United States of America

Congressional Record

PROCEEDINGS AND DEBATES OF THE 105th CONGRESS, FIRST SESSION

Vol. 143 WASHINGTON, FRIDAY, SEPTEMBER 19, 1997 No. 126

House of Representatives

The House was not in session today. Its next meeting will be held on Monday, September 22, 1997, at 12 noon.

Senate

FRIDAY, SEPTEMBER 19, 1997

The Senate met at 9:30 a.m. and was called to order by the President pro tempore [Mr. THURMOND].

PRAYER

The Chaplain, Dr. Lloyd John Ogilvie, offered the following prayer:

Gracious God, it is startling to realize that there are over 6,000 people who work together to keep this Senate moving forward effectively. We thank You for the chiefs of staff, the schedulers, the legislative assistants, the secretaries, the media liaisons, the State staffs, and the interns who work in the Senators' offices. We thank You for the officers of the Senate, the Senate committee staffs, the security force, the custodians, and waiters and waitresses. Wherever we turn there are people employed to assist 100 men and women do their work of leading our Nation with excellence. Help us to take no one for granted. May this be a day in which we say, ''I appreciate you; thanks for what you do!'' to the people who work for us and those with whom we work. We are grateful for the gift of each person. In the name of our Lord and Saviour. Amen.

RECOGNITION OF THE ACTING MAJORITY LEADER

The PRESIDENT pro tempore. The able acting majority leader.

SCHEDULE

Mr. JEFFORDS. Mr. President, I announce on behalf of the majority leader that today the Senate will resume consideration of S. 830, the FDA reform bill, with Senator KENNEDY being recognized until the hour of 10:30 a.m. for debate only. Under the previous consent, at 10:30 a.m. Senator DURBIN will be recognized to debate his two amendments. Further, at 12 noon the Senate will proceed to a period of morning business, with Senator COVERDELL or his designee being recognized for 90 minutes from 12 noon until 1:30 p.m., and Senator DASCHLE, or his designee being recognized for 90 minutes, from 1:30 p.m. to 3 p.m.

As previously announced, there will be no rollcall votes during today's session of the Senate. Also as announced, the next rollcall votes will occur on Tuesday, September 23, at 9:30 a.m., on Senator DURBIN's amendments to S. 830, the FDA reform bill.

I thank my colleagues for their attention.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The PRESIDING OFFICER (Mr. SESSIONS). The clerk will report S. 830.

The assistant legislative clerk read as follows:

A bill (S. 830) to amend the Federal Food, Drug and Cosmetic Act and the Public Health Service Act to improve the regulation of foods, drugs, devices and biological products, and for other purposes.

The Senate resumed the consideration of the bill.

Pending:

Modified committee amendment in the nature of a substitute. (The modification incorporated the language of Jeffords amendment No. 1130, in the nature of a substitute.)

Harkin amendment No. 1137 (to amendment No. 1130), authorizing funds for each of fiscal years 1998 through 2000 to establish within the National Institutes of Health an agency to be known as the National Center for Complementary and Alternative Medicine.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized for up to 1 hour.

Mr. KENNEDY. Mr. President, I yield myself 50 minutes.

Mr. President, this morning we continue the discussion of one of the most important and one of the most controversial and I believe one of the most dangerous provisions of S. 830. We are hopeful that we will be able to garner the attention of the Members of the Senate to support an amendment that will be offered and voted on Tuesday next that will address this dangerous provision that puts the American consumer at risk.

At the outset, I want to mention that those of us who are concerned about this particular provision are many. The Department of Health and Human Services, which is the principal agency of our National Government responsible for the health and safety of the American people, is strongly opposed to section 404, and supports the position that I have taken here today.

Other groups opposed to section 404. Those groups that are opposed to the provision also include the Patients' Coalition, which represents patients from all over this country, a real grassroots organization that understands, at the grassroots level, or the Main Street level, the dangers that this particular provision will mean unless we address

● This "bullet" symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor.

