17 years from date of approval to 20 years from the filing date. In addition, the legislation allowed generic companies to market their products as of the 17 year expiration date if they had made a substantial investment and would pay a royalty to the patent holder. The carefully constructed transition rules were meant to apply to all industries. However, because conforming language to the Federal Food, Drug, and Cosmetic Act was inadvertently omitted, this provision does not apply to the generic pharmaceutical industry. The drug industry is the only industry that is shielded from generic competition under GATT during the extended patent term.

The U.S. negotiators have indicated that it was not their intent to exclude the pharmaceutical industry from this provision, and that the omission of the conforming language was an oversight. According to U.S. Trade Representative Mickey Kantor in a letter to Senator CHAFEE,

> This provision—the transition rules—was written neutrally because it was intended to apply to all types of patentable subject matter, including pharmaceutical products. Conforming amendments should have been made to the Federal Food, Drug, and Cosmetic Act and Section 271 of the Patent Act, but were inadvertently overlooked.

This oversight means consumers will pay more for their drugs than would otherwise have been the case. If generic drug companies cannot bring their versions of drugs to market under the transition rules, consumers will be forced to pay more for their prescriptions. Nationwide, it is estimated this may cost consumers $2.5 billion. West Virginians and the West Virginia State government will pay an additional $43 million in drug costs. Those who will likely be impacted greatly by this Congressional oversight are senior citizens. Although seniors comprise 12 percent of the population, they use one third of prescription drugs. At the same time, seniors live on fixed incomes and oftentimes experience difficulty in affording their prescriptions. it is outrageous that Congress would worsen their situation by failing to enact legislation to correct this Congressional oversight.

Mr. President, this situation can easily be remedied by adopting the Pryor amendment. I urge my colleagues to support the Pryor amendment, and I would like to be added as a cosponsor of this amendment.

Mr. PELL. Mr. President, today the Senate considered an amendment authored by my friends and colleagues, Senators PRYOR and CHAFEE meant to clarify confusion that has resulted from the implementing legislation Congress wrote following approval of the GATT Treaty last year. Specifically, the issue involves when the patent terms on domestic pharmaceutical products expire and when generic companies can begin to market copies of those products to the general public.

Since this issue has been brought to public attention, many contradictory charges have been levelled which have served to create a sense of confusion over whether or not certain entities are receiving unfair advantage over the other. Unclear are such issues as: What was the intent of our GATT negotiators, and did this intent change as the negotiations went on? What was the intent of Congress on this matter or, as the Federal courts have found, was there no intent expressed at all? How do our trading partners feel about our addressing this issue now, long after we approved the implementing legislation approving GATT? Who benefits and is that benefit justified or fair?

The answers to these questions are not clear at present. And given the enormous stakes on both sides, I find that reaching a satisfactory conclusion difficult given the incomplete record. Moreover, this is not an abstract policy issue for me as a Senator from the State of Rhode Island, where Glaxo-Wellcome, one of the pharmaceutical companies with much at stake here, has a manufacturing facility. Prior to making a decision that could affect so many Rhode Islanders, I feel that a clear airing of the ramifications of this proposal is required. Given the assurances that these hearings will occur within 120 days, I feel confident that this issue will be addressed and when it does, we will have an adequate record on which to base our decisions.

I do wish to note that by supporting the effort to refer this to the Judiciary Committee for hearings, I am not stating my opposition to the proposal per se. I will wait to come to the conclusion once the hearings have been completed and when the full weight of the proposal is more clear.

Mr. COHEN. Mr. President, I rise to support the Pryor generic drug amendment which will correct an oversight in the General Agreement on Tariffs and Trade [GATT] implementing legislation that has unintentionally postponed the date at which certain generic prescription drugs can enter the market. While this delay only affects a handful of drug products, consumers who take these drugs are paying a big price for this technical mistake.

This amendment would clarify the intent of transition rules in the trade bill allowing manufacturers who had made substantial investment in product development, based on pre-GATT patent expiration dates, to go to market as planned once they pay the patent-holder the required royalty. This correction is needed because certain provisions in the Hatch/Waxman Act, dealing with drug development, have had the unintended consequence of prohibiting generic companies from using the GATT transition rules. Pharmaceuticals are the only industry unable to use these rules.

Under GATT, new pharmaceuticals are given patent protection for the longer of 20 years from the filing date or 17 years from the patent issuance. Transition rules were enacted to provide fairness to all industries and parties—patentee and competitor—during transition to the new patent-term law. We must correct this rather technical error in the trade bill to ensure these rules are available to all industries.

Both Mickey Kantor, U.S. Trade Representative, and David Kessler, FDA Commissioner, agree with this interpretation and believe a legislative fix is needed to allow generic companies to go forward. This amendment is tightly constructed and would have no impact on other trade issues included in the GATT.

While I am aware that this amendment will dip into the profits of a few pioneer drug companies, I believe this error has already given them an unintended windfall. If left uncorrected, it is estimated that the delay of several generic medications could cost consumers and government health programs nearly $2 billion.

We have a responsibility to pass this amendment and help consumers gain access to more affordable medications. For millions of Americans, especially senior citizens, prescription drugs represent their largest out-of-pocket health expense. Many life-sustaining drugs are already out of their reach. We can not let the desire of a few drug companies to let this error go uncorrected place an even greater burden on consumers who struggle daily to pay for their prescription drugs.

Mr. SPECTER. Mr. President, I support the intent of Senator PRYOR to remedy what was apparently an unintended omission when the Senate ratified the implementing legislation for the General Agreement on Tariffs and Trade (GATT) in the 103d Congress. However, I remain concerned with ambiguities in the Pryor amendment with respect to the definition of substantial investment.

When the GATT implementing legislation was approved last year, it contained a provision harmonizing U.S. patent law with the rest of the world by changing patent terms to 20 years from the initial patent application rather than 17 years after granting of the patent. In order to be fair to existing patent holders, the legislation gave them the option of utilizing the longer of the pre-GATT and post-GATT patent terms.

However, because the legislation affected many generic manufacturers who had been preparing to go to market with competing products upon the

expiration of the original patent term, Congress agreed to allow generic manufacturers who had already made a substantial investment in that product to utilize the original patent expiration date and commence marketing, upon paying of a royalty to the patentee.

Some have argued that the courts can interpret the definition of substantial investment, and consequently, there is no need for legislative guidance on that definition. I disagree. By retaining this legislative ambiguity, we are ceding the legislative role to the courts. We are also creating considerable costly litigation because of this ambiguity which should be made clear in the statute. These are resources which could be better devoted to developing new products and making them available to the public.

I have discussed with Senator PRYOR my willingness to work with him to correct this ambiguity and then accomplish his intended remedy.

Mr. HATCH addressed the Chair.

The PRESIDING OFFICER. The Senator from Utah.

Mr. HATCH. Mr. President, I take a tremendous interest in this subject, in part because I chair the Judiciary Committee, which handles all patents, copyrights and trademark legislation and problems. Since the amendment would made changes in the patent code, the matter would come before the Judiciary Committee as it has in the past.

In addition, I want to point out that my colleague from Arkansas was mistaken when he said the Judiciary Committee has never handled anything regarding FDA matters. In fact, I think he said, if I am correct, that the Judiciary Committee never looked at the Food, Drug and Cosmetic Act.

Perhaps he was not aware that the 1962 Drug Amendments, which established the safety and efficacy standards for drugs reviewed by the FDA, were written in the Judiciary Committee.

This is a result of the Kefauver hearings, which led to adoption of new amendments providing the efficacy standards which are often heralded as the model standards for the world.

If there is any one thing you can point to at the FDA that protects human beings and makes sure that the medical products Americans use are safe and efficacious, it comes from work done by the Judiciary Committee. But that is not the point.

Before I go to the broader policy issue, which is much more important than I think my colleagues would acknowledge, let me just call their attention to other Judiciary Committee work on the GATT intellectual property provisions. I am referring to a joint hearing in the 103d Congress before the House Judiciary Subcommittee on Intellectual Property and Judicial Administration and the Senate Judiciary Subcommittee on Patents, Copyrights and Trademarks.

Pharmaceutical industry representatives, including those representing biotech organizations, and academic researchers appeared before these two combined committees.

I do not want to take too long on this, but let me just take a moment or two to read from this very important joint hearing transcript.

Representative William Hughes, who then was the chairman of the House Subcommittee said to Mr. Bruce Lehman, Commissioner of Patents and Trademarks:

> There have been some concerns raised particularly by the biotech industry, that grants of patents will be delayed because of unreasonable requests from the PTO for human trials which, as you well know, could take years for some biotechnology products to prove utility, a requirement of patentability. Is that a legitimate concern on their part?

PTO Commissioner Lehman said:

> Well, to the extent that that is a legitimate concern, Mr. Chairman, I think that is addressed in the Patents Term Restoration and Drug Price Competition Act that extends patent terms specifically to deal with regulatory delay. Perhaps that act should be adjusted if it is not addressing the concerns of industry.

By the way, the Drug Price Competition and Patent Term Restoration Act happens to be the bill that Representative HENRY WAXMAN and I wrote back in 1984, which is considered to be one of the finest pieces of consumer legislation in the last 30 years, if not in the entire history of the country.

I am very proud of that law.

It is one of the reasons why I am saying this is not a question of whether somebody is going to get a windfall profit or not.

This issue has very broad policy considerations. It is not just something that can be couched in terms of ''gouging the consumers,'' because there are two sides of this issue.

The Drug Price Competition and Patent Term Restoration Act, the Hatch–Waxman bill, brought the two sides together.

I know it. It was negotiated in my office over a 2-week period, 18 hours a day. One reason I remember it so well is because I had a root canal during that time, and by the time we got near the end I threatened to kill everybody in the room if they did get together and get it done.

We finally did.

It was a tense time. It was a tough time. When we got it done, almost everybody agreed that this is one of the finest pieces of consumer legislation ever.

It has saved an average of $1 billion a year to consumers every year since its enactment in 1984, as we predicted it would.

So, naturally, I am concerned when I hear that that act is going to be amended in an unwise fashion.

If the USA, whose officials have asked heads of states all over the world to live up to these hard-won international intellectual property agreements, changes this major treaty right off the bat by reducing patent terms just because we think some companies may benefit, then all the intellectual property work we have done over all these years is going to go down the drain.

But let me talk again about the Hatch–Waxman bill.

There were two sides to it. There were those who were spending billions of critical dollars in research that is going to help bring down health care costs. These manufacturers are putting their money where their mouths are in order to find these breakthrough drugs that will reduce the costs of medicine over the long run and help to relieve some human misery.

But one of the problems these research-based companies face is that the FDA approval process has taken so long. The agency is supposed to approve drugs in 180 days, according to the statute.

That has not happened in fact. It has taken so long that the patent terms are eaten up by the delays.

So, there were those on the side of the research companies who said—and I was one of them—that what we must do is restore some of the patent term lost through unnecessary regulatory delays. The other side consisted of those representing the interests of the generic drug industry.

I understand that those who support the Pryor amendment do so because they are worried about consumer costs. What their arguments neglect however, are two simple questions:

What are consumers going to consume if we do not put money into research?

And what will consumers consume if there are not the incentives to produce the products they need?

The thing that has made the United States the greatest research country in the world is that we protect patents as a property right in the Constitution itself.

This, again, is another Judiciary Committee concern for those who do not seem to appreciate that point.

There are those on the consumer side who legitimately asked why it takes so long to get generic drugs approved after the innovator drugs come off patent. They suggested the availability of an abbreviated new drug application so they did not have to go through the whole safety and efficacy process.

It would have taken them 2 to 3 years to take a product like Zantac—which I mention since that product has been attacked here—and duplicate it so that they can reduce the price for the benefit of consumers.

So what did we do? We worked hard to enable those generic companies to be able to do what would be called infringement in any other industry.

As a consequence of this change, these generic manufacturing companies were able to borrow from the work of the research-based companies who are spending as much as half a billion dollars to produce one marketable drug, and produce a bioequivalent of a

drug such as Zantac that becomes effective the day Zantac comes off the patent.

Or a better illustration might be Valium. When Valium's patent expired, the Hatch–Waxman bill provided that all kinds of generic companies were able to produce their version of Valium that very day, rather than be delayed the 2 or 3 years through the whole process again.

That is important, because what we did is bring both sides together to create the generic industry as we know it today. In fact, I am proud to have been called on occasion ''the father of the generic drug industry.''

So I have a tremendous interest in making sure that the generic industry is solid and producing lower-cost drugs.

But I also have a tremendous interest in seeing that research companies are given fair deals on their patents.

Now, when we came up with the Hatch–Waxman bill we knew there would be winners and losers.

Both sides knew this.

They were willing to make trade-offs in order to accomplish a greater goal.

We knew there were winners and losers with the Waxman-Hatch bill, and we also knew that when GATT was finalized there would be winners and losers.

Now, I think Dr. Koop's position has been misrepresented by the other side, some of whom do not think he understands what really went on. There seems to be some confusion about Dr. Koop, our former Surgeon General, who is probably the leading doctor in the history of this country.

I think Dr. Koop has a pretty good reputation in the field of public health. He was a most outstanding Surgeon General. I did not always agree with him, but I always respect his views.

Dr. Koop wrote a letter to clarify that those on the other side could not misrepresent his position any more.

That letter is printed in today's issue of Roll Call. It makes, I believe, an eloquent case against the Pryor amendment.

I will submit for my colleagues' consideration this letter to Morton Kondracke, Executive Editor of Roll Call, from Dr. C. Everett Koop, former Surgeon General of the United States. I ask unanimous consent that the full letter be printed in the RECORD at this point.

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

KOOP ON PHARMACEUTICALS

To the Editor:

In your Food & Drug Policy Briefing (Oct. 9), an article appeared concerning patent protection under the General Agreement on Tariffs and Trade. I am of the firm belief that any action on the part of the Senate to weaken the hard-fought patent protections of GATT would imperil the future of intellectual property rights and undermine the research activities of pioneering pharmaceutical companies.

The right to claim ideas as property allows innovators to invest their time and money bringing those ides to fruition. It is the basis of our patent system that allowed American ingenuity to prosper throughout the Industrial Age. Today, we are at the dawn of an Information Age and now, more than ever, the rights of intellectual property holders must be protected.

Consider the enormous investment in time, money, and brainpower required to bring a single new medicine to patients: 12 years and more than $350 million is the average investment. Only 20 percent of new compounds tested in a laboratory ever find their way onto pharmacy shelves. Only a third of those ever earns a return on the colossal investment made to discover it.

Though risky and expensive, this process works. The U.S. is the world leader in the development of innovative new medicines. Proceeds from the sales of these medicines support the work and research invested in new successful drugs, as well as the thousands of drugs that never make it out of the lab.

Patent protection makes that investment in research worthwhile—and possible. Recently, patent protection around the world was strengthened and harmonized by GATT, which required changes that equalized intellectual property protection in all participating countries. These changes are important to encourage the risky, expensive research necessary to provide new medicines to fulfill unmet medical needs.

Now, some generic drug companies are challenging GATT's advance in intellectual property protection. They are urging Congress to amend the 1984 Hatch-Waxman Act to give them an advantage under GATT that no other industry enjoys.

A key provision of the Hatch-Waxman Act gives generic drug companies a jump-start on marketing by allowing them to use a patented product for development and testing before the patent expires. This special exemption from patent law is not allowed for any other industry.

In return for these special benefits, the Hatch-Waxman Act requires generic drug companies to wait until the expiration of the research companies' patents before they can begin marketing their drugs. Now, the generic drug industry is asking Congress to give it a special exemption from that restriction as well.

In my opinion, that would be unwise. Treatment discovery has already slowed; we should reverse that process, not ensure it.

Generic drugs play an important role in helping lower the cost of medicines. But it is the pharmaceutical research industry that discovers and develops those medicines in the first place, investing billions of dollars in research and development that can span decades without any guarantee of success—an investment made possible by our system of patent protection.

Mr. HATCH. Preserve patent protection and you preserve the opportunity for the discovery of future cures and treatment for disease. Undercut that protection and you undercut America's hope for new and better answers to our health care needs.

It is for this reason that I must rise tonight in opposition to the amendment offered by Senators PRYOR, CHAFEE, and BROWN.

Whenever Senator PRYOR and I join in debate over pharmaceutical issues, I am sure some of our colleagues want to say, ''Here we go again.''

Well, here we go again.

Mr. President, I oppose this amendment because the current statutory framework, as interpreted by several recent court decisions, reflects sound policy and should not be disturbed.

I am glad we are having this debate today, as I welcome the opportunity to put the issue in better perspective.

This is a debate that cuts across party lines.

Reasonable people may disagree about the best course of action to take on this amendment, but it is still the same debate: Who is going to benefit, the research companies or the generic companies?

The generics have benefited greatly from what I have personally done for them, and so have the research companies.

But our overriding goal here must be to make sure we keep in place the incentives necessary for America to continue as the world leader in developing innovative medical technologies that can be delivered at competitive prices. The bottom line is that the Pryor amendment would undermine that goal.

At the end of this debate, I am hopeful that my colleagues will share my strong conviction that two relevant laws—the Drug Price Competition and Patent Term Restoration Act, sometimes known as Waxman-Hatch or Hatch-Waxman and the GATT Treaty—act together to advance important public health and trade policies.

I believe it is clear that the Senate must reject the Pryor amendment if we are to maintain that balance.

Let me summarize my three basic objections to this amendment:

First, many experts in international trade believe that the adoption of this amendment would send precisely the wrong signal to our trading partners, some of whom have had notorious track records of being patent-unfriendly.

A major gain we made with GATT was to win international harmonization with a 2-year patent term. Adoption of the Pryor amendment could cause backsliding on the part of foreign countries required to implement and enforce their obligations under GATT. Let us not steal defeat from the jaws of victory.

Second, the Waxman-Hatch Act achieved a careful balance between the generic and innovator sectors of the pharmaceutical industry.

The proponents of the Pryor amendment urge that only one industry is singled out for different treatment under the GATT implementing legislation.