Printed on recycled paper.

it; the Consumer Federation of America; the National Women's Health Network; the National Organization for Rare Disorders; the American Public Health Association, which is charged with protecting the public health of Americans; the Consumers Union, another grassroots organization that looks after the interests of the consumer for a range of different issues and has targeted this particular provision; the Center for Women's Policy Studies; the National Parent Network on Disabilities; the National Association of Social Workers; the Policy Center for Children, Youth and Families; the American Council on Consumer Awareness; and the TMJ Association, they are the victims of the artificial jaw joint group. All of these organizations, and there are many more, are reflecting the anxiety and very deep concern and legitimate concern that consumers have about a particular provision that is included in this legislation, which will effectively handcuff the FDA from looking beyond just the manufacturer's label to get to the bottom line, whether a particular device which has a manufacturer's label is really going to be both marketed and utilized in such a way as to pose a serious and grievous health hazard to the American consumer.

I think the National Women's Health Network states the situation very well. I will just take a moment, before getting into the principal reasons for hoping that we will be able to alter and change this provision on Tuesday next, to read it, because it really summarizes the concerns of, in this case, the National Women's Health Network representing the millions of women across this country.

> On behalf of the 13,000 individual and 300 organized members of the National Women's Health Network, I am writing to express our continued opposition to S. 830 because of the serious implications this legislation has for our Nation's women. The network is extremely concerned that section 404 prevents the FDA from requiring medical device companies to perform complete reviews of the safety and effectiveness of a medical device. This provision must be amended to give the FDA the authority to verify that the label used is not false or misleading.

That is what we are talking about this morning, labeling, by the manufacturing company, of a medical device, that is false and misleading. The amendment which we will offer next Tuesday will say that when FDA finds that the medical device company is filing a false and misleading label, that the FDA will be able to look at the safety considerations of that device in order to protect the American consumer.

The Food and Drug Administration has a staff of scientists and researchers, individuals who have expert knowledge of different medical devices, whose only purpose is to protect the public. It is that group of individuals that we entrust—we recognize that they are human and are capable of making mistakes, nonetheless, they are the principal agent to trust to protect the American public's health and safety. When we have false and misleading labels by medical device industries, we need to make sure that the FDA scientists and researchers, who are charged with protecting the American public, are going to be able to make a thorough determination as to the safety and the efficacy of the devices. This is the issue. That is what the National Women's Health Network illustrates. The letter continues:

> Women need the FDA to act as a safety sieve, screening out drugs and devices which are hazardous or ineffective. If section 404 were enacted, a device manufacturer could label its product for a very simple use and the FDA would be limited to asking for proof in safety and effectiveness about that use only. Even if it were clear from the device's technical characteristics that it might be used for other, riskier purposes, the FDA would be prevented from looking beyond the conditions of use on the label.

If we are concerned about protecting the American consumer, this makes no sense. We should not be tying the hands of the FDA when we should be protecting the health of the American consumer. Look at recent history and the medical device disasters that this country has faced. This bill opens the potential for those diasters to be replicated. We all hope they will not be. But one of the principal safeguards for preventing this is the FDA being able to examine the safety of devices. The letter goes on:

> Section 404 is a serious danger to women's health.

I repeat, this particular section, section 404—

> is a serious danger to women's health, which must be fixed before S. 830 is acted upon by the Senate. In light of today's front page coverage of the fen/phen catastrophe, in which women were the victims of off-label drug use, we find it inconceivable that the Senate would pass a bill with this provision.

There it is. They have it right. We just had the fen/phen disaster, in which scores of individuals have suffered—have perhaps lost their lives—as a result of off-label use. And here we have on the U.S. Senate floor a particular provision that will invite unscrupulous medical device companies not to clearly and accurately state what their medical device is going to be used for. This is the issue. We have scores of other letters, similar to the one I just read, expressing concern about section 404.

The issues are clear. Will the Senate vote in favor of approving a medical device based on false and misleading labels? Will the Senate allow dangerous medical devices that have not been tested for safety and effectiveness to be foisted on the American people? Will companies like U.S. Surgical Corp. be rewarded for deceiving the FDA? Will the Senate put a higher value on the profits of the powerful than the health of the American people?

Mr. President, let me point out, that if U.S. Surgical Corp. is able to have their way—if they are allowed to misleadingly label their medical device as being substantially equivalent—they will be virtually guaranteed approval under the language of this bill. Because this bill says that if the medical device is substantially equivalent to one that has been approved and meets those safety requirements, it must be approved. Despite the fact that this corporation, U.S. Surgical Corp., has a device that is being advertised and will be used for an entirely different purpose. A purpose for which it has not been tested for safety. What happens to the ethical companies? What happens to the other medical device companies that are trying to provide safe medical devices?

They are going to be at a competitive disadvantage because they will come up and say to the FDA, ''Look, our device is for this purpose and we have conducted these expensive safety tests.'' That is going to cost that company, and it means that their medical device is going to be more expensive. What happens to these other companies when a company like the U.S. Surgical Corp. is able to get in the door without providing safety information, without doing that kind of testing? This is also an issue.

It is not the most important argument. The most important one is health and safety. If this language is not altered or changed, it will be an invitation for medical device companies all over America to jump through this loophole in order to get their products on line. Will the Senate put a higher value on the profits of the powerful than the health of the American people?

Section 404 of the bill requires FDA to approve a medical device based on the use claimed on the label submitted by the manufacturer—even if that label is false and misleading.

Think of it. The FDA will be required to give approval even though the label is false and misleading. Whose interests are we protecting? Are we protecting the American consumers' interests, or are we protecting the profits of the medical device company? The way this law is currently constructed, it will help protect the profits of companies like U.S. Surgical Corp. It prevents the FDA from requiring manufacturers to demonstrate that their product is safe and effective for the purposes for which it will be used as opposed to the purpose falsely claimed on the label.

It stands 20 years of progress toward safer and more effective medical devices on its head. For 20 years, since 1974, we have tried, through the FDA, to make sure that medical devices are safe and efficacious. This is the first time in over 20 years that we are taking a step backward. We take modest steps forward on the basis of experience, at both the FDA and across the country, to provide additional protections for the American consumer. Now we are faced with the first significant and major step backward.

Mr. President, to illustrate that, the U.S. Surgical Corp., a large and successful manufacturer of medical devices, submitted a new machine to the FDA for approval. This machine was called the Advanced Breast Biopsy Instrumentation System. The company claimed that the machine was to be used only for taking biopsies of breast tumors suspected of being cancerous. Cancer is a word that any family in America hates to hear. Many Members of this body, many Members of the House of Representatives and so many American families have been touched by cancer. There are few people listening today whose family has not been touched by cancer in some way. With the increasing number of breast cancers, this particular medical device is the most offensive, because the principal disaster is not only contracting cancer, but it is in the failure of being able to diagnose it and treat it effectively.

What has the U.S. Surgical Corp. done? The company claimed that the machine was to be used only for taking biopsies of breast tumors suspected of being cancerous, but the machine was designed to excise a piece of tissue 50 times as large as other biopsy devices already on the market. It was obvious from the machine's design that it was intended to remove breast cancer tumors, not simply take samples for biopsy.

Maybe it works. Maybe it is a major breakthrough. Maybe it can do all the things that the U.S. Surgical Corp. says can be done. Wouldn't that be wonderful? But we don't know. Maybe it doesn't. Maybe it doesn't work. Maybe when the doctor says we have excised the tumor, it doesn't do it completely. We don't know. Maybe when that woman walks out of the doctor's office or leaves the hospital, she is still in danger. She believes she has been treated effectively, but maybe this device isn't effective at removing tumors. Then there is the possiblity that in 4 weeks, 5 weeks, 6 months, 1 year, 1½ years, the cancer is still present and life and health are still at risk.

Why are we taking a chance, Mr. President? Because the medical device companies want this provision.

It was obvious from the machine's design that it was intended to remove breast cancer tumors. In fact, we have obtained a videotape, made in Canada, that demonstrates that the company knew it would be used for that purpose, despite their false claims to the FDA.

Here you have the U.S. Surgical Corp. saying to the FDA that we have a small biopsy needle the size of the lead in a pencil, that will be used to check a tumor, returning to the FDA for approval of what they label as a substantially equivalent medical device. Under this legislation—even though the company is out advertising that medical device for an entirely different purpose, for which they have not provided any health or safety information to the FDA and under this legislation—FDA would have to approve it. Despite the fact the FDA knows the device will be used for another purpose. Under this bill, the FDA could not say, ''Provide the information to show that this is safe and effective.''