What is absent from that line of argument is the fact that only one industry, the generic drug industry, is permitted by current law to engage in activities that in any other industry would constitute patent infringement, as I have said before.

A recent Federal district court reviewed the relevant provisions of law and concluded, ''This was no more a windfall to the * * * [pioneer firms] * * * than the windfall which benefited many patent holders when the seventeen year term of patents was extended to twenty years.''

Third, if the Pryor amendment is adopted, it may run afoul of the takings clause of the fifth amendment to the Constitution. Patents are recognized and protected by American courts and by our Constitution as property.

By repealing patent extensions granted under the GATT legislation and reducing vested patent terms, the Pryor amendment could trigger the guarantee that affected property holders receive just compensation.

I ask unanimous consent that a copy of an October 24 ''Dear Colleague'' letter signed by a bipartisan group of 11 Senators, and a December 6 ''Dear Colleague'' letter discussing these issues be printed in the RECORD at this point.

There being no objection, the letters were ordered to be printed in the RECORD, as follows:

U.S. SENATE,
Washington, DC, October 24, 1995.

DEAR COLLEAGUE: We are writing to indicate our bipartisan opposition to an amendment which may be offered during Senate consideration of S. 1357, the Balanced Budget Reconciliation Act of 1995. That amendment would deny U.S. innovator pharmaceutical manufacturers international patent protections provided under key provisions of the GATT implementing legislation.

The Uruguay Round Agreements Act (URAA) implemented the United States' obligations under GATT by providing that the term of any patent in force on June 8, 1995, be the greater of 20 years from the applicable filing date or 17 years from the date of grant. These critically-important patent provisions benefit all industries and all patent holders.

Nevertheless, a handful of generic drug companies have urged Congress to rewrite the law in effect to eliminate the 20-year term for certain prescription drug patents by allowing generic companies to sidestep existing statutory provisions under the Drug Price Competition and Patent Term Restoration Act of 1984 (''Hatch-Waxman'') that preclude the generic from entering the market until the full term of the pioneer's patent has expired.

Repealing this provision of the URAA would: weaken the U.S. position in negotiating and enforcing strong international patent protection which was a major achievement of the GATT; have a chilling effect on biomedical research in the pharmaceutical industry; and be subject to legal challenge as an unconstitutional taking of property.

It is inappropriate to consider a change of this magnitude in the context of budget reconciliation. Both Hatch-Waxman and the Uruguay Round were hard-won compromises which were negotiated very carefully. The amendment has both trade and intellectual property implications, as well as substantial implications for food and drug law. Furthermore, this issue is now before the Federal courts in ongoing litigation and any action at this time would be premature.

For these reasons, as discussed in detail in the attachments, we urge you to oppose consideration of the GATT patent amendment during debate on budget reconciliation.

Sincerely,

Christopher J. Dodd; Orrin G. Hatch; Joseph I. Lieberman; Alfonse M. D'Amato; Charles E. Gressley; Lauch Faircloth; Mike DeWine; Carol Mosely-Braun; Ernest F. Hollings; Jesse Helms; Dan Coats.

THE GATT AMENDMENT WOULD UNDERMINE AMERICA'S TRADE POSITION

Intellectual property rights were addressed on a multilateral trade basis for the first time in the history of GATT during the Uruguay Round. As a result of hard-fought compromises, worldwide standards for protecting and enforcing intellectual property rights were established, and intellectual property protection was significantly improved.

The decision to tackle patent rights during the Uruguay Round, despite the reluctance of some developing countries, reflects the complexity of international trade and the international significance of patent rights.

As the principal source of inventive activity, the U.S. stands to gain substantially from the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs) improvements in patent protection worldwide. In countries that previously provided limited patent protection, a minimum 20-year patent term must be granted immediately upon their acceptance of the TRIPs obligations. Enhanced patent protection overseas will have a significant impact on the commercial interests of the United States and the resulting economic gains and job creation in the United States will be considerable.

The Uruguay Round agreement was a landmark achievement, but the real test comes when countries implement their multilateral obligations under GATT. Since the U.S. insisted on the inclusion of enhanced patent protections in the Uruguay Round agreements and historically has been the leading international advocate for broadening patent rights, it is essential that the U.S. be a world leader on GATT implementation.

Enhanced patent protection will be diminished abroad if the United States itself violates the patent term embodied in TRIPs. It is almost certain that such an action would provide foreign-based pirates and patent infringers with potent ammunition in seeking to have their domestic governments devise measures that are inconsistent with TRIPs—thereby denying U.S. patent holders their rights secured by TRIPs.

A report just released by two American Enterprise Institute (AEI) analysts concludes that such ''weaken[ing] [of] the patent system during this critical period of implementing the TRIPs agreement could well give developing countries a pretext for backing away from their GATT commitments to strengthen the protection of intellectual property.'' They point out several developing nations, including India, Singapore, and Thailand, which are already attempting ''to dilute and evade'' the patent protection commitments they accepted during the Uruguay Round.

It is clear that, in this patent-unfriendly context, the proposed amendment would be interpreted internationally as encouraging a minimalist's interpretation of GATT's improvements in patent protection. As the AEI analysts conclude, America's trading partners will construe the amendment as a green light to act inconsistently with GATT: ''Thus, any signal that the United States itself is contemplating weakening its TRIPs obligations will undoubtedly be seized upon by these countries as a pretext to resist pressure to put in place strong intellectual property protections.'' Having redefined patent terms domestically in order to secure enhanced patent rights overseas, it would be imprudent for this Congress to send any such signal.

The international trade ramifications extend beyond questions of intellectual property protection. The positions advocated by proponents of this amendment ''are likely to be turned against the United States in future trade negotiations,'' according to the AEI analysts. The AEI report concludes that arguments advanced in support of the amendment ''will come to haunt U.S. negotiators'' and ''play rights into the hands of developing countries who still maintain and defend compulsory licensing.''

For all of these reasons, the AEI analysts conclude that USTR Kantor's contention that the amendment would not undermine America's position in international trade negotiations ''would seem to come under the heading of '' 'whistling in the wind.' ''

Significantly, USTR Kantor's position has been strongly countered by his predecessors, former-Ambassadors Clayton Yeutter and Bill Brock. Ambassador Brock asserts that nations which in the past have denied American investors patent protection ''will see this retreat on our part as a ready excuse to implement their own minimalist versions of intellectual property protection.'' Thus, Ambassador Brock concludes, we would be unable ''to force other nations to adhere to the TRIPs agreement if we set this unfortunate precedent.''

Similarly, the Emergency Committee for American Trade (ECAT) concludes, ''A U.S. retreat from its own commitments to increased intellectual property protection for all patented products would be a destructive precedent that could lead to an unraveling of hard-won gains.''

The European Community (EC) has expressed similar ''serious concerns'' about any such precedent. The Vice-President of the European Commission believes the amendment ''would contradict our mutual aim of providing a reasonably high and secure protection for the huge investments made by EC and US research-based pharmaceutical companies'' and ''send a negative and highly visible signal to those numerous countries which are still in the process of preparing new legislation on the protection of pharmaceutical inventions.''

As America's trading partners implement GATT, it is vital that the U.S. be in a position to demand that they adopt legislation consistent with the requirements embodied in the Uruguay Round agreements. In order to do so, we cannot be childed into adopting an ill-considered amendment that vitiates patent protection for American patent holders.

THE GATT PATENT AMENDMENT WILL CHILL R&D IN RESEARCH-INTENSIVE INDUSTRIES

Intellectual property rights are critical to all American industries and should not be lightly disregarded. They are particularly important to the pharmaceutical industry because they fuel the engine that drives the biomedical research enterprise and result in numerous therapeutic advances.

An amendment that eliminates the GATT patent benefits for pharmaceutical products would undermine a critically important incentive for research and development.

As with other research-incentive industries in the United States, the pioneer pharmaceutical industry has benefited significantly from America's patent system. Due to the high costs and significant risks associated with developing and marketing prescription drugs, patents have allowed pharmaceutical manufacturers to attract the risk capital necessary to develop and clinically test innovative new therapies.

The results of such ground breaking biomedical research flows directly to patients who have access to drugs for complex and life-threatening diseases which are developed only by pioneer pharmaceutical companies. We should continue to reward their ingenuity and encourage their innovation.

If Congress encourages a curtailment of biomedical R&D by limiting incentives, it inevitably will cause a downturn in the rate at which biomedical inventions will become available to the public. For this reason, an array of patient and research groups—including the American Association for Cancer Research, the Alliance for Aging Research, the Cystic Fibrosis Foundation, the Allergy and

Asthma Network/Mothers of Asthmatics, and the Autism Society—oppose the amendment.

THE GATT PATENT AMENDMENT COULD EFFECT AN UNCONSTITUTIONAL TAKING OF PROPERTY

Legal analysis supports the view that the proposed GATT amendment ''would clearly deprive the patent holders of their property rights. . . .'' Patents have traditionally been recognized and protected by American courts as property.

Based upon existing precedents, it can be argued that any legislation affecting either the exclusive use of a product to which a patent holder is entitled, or the time during which the patent holder is entitled to that exclusive use, affects core elements of the property right represented by a patent.

By repealing patent extensions granted under the URAA, and reducing vested patent terms to which existing patent holders are currently entitled, this amendment could trigger the Fifth Amendment guarantee that the property holders receive just compensation.

In this era of fiscal constraints, and particularly in the context of the budget reconciliation debate, it would be ironic indeed for Congress to impose such financial obligations on an already-strained federal budget. We should carefully consider whether the amendment would have such an effect.

IT IS INAPPROPRIATE TO CONSIDER THE GATT PATENT AMENDMENT DURING RECONCILIATION

Regardless of one's views about its merits, it is clear that a GATT patent amendment would be inappropriate at this point.

The proposed amendment is not a technical amendment as it has been characterized by its proponents, who suggest they are simply trying to correct a ''simple mistake in legislative drafting'' that resulted in a ''legal loophole'' in the URAA. The facts are quite different.

The amendment would result in substantial changes in two statutes—the URAA and the 1984 Hatch-Waxman Act. The Hatch-Waxman Act represents a careful balance between the interests of innovator manufacturers and generic drug companies. It has worked well for over 10 years and should not be amended lightly. Even minor changes to Hatch-Waxman could have profound effects on all segments of the pharmaceutical industry.

Under Hatch-Waxman, generic drug companies are already given significant advantages. They are allowed to begin development of their generic drugs while the pioneer's patent remains in effect, and they can rely on the safety and efficacy data developed by the innovator. The proposed GATT amendment would negate a complementary provision in the Hatch-Waxman Act; that provision requires generic companies to respect the pioneer's full patent term, and thereby upset the balance codified in that statute.

The dramatic changes that would result from the proposed amendment would occur without the benefit of prior congressional consideration. The proposed amendment would have a direct and significant effect on patent rights, which fall squarely within the jurisdiction of the Judiciary Committee.

We should not rush to legislate in this area before all Committees of relevant jurisdiction have had a reasonable opportunity to hold hearings and give careful consideration to all of the proposed amendment's potential ramifications.

Finally, questions relating to implementation of the URAA are currently in litigation. One lawsuit addressing the precise issue covered by the proposed amendment has been expedited for consideration by the U.S. Court of Appeals for the Federal Circuit (CAFC). The CAFC heard arguments in that case just two weeks ago. An amendment on this issue would be premature at this time.

U.S. SENATE,
Washington, DC, December 6, 1995.

DEAR COLLEAGUE: We are writing to urge your opposition to the Pryor amendment to H.R. 1833, the partial birth abortion ban bill. This amendment would deny the benefits of GATT to U.S. innovator pharmaceutical companies.

The Pryor amendment is bad policy. It undermines the purposes of GATT, and it fundamentally upsets the delicate balance we forged in 1984 upon adoption of the Drug Price Competition and Patent Term Restoration Act (''Hatch-Waxman''). That Act was designed to ensure that innovator companies continue to have sufficient incentive to invest the billions of dollars necessary to produce new medicines while at the same time allowing generic companies a quick and inexpensive way to get their versions of the drugs on the market after the patent has expired.

The Hatch-Waxman Act also gave generic drug companies an advantage possessed by no other industry in either the United States or the industrialized world. It specifically repealed those provisions of patent and case law that forbade any testing, plant construction, or investment in something which is still under patent, thus enabling the generic industry to conduct its bioequivalency tests and even produce a drug before the patent expires. It is generally agreed that this reduces the effective life of a drug patent about three years. This is in addition to the fact that Hatch-Waxman allows generics to avoid the lengthy, multiyear approval process by using the safety and efficacy testing data of the innovator company. This is estimated to save the generics between $350 million and $500 million per drug.

We are enclosing a previous dear colleague letter which provides you with information on this subject, as well as a letter to the editor that will appear in tomorrow's Roll Call from Dr. C. Everett Koop, the former Surgeon General of the United States. We urge you to read this letter carefully as it eloquently and persuasively argues our case. We are also including a collection of statements from various patient groups who also oppose the Pryor amendment because these individuals know first-hand that intellectual property is the key to new discoveries which mean life or death for millions of people.

We urge you to join us in opposing the Pryor amendment.

Sincerely,

CHRISTOPHER J. DODD,
United States Senator.
ORRIN G. HATCH,
United States Senator.

November 30, 1995.

MR. MORTON KONDRACKE,
Executive Editor,
Roll Call, Washington, DC.

In your special supplement on the FDA (October 9, 1995), an article appeared concerning patent protection under the General Agreement on Tariffs and Trade (GATT). I am of the firm belief that any action on the part of the U.S. Senate to weaken the hard-fought patent protections of the GATT would imperil the future of intellectual property rights and undermine the research activities of pioneering pharmaceutical companies.

A little-known revolution has taken place in my lifetime. When I started practicing medicine, only a fraction of the drugs that we now take for granted existed. Over the years, I have witnessed great suffering endured by patients and their families that, just a few years later, could have been eased because of the advent of the latest ''miracle drug.'' These breakthrough treatments have brought hope and, in many cases, renewed health to thousands of patients. They are the product of an increasingly important concept: the sanctity of intellectual property.

The right to claim ideas as property allows innovators to invest their time and money bringing those ideas to fruition. it is the basis of our patent system that allowed American ingenuity to prosper throughout the Industrial Age. Today, we are at the dawn of an Information Age and now, more than ever, the rights of intellectual property holders must be protected.

Consider the enormous investment in time, money, and brain power required to bring a single new medicine to patients: 12 years and more than $350 million is the average investment. Only 20% of new compounds tested in a laboratory ever find their way onto pharmacy shelves. Only a third of those ever earns a return on the colossal investment made to discover it.

Though risky and expensive, this process works. the U.S. is the world leader in the development of innovative new medicines. proceeds from the sales of these medicines support the work and research invested in new successful drugs, as well as the thousands of drugs that never make it out of the lab.

Patent protection makes that investment in research worthwhile—and possible. Recently, patent protection around the world was strengthened and harmonized by the GATT, which required changes that equalized intellectual property protection in all participating countries. These changes are important to encourage the risky, expensive research necessary to provide new medicines to fulfill unmet medical needs.

Now, some generic drug companies are challenging the GATT's advance in intellectual property protection. They are urging Congress to amend the 1984 Hatch-Waxman Act to give them an advantage under the GATT that no other industry enjoys.

A key provision of the Hatch-Waxman Act gives generic drug companies a jump start on marketing by allowing them to use a patented product for development and testing before the patent expires. This special exemption from patent law is not allowed for any other industry. For example, a television manufacturer who wants to market or use its own version of a patented component must wait until the patent expires; otherwise, it risks liability for patent infringement.

in return for these special benefits, the Hatch-Waxman Act requires generic drug companies to wait until the expiration of the research companies' patents before they can begin marketing their drugs. Now, the generic drug industry is asking Congress to give it a special exemption from that restriction as well.

In my opinion, that would be unwise. Treatment discovery has already slowed; we should reverse that process, not ensure it.

While the generic drug industry continues to prosper as a result of the benefits received in the 1984 Act, medical research has continued to become more complex, more costly, and more time consuming, further limiting the effective market life for patented products.

Generic drugs play an important role in helping lower the cost of medicines. But it is the pharmaceutical research industry that discovers and develops those medicines in the first place, investing billions of dollars in research and development that can span decades without any guarantee of success—an investment made possible by our system of patent protection. Preserve protection and

you preserve the opportunity for the discovery of future cures and treatments for disease. undercut that protection, and you undercut America's hope for new and better answers to our health care needs.

Sincerely yours,

C. EVERETT KOOP, M.D.

PATIENT ADVOCATES OPPOSE EFFORTS TO WEAKEN STRONG PATENT PROTECTION

''At a time when health care delivery, research and development are evolving faster than anyone can accurately monitor, Senator Pryor's efforts to lead Congress down a road that chips away at patent protections for U.S. pharmaceutical products will dig a health care grave for Americans.''—Nancy Sander, President, Allergy and Asthma Network/Mothers of Asthmatics, Inc.

''Congress cannot expect the private sector to continue making high-risk investments in research and development if there is no assurance of strong patent protection . . .''—Daniel Perry, Executive Director, Alliance for Aging Research.

''The risk of supporting [Senator Pryor's] legislation would be to weaken the incentives for innovation in academia, research institutions, and medical research-based companies. We believe that this will impede our capacity to address the growing epidemic of cancer.''—Joseph R. Bertino, M.D., President, American Association for Cancer Research, Inc.

''The ASTMH members have dedicated their lives to easing the suffering of patients under their care and returning them to health whenever possible. In this effort, modern medicines are among our most effective tools. Congress' steadfast support of strong patent protection has encouraged the investments in research and development that make these medicines possible.''—Carole A. Long, Ph.D., President, American Society of Tropical Medicine and Hygiene.

''While we certainly support patient access to lower cost treatments for disease and disability rehabilitation, that short-term benefit pales if it comes at the long-term expense of finding cures to life-threatening illnesses.''—Sandra H. Kownacki, President, Autism Society of America.

''Because of the discoveries born of these investments [in pharmaceutical research], the patients we come in contact with every day benefit through saved lives and improved quality of life.''—Robert J. Beall, Ph.D., President and CEO, Cystic Fibrosis Foundation.

''Patients afflicted with disease look to biomedical research, especially research taking place in America's pharmaceutical industry, for new and better treatments to restore them to health.''—Patti Munter, President, The National Organization on Fetal Alcohol Syndrome.

''Our patients have experienced the direct benefits of the tremendous investments that the pharmaceutical industry has made in research and development. Research-based companies need and deserve the incentives provided by strong intellectual property protection.''—Judith Simpson, R.N., Ed.S., President, United Patients' Association for Pulmonary Hypertension, Inc.

Mr. HATCH. As the ''Dear Colleague'' letters point out, what is at stake here is not just the patent status of a few drugs, but also our international trade posture and the complex set of incentives and regulations that govern our Nation's biomedical research and development network.

Let me turn to a more detailed explanation of my position.

As my colleagues are aware, the Uruguay Round Agreement Act—the URAA—is the statute that implements the GATT Treaty.

Some have said today that the GATT patent amendment merely corrects a simple oversight made in drafting the GATT implementation bill.

This is simply not true.

And wishing will not make it so.

Negotiations on the GATT Treaty were exceedingly detailed and complex. They took place over many years—in fact, across the terms of four American Presidents.

Given the ample opportunity for this issue to have arisen previously, it seems to me that those who argue we should adopt this after-the-fact technical correction amendment should face a heavy burden.

Their case is, and should be, severely undercut by the fact that the Congress made changes in the very sections of the relevant laws that we are now being told were not amended as a simple matter of oversight.

One of the chief benefits that the GATT Treaty can achieve for the American people is to increase international protection of intellectual property.

These important agreements are set forth in the Agreement on Trade-Related Aspects of Intellectual Property, the so-called TRIPS provisions. A key aspect of TRIPS was to require that all 123 GATT signatory countries adopt a minimum 20-year patent term, measured from the date that a patent application is filed.

Strengthening international recognition of intellectual property rights such as patents was one of the most important gains we made in the adoption of the GATT Treaty. These rights act to protect innovative American firms, which all to often have been the victims of unscrupulous behavior by foreign competitors who have expropriated American know-how.

Obviously, all World Trade Organization member countries must take seriously their obligations to respect intellectual property rights under the GATT Treaty and ensure that there will be no back sliding.

It is vital that America must also be perceived as honoring its obligation as a World Trade Organization member.

I recognize that Ambassador Kantor has been identified as one who is supportive of this type of Pryor amendment.

In a September 18 letter to Senator PRYOR, Mr. Kantor takes a view that the approach advocated by the Pryor amendment does not weaken the campaign for stronger patent protection abroad and reflects the intent of the drafters of the URAA. I disagree with him, and I disagree with Senator PRYOR on both scores.

First, I would like to point out that two former U.S. Trade Representatives, William Brock and Clayton Yeutter, have stated that the recently adopted GATT Treaty is a major improvement that benefits the American public.

They have explained that changing the implementing legislation now sends exactly the wrong message.

Mr. President, both of these international trade experts were active participants in the TRIPS negotiations during their respective stewardships at the U.S. Trade Representatives' Office as U.S. Trade Representatives.

As Mr. Yeutter wrote to the Finance Committee in September of this year:

In the Uruguay Round, one of the principal objectives of the United States was to strengthen international protection of patents, trademarks, copyrights, trade secrets, and semiconductor lay-outs. The United States leads the world in ideas and innovation, particularly in cutting-edge technologies such as pharmaceuticals and biotechnology. Thus, . . . TRIPS . . . was a major breakthrough for the United States.

He goes on to say:

In my view, adding further preferential exceptions to the Uruguay Round's 20-year minimum patent term, for the generic drug industry or anyone else, would set an unfortunate precedent and seriously undermine U.S. efforts to secure stronger International IPR disciplines. Many developing countries have long opposed effective patent protection for pharmaceuticals and agricultural chemicals in order to protect domestic industries engaged in illicitly copying American products.

As Mr. Yeutter clearly indicates, there are strong trade policy arguments for standing firmly behind this new 20-year rule. These concerns were also shared by another former U.S. Trade Representative, William Brock.

In a recent letter, Senator Brock explained the significance of the GATT intellectual property provisions:

When I first proposed international agreements to extend intellectual property protection worldwide under the GATT, no one believed it could be done. Yet it was the crowning achievement of the recently successful Uruguay Round. . . Now I hear that some pending proposals could imperil the implementation of that agreement. I refer specifically to legislation recently introduced by David Pryor. . . .

Proponents suggest that this legislation is only a ''technical'' correction to the . . . URAA . . . and neither weakens patent protection . . . nor diminishes the United States' ability to fight for stronger international patent protection. I disagree!

Senator Brock goes on to say as former Trade Representative:

It will be difficult, if not impossible for the United States to force other nations to adhere to the TRIPS agreement if we set this unfortunate precedent.

In sum, in exchange for the hope of short term savings, the PRYOR proposal could cost all U.S. firms and workers the enormous long term gains we worked so hard to achieve in the Uruguay Round. That is penny wise and pound foolish.

When the comments of these two former U.S. Trade Representatives are contrasted with the views of Mr. Kantor, and my friend from Arkansas, Senator PRYOR, it is clear that this is the type of issue upon which reasonable and honorable people may disagree.

I understand that the proponents of this amendment are motivated by good intentions, but I think they are on the

wrong side of both the law and the policy on this issue.

In further support of my viewpoint I point out that Ambassador Kantor's counterpart at the European Commission finds the Pryor approach extremely troublesome. Now, if you know the British, when they say ''extremely troublesome,'' that is about as strong a statement as they can make.

Sir Leon Brittan has informed the current U.S. Trade Representative:

I am therefore concerned that the adoption of these proposals (or for that matter, any other bill which aims at achieving the same objectives) would send a negative and highly visible signal to those numerous countries which are still in the process of preparing new legislation on the protection of pharmaceutical innovation.

This information should dispel the myth that there are no important trade implications at stake in this debate.

It should dispel the myth that the Pryor amendment has no potential negative impact on our efforts to enhance international respect for intellectual property laws.

I ask unanimous consent that the remarks of Clayton Yeutter, Bill Brock, and Sir Leon Brittan be printed in the RECORD.

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

THE RIGHT HONOURABLE SIR LEON BRITTAN, OC, VICE-PRESIDENT OF THE EUROPEAN COMMISSION,
Brussels, Belgium, October 20, 1995.

Hon. MICKEY KANTOR,
U.S. Trade Representative,
Washington, DC.

DEAR MICKEY: My attention has been drawn to draft legislation recently introduced in the United States Senate (S. 1191 and S. 1277), concerning the marketing of generic pharmaceutical products. As I understand it, the effect of these Bills would be to deprive the owner of a pharmaceutical patent of the full benefits of the patent term provided for in the TRIPs Agreement of the Uruguay Round.

This threat causes serious concern to the European research-based pharmaceutical industry and to the Commission, and seems to be in contradiction with the long-standing US policy of providing strong protection for research-based intellectual property rights, both at home and abroad.

The United States and the European Community combined their forces during the Uruguay Round on patent questions. We fought successfully together, for example, for the principle that existing subject matter should benefit fully from the reinforced standards included in the TRIPs Agreement. The unqualified adoption of these provisions by our trading partners, especially in the developing countries, is of great importance for American and European industry alike. Any deviation from these principles should therefore be treated with utmost care. This also applies to the use of the exceptions clause contained in Article 70(4) of the TRIPs Agreement. In my view, these proposals have several significant shortcomings, and the basic philosophy which they translate into legislative language would contradict our mutual aim of providing a reasonably high and secure protection for the huge investments made by EC and US research-based pharmaceutical companies.

I am therefore very much concerned with the potential impact of the adoption of such legislation on third counties. For several years both the US and the Community have made major efforts, jointly in the GATT but also in the context of our respective bilateral negotiations with third countries, to improve the protection of intellectual property rights. This effort has been successful, both in the GATT where the TRIPs Agreement has now been adopted as part of the Uruguay Round, but also in our relations with many third countries. This includes not only significant improvements with respect to the adoption of higher substantive standards for patent protection but also so-called pipeline protection for pharmaceutical and agrochemical product inventions. Nevertheless, there is still a long way to go before the TRIPs Agreement is implemented by our WTO partners, and we both have further objectives to pursue at the bilateral level in terms of improved protection of our intellectual property rights. I am therefore concerned that the adoption of these proposals (or, for that matter, any other bill which aims at achieving the same objective) would send a negative and highly visible signal to those numerous countries which are still in the process of preparing new legislation on the protection of pharmaceutical inventions.

I very much hope that you share my worries and the United States Administration will convey these concerns to the United States Congress.

Sincerely,

LEON.

HOGAN & HARTSON L.L.P.,
Washington, DC, September 26, 1995.

Re amendment to shorten pharmaceutical patent terms under Uruguay Round Agreements Act.

Hon. WILLIAM V. ROTH, Jr.,
Chairman, Committee on Finance,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: I am writing at the request of Glaxo-Wellcome, Inc. to offer my views on the application of the Uruguay Round Agreements Act (''URAA'') to certain pharmaceutical patents. As I understand it, an amendment may be offered by Senator Pryor in the Finance Committee to extend the transition rules of Section 532(a)(1) of the URAA to generic drug manufacturers that already receive preferential treatment under the Hatch-Waxman Act. The Pryor Amendment (S. 1191) would in effect shorten the terms of these patents in order to safeguard the activities of generic drug manufacturers that would otherwise be deemed to be infringing under U.S. law.

In the Uruguay Round, one of the principal objectives of the United States was to strengthen international protection of patents, trademarks, copyrights, trade secrets, and semiconductor lay-outs. As you will recall, we fought long and hard even to get this issue on the Uruguay Round agenda. The United States leads the world in ideas and innovation, particularly in cutting-edge technologies such as pharmaceuticals and biotechnology. Thus, the Agreement on Trade-Related Intellectual Property Rights (''TRIPS''), which established effective legal protection for patents (including a minimum 20 year patent term), was a major breakthrough for the United States.

In my view, adding further preferential exceptions to the Uruguay Round's 20 year minimum patent term, for the generic drug industry or anyone else, would set an unfortunate precedent and seriously undermine U.S. efforts to secure stronger international IPR disciplines. Many developing countries have long opposed effective patent protection for pharmaceuticals and agricultural chemicals in order to protect domestic industries engaged in illicitly copying American products. This is one reason the United States finally agreed to extremely long transition periods in TRIPS. The proposed amendment would provide further aid and comfort to foreign pirates that want to continue infringing American patents. It would be thrown back at U.S. trade negotiators every time they complain that a foreign government is not adhering to its TRIPS obligations.

In Section 532(a)(1) of the URAA, Congress made the right choice by rejecting proposals to in effect shorten the 20 year minimum patent term established in TRIPS. To reconsider that decision now would be a mistake; the proposed amendment would clearly undercut future U.S. efforts to enforce strong international IPR disciplines.

Sincerely,

CLAYTON YEUTTER.

THE BROCK GROUP, LTD.,
Washington, DC, September 20, 1995.

Senator WILLIAM V. ROTH, JR.,
Hart Senate Office Building,
Washington, DC.

DEAR SENATOR ROTH: When I first proposed international agreements to extend intellectual property protection worldwide under the GATT, no one believed it could be done. Yet it was the crowning achievement of the recently successful Uruguay Round—thanks almost solely to the persistent and active support of the U.S. business community and U.S. governmental leaders.

Now I hear that some pending proposals could imperil the implementation of that agreement. I refer specifically to legislation recently introduced by David Pryor, called the Consumer Access to Prescription Drugs Act (S. 1191). S. 1191 creates special rules so that the generic pharmaceutical manufacturers can take advantage of preferential treatment under the Drug Price competition and Patent Term Restoration Act of 1984 (''Hatch/Waxman Act'') without adhering to the 20 year patent term negotiated during the GATT Uruguay Round negotiations.

Proponents suggest that this legislation is only a ''technical'' correction to the Uruguay Round Agreements Act (URAA) and neither weakens patent protection under URAA nor diminishes the United States' ability to fight for stronger international patent protection. I disagree! This issue is far too important to risk on the basis of hoped-for ''good intentions'' in nations which have never favored intellectual property protection.

Countries around the world are still in the process of implementing the Uruguay Round Agreement. A number have withheld their own action to wait and see what we do. We all know those whose prior actions have cost American inventors and entrepreneurs billions. The will see this retreat on our part as a ready excuse to implement their own *minimalist* versions of intellectual property protection. It will be difficult, if not impossible for the United States to force other nations to adhere to the TRIPS agreement if we set this unfortunate precedent.

In sum, in exchange for the hope of short term savings, the Pryor proposal could cost all U.S. firms and workers the enormous long term gains we worked so hard to achieve in the Uruguay Round. That is penny wise and pound foolish. The United States must continue to be a leader on full implementation of every aspect of the agreement on intellectual property in both substance and in form.

One final additional point. Domestically, this legislation would upset the delicate balance provided for in the Hatch/Waxman Act, which already grants generic pharmaceutical

firms special treatment in the area of patents not available to other industries. S. 1191 would further the bias against pioneer pharmaceutical firms.

Please give careful consideration to the negative impact this legislation would have. I would be delighted to give you additional specifics if it would be helpful.

Sincerely,

WILLIAM E. BROCK.

Mr. HATCH. I also take exception to those such as Senator PRYOR and Ambassador Kantor who suggest this amendment achieves a result clearly intended by the URAA.

This is the position that was taken in a September 27 letter from the FDA Deputy Commissioner for Policy, William Schultz.

I must highlight with great skepticism the portion of the FDA letter that states in part: ''the URAA does not address the effect of the URAA patent term extensions on the drug approval process under the Federal Food, Drug, and Cosmetic Act * * *''

It may be true that the URAA does not address the question in a way the FDA and proponents of the Pryor amendment would like, but let us be crystal clear that the relevant statutes do, in fact, address this question.

I find the characterization in the September FDA letter particularly interesting in light of the earlier May 25, 1995 FDA response to a citizen petition filed by several innovator drug firms.

The May FDA statement of policy is quite explicit on what the law addresses. In that statement, the FDA acknowledged that the Supreme Court's 1984 Chevron decision provides guidance in the area of statutory construction. In Chevron, the Supreme Court instructed ''If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.''

Consider the following five direct quotes from the May FDA statement signed by Deputy Commissioner Schultz:

No. 1:

The agency believes that interpretation of the interrelationship between the transitional provisions of section 532(a)(1) of the URAA and 35 U.S.C. is governed by the plain language of the URAA.

The second direct quote from the FDA May statement signed by the very same Deputy Commissioner Schultz:

The URAA is not 'silent or ambiguous' on the question of applying the transitional provision to the generic drug approval process.

Let me give you the third:

Moreover, this apparently is not an example of Congress having overlooked a statutory provision that might have been changed had it been aware of its existence . . .

No. 4:

. . . the agency does not believe that it can assert that Congress was unaware of the existence of these remedies for infringement of patents on drug products, and, therefore, did not include them among the unavailable remedies. . . of the URAA.

And finally, No. 5:

In the present matter, therefore, the plain meaning of the URAA is dispositive.

This is quite a contrast from the recent letter from Mr. Shultz which can be called nothing less than political.

In the May letter, this FDA official makes some very compelling and categorical findings which support my arguments about the proper interpretation of the relevant statutes. A number of courts have issued rulings consistent with this interpretation.

For example, on August 8, 1995 the United States Court of Appeals for the Federal Circuit issued a ruling in the case of DuPont Merck Pharmaceutical Company versus Bristol-Myers Squibb.

Upon reviewing the relevant statutes the court found that, ''* * * the URAA does not clash with the Hatch–Waxman Act,'' and precluded the generic manufacturers from entering the market via the Waxman-Hatch route until the expiration of the affected patent. Likewise, as I stated earlier, on October 16, the United States District Court for the Eastern District of Virginia issued an opinion in a group of four consolidated cases that raised similar but not identical URAA/Hatch-Waxman issues.

In this case, Merck versus Kessler, the court was unpersuaded by the arguments made by the generic drug industry and stated ''This was no more a windfall * * * than the windfall which benefited many patent holders when the 17-year term of patents was extend to 20 years.''

I think the District Court got the law on the windfall issue exactly right.

Finally, I would note that on November 1, the Federal Circuit, the court that handles patents, copyrights, and trademark issues, overturned a decision rendered by the United States District Court for the Southern District of Florida in the case of Bristol-Myers Squibb versus Royce Labs.

Although, as I have laid out, various officials in the current administration and the proponents of the amendments now flatly assert that Congress clearly intended the result they wish to achieve, it is instructive that the Federal Circuit ruling—this is last November 1, just a little over a month ago—noted:

The parties have not pointed to, and we have not discovered, any legislative history on the intent of Congress, at the time of passage of the URAA, regarding the interplay between the URAA and the Hatch-Waxman Act. Therefore, we limit our inquiry to the wording of the statute.

I wonder what tangible information that Ambassador Kantor and the FDA possess on this issue of intent and why neither the litigants nor the Federal Circuit appear to have it at their disposal?

In finding against the generic manufacturer the Federal Circuit makes a number of points in the Bristol-Myers Squibb versus Royce Labs case that I wish to bring to my colleagues' attention:

1. The decision notes the unique treatment afforded to new drugs by the 1984 law. The Federal Circuit said:

Yet, as the Supreme Court stated in *Eli Lilly Co*. v. *Medtronic Inc*., the Hatch-Waxman Act created an important new mechanism designed to guard against infringement of patents relating to pioneer drugs, with enforcement provisions that apply only to drugs and not to other products.

2. The Court also observed, citing as authority the 1990 Federal Circuit decision in the VE Holding Corp. case: ''We presume 'that Congress is knowledgeable about existing law pertinent to legislation it enacts.' ''

3. The Court went on to say that:

We believe that if Congress had intended that the URAA affect the Hatch-Waxman Act's finely crafted ANDA approval process in the manner urged by [generic manufacturers], at the very least it would have referred to 21 U.S.C. 355(j) and 35 U.S.C. 271(e) in the URAA.

4. Finally, the Federal Circuit boiled down the situation as follows:

The statutory scheme does not say, as [the generic manufacturer] argues . . ., ''If normally you would infringe, you do not infringe during the Delta period.'' Rather, it says, ''If normally you would infringe, you also infringe during the Delta period.''

So let there be no doubt in anyone's mind about the clarity of the law or the intent of Congress in this area.

Having discussed the trade policy argument and the ''it-is-merely-an-unintended-technical- oversight'' argument, I would like next to address this windfall issue since it goes to the heart of the argument advanced by those behind this amendment.

Let me say to my colleagues that my involvement in the Hatch-Waxman Act of 1984 compelled me to think carefully about the need for balancing incentives.

The American public should enjoy the benefits both of low-cost generic medications and breakthrough products developed by R&D-based firms. I have worked hard to see that both sides are taken care of. Let me repeat that: Both lower-cost generic drugs and breakthrough drugs ought to be available to American consumers.

The challenge is to devise incentives that foster the availability of both breakthrough and generic drugs. That is precisely what Hatch-Waxman attempts to do and has done.

Let there be no doubt that I am a supporter of both the generic and the innovator sectors of the pharmaceutical industry. One of my great regrets is that neither sector has as large a presence in my State of Utah as they do in many other States across the Nation. But both are there.

Nevertheless, both of these players in the pharmaceutical market produce products that have enormous benefit for citizens in Utah and everywhere. It is for that reason that we must weigh heavily any legislation that would adversely affect their ability to deliver these products to the public.

The fact that I oppose this particular amendment does not change the fact that I am, and will remain, a devoted supporter of the generic drug industry. Unlike my colleagues proposing this

amendment, however, I am convinced that it would be unwise to adopt this measure.

The proponents of the Pryor amendment urge that only one industry is singled out in current law for different treatment under the URAA transition rules. What is absent from this line of reasoning is the fact that only one industry, the generic drug industry, is permitted by current law to engage in activities that would ordinarily constitute patent infringement—and I am one of the people who helped them get there.

Mr. President, I remind my colleagues that before we so hastily throw around the terms ''windfall'' and ''unjust enrichment'' let us clearly understand the laws and policies at issue and how they affect incentives for biomedical research.

One of the centerpieces of this debate is the operation of the so-called ''Bolar Amendment'' contained in the Hatch-Waxman Act and codified at 35 U.S.C., section 271.

In the 1984 Roche versus Bolar case, the Federal Circuit held that the manufacture or use of a patented product for the development of data to submit to FDA constituted patent infringement.

It is this provision of the Hatch-Waxman Act that treats generic drug manufacturers differently from every other industry in our economy.

Under the Hatch-Waxman Act generic drug firms may legally use a pioneer product to help secure FDA approval and can gear up production to go on the market before the pioneer product patent expires. Normally such activities would constitute patent infringement, clear and simple.

There is nothing similar to the special treatment afforded the generic industry elsewhere in the patent code. This unique status is sufficient to justify treating generic drug products differently treatment under the URAA transition rules.

One of the things that I find troubling about this amendment today, like the previous amendment offered at the Finance Committee mark-up, is that the Senate floor—when debating a bill to ban partial-birth abortions—may not present the best time or place to reconsider the details of such carefully crafted bills such as the URAA and the Hatch-Waxman Act.

The FDA policy statement issued in May states:

> The 1984 Waxman-Hatch Amendments to the Federal Food, Drug, and Cosmetic Act represent a careful balance between the policies of fostering the availability of generic drugs and of providing sufficient incentives for research on breakthrough drugs . . . There is certainly a strong argument to be made that such a compromise should not be upset without hearings and careful deliberation as to the impact on the twin interests served by the Waxman-Hatch Amendments.

As Chairman of the Judiciary Committee, I can say that the Committee has an interest in any legislation, such as Senator PRYOR's, that affects patent rights. As one of the authors of Waxman-Hatch and as an advocate for both the generic and pioneer sectors of the industry, I have a special interest in the legislation under debate.

But since this debate is taking place now, I believe that I have a responsibility to provide perspective on some of the changing pressures on the biomedical research and development that have occurred since the passage of Hatch-Waxman back in 1984.

Let me turn to some charts which I believe illustrate this, and I will do this to try to move along. However, this is an important issue, which should not just be tossed aside. Nor should we act like this is just a simple little issue between consumers and gouging drug companies.

Let me turn now to some charts which I believe illustrate the broader context in which this amendment must be evaluated.

There are a number of complex factors that shape the environment of the biomedical research enterprise in this country.

By placing their sole focus at the back end of the R&D pipeline and on those few products that are successfully commercialized, the proponents of the amendment do not take into account the nature of the risks involved in conducting the necessary research leading to development of new drugs.

If the United States is to remain the world's leader in health care technology and our citizens are to continue to receive the latest in medical advances, it seems to me that the Senate has a responsibility to look at the factors that influence participation in the front end of the development pipeline.

In my view, it is critical that we work to create the incentives necessary to attract trained personnel and resources into biomedical research and development.

This first chart shows pharmaceutical research and development as a percentage of sales. As you can see, the electrical products industry spends 2.5 percent on research and development as a percentage of sales, the telecommunications industry 3.7 percent, the aerospace industry 4.2 percent, the scientific instruments industry 5.4 percent, and the office/computer machinery industry 8.0 percent. On the other hand, in 1993 the pharmaceutical research and development companies spent 18.3 percent of their total sale on research and development.

That is what is involved here—research, research, research—the hope for the future that we might solve some of these immense medical problems.

As you can see, the ratio of R&D investment as a percentage of product sales is significantly higher than for other representative R&D industries such as electronics, computers, aerospace, and telecommunications.

As a result of this investment, the United States still enjoys a positive balance of trade in the area of pharmaceuticals. Between 1989 and 1994, the sum of these annual positive balances was over $5.2 billion.

Maybe if other industries would invest as much in R&D as the drug industry, the United States could once again have a favorable overall balance of trade.

A favorable balance of trade means jobs for Americans, and that is an important consideration in today's economic climate.

Let me go to the next chart. This next chart shows how many research misses it takes for pharmaceutical companies to find a hit that is commercially viable. This shows how many chemically synthesized drugs there are. The reason we have the break here is because the poster is not large enough to show how high this bar would really go—5,000 drugs identified. Of those 5,000, only 500 were tested in organ preparations. Of those, only 250 were tested in animals, 5 in human clinical studies, and only one was eventually approved for use in humans by the FDA. One out of 5,000 tries becomes a hit—one.

These companies take tremendous risks in trying to come up with a marketable drug, one that will return what it costs for the research and development to develop it.

As you can see, for every successful drug that emerges out of the pipeline, 5,000 potential products drop by the wayside.

One other fact to note as we go from activity to activity across the bottom of this chart is that these activities get costlier as we move from test tube to the patient's bedside.

Let me go to the next chart because these are things you should not ignore. This chart shows that this is a bigger policy issue than the belief by some that these companies are gouging.

This next chart shows the drug development cost rising over time. In 1986, the cost to develop a new drug was $151 million. In 1990, the average cost for the approval of a new drug was $359 million.

As you can see, it costs a lot of money to bring a new drug to market. In addition, these costs have risen since the passage of the Hatch-Waxman law in 1986. And these costs continue to rise today.

Clinical and preclinical tests are costly. They are difficult. And they are highly regulated activities.

As you can see, a significant amount in gross sales must be generated by each one of these research companies, like any one of the ones they are complaining about here, to recover the huge drug development costs. There has to be in the billions of dollars of sales to recuperate their research and development companies.

If they do not recuperate those moneys at least a part of the time—and they do not a lot of the time—they are not going to stay in business. If this happens, we will not have these blockbuster drugs, and we will not have the

life-saving pharmaceuticals that are saving people's lives every day.

We will not have a cure for AIDS, and we will not have a cure for Alzheimer's disease or any other number of diseases.

The next chart shows that there is a public/private partnership in drug research and development.

Mr. CHAFEE. Mr. President, I wonder if I might ask the Senator a question, if it is possible to reach a time agreement on this?

Mr. HATCH. There sure is. I will be through in a few minutes. I do not think that I will have any more to say, unless somebody asks questions. I am happy to reach a time agreement.

Mr. CHAFEE. I ask the sponsor. We are all here. Can we arrive at a time agreement?

Mr. HATCH. Why don't you get your side together, let me finish my remarks and then we will agree on a time agreement?

Mr. CHAFEE. You are in such flying form. You have all of your engines running.

Mr. HATCH. That is why I want to finish my remarks. This is an important issue. As the author of the Hatch-Waxman Act, I am very concerned about it. However, I do not intend to take too much longer. We are going through the salient points.

This particular chart shows R&D expenditures. NIH expenditures are the blue bars. The private sector expenditures are the green bars. The private sector means the pharmaceutical research company.

In 1985 we spent more on research and development in the NIH —$4.8 billion— than was spent by the pharmaceutical companies —$4.1 billion on R&D.

In 1988, R&D for the pharmaceutical companies started to surpass NIH—$6.3 billion for NIH, and $6.5 billion for the pharmaceutical companies.

In 1991, the NIH spent $7.7 billion, and the pharmaceutical companies jumped to $9.7 billion.

In 1995, the NIH will spend $11.3 billion on research and development. The pharmaceutical companies will spend almost $15 billion.

Pharmaceutical companies are doing the job. Do not undercut them. This amendment undercuts them. This amendment appears to be a populist amendment. It seems to have appeal to those who think they are on the consumer side. But the consumer really is on both sides—one side would lead to lower drug costs on the short run, our side would lead to continued support of the research and development of drugs for the long term.

Research and development benefit the generic companies because if they do not get to blockbuster drugs, the generic companies will not be able to copy them.

I have already shown that the drug industry spends a relatively large proportion of its earnings in R&D and that the cost of bringing the successful drug to market is high and rising.

That chart shows one of the most significant developments in the biomedical research enterprise since the passage of Hatch-Waxman in 1984.

The R&D expenditures by pioneer drug companies now—for the first time in recent history—exceeds the funding of the National Institutes of Health.

One of the major reasons that the United States is the world's recognized leader in biomedical research is the public investment made in NIH since World War II.

American citizens have enjoyed the benefits of the close partnership that has developed among pharmaceutical and medical device firms, academic medical centers, and the NIH.

The basic research conducted at and supported by the NIH is complemented by the private sector R&D efforts.

This is the type of public-private partnership that we can all take pride in and should fight to retain in the future.

We do not want to take away the incentives of R&D. That is what this amendment does.

We all know of too many instances in which our foreign competitors have exploited their close linkages between Government and industry to wrest away U.S. industrial leadership. If we Americans leverage together our public and private sector resources, we can compete against anyone in the world.

As we tighten our budget belt to put the Nation's fiscal house in order, I do not think it is realistic to expect that we will continue to see the growth rate in the NIH budget that is represented on this chart.

But I want to see this growth rate of the research companies continue.

Since 1988, the NIH budget has almost doubled.

If we are to retain our world leadership in biomedical research it will be important to retain the incentives that will encourage drug firms and the capital markets to invest their resources in this research.

This chart shows that industry is stepping up to the plate.

American citizens and families around the world will benefit from this research.

What is the difference between the regulatory review requirements for generic versus pioneer drugs?

Let me show the difference for those of you who may not have a knowledge of FDA law. These are the steps to establish safety and efficacy for innovator drugs for these research companies, which take 12 years to complete. In 1990, this process cost $359 million. Lab and animal studies, 3.5 years; phase one safety studies, 1 year; phase 2, testing effectiveness of studies, 2 years; phase 3, extensive clinical testing, 3 years; FDA review, 2.5 years.

Under Hatch-Waxman, look at how the generic benefit. We provide a shortcut for generic drugs. All they have to do to take their drug to market is to complete a bioequivalency test and establish that their drug is bioequivalent. That takes 10 to 18 weeks.

That takes 10 to 18 weeks, and an abbreviated new drug process which is 6 months. That is all they have to do. They do not have to spend $359 million. They can copy that drug the minute it comes off patent and eliminate the costs. This has made and built the whole generic industry and has benefited consumers through saving billions and billions of dollars since 1984.

Are we going to just make it even more difficult for these companies that have made this whole industry by now, under Hatch-Waxman, and let them just take these drugs and run with them? I fought to get this done. I believe in generics. I think this ought to continue. Let us be very, very clear about it. This is a privilege that we give no one else in patent law, and we do it for consumers.

Now, are we going to now to make it very, very difficult to produce the drugs that these people have to have to be able to survive? I hope not.

A study by the Tufts University Center for the Study of Drug Development estimated that it takes on average $359 million and 12 years to get a new drug approved by the Food and Drug Administration. I know that is insane, but that is what it takes.

A lot of time elapses in the laboratory just determining the best drug candidates through test tube and animal studies. Three complex and time-consuming phases of human clinical trials are required to develop the necessary safety and efficacy data that must be submitted to the FDA. This testing takes time and money.

It is essential in this debate to understand that the generic drug manufacturers are not required to undertake any of this extensive and expensive testing.

Let no one undervalue the importance that this testing process has for the health and safety of every American.

In contrast to the rigorous safety and efficacy requirements placed on the pioneer drug firms—these up here that takes 12 years and $359 million to develop a drug,—the Hatch-Waxman law provides for a much simpler and easier approval standard for generic drugs.

Generic drug manufacturers can rely upon the safety and efficacy data of pioneer firms and must only show that their product is bioequivalent to the pioneer product. That can be done in a matter of weeks, not years, at a fraction of the cost and none of the risks that are faced by these pioneer firms.

According to a 1992 Frost & Sullivan study, after the passage of the Hatch-Waxman Act, the average cost for a generic drug company to prepare and file an abbreviated new drug application is ''well below the million mark.''

A large part of the reason why generic drugs can be sold for less than brand-name products is that the generic companies do not have to perform the extensive research and clinical

trials required of innovator drug companies. Nor do generic drug firms have to finance all the products that fall by the wayside.

Generic drug companies piggyback on the fruits of the pioneer's research. We permit that. We want that to occur. But we should not ignore what a great thing the pioneer companies do for us.

There is a tremendous amount of appeal to an amendment which appears to provide consumers with the opportunity to greater access to lower-cost drugs. If Senator PRYOR's proposal were that simple, I would be for it. It is easy to get up and make it look like your approach is the only approach for consumers.

But if the companies that go through these 12 years, $359 million, 5,000 tries to get one drug are undercut, we are all undercut, and the generics will not have any drugs to copy so that they can keep their industry going.

It is penny-wise and pound-foolish to treat this like it is some simple little consumer versus gouger issue. It is a lot more than that.

Senator PRYOR's proposal is not that simple. You cannot accept it on face value. You have to delve into all the facts and the case law. Failure to examine this information about the nature of these two industries would be shortsighted at best.

In fact, there could be some short-term financial gains for some if we did not provide full patent term for a whole range of products. By that logic, however, we ought to just make everything generic—generic appliances, automobiles, electronics, everything. It would save the consumers all kinds of money.

It would also dry up all research and development, all technology, all the investment in quality and efficient production, including jobs and the vast array of choices Americans have as consumers.

We would no longer have breakthrough drugs which are improving and saving the lives of so many millions of Americans.

As I have said, I have a tremendous affection for both the brand name and generic industries. They are both important to our Nation's health care.

In my view, it is clearly in the best interests of consumers that both pioneer and generic drug companies exist harmoniously in our competitive drug and medical marketplace.

It serves neither the public nor this body well for us to berate continually the R&D-based pharmaceutical industry which is doing so much good in this world and ironically is the industry upon which the generic companies themselves rely.

I believe we have to defeat this amendment. I understand the distinguished Senator from Ohio has an amendment to this amendment. My personal preference would be to defeat this amendment and to stand up for American trade, American technology, American research and development, for the right to keep these products coming to these generic companies, for the right of all Americans to have access to reasonable and good and life-saving drugs and to have the incentives to get us there.

By the way, just to choose Zantac as an illustration, Zantac is a therapeutically important drug. It is one of the best antiulcer medications in the world today. Of course, there are other drugs of this class. Tagamet, for instance, is already subject to generic competition. It just so happened that the company that makes Zantac, Glaxo, had gone through this long, expensive research and development process, and they were left with an effective patent term of around 12½ years after FDA approved this product. The URAA will extend its patent life for an additional 20 months or thereabouts.

The fact is that the drug Zantac came out in 1983, 1 year before the Hatch-Waxman bill, and therefore had it been approved 1 year later it would have qualified for, as I understand it, 2 full years of further patent protection under the transition rules of Hatch-Waxman.

In fact, Zantac was a loser under Hatch-Waxman. Well, it happens to be a winner under the GATT Treaty and Uruguay Round Agreement, and if we undercut that, yes, you might be able to say, well, they are going to make some additional revenues—I see your chart here—$3 billion, but let me tell you something. They spent millions of dollars developing this product, and they lost a substantial time of their patent term before the product was approved. Even with the time it receives under the URAA, it still does not get a full 17-year patent term.

There is another side to the coin. I do not want anybody to get an unfair windfall, but it is hardly a windfall when firms are investing billions of dollars in research annually. I have to say that there were winners and losers under Hatch-Waxman, and there will be winners and losers under the GATT Treaty.

But the bigger policy concern is how not to undercut the treaty and send the wrong message to the rest of the world. Undercutting intellectual property protection would be injurious to the whole world, or at least the 123 nations that agreed to GATT, and not undermining the incentives for pharmaceutical research that enables our country to be the leader in the world in this important endeavor.

I do not think there is any reason for the generic companies to come in here and complain since their whole industry was created by the very bill that they are now trying to amend and take even further advantage when, in fact, they have a tremendous advantage today and will have every year that the Hatch-Waxman bill is in effect. So this is not some simple little gouging issue or some simple little equity issue.

Mr. President, I have a number of concerns relating to the manner in which the language of the amendment is drafted. These concerns include: On substantive grounds, as I have argued earlier, I am opposed to the manner in which sections (a) and (b) of the amendment, respectively, act to overturn the 17 year from grant/20 year from filing choice of the URAA transition rules and the elimination of section 271(e) of title 35, United States Code, as the sole and unique remedy provided by the Hatch-Waxman Act.

I am also concerned about the operation of the equitable remuneration provisions contained in section (c) of the proposed amendment. It appears to me that this provision puts the cart before the horse. Under the Hatch-Waxman law patent rights are carefully determined before a generic drug product may be approved for marketing.

Section (c) of the amendment appears to reverse the operation of the URAA transition rules. Specifically, the amendment seems to allow a generic drug manufacturer to infringe and only allows a patent holder to seek equitable remuneration after the infringement has taken place. This is opposite of current law which makes a potentially patent-infringing ANDA applicant subject to an infringement action and an equitable remuneration determination prior to the commission of any infringing act.

I also will seek clarification of whether this amendment would permit the marketing of generic versions of products that vary slightly from innovator products without triggering the equitable remuneration provisions. Specifically, I will seek clarification of whether the phrase in section (c), ''an approved drug that is the subject of an application described in subsection (a)'', refers to the innovator drug or the generic copy.

I am also concerned about the lack of guidance on the question of what constitutes a ''substantial investment'' under this amendment and whether an innovator firm may contest such an assertion made be a generic firm. In addition, I will seek a better understanding of what standards a court should apply when reviewing the apparently unilateral finding on the part of a generic manufacturer that it has made a substantial investment.

So, there are many technical questions that can be raised about this amendment.

At this point, I hope I have made the case for this side, and I personally hope that Senators will defeat the Pryor amendment and that we go about keeping the industry going the way it has been going in both areas for the benefit of all mankind.

I yield the floor.

Mr. CHAFEE addressed the Chair.

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. CHAFEE. Mr. President, with the principals in the Chamber here, I wonder if it would be possible to set a specific time that we might vote.

I know a lot of Senators are out, so I do not think we are in the position

where we can go immediately to a vote in 15 minutes or so. I would offer the suggestion that we agree to vote at 8:30, while allowing time for the Senator from Ohio and others to speak.

I defer to the Senator from New Hampshire.

Mr. SMITH. I would say to the Senator from Rhode Island, we are working on that. We are very close. We are not quite there. We need to confer with Senator HATCH for a few moments. We may very well be able to come up with an agreement very similar to what the Senator just indicated, if he could give us a few more minutes.

Mr. CHAFEE. Fine. I am just I suppose a catalyst here. But I do know that people are away, so that as much notice as can be given the better.

Mr. DEWINE addressed the Chair.

The PRESIDING OFFICER. The Senator from Ohio.

Mr. DEWINE. Mr. President, Senator DODD and my second-degree amendment to the Pryor amendment expresses the sense of the Senate that the Senate should, through the Committee on the Judiciary, conduct hearings to investigate the effect of these new patent provisions in title 35. I think it makes eminent sense to do this. Let me just, while I see my colleague from Utah on the floor, get his attention for a moment and ask him if he could respond to a question.

Mr. HATCH. Sure.

Mr. DEWINE. The second-degree amendment Senator DODD and I have offered provides that this issue would be referred to the Judiciary Committee for hearings. And as chairman of the Judiciary Committee, I wonder if the Senator could give the Members of the Senate some indication of how he intends to conduct the hearing or what time there would be in that event. There have been some questions on the floor. And I think we should respond to the Members before the voting in regard to that.

Mr. HATCH. I am not adverse to hearings. I think this is that important. In fact, I think it is an appropriate way to proceed. I have to tell the Senator that we have about all we can handle for the rest of the year on the Judiciary Committee. I do not think anybody doubts that. We have the judges, the matters on the floor, and hearings scheduled.

So I would be very happy to agree to some sort of date certain, at least within a time period. I think you ought to give us, I would say, at least 120 days in which to hold a hearing. But I will try to hold it as expeditiously as possible within that period. We will be fair to both sides, because I think both sides need to be fully aired on this matter.

If we hold such a hearing, if the Senator prevails on his amendment, I would do that expeditiously. It would probably be some time after the first of the year, but hopefully within 120 days.

The hearing will give both sides a real airing of this. We will treat this issue—not like some demagoged issue, but treat it like it should be treated, that is, as one of the most important issues in the history of trade negotiations.

So it is up to the Senator. It is his amendment. But I will be happy to put it within a certain timeframe. If the Senator will tell me what he wants, I will be happy to try to do that. If the majority leader tells me, I will be happy to do that.

Mr. DEWINE. It would be my understanding, from the statement made by the chairman, that he would be willing to hold these hearings, and Members of the Senate could be advised these hearings would take place sometime within the next 120 days. Is that correct?

Mr. HATCH. If I understand the distinguished Senator, I would be willing to set it within 120 days, and notify all Members when it will occur, of course. I have no problem with that. I will give advance notice about it.

Mr. DEWINE. I thank the Senator very much.

(Mrs. HUTCHISON assumed the chair.)

Mr. DEWINE. Madam President, let me continue briefly in regard to this matter.

Madam President, I think it is abundantly clear after we have listened to this debate—my colleague from Rhode Island, my colleague from Arkansas, both have been very, very eloquent in regard to this issue—I think it is clear, after listening to my colleague from Utah, the chairman of the Judiciary Committee, that there are two sides to this issue, that there is a very complicated, a very serious issue, and it is the type of issue, quite frankly, that we should have hearings.

We should, as the chairman of the Judiciary Committee just said, hold those expeditiously. We should hear from both sides of the particular issue. And then I believe we will be in a much better position for this Senate to take a position and to actually hold a vote.

I think as we listen to this debate it is just abundantly clear that there are legitimate issues, arguments on both sides of the debate and that we should examine those. Frankly, the only way this Senate has to examine them at length is not just by debate on this floor, but it is also by actual hearings. So I think Members of the Senate should understand that the vote in favor of the DeWine-Dodd amendment would, in fact, guarantee that these hearings would take place and the Senate would have the opportunity to have the benefit of hearings.

There are two sides to this. On the one hand opponents of the Pryor amendment argue that shortening the patent term contained in the agreement on trade related aspects of intellectual property rights, that provision in the Uruguay round of GATT would have detrimental effects on both the development of new and innovative medicines and also the global patent protections gained for United States manufacturers in Uruguay.

In fact, Madam President, according to former Surgeon General Dr. C. Everett Koop, who my colleague from Utah has already quoted, to bring a new single medicine to patients requires on the average an investment of 12 years and $350 million. Of the components tested in a laboratory, only 20 percent ever make it onto pharmacy shelves, and only a third of those ever earn a return on the investment made through the discovery.

Madam President, if we weaken patent protections on these products, we will stifle innovation, and slow down further the discovery of new treatments for diseases such as possibly AIDS or cancer.

Two former U.S. Trade Representatives, Clayton Yeutter and William Brock, argue that passage of the Pryor amendment would set a bad precedent. It would cost all U.S. firms and workers the enormous long-term gains that the Trade Representatives worked so hard for in Uruguay. It would do this by making it nearly impossible for the United States to force other nations to adhere to the intellectual property protections of this agreement.

Robert L. McNeill, executive vice Chairman of the Emergency Committee of American Trade, said the following:

> . . . enhanced protection of intellectual property rights will be diminished abroad if the United States itself violates the patent term contained in the [intellectual property rights protections] agreement. It is almost certain that such an action would provide foreign-based pirates and patent infringers with potent ammunition in seeking to have their domestic governments devise measures that are inconsistent with [these protections.]

Madam President, on the other hand, supporters of the Pryor amendment argue that failure to amend the Hatch-Waxman Act would place a substantial burden on consumers. Moreover, according to U.S. Trade Representative Kantor, amending the act would ''in no way increase the ability of our trading partners to justify their failure to provide * * * consistent patent protection [for intellectual property rights.]''

So clearly, Madam President, this amendment is not as straightforward—the underlying amendment by my colleague from Arkansas is not as straightforward as it might appear on the surface. This is legislation that should be debated fully and not thrown in as an amendment to the partial-birth abortion bill.

Madam President, I yield the floor.

Mr. DODD. Regardless of one's view about the merits of the issue, an abortion bill is not the appropriate place to take up the GATT patent issue. This amendment is complicated, involving issues of patent law, trade, innovation and new drug therapies. This issue needs a full hearing, so that we can get past demagoguery and really look at the issues carefully.

That is why Senator DEWINE and I are suggesting that we hold at least one hearing on the issue before adopting an amendment that would deny the

benefits of GATT to U.S. innovator pharmaceutical companies.

The underlying amendment would result in substantial changes in two statutes—the GATT implementing statute and the 1984 Hatch-Waxman Act. The first is a trade treaty that we negotiated in good faith with many other countries who are relying on our commitment to abide by the strong international patent protections that were a major achievement of GATT. The Hatch-Waxman Act provided special rules for generic drugs that give the generic drug industry an advantage possessed by no other industry in the United States or the industrialized world. These two statutes were developed carefully to ensure that this country continues to lead the world in innovative drugs and new therapies.

These are not issues to be treated lightly. The proposed Pryor amendment is not a technical amendment to the GATT law, though that's how its been characterized. The GATT language was carefully negotiated and should not be amended without careful thought and consideration of the implications.

The Hatch-Waxman Act represents a careful balance between the interests of innovator manufacturers and generic drug companies. It has worked well for more than 10 years and should not be amended lightly.

The proposed amendment also would have a direct and significant effect on patent rights, which fall squarely within the jurisdiction of the Judiciary Committee. The dramatic changes that would result from the proposed amendment would occur without the benefit of prior congressional consideration.

We should not rush to legislate in this area before we hold hearings and give careful consideration to all of the proposed amendment's potential ramifications. I urge my colleagues to support holding a hearing on this issue before voting on a measure that could send a very dangerous signal to our trading partners

Mr. PRYOR. Madam President, I now ask for the yeas and nays on the second-degree amendment.

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be. The yeas and nays are ordered.

The yeas and nays were ordered.

The PRESIDING OFFICER. Is there further debate?

Mr. PRYOR. Madam President, do I have the floor at this time?

The PRESIDING OFFICER. You have been recognized.

Mr. PRYOR. Madam President, I do not know where the time agreement stands. We have been negotiating during the course of the evening. I know Members of the Senate are at home for dinner and need at least 30 minutes notification.

I would like to say, and I think I can speak for Senator CHAFEE, that we are reaching a point where we are ready to determine a time certain to vote. I would strongly encourage that. I do not know of any other speakers we have on our side. I have a few more comments I would like to make about this subject. I wonder if the Senator from New Hampshire, the manager of the bill, might have any comments on a time agreement, or a time certain?

Mr. SMITH. Mr. President, I believe everyone on our side has spoken who wishes to speak. How much time does the Senator wish?

Mr. PRYOR. I might suggest that we vote at 8:35. If there are no speakers on the other side, I would like to take the remaining time.

Mr. BIDEN. If the Senator will yield, is it possible to consider—I guess it is a leadership decision—starting the vote at 8:25 and let the vote extend, so that those of us who are trying to get transportation out of the city on an 8:30 train could make the train? I will not insist on that, but if it is possible, that would be nice—since no one else wants to speak and we are worried about getting people in here to vote. A couple of us want to get out of here. Is it possible to do that?

Mr. SMITH. Did the Senator say 8:30?

Mr. BIDEN. I only need 7 minutes to make it to the train.

Mr. SMITH. That depends on whether or not the Senator wants to miss the vote.

Mr. BIDEN. No.

Mr. PRYOR. I think, more importantly, is the Senator going to vote?

Mr. BIDEN. Yes.

Mr. SMITH. The Senator from Arkansas asked for how much time?

Mr. PRYOR. Here is what our policy committee has requested. We think it is going to take at least 30 minutes to get our Members here. Therefore, I would like to respectfully suggest that we vote at 8:45 on the motion to table the second-degree amendment.

Mr. HATCH. If the Senator will yield, can we protect a few minutes on this side? I understand Senator HELMS may want to speak. I might want to say one or two things.

Mr. PRYOR. If we can divide the time equally, we can have 15 minutes and you could have 15 minutes.

Mr. HATCH. We may yield back subsequent to that time if it helps our colleagues.

Mr. SMITH. I will propound a unanimous consent request.

I ask unanimous consent that a vote occur on or in relation to the Smith amendment at 8:45 and the time between now and 8:45 be equally divided between the two sides.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. PRYOR. Madam President, I think this has been a very educational debate, to say the least. During the course of the evening, it has been proposed that we try to have a time certain placed on the sense-of-the-Senate resolution offered by the Senator from Ohio and others. It has further been proposed that if this issue goes before the Senate Judiciary Committee, there might be, for example, a 120-day period when the report from the committee comes back to the floor of the Senate.

Madam President, with all due respect to that idea, let us just look for a moment at what that would do. We have done a little calculation here. If we extend 120 days of protection to Glaxo for Zantac alone—and this does not include the other dozen or so drug companies under this umbrella— 120 days of not resolving this problem will give them unlimited opportunities to charge the highest price for their drug. They will have unlimited protection from any generic that wants to come to the market. Simply put, we are going to be depositing $720 million to the bank account of Glaxo, because by next Christmas of 1996, which is just about 12½ months from now, Glaxo will have made an extra $2.328 billion if we fail to close this loophole.

Madam President, I, as a U.S. Senator, am not a stockbroker. I will never advise anybody to buy any stock or make investment because I have never been very successful at that myself. But if we extend this for 120 days, or even another 30 days, without closing this loophole, I suggest that we all go out in the morning and buy Glaxo stock because they are going to continue receiving an enormous windfall that they had no idea they would receive.

Madam President, second, I ask unanimous consent to add three additional original cosponsors: Senator BRYAN, Senator LEAHY, and Senator DORGAN.

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

Mr. PRYOR. Next, Madam President, there has been a discussion this evening and quotes by my friend from Ohio, Senator DEWINE, and from Senator HATCH of Utah, about Dr. Koop. Well, Dr. Koop got drawn into this issue in a very interesting way, and it appears to me, after talking to Dr. Koop some days ago, that Dr. Koop may not have been aware of—or the Glaxo people may not have presented the true case to—Dr. Koop when they had him sign a particular advertisement which appeared in The Hill newspaper. It also appeared earlier in the Washington Post. This is the advertisement that Dr. Koop signed on October 25, 1995. The advertisement appears to have been purchased by Dr. Koop to say that ''Senator PRYOR's bill would weaken the patent protection needed for the next generation of pharmaceuticals.''

I called him up and I said, ''Dr. Koop, I am probably your No. 1 fan in this country. I have supported you, I have revered you, and now you have signed this advertisement in all these papers saying that you are opposed to my amendment.'' He says, ''What amendment?'' I said, ''The amendment with which we are trying to close this loophole.'' He said, ''I did not know that was what it was all about.''

Well, on December 3, a Journal of Commerce appeared about Dr. Koop. ''In a brief interview, Dr. Koop said he did not know the details of the lobbying campaign by Glaxo-Wellcome when he agreed to lend his name to what was described to him as an effort to preserve patent drugs from foreign piracy.'' In fact, the lobbying was an effort by a British drug company to retain an inadvertent million-dollar loophole in last year's trade bill at the expense of generic drug companies. Dr. Koop said he was unaware that a general statement he had made on patent rights would be used in the Glaxo campaign. When asked by a reporter if he had been done a disservice by Glaxo officials, Dr. Koop responded, ''I would have to say I was,'' and expressed regret that he had ever been involved in the fight over Glaxo's loophole.

Madam President, I have heard my very good friend from Utah talking about all of the research dollars that are being expended to find all of these cures for all of the problems and ailments and diseases that we have today. I want to compliment the pharmaceutical companies for doing a wonderful job. They are second to none in the world.

But, Madam President, I do not think we need to shed any crocodile tears for the company Glaxo. One, it is the biggest drug company in the world, and when the Glaxo research was done on Zantac alone, which was over two decades ago—and they have had patent protection, no competition whatever for a period of 17 years, no competition, Madam President—when that research was done, not only was most of it done by NIH and farmed out to universities throughout the educational system across the land, but taxpayers' dollars helped dramatically in finding the research and the answers that this particular drug/pharmaceutical was intended to cure.

Let's don't shed too many crocodile tears when we are talking about research. First, Glaxo is probably much like the other drug companies. They are spending more today to market and advertise their drugs than they are to research the new—as they say, blockbuster—drug breakthroughs. They are spending more now for marketing than they are for research.

Let's look at Glaxo itself, and at the pretax profits for the last 12 months: $3.3 billion—not millions of dollars, but $3.3 billion. And much of this came from the best-selling drug in the world today, Zantac, which, unless we close this loophole, we are going to provide further protection from competition.

Madam President, we have also heard a lot of discussion about patent rights and intellectual property rights. Let me once again refer, as I have in the past and as Senator CHAFEE has, to a letter that I received, or actually Senator CHAFEE received.

I think I received an identical letter, dated September 25, in which our U.S. Trade Representative, Ambassador Mickey Kantor, said, ''This provision [the transition rules] were written neutrally because it was intended to apply to all types of patentable subject matter, including pharmaceutical products. Conforming amendments should have been made to the Federal Food, Drug, and Cosmetic Act and section 271 of the Patent Act, but were inadvertently overlooked.''

That is a direct statement, Madam President, from our trade Ambassador who negotiated the GATT Treaty and who is there to protect not only our patent rights but also our intellectual property rights.

Madam President, I am going to reserve the balance of my time. I look forward to hearing additional statements from my colleagues.

Mr. SMITH. I yield whatever time the Senator from Utah consumes.

Mr. HATCH. I do not know why some on the other side said that Dr. Koop said he was sorry he was ever involved. Dr. Koop's letter, dated November 30, makes it very clear he wants to be involved, that this is an important issue. Here is the letter he wrote.

I know Dr. Koop as well, if not better, than anybody in this body. I was the one who, as ranking member on the Labor and Human Resources Committee, fought for his nomination through a full 9 months, if my recollection serves me correctly. I am very close to him.

I did not ask Dr. Koop to write this letter. He voluntarily wrote the letter. Anybody who reads that letter and thinks there is an argument on the other side, just does not enjoy good reason. Dr. Koop is extremely clear. I think he probably would not appreciate being misrepresented.

Now, with regard to congressional intent, the Federal Circuit Court of Appeals backs my position. It says:

> The parties have not pointed to and we have not discovered any legislative history on the intent of Congress at the time of passage of the URAA regarding the interplay between the URAA and the Hatch-Waxman Act. Therefore, we limit our inquiry to the actual wording of the statute.

That is a Federal Circuit Court of Appeals, the court that has the expertise to decide these issues. I do not think anybody can doubt for a minute that the arguments I have made do not have legal backing, legislative backing, and good, commonsense backing, because they do.

Recently, a Federal district court, as I mentioned before, reviewed the relevant provisions of law and concluded, ''This was no more a windfall to the''—and he names the pioneer firms which include Glaxo—''then the windfall that benefited many patent holders when the 17-year term of patents was extended to 20 years.'' No more of a windfall now than that was then.

I might add that it is not a windfall because, in all honesty, the generic drugs will benefit greatly and have benefited greatly from the pioneer companies' development of these blockbuster drugs like Zantac.

Many believe this debate is prompted by the patent status of one drug, Zantac. I do not know if that is true or not. It has certainly been a tremendously successful drug which has literally helped millions of people and would not have been developed if the logic of the other side had been adopted years ago.

One of the facts that has been obscured in this debate is that, ironically, this patent has never been extended. Let me give the facts on this drug. Keep in mind it takes up to 12 years, between $359 million and a half billion dollars to put a drug like Zantac through.

Here are the facts: the patent application for Zantac was submitted July 5, 1977. That patent was issued December 5, 1978 and an investigational new drug application was filed with FDA on December 3, 1979. On June 9, 1983, 3½ years after initial submission to FDA, more than 6 years after the patent application was made, the drug was approved.

Upon approval, this product only had an effective patent term of about 12.5 years on the day that FDA approved this product.

Now, the concern that the regulatory review period at FDA was eating substantially into the patents of new drugs was a major motivating force behind the Waxman-Hatch Act.

The Food, Drug and Cosmetic Act specifies that the drug review period is 180 days. But this, as in the case of Zantac, is virtually never met by the FDA. In fact, to the contrary, it takes years to get these drugs through, at a tremendous cost.

Only because Zantac was approved about a year earlier than the Hatch-Waxman law was passed, it was not eligible for the patent term extension part of the bill.

In other words, it was an unfortunate fact that it did not benefit from the Hatch-Waxman bill. Had Zantac been approved after Hatch-Waxman was enacted, it could have been qualified for patent extensions that this law calls for and provides.

So, Zantac, a loser under Hatch-Waxman because it could not qualify for the patent extensions that have been routinely granted as a matter of congressional policy since 1984, is now under sharp criticism for trying to take advantage of the same benefit that millions of patent holders were accorded under GATT.

Not only is this ironic, it does not strike me as fair, that a product with only 12.5 years of effective patent life, which expected to have 17 years upon FDA approval, is being castigated as somehow ''unfairly'' manipulating the patent system.

Even under the GATT transition rules, Zantac will receive much less than the 17-year patent life that it was supposed to receive.

Yet, here we face suggestions that it is greedy for a patent holder to want to take full advantage of its patent.

The proponents of the amendments are circulating talking points that state:

But the Waxman-Hatch amendments did a second thing: They gave brand companies a 5-year patent extension. In other words, Glaxo can receive up to 25 years of patent protection under current law. And now this company receives the GATT patent protection as well. It is trying to block the generic competition Congress calls for in the GATT treaty.

Now, let us just be honest about it.

That information has been sent out to people here in Congress as though it were true.

In fact, the statement is misleading in several ways.

First, let us be clear that Zantac, as a pre-Hatch-Waxman product, did not qualify for any of the benefits of Hatch-Waxman.

Second, to suggest that a company can receive up to 25 years of patent protection under current law is not only misleading, it is false.

It would seem to me that the normal patent term will have to be a period of something less than 20 years, unless you make the unlikely assumption that the Patent Office approves the patent on the day the application is submitted.

Also, since Hatch-Waxman time is only calculated after a patent issues, I do not see how you can ever reach 25 years, even hypothetically.

I would welcome an explanation of this 25-year period. I think every patent lawyer in the country would be just fascinated with it, if it could be given.

It is also the case that many believe the biotechnology patents are among those that might actually routinely lose time under the new 20-year-from-time-of-filing rule established by GATT.

This is because these products often present difficult, novel issues of patentability.

I cite with particularity that joint hearing between the two intellectual property committees of the House and Senate, where Lita Nelsen, Director of the Technology Licensing Office of the Massachusetts Institute of Technology, said:

The 20-year-from-filing change proposed in the current bill runs the risk of substantially reducing the patent protection available for companies investing in university technology.

She goes on to say:

Any shortening of patent life most seriously impacts the most forward-thinking technologies, which are the very types of technologies which universities should specialize in and which we believe will most benefit the country's future technical and economic development.

The 20-year-from-initial-filing rule currently being proposed offers a significant danger of shortening the time available for patent protection and therefore may have a detrimental effect on development of university technologies.

She also goes on to say:

Also, leading-edge technology patents, such as those in biotechnology, software and microelectronics usually take significantly longer than the so-called average patent to issue.

She concludes:

Finally, no one should be led to believe the 20-year-from-filing rule will lengthen effective patent life. Most of the time, for high technology patents, it will shorten the life and, more importantly, will shorten the remaining life of patent protection after the long development period is finally over and products are on the market.

The fact is this. Zantac has never had a patent extension until the GATT transition rules, because it did not—it simply did not—qualify under the Hatch-Waxman statute.

So, to indicate that it is going to reap the benefits of some sort of windfall is not only a misrepresentation, but it ignores several significant facts. It ignores all of the research costs which go into the pharmaceuticals we use. It ignores all of the incentives for research which must be a part of our intellectual property laws. It ignores all of the balancing we did in the 1984 law in order to accommodate the interests of these two great industries.

At the same time, it attacks our international agreements for which we fought so hard for decades, as reflected in the GATT agreement and Uruguay Round agreement. It does this in a way that sends a signal to all those countries that do not believe in patents or have difficulties with our position on patents that they do not have to honor it. It shows that the United States is not serious about this agreement either.

The fact of the matter is this: There are winners, there are losers in the Hatch-Waxman Act. There are winners and there are losers in GATT, and everybody knew it.

Now we have one industry that has been given special privileges, privileges that I personally have helped them to get, coming in and saying we want more special privileges and we want to amend the very act that benefited them and created their industry.

Frankly, I do not think that what specific company benefits and what company does not should be our focus here. Our focus should be on the right thing to do, which is to uphold GATT and vote down the Pryor amendment.

I reserve the remainder of our time.

The PRESIDING OFFICER. Who yields time?

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

The PRESIDING OFFICER. The time of the quorum would be charged to both sides equally? Without objection, it is so ordered.

The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

Mr. PRYOR. Madam President, may I inquire as to how many minutes I have left?

The PRESIDING OFFICER. The Senator has 5 minutes 43 seconds.

Mr. PRYOR. Thank you, Madam President.

Madam President, this debate is coming to conclusion at long last. We are about to make a tentative decision on this matter.

Let me say to my colleagues, Madam President, that somehow or another, sooner or later, we have to correct this problem. We have to close this loophole. If we fail to table the second-degree amendment, sometime or another I am going to be back. I want my colleagues to know that this is not the last they will hear of this amendment and this issue, because I think it is so absolutely atrocious that this could happen, is happening, and that we have yet not closed this loophole. Like MacArthur, Madam President, I shall return.

This has been a fascinating debate. It has lasted 2½ hours, about as long as a typical Senate hearing would last. And now, at the end, we see the facts have not changed. They have not changed at all. Those facts are as follows: the Congress made a mistake and we have a very rare opportunity to correct that mistake.

Let us look now at who is on the side who thinks that we made a mistake and who believes that we should rectify that mistake.

First, our U.S. Trade Representative, Mickey Kantor, said that Congress made a mistake, that it was never intended that these drug companies would be given this extra amount of unearned protection to market without any competition. The Food and Drug Administration said the Congress made a mistake. FDA tried to rectify the situation but they failed, and it is too bad that they did. Our U.S. Patent Office said that a mistake has been made by implication, and their decision was taken to court. Because of the technical aspects of the language, the Patent Office was overruled.

If we review the CONGRESSIONAL RECORD we will find that at no time during the debate on the issue of the GATT Treaty, leading to the adoption of the GATT Treaty, at no place do we find reference to this issue by anyone—not by any of the drafters or the debaters, nor by those opposed to or in favor of that treaty. At no time did anyone even hint that we were going to carve out a special exception for a few drug companies in order to give them extra monopolistic opportunities to compete unfairly in the marketplace, and to keep generic drugs from competing.

The State Medicaid directors, Madam President, have written in support of our efforts. They say that unless we correct this loophole, the Medicaid programs in each of the 50 States are going to continue to suffer and pay the highest price for these particular drugs, especially Zantac, and will be kept from buying generic drugs for the poorest of the poor population.

The elderly, the consumers—none will benefit from the efforts of the generic drug companies to reduce the cost of drugs like Zantac by as much as 50 percent or 60 percent. Yet, we may be about to vote and say that we are going to continue to give these enormous profits, these windfall profits, to a few pharmaceutical companies, and to take those profits, to give them those profits at the expense of taking those dollars from the consumer and the taxpayers of America.

This amendment that we are about to vote on is very simple. It is an attempt to kill our desire to close this loophole. That is what it is.

I respect my colleagues who offer it. I realize that some may believe that this particular issue is complex. But I must say, as my colleagues have said, that this is, in fact, a very simple issue. We have made a mistake. And now it is time to rectify it.

Madam President, I have frequently used the following analogy: You are walking down the street on the sidewalk, or wherever, and find a billfold, and you open that billfold up. And there is a $100 bill in there, and there is also the name of the owner. Do you take that billfold and the $100 to the owner? Do you try to find the lawful and rightful owner of that billfold that contains the $100, or, do you put it in your pocket?

In this case, these drug companies have found a billfold. It has a lot of money in it. Rather than returning it to the rightful owner—the taxpayer and the consumer, in this case—Madam President, they are taking that billfold, they are taking the money, and they are putting it right in their pocket.

I urge the defeat of the second-degree amendment.

Mr. HATCH. Madam President, if we want a cure for Alzheimer's, or for AIDS, or for so many other dreaded diseases, we had better not undercut the patent process.

We had better not undercut the GATT process.

If we want free and fair trade throughout this world, we had better make sure that we do not undercut something we fought to obtain for so many years.

If we want to keep America's medical research base premier among world nations, and continue to bring forth promising technologies which help our senior citizens and so many others, this body should vote down the Pryor amendment.

It would send our world trading partners the wrong message, and in the end put a huge dent in what is already a well-functioning system that benefits both the research company and the generic companies in a fair way.

That is what is involved here.

Let me just say one other thing.

I commit here and now that we will hold hearings on this should the amendment of the Senators from New Hampshire and Ohio pass.

We will hold hearings on this issue before the end of 120 days. I will commit to that as chairman of the Judiciary Committee, and I do not think anybody doubts in this body that I will not live up to that commitment, because I will.

I think that is the way we should handle it and I hope my colleagues will vote against the motion to table.

Mr. SMITH. Madam President, is there any time remaining?

The PRESIDING OFFICER. There are 29 seconds.

Mr. SMITH. Madam President, let me just say that no matter what the pros and cons are of this amendment it is irrelevant to the issue at hand. Regardless of how you feel about GATT or the patent protections, let us not load this historic bill up with this controversial unrelated amendment.

I urge my colleagues to vote ''no'' on the motion to table.

Mr. PRYOR. Madam President, I ask unanimous consent that Senator DASCHLE, Senator LEAHY, Senator BRYAN, and Senator FEINSTEIN be added as original cosponsors of my amendment.

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

Mr. PRYOR. Madam President, I move to table the pending amendment, the second-degree amendment, and I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. The question is on agreeing to the motion of the Senator from Arkansas to lay on the table the amendment of the Senator from Ohio. On this question, the yeas and nays have been ordered, and the clerk will call the roll.

The bill clerk called the roll.

Mr. SIMPSON (when his name was called). Present.

Mr. FORD. I announce that the Senator from New York [Mr. MOYNIHAN] is necessarily absent.

The result was announced—yeas 48, nays 49, as follows:

[Rollcall Vote No. 594 Leg.]

YEAS—48

Akaka	Exon	Levin
Baucus	Feingold	Lugar
Bingaman	Feinstein	McCain
Bond	Ford	Mikulski
Boxer	Glenn	Murray
Bradley	Graham	Nunn
Breaux	Hatfield	Pressler
Brown	Heflin	Pryor
Bryan	Inouye	Reid
Bumpers	Jeffords	Robb
Byrd	Kassebaum	Rockefeller
Chafee	Kennedy	Roth
Cohen	Kerrey	Sarbanes
Conrad	Kerry	Simon
Daschle	Kohl	Snowe
Dorgan	Leahy	Wellstone

NAYS—49

Abraham	Cochran	Domenici
Ashcroft	Coverdell	Faircloth
Bennett	Craig	Frist
Biden	D'Amato	Gorton
Burns	DeWine	Gramm
Campbell	Dodd	Grams
Coats	Dole	Grassley
Gregg	Lautenberg	Shelby
Harkin	Lieberman	Smith
Hatch	Lott	Specter
Helms	Mack	Stevens
Hollings	McConnell	Thomas
Hutchison	Moseley-Braun	Thompson
Inhofe	Murkowski	Thurmond
Johnston	Nickles	Warner
Kempthorne	Pell	
Kyl	Santorum	

ANSWERED ''PRESENT''—1

Simpson

NOT VOTING—1

Moynihan

So the motion to lay on the table the amendment (No. 3088) was rejected.

AMENDMENT NO. 3082 WITHDRAWN

Mr. PRYOR. Mr. President, if I may have just a few seconds, I know this was a very hard vote, a very close vote. I want to compliment those on the opposing side. They made a very, very strong argument, and they prevailed this evening. But I will make it possible for the Senate to revisit this issue in the very, very near future, Mr. President. I want to thank those who supported us, and at this time I withdraw my amendment.

AMENDMENT NO. 3085

The PRESIDING OFFICER (Mr. SANTORUM). The question recurs on the Brown amendment No. 3085.

Mr. BROWN. Mr. President, may we have order.

The PRESIDING OFFICER. The Senate will please come to order.

Mr. SMITH. Will the Senator yield for a unanimous-consent request?

Mr. BROWN. Yes.

UNANIMOUS-CONSENT AGREEMENT

Mr. SMITH. Mr. President, I have a unanimous-consent request here, and I think Members will be interested in hearing it.

Mr. President, I ask unanimous consent that following the disposition of the Pryor amendment, the following be the only amendments remaining in order and limited to the following time restraints: The Brown amendment No. 3085, 5 minutes equally divided; a Feinstein amendment, supporting current law, 35 minutes, 20 minutes under the control of Senator FEINSTEIN, 15 minutes under the control of Senator SMITH; a Brown limiting liability amendment, 15 minutes equally divided; a Smith affirmative defense amendment, 5 minutes equally divided.

I further ask that the votes be stacked to occur on or in relation to the above-listed amendments at the conclusion or yielding back of all time, and that prior to the votes, there be 4 minutes equally divided for closing remarks on the bill, with the votes occurring in the order in which they were debated, and following disposition of the amendments, the bill be advanced to third reading, and final passage occur, all without further action or debate.

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

Mr. SMITH. Mr. President, to recap for all Members, we expect two additional votes to occur within the next 40 minutes. That is the essence of it.

AMENDMENT NO. 3085

Mr. BROWN. Mr. President, the bill as it is now drafted creates a new cause of action and allows a variety of parties to bring suit against those who have been involved in the restricted prohibited abortion practice.

Among those allowed to bring suit is the father. Unfortunately, the bill does not now restrict which father can bring suit. Literally, someone who is the father of the fetus but has not acknowledged the child, has not married the woman, and has not supported the child in any way or any process can bring legal action and get a bonanza by suing the physician.

In my mind, to provide a financial benefit to someone who has fathered a child and not acknowledged it nor married the woman is a mistake. I don't think we ought to be about providing a new avenue of financial reward for a man who does not live up to his responsibilities.

The amendment is very simple. It restricts the fathers who can bring legal actions in this case to ones who have married the mother.

Mr. President, I think it is a pretty straightforward amendment. I yield the floor. I believe this has been cleared on both sides. I think a voice vote may well be appropriate.

Mr. SMITH. The Senator from Colorado is correct. As far as I know, there is no objection on this side, and I do not believe there are any objections on the other side.

Mrs. BOXER. Mr. President, that is right. I applaud the Senator for this amendment.

The PRESIDING OFFICER. The question is on agreeing to the amendment.

The amendment (No. 3085) was agreed to.

Mr. BROWN. I move to reconsider the vote.

Mr. SMITH. I move to table the motion.

The motion to lay on the table was agreed to.

AMENDMENT NO. 3090

(Purpose: To limit liability under this act to the physician performing the procedure involved)

Mr. BROWN. Mr. President, I rise to offer an amendment and ask for its immediate consideration

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Colorado [Mr. BROWN] proposes an amendment numbered 3090.

Mr. BROWN. Mr. President, I ask unanimous consent that reading of the amendment be dispensed with.

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

The amendment is as follows:

On page 2, line 6, strike ''Whoever'' and insert ''Any physician who''.

On page 2, line 10 strike ''As'' and insert ''(1) As''.

On page 2, between lines 13 and 14, insert the following:

''(2) As used in this section, the term 'physician' means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which the doctor performs such activity, or any other individual legally authorized by the State to perform abortions. *Provided, however,* That any individual who is not a physician or not otherwise legally authorized by the State to perform abortions, but who nevertheless directly performs a partial-birth abortion, shall be subject to the provisions of this section.

Mr. BROWN. Mr. President, this particular amendment was allowed 15 minutes equally divided. I do not intend to take a significant amount of time with it. I do want to make it clear to the Members what is involved.

The current bill makes liable or potentially liable not only for the attending physician in this case but also, in reading the language of the bill, the hospital where the procedure took place. Both could be subject to civil and criminal actions. Also included could be the nurses, as well other people called in to help with other medical procedures that may stem from the abortion procedure. In my mind, to have hospital administrators, to have hospital trustees, to have hospitals themselves, to have nurses, to have other medical personnel who may be called in to assist if something goes wrong, subject to possible prosecution and civil liability is a great mistake. This amendment limits the liability, and limits the people who can have actions brought against them to the physician or to someone who takes the place of the physician such as the person who directs the abortion procedure.

Specifically, we are trying to get at the person who performs the abortion itself. The whole purpose of this is to make sure that nurses and other attending personnel who are not the decisionmakers here are not subject to civil and criminal liability.

Mr. President, I believe the amendment is fairly clear. I believe it is cleared on both sides. My hope is at the appropriate time we could have a rollcall vote on it.

I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

Mr. BROWN. I yield the floor.

Mrs. BOXER. Mr. President, I want to say to my friend from Colorado I intend to support his amendment.

I believe it is tragic that we are about to criminalize a medical procedure which many doctors say is necessary to save the life of a woman or to protect her from serious adverse health consequences. I think it is tragic we are going to put doctors through this Kafkaesque expense of winding up in prison for saving the life of a woman.

However, what the Senator from Colorado is pointing out to us, as currently written, we might wind up putting other people in jail—other people associated with the hospital, other people who clearly should stay clear of this.

Although I believe the underlying bill is leading us down a terrible path where we are going to haul doctors into prison for saving a woman's life, I certainly believe what the Senator is doing to at least narrow it to the doctor is something we should support.

I will be supporting his amendment. I yield the floor.

Mr. SMITH. We have no objection to the Brown amendment.

The PRESIDING OFFICER. If there is no further debate on the amendment, the Chair would advise the Senator the yeas and nays have been ordered.

Mr. BROWN. Mr. President, I ask unanimous consent to vitiate the request for the yeas and nays.

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

The question is on agreeing to the amendment.

The amendment (No. 3090) was agreed to.

Mr. SMITH. I move to reconsider the vote.

Mrs. BOXER. I move to lay it on the table.

The motion to lay on the table was agreed to.

AMENDMENT NO. 3091

(Purpose: To strike the affirmative defense)

Mr. SMITH. Mr. President, I say to the Senator from California who is waiting to go on her amendment, briefly I will do the affirmative defense amendment and then be ready for her amendment.

I send an amendment to the desk and ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from New Hampshire [Mr. SMITH] proposes an amendment numbered 3091.

Mr. SMITH. I ask unanimous consent reading of the amendment be dispensed with.

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

The amendment is as follows:

On page 3, strike lines 8 through and including 16.

Mr. SMITH. Mr. President, in view of the fact that the Senate adopted the life-of-the-mother exception amendment, the affirmative defense section of the bill is no longer necessary and I had agreed that we would remove that provision, providing the life-of-the-mother exception prevailed.

Since it did prevail, this amendment would strike the entire subsection E of the bill which talks about the affirmative defense to a prosecution or a civil action.

So, it is my understanding that the Senator from California agrees with this amendment, so unless the Senator wishes to speak, I urge its adoption.

The PRESIDING OFFICER. The question is on agreeing to the amendment.

The amendment (No. 3091) was agreed to.

Mr. SMITH. I move to reconsider the vote.

Mrs. BOXER. I move to lay it on the table.

The motion to lay on the table was agreed to.

AMENDMENT NO. 3092

(Purpose: To provide for a substitute amendment)

Mrs. FEINSTEIN. Mr. President, I send an amendment to the desk for Senator SIMPSON and myself and ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from California [Mrs. FEINSTEIN], for herself, Mr. SIMPSON, Mrs. BOXER, Mr. SIMON, and Ms. MOSELEY-BRAUN, proposes an amendment numbered 3092.

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SENSE OF THE SENATE.

(a) FINDINGS.—The Senate finds that—

(1) the United States has the most advanced medical training programs in the world;

(2) medical decisions should be made by trained medical personnel in consultation with their patients based on the best medical science available;

(3) it is the role of professional medical societies to develop medical practice guidelines and it is the role of medical education centers to provide instruction on medical procedures;

(4) the Federal Government should not supersede the medical judgment of trained medical professionals or limit the judgment of medical professionals in determining medically appropriate procedures;

(5) the Federal criminal code is an inappropriate and dangerous means by which to regulate specific and highly technical medical procedures; and

(6) the laws of 41 States currently restrict post-viability abortions.

(b) SENSE OF SENATE.—It is the sense of the Senate that Congress should not criminalize a specific medical procedure.

SEC. 2. RULE OF CONSTRUCTION.

Nothing in Federal law shall be construed to prohibit the States, local governments, local health departments, medical societies, or hospital ethical boards from regulating, restricting, or prohibiting post-viability abortions to the extent permitted by the Constitution of the United States.

The PRESIDING OFFICER. The Senator from California is recognized for 20 minutes. The Senator from New Hampshire is recognized for 15 minutes.

Mrs. FEINSTEIN. Mr. President, I want to make clear that this amendment is presented as a substitute.

I am pleased it was read because it makes clear the following: First, that it is the sense of the Senate that Congress should not criminalize a medical procedure.

Second, that nothing in Federal law should be construed to prohibit the States, local governments, local health departments, medical societies, or hospital ethical boards from regulating, restricting, or prohibiting postviability abortions to the extent permitted by the U.S. Constitution.

The U.S. Congress is not the appropriate place to be making decisions about medical procedures, whatever they are. The bill before us would criminalize one procedure, a procedure that does not appear in medical literature, a procedure that is worded vaguely.

All I ask is that the Members of this body read the actual legislation. Many Members who have spoken in favor of the legislation point to the use of scissors, the cutting of tissue, the draining of fluid from the brain. Nowhere does the legislation itself specifically refer to that kind of procedure. In its very vagueness, it affects more than one procedure and it can affect more than postviability abortions.

So, my point is twofold. One, that this body is not the appropriate place to be making medical decisions and that, two, under current Federal law, States can choose to regulate, restrict, or prohibit postviability abortions as 41 do now.

When physicians make a decision to use a particular treatment, they very thoroughly evaluate a number of factors: evidence from scientific literature, the risks and benefits for the patient—for example, possible side effects—future health, quality of life, the efficacy of the treatment—what the outcome will be—the safety of the treatment, the patient's preferences. These are often complicated decisions, representing a systematic strategy developing from multiple decisional building blocks. Medical decisionmaking is not simple and these are not decisions we should or can make.

We should also understand that medical decisionmaking is individualized. Every case is different. Every human body is different. Every patient brings a unique medical history into the doctor's office. Physicians have to evaluate every situation as it presents itself and often at the last minute.

The risks of a particular procedure depend, often, on the patient. For example, a hip replacement that restores function in one patient can be life-threatening to another, for example, to one who has heart disease. Medical science and treatments are constantly evolving. Medicine is becoming increasingly specialized. Technology is advancing. Today's standard of practice can be out of date in 5 years. The human body will always have some degree of mystery, as science stretches to understand how the body works and does not work. Congress cannot keep up with these changes. That is not our job.

Mr. President, physicians go to college for 4 years, to medical school for 4 years, to residency training for 3 to 6 years. In some States, to keep their licenses current, they are required to undergo continuing education annually. They get extensive training. Medical decisionmaking, I believe, is a job for trained physicians.

AN EXAMPLE OF DECISIONMAKING: MEDICAL PRACTICE GUIDELINES

For almost 60 years, the medical profession in this country has been developing medical practice guidelines. According to the Institute of Medicine, clinical practice guidelines are ''systematically developed statement to assist practitioner and patient decisions about appropriate health care for a specific clinical circumstances.'' They are guidelines—guidance—not enforceable rules. There are over 24,000 developed by over 75 organizations.

Medical practice guidelines are designed to improve patient outcomes. They help medical practitioners and patients make decisions about prevention, diagnosis and treatment of specific clinical conditions. For example, guidelines have been developed for the treatment of benign prostatic hyperplasia, pressure ulcers, and stroke rehabilitation.

Developing practice guidelines is a complicated process. To develop a guideline, panels of experts are convened. They review all available literature, all available evidence of patient outcomes, a review that can take up to 9 months. They are subjected to peer review for scientific validity and pilot testing. Development of one guideline can take from 1½ to 3½ years.

The point here is that there is an orderly, scientific, deliberative, professional, and balanced approach for making medical decisions. It is complicated. It is based on the patient's best interest.

Medical decisionmaking is not and should not be a legislative or political process.

UNPRECEDENTED

Congress has legislated medical benefits, reimbursement policies, quality standards, training requirements. But Congress has never banned or criminalized a specific medical procedure. This is the first time Congress has tried to outlaw a medical procedure.

My amendment is quite simple. It says, in essence, that Congress should not be making medical decisions and that States can regulate post-viability abortions.

I can go on, but in the interest of time, and giving my cosponsors the opportunity to speak, I want to just say one other thing. I have followed this debate very carefully. I want particularly to commend my friend and colleague, the junior Senator from California. I think she has been quite eloquent in defining what this procedure is, and what this procedure is not, the enormous vagueness of the bill and the human tragedies involved.

Post-viability abortions can be banned by every State and 41 have chosen to do so. This legislation is not necessary. This legislation puts the Congress in the position of deciding medical procedures, and I do not believe we can or should do this. This substitute amendment clearly states what I believe is right.

Mr. President, I yield 10 minutes to the Senator from Wyoming.

The PRESIDING OFFICER. The Senator from Wyoming is recognized for 10 minutes.

Mr. SIMPSON. Mr. President, I rise in support of the Feinstein substitute

which is a reiteration of current law. Under the substitute, nothing in Federal law shall be construed to prohibit the States, local governments, local health departments, and medical societies from regulating, restricting, or prohibiting post-viability abortions to the extent permitted by the Constitution. Let me say it again, this is current law and this substitute explicitly states what the law of the land is. Under Roe versus Wade, States may proscribe post-viable abortions except when it is necessary to preserve the life or health of the mother—41 States currently regulate post-viable abortions. We do not need H.R. 1833 because we already have current laws which address the central issue of the pending legislation.

I have been pro-choice throughout my entire public life, never wavered, never waited to take a poll, ever since that first wrenching debate in the Wyoming State Legislature because our law was the same as Missouri's, which was struck down by Roe versus Wade. And so we had to change it, and we did, and I shall never forget the debate. Abortion is such a deeply personal and, to some, a spiritual issue. It is not one that belongs in the public domain. That is my view. It is not one that should be in a legislative body, to me, as a man—not a legislator, but a man, I cannot presume to limit the options of any woman who is anguishing over a crisis pregnancy. That is what I have always believed, and what I have always tried to state so clearly. And as a man, I do not think a man should even vote on this issue. That is how I feel about this.

I do not advocate or promote abortion. It is obviously one of the most difficult choices or options that any woman should ever, ever make. I really do not know many folks who advocate or promote abortion, nor does anybody else in this land. That is not what people do—promote abortion. It is an alternative. It is an option. It is obviously one of the most difficult choices or options that any man or women—sometimes men must make—buy principally the woman. I have always supported alternatives to abortion—and think it is so very important to assure a pregnant woman that there are many alternatives to abortion and that there are many fine support systems available for those who may choose any of the alternatives. And yes, yes, abstinence is still the best, and Who would disagree with that? But that is not what we are talking about.

And I respect and am acutely conscious of the fact that many persons who grapple with the issue of abortion do so from very different moral or religious or philosophical differences, and I do not spend any part of my life trying to inflict—and that is the word I want to use—inflict my personal views on others. I see that happening here. Not with the Senator from New Hampshire, a lovely friend, but from others, especially in the hallways, who do it with steely-eyed zealotry that I tire of.

My respect for this very real facet of the human condition has led me to the conclusion that abortion presents a deeply personal decision for any woman—decisions which should not and realistically could not be prescribed or directed through the legislative process in any way.

We in the Senate should never be criminalizing a specific medical procedure. That is what the substitute states.

So here we are overstepping court cases. There is a strong absence of Government interest in this legislation. It is not here. It purports to prohibit abortions using a particular procedure, and then says abortions will be performed only in a particular manner. There is no reasonable Government interest served by forcing a patient to undergo one type of abortion instead of another, especially if the prohibited procedure is safer for the health of the woman.

We in this Congress should not be legislating in this area. This is overreaching in every sense. Under this bill, it would remain legal. Get this—somebody has to really explain this to me. It would remain legal for a woman to obtain this procedure only if she did not cross State lines. This seems to me too clever by half. I thought this was the most horrendous, searing, murderous, vicious procedure that we have seen in modern times, and yet you are going to be able to do it in your own backyard, in your own State. That is absurd.

Now we have a new Federal court case, the Lopez decision. That is how they got clever by half on this one.

This bill also uses a term I have never before seen in the statute, and I have been doing this for 30 years. Anyone who knowingly performs a partial-birth abortion ''and thereby kills a human fetus.'' That is what it says. ''Abortion is thereby killing.'' On line 15 of the bill, the language reads, ''partially vaginally delivers a living fetus before killing the fetus.'' I have never seen that in my life in a statute. Where did it come from? It is a manifestation of a manipulative group trying to desperately knock off Roe v. Wade. That is what it is. It is exceptionally unclear about the precise nature of the procedure. Six doctors testified they never heard of the procedure before.

I sat and listened to that. I have seen all of the pictures before. We are going to have all of them—one-eyed children, brains on the outside, compressed skulls. I have seen it all. I have seen the whole works, always with the eternal difficulty of imposing restrictions on a decision which must be made from one's only very unique position, and principally by a woman, from one's own culture, one's own history, and one's own deep personal and spiritual viewpoint.

All through the years I have had the accolades sometimes of being called a baby killer. I really do not appreciate that. I handle it very well now. I just say, I do not have to take that guff from you. So I have been there.

In my fine State of Wyoming—and I am going to conclude my remarks within my limit—listen to what we have to do in this. It should not be partisan. And in our State, the Wyoming Republican Party passed a platform plank in 1994 at its State convention that said this: ''The Wyoming Republican Party welcomes individuals on each side of the abortion issue, encourages their open discussion, solicits their active participation in the party, and respects their positions and beliefs.''

Then, do you know what we did? We did a resolution because we had a November resolution on the ballot which was soundly rejected. Here is what it said: ''The Republican Party believes that Republicans are people of principle on each side of the abortion issue who firmly and intractably hold their beliefs; by establishing a party position, we recognize that a resolution will never change these beliefs, but it will serve to divide the party on other issues, and we urge all Republicans to firmly debate these beliefs.''

That passed unanimously by voice vote. We ought to do more of that in America. And men, in my mind, should never be in this intensely intimate personal struggle for a woman.

I urge my colleagues to vote in favor of the substitute.

Mr. JEFFORDS. Mr. President, I rise today in support of the amendment expressing the sense of the Senate that the Congress should not criminalize a specific medical procedure, and that the States should not be prohibited from regulating or restricting postviability abortions to the extent that the Constitution permits them to do so. I also want to state again my firm belief in the wisdom of the Supreme Court decision Roe versus Wade, which held that under the constitutional right to privacy, a woman has a right of self-determination with regard to her pregnancy and reproductive health.

In November I spoke in support of referring this bill to the Judiciary Committee for a hearing, and I'd like to thank my colleagues for joining me to support the passage of that motion. I think we learned a great deal from the hearing. One of the things that struck me was that the term ''partial birth'' is not a term that is clearly defined in the medical profession. This bill purports to be a very narrow measure that outlaws only one alternative to a woman who learns late in her pregnancy that it is not possible for her to carry her child to term. But we've learned that there is not a medical procedure known as a partial birth abortion. I suppose you can argue that those of us on this side of the issue shouldn't have a problem criminalizing a procedure that doesn't really exist. My response to that argument is predictable: why bother to criminalize a procedure that doesn't really exist?

Moreover, rules of statutory interpretation will demand that the courts find some meaning in this law, because Congress is assumed to do nothing in vain. Somehow, the courts will have to put some definition on the term ''partial birth abortion,'' even though a clear understanding of what we're outlawing has eluded many of us.

I'd like to quote briefly Dr. J. Courtland Robinson, who spoke at the hearing a couple of weeks ago and highlighted this point:

I have to wonder what you are really trying to ban with this legislation. It sounds as if you are trying to leave any later abortions open to question.

Dr. Robinson continues:

I know that a number of physicians who have performed abortions for years, who are experts in the field, look at this legislation and do not understand what you mean or what you are trying to accomplish. It seems as if this vagueness is intentional, and I, as a physician, cannot countenance a vague law that may or may not cut off an appropriate surgical option for my patients. Sometimes, as any doctor will tell you, you begin a surgical procedure expecting it to go one way, only to discover that the unique demands of the case require that you do something different.

Dr. Robinson highlights a point I've made many times before. We can't adequately define the procedure we mean to outlaw because we're not doctors. I share Dr. Robinson's fear that because this law is so vague and because we are denying doctors the ability to use their best medical judgment, physicians will be deterred from performing any late term abortion procedure. Late term abortions will be unavailable and women will die.

This is an unprecedented intrusion into the practice of medicine. In my view decency and common sense would require us to recognize that it is not the job of the Congress to come between physicians and their patients.

I also want to speak briefly in support of section two of Senator FEINSTEIN's amendment. I think her amendment is entirely consistent with the thinking in much of the legislation we have debated recently. On a number of matters we are choosing to leave regulation to the States; indeed, we are deregulating at the Federal level so that we may leave the States the flexibility to enact their own laws on welfare, Medicaid, and so forth. I must admit that it seems strange to me that in this area alone we are undertaking Federal regulation where there has been none. In doing so we are taking away from the States the right to legislate on this issue as they see necessary. In fact, we know that 41 of the States already have laws regulating access to post-viability abortions.

I have expressed before my support for the enduring wisdom of Roe versus Wade decision. I think Senator FEINSTEIN's amendment is consistent with that decision. In Roe, the Court found that under the constitutional right to privacy, a woman has the right to make her own decisions where her pregnancy and reproductive health are concerned—especially, the Court said, ''when her right to life is threatened.'' The bill we are now considering is a direct challenge to that historic decision's protection of a woman's life and health. Concern about a woman's life has been abandoned in the partial birth abortion legislation we've been discussing, but Roe versus Wade requires that even where a state chooses to outlaw post-viability abortions, it may not under any circumstances outlaw abortions necessary to preserve the life or health of the mother.

I will say again that I believe doctors must be able to put the welfare of their patients first. Doctors should be able to use whatever procedure will, in their professional judgment, be safest for the mothers, their patients. Toward this goal, I wholeheartedly support the sense-of-the-Senate amendment that Congress should not criminalize a specific medical procedure, and the rule of Construction permitting the States to regulate post-viability abortions to the extent permitted by the Constitution.

The PRESIDING OFFICER. Who yields time?

Mrs. FEINSTEIN. Mr. President, how much time remains?

The PRESIDING OFFICER. Six minutes and thirty seconds.

Mrs. FEINSTEIN. Mr. President, I ask unanimous consent that the following be added as cosponsors: Senator BOXER, Senator SIMON, Senator MOSELEY-BRAUN, and Senator BRYAN.

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

Mrs. FEINSTEIN. I yield the remainder of my time to the junior Senator from Illinois.

The PRESIDING OFFICER. The Senator from Illinois.

Ms. MOSELEY-BRAUN. Thank you, Mr. President. I will be brief.

I want to thank the Senator from California for the amendment, and I am delighted to be a cosponsor of it.

Mr. President, this bill represents the first time, to my knowledge, that the Congress has attempted to tell a doctor that he or she cannot perform a specific medical procedure.

Let us be clear about what Congress is proposing to do with this legislation. We are proposing to criminalize a medical procedure against the recommendation of this Nation's OB-GYN's and against the recommendation of this Nation's 2.2 million registered nurses.

This bill arbitrarily prohibits one type of procedure even when the procedure best protects the life and health and fertility of a woman, a citizen of this country. If a woman has a late-term abortion, her decision relies on the best medical advice of the doctor, advice based on years of medical training and service.

None of us, or few of us in this body, have spent years studying and practicing medicine. How many of the Members of this body are physicians? We have only one doctor serving in the Senate, and he is not an OB-GYN. Are we qualified to make a medical judgment—a medical recommendation—that could leave a woman sterile, or severely ill, or, worse yet, dead? I think not.

I know, frankly, that if I were ill, or the Presiding Officer were ill, his family would take him to a doctor, not to another Senator, unless, of course, that Senator was a doctor, and there is only one of those.

The fact of the matter is that this is a medical decision, and the decision here that a woman makes regarding her pregnancy should be made with her family in consultation with her doctor and, of course, her faith.

Yesterday, I talked about this as an issue of fundamental liberty for female citizens. Let me submit to you that it is not only a matter of a woman's liberty and right to control her own body that is at stake with this legislation; it is also a doctor's right to treat—to treat his patient, and to treat his patient under very difficult circumstances indeed.

It seems to me that as we dabble around we are in the process of limiting the liberties of the unborn that have been spoken of will be born to. I think, Mr. President, that is a grievous error for which we will all have great regret.

I thank the Senator from California. The good news about this amendment is that it can improve what is a bad bill. The bad news about it, or maybe the good news about it, is hopefully medical science will overcome this situation. But, quite frankly, for the present we should not be dabbling where we have no knowledge, where we have no expertise, and in a way that will injure and jeopardize the health, safety, and indeed even the lives of millions of American women.

Thank you. I yield the floor.

Mr. President, I do not know if this letter has been made a part of the RECORD. I ask unanimous consent that it be printed in the RECORD. It is a letter dated November 6 from the American College of Obstetricians and Gynecologists in opposition to this legislation.

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

THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS,
Washington, DC, November 6, 1995.

Hon. ROBERT DOLE,
Majority Leader, The Capitol,
Washington, DC.

DEAR MAJORITY LEADER DOLE: The American College of Obstetricians and Gynecologists (ACOG), an organization representing more than 35,000 physicians dedicated to improving women's health care, does not support H.R. 1833, the Partial-Birth Abortion Ban Act of 1995. The College finds very disturbing that Congress would take any action that would supersede the medical judgment of trained physicians and criminalize medical procedures that may be necessary to save the life of a woman. Moreover, in defining what medical procedures doctors may or may not perform, H.R. 1833 employs terminology that is not even recognized in the

medical community—demonstrating why Congressional opinion should never be substituted for professional medical judgment.

Thank you for considering our views on this important matter.

Sincerely,

RALPH W. HALE, MD,
Executive Director.

Mr. SMITH. Mr. President, so we all understand, the Feinstein substitute amendment is the killer amendment. It simply guts the bill. The earlier amendment was the Boxer amendment, which was defeated.

This amendment, no less than the Boxer amendment before it a short while ago, is the partial-birth abortion-on-demand amendment. And this amendment would totally eliminate the Partial-Birth Abortion Ban Act.

So if you support the bill, and you voted no on the Boxer amendment, you should vote no on the Feinstein amendment because it would replace the bill with current law. Current law is partial-birth abortion on demand—I might add, through all 9 months of pregnancy for whatever reason.

In other words, Mr. President, if you want to go back on what you voted for, what you support, the partial-birth abortion ban, then you would have to vote for Feinstein.

In essence and in conclusion, this is a gutting amendment. It goes back to current law. It just eliminates the entire bill.

For that reason, obviously, we oppose it, and I encourage all of those who voted no on Boxer who want the partial-birth abortion ban as described in our legislation to vote no on the Feinstein amendment.

At this point, unless my colleagues would like some of my time—I would be happy to yield it—I have no further desire for time.

Mrs. FEINSTEIN. I thank the Senator. I yield the time.

Mr. SMITH. I yield back the remainder of my time.

The PRESIDING OFFICER. The Senator yields back the remainder of his time.

The question is on agreeing to the amendment.

Mrs. FEINSTEIN. Mr. President, I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

Mr. SMITH. Mr. President, I would just ask unanimous consent that Senator BROWN and I be allowed to do a brief colloquy on a matter that I neglected to mention and then we will vote.

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

Mr. BROWN addressed the Chair.

The PRESIDING OFFICER. The Senator from Colorado.

Mr. BROWN. Mr. President, this bill would expose physicians to criminal and civil liability for performing a partial-birth abortion, and I believe it is critical that we be very clear as to what is covered by the bill. The bill defines a ''partial-birth abortion'' as ''an abortion in which the person performing the abortion partially vaginally delivers a living fetus before killing the fetus and completing the delivery.''

It is my understanding that ''partially vaginally delivers'' means the person performing the abortion actively removes a portion of the fetus from the uterus, through the cervyx and into the birth canal. And I would ask the manager if this is his understanding as well?

Mr. SMITH. The Senator from Colorado is correct. ''Partially vaginally delivers'' means the physician delivers part of the baby through the cervyx and into the birth canal.

Mr. BROWN. At the Judiciary Committee hearing, Dr. Robinson, of the Johns Hopkins University, mentioned that it is possible for a portion of the fetus, such as a hand or foot, to slip accidentally through the cervyx and into the birth canal without active removal by the physician. I assume the manager does not intend to include those cases in the definition of partial-birth abortion. Am I correct?

Mr. SMITH. The Senator from Colorado is correct. This bill would only cover those circumstances where someone intentionally delivers part of a living baby through the cervyx and into the birth canal.

Mr. BROWN. The definition also states that it only applies to ''partial vaginal delivery of a living fetus.'' In other words, if the fetus had died before being partially removed from the uterus, this measure would not prohibit a physician from safely removing the dead fetus from the mother. Is that correct?

Mr. SMITH. The Senator is correct. That is correct.

Mr. BROWN. Finally, Mr. President, it is my understanding this bill applies only to those who knowingly perform a partial-birth abortion. In other words, a physician must intentionally partially deliver a living fetus and then deliberately kill the fetus to be subject to criminal or civil liability. For example, under this bill, if a doctor fully intends to deliver a living baby but due to an accident during delivery the fetus dies, the doctor would not be subject to criminal or civil liability. Is that correct?

Mr. SMITH. The Senator is correct.

Mr. BROWN. I thank the Senator for his time and particularly for what I think will be a helpful colloquy in being very specific as to what the words and terms used in the bill mean.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The question is on agreeing to amendment No. 3092 offered by the Senator from California. The yeas and nays have been ordered. The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. LOTT. I announce that the Senator from Alabama [Mr. SHELBY] is necessarily absent.

Mr. FORD. I announce that the Senator from New York [Mr. MOYNIHAN] is necessarily absent.

The PRESIDING OFFICER (Mrs. HUTCHISON). Are there any other Senators in the Chamber who desire to vote?

The result was announced—yeas 44, nays 53, as follows:

[Rollcall Vote No. 595 Leg.]

YEAS—44

Akaka	Glenn	Mikulski
Baucus	Graham	Moseley-Braun
Bingaman	Harkin	Murray
Boxer	Hollings	Nunn
Bradley	Inouye	Pell
Bryan	Jeffords	Pryor
Bumpers	Kassebaum	Robb
Byrd	Kennedy	Rockefeller
Campbell	Kerrey	Sarbanes
Chafee	Kerry	Simon
Cohen	Kohl	Simpson
Daschle	Lautenberg	Snowe
Dodd	Leahy	Specter
Feingold	Levin	Wellstone
Feinstein	Lieberman	

NAYS—53

Abraham	Exon	Lott
Ashcroft	Faircloth	Lugar
Bennett	Ford	Mack
Biden	Frist	McCain
Bond	Gorton	McConnell
Breaux	Gramm	Murkowski
Brown	Grams	Nickles
Burns	Grassley	Pressler
Coats	Gregg	Reid
Cochran	Hatch	Roth
Conrad	Hatfield	Santorum
Coverdell	Heflin	Smith
Craig	Helms	Stevens
D'Amato	Hutchison	Thomas
DeWine	Inhofe	Thompson
Dole	Johnston	Thurmond
Domenici	Kempthorne	Warner
Dorgan	Kyl	

NOT VOTING—2

Moynihan	Shelby

So the amendment (No. 3092) was rejected.

Mr. SMITH. Madam President, I move to reconsider the vote.

Mr. GRAMM. I move to table the motion.

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. The question is on the engrossment of the amendments and third reading of the bill.

The amendments were ordered to be engrossed, and the bill to be read a third time.

The bill was read a third time.

Mr. DOLE. I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. We now have 4 minutes of debate equally divided.

Mrs. BOXER. Madam President, I ask my colleagues if they could give me their attention for 2 minutes of what has been a very difficult debate. Just for 2 minutes.

I ask you to vote ''no'' on the final passage of this radical bill. It outlaws an emergency medical procedure which doctors have testified is used to save the life of a woman or to avert serious adverse health consequences.

A woman like this, Coreen Costello, who asks us to put aside our party affiliation and remember her. Despite

the other side saying she did not have the procedure outlawed in this bill, she did. She wrote us and told us that today and she testified that she did.

My colleagues, I am down to the last 60 seconds. This is what Coreen Costello said. Please listen:

When families like ours are given this kind of tragic news the last people we want to seek advice from are politicians. We talk to our doctors, lots of doctors. We talk to our families and other loved ones, and we ponder long and hard into the night with our God.

Coreen asks us to vote against this bill.

It will deny women a life saving and health saving option in a tragic emergency situation. You would not do it to your own wife. You would not do it to your own daughter. I ask you, please, do not do it to America's wives and to America's daughters.

There is no true life exception. It was a partial exception. It was different than the normal Hyde language. So this is indeed a radical proposal. Please vote ''no'' on final passage. President Clinton will veto this bill.

The PRESIDING OFFICER. The Senator from New Hampshire is recognized for 2 minutes.

Mr. SMITH. Madam President, the House of Representatives recently voted overwhelming by a two-thirds majority to ban partial-birth abortion. The vote on the ban was 288–139.

This is not a radical extreme bill. It was supported by liberal Democrats such as PATRICK KENNEDY; liberal Republicans, moderate Republicans, such as SUSAN MOLINARI; pro-choice, prolife. It is not a radical bill. RICH GEPHARDT supported it and others.

We have added a life-of-the-mother exception which was requested by some of my colleagues on both sides of the aisle. We did that. I hope we can get a similar, bipartisan overwhelming majority here in the Senate like we had in the House to stop what I believe is a very cruel practice.

Let me conclude on this point, because Senator BOXER and I have been debating this on and off for several days now. The photograph that is being displayed here is of a woman who went through a terrible ordeal. We all know that. We have great sympathy for what she went through. But she did not have the partial-birth abortion. She did not have a partial-birth abortion. This would not have stopped the procedure that Coreen Costello had.

I urge my colleagues to vote for final passage. I yield the floor.

The PRESIDING OFFICER. All time has expired.

The bill having been read the third time, the question is, Shall the bill pass?

The yeas and nays have been ordered.

The clerk will call the roll.

The legislative clerk called the roll.

Mr. FORD. I announce that the Senator from New York [Mr. MOYNIHAN] is necessarily absent.

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 54, nays 44, as follows:

[Rollcall Vote No. 596 Leg.]

YEAS—54

Abraham	Exon	Lott
Ashcroft	Faircloth	Lugar
Bennett	Ford	Mack
Biden	Frist	McCain
Bond	Gorton	McConnell
Breaux	Gramm	Murkowski
Brown	Grams	Nickles
Burns	Grassley	Pressler
Coats	Gregg	Reid
Cochran	Hatch	Roth
Conrad	Hatfield	Santorum
Coverdell	Heflin	Shelby
Craig	Helms	Smith
D'Amato	Hutchison	Stevens
DeWine	Inhofe	Thomas
Dole	Johnston	Thompson
Domenici	Kempthorne	Thurmond
Dorgan	Kyl	Warner

NAYS—44

Akaka	Glenn	Mikulski
Baucus	Graham	Moseley-Braun
Bingaman	Harkin	Murray
Boxer	Hollings	Nunn
Bradley	Inouye	Pell
Bryan	Jeffords	Pryor
Bumpers	Kassebaum	Robb
Byrd	Kennedy	Rockefeller
Campbell	Kerrey	Sarbanes
Chafee	Kerry	Simon
Cohen	Kohl	Simpson
Daschle	Lautenberg	Snowe
Dodd	Leahy	Specter
Feingold	Levin	Wellstone
Feinstein	Lieberman	

NOT VOTING—1

Moynihan

So the bill (H.R. 1833), as amended, was passed.

Mr. SMITH. Madam President, I move to reconsider the vote by which the bill was passed.

Mr. FORD. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. BINGAMAN addressed the Chair.

The PRESIDING OFFICER. The Senator from New Mexico.

ORDER OF PROCEDURE

Mr. BINGAMAN. Madam President, I wish to state a couple of questions and ask for the majority leader's response, if I could, at this time.

Madam President, I know that there has been an agreement worked out with regard to the voting on the nominations and on the START II Treaty. I know that yesterday we had another discussion on the Senate floor, and the majority leader referred to his intention to, also in addition to the nominations for ambassadors, clear the rest of the items on the Executive Calendar before we left.

I just wanted to once again ask for his assurance that that is his desire and his intention before we adjourn this fall.

Mr. DOLE. Madam President, if the Senator will yield, I will just say, as I did yesterday, that it is certainly my hope that we can clear everything on the Executive Calendar before we leave this year.

I cannot give a 100 percent guarantee. Somebody might have a hard hold on something. They may not be able to get it up, and we might not be able to get cloture. But my view is we ought to accommodate where we can the executive branch, and I have always tried to do that.

Mr. BINGAMAN. I appreciate that very much. I certainly agree that that is an important thing to do.

The other issue I wanted to clarify is that the agreement calls for us to proceed to consider START II before we go out of session this year. Yesterday, again the majority leader said that it was his intent that we complete action on START II. I think it is very important that we do that.

Again, I would just ask if it is his view that we can go ahead and get that treaty voted on and sent on before we go off on the holidays.

Mr. DOLE. Again, let me indicate that I hope to take it up before Christmas. I would like to complete action before Christmas. If not, we will do it as quickly as we can when we are back here.

But I think we need to take a look at the calendar. A week from today will be the 15th. One week later is the 22d. Next week we have this State Department reorganization, Bosnia, and rangeland reform. Again, it is a question of whether we can do it.

I am advised by the distinguished chairman of the Foreign Relations Committee that he does not know of any amendments to the START II Treaty. There may be amendments. But it may not take more than a couple of hours.

So, certainly, I would like to dispose of it before we leave from here this year. We will make every effort to do so.

Mr. BINGAMAN. Madam President, let me just say that I appreciate the fact that we do have an agreement in this unanimous-consent agreement to bring it up before we conclude the session and move to the consideration of it.

I am encouraged by the statement and by the indication of the Senator from North Carolina, the chairman of the Foreign Relations Committee, that he thinks we can move to it very expeditiously.

I appreciate the majority leader's very good work on the issues. I appreciate the Senator from North Carolina, and I also, of course, appreciate the Senator from Massachusetts, who I know has worked very hard to get this agreement and, of course, the Democratic leader as well.

So thank you all.

I no longer object to proceeding on the flag amendment. I know the majority leader intends to do that tomorrow.

I have no objection.

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Mr. DOLE. If there is not, I ask at this time then that the cloture vote scheduled for Friday be vitiated, and I