This is the example, Mr. President. We are talking about cancer—breast cancer. We are talking about 1 out of 7 women who are going to be affected at some time in their lives. We know the enormous legitimate concerns that women have, that mothers have, that daughters have. And we are going to say we are prepared to allow them to have less than the best protections we can offer?

Mr. President, under this section of the FDA bill, the FDA would be forced to approve the new device without any evidence on the safety and effectiveness for new uses. American women do not want to die from breast cancer because the companies are allowed to sell devices whose safety and effectiveness have not been demonstrated.

No Senator would want their wife or mother or daughter to be subjected to such an untested device solely because a greedy company wants higher profits. The issue goes far beyond the products to excise breast cancer. It applies to lasers to treat prostate disease, stems to be placed in carotid arteries, imaging systems to detect breast cancer, and a host of other treatments for dreaded diseases.

Public health professionals will tell you as we continue to develop new technological advances this problem will only grow along with the threats to public health and safety. We will be rolling the dice. How many people are willing to roll the dice for a member of their family and use a medical device that has not been adequately tested? The companies are out there, Mr. President, and they won't mind if we roll the dice. Are we going to permit that?

This provision will give unscrupulous companies incentives to lie to the FDA. It will penalize ethical companies who are truthful and doing the necessary testing to demonstrate that their products are safe and effective. Most of all, it will put the health of the American people at risk so that a greedy few can increase profits. Companies that hope to benefit by weakening the FDA are already powerful and profitable. They believe they have the votes to push this disgraceful provision through the Senate—and this morning they probably would have. It is absolutely untenable and outrageous and unnecessary that we would, except to provide additional profits for a company that will use this loophole to get their devices on market earlier.

If the American people truly understand what is at stake, I do not believe they will permit this dangerous provision to become law. When the vote comes on Tuesday, we will see how many Senators are willing to stand with the American people and how many are willing to vote in favor of false and misleading labels. Let me make it very clear that the Tuesday vote will not be the end of the story. We will continue to fight to keep this provision from becoming law, and I believe we will succeed in the end. The FDA bill has many constructive elements, but this disgraceful provision should be eliminated. The false or misleading label should have no place in the approval of medical devices. Unscrupulous manufacturers do not deserve a free ride at the expense of the public.

Mr. President, what we are talking about is S. 830, and section 404, which prohibits the FDA from reviewing the safety of a device for uses not listed by the manufacturer.

This provision handicaps the principal agency of Government that is charged with safety, and we are writing into the law language that will prohibit FDA—which is the agency charged with protecting the American people from unsafe pharmaceutical drugs and medical devices—from doing its job. The FDA would be prohibited from reviewing the safety of a device for uses not listed by the manufacturer.

What our amendment says is, OK, we'll prohibit the FDA from reviewing the safety of a device for uses not listed by the manufacturer—unless the label is false or misleading. How can Members of this body say that they will refuse to stand with those of us who support the Reed amendment that says ''unless the label is false and misleading''?

We have the example of U.S. Surgical Corp.'s biopsy needle. A needle designed to extract a small amount of cancerous tissue, maybe the size of a pen or the lead of a pencil. Now what has the company done? It has developed a much larger device that may be able to take a biopsy, but which, in fact, is primarily designed for tumor removal. But all they will have to be able to do is show that they are substantially equivalent.

Under this proposal, the FDA will not be able to look at what the real purpose of this medical device is. We know what the U.S. Surgical Corp.'s real purpose for this medical device is. We know because we have seen the advertisement they have already prepared. This device which can take out 50 times more material than its predecessor—50 times more material—is not intended to be used for a biopsy, but is designed to excise the tumor. Maybe it can do it well, Mr. President. Maybe it is an important and major step forward. But any woman who has a procedure done with this device, will not be able to judge from the safety information that is provided to the FDA because there has been none provided. They won't know the results of testing conducted on this device because there have been no tests submitted to the FDA. They won't know whether this is a successful device because there is no information to indicate its success.

We are talking about women and breast cancer. We are talking about a medical device that is put forward with virtually no intention for use for biopsies. Where an earlier smaller, less intrusive device already exists for biopsies. A device that is going to be used to remove tumors, and is advertised to doctors as such.

What are the American doctors supposed to believe? They say, ''Well, we have FDA approval.''

''Well, isn't that fine. Then it must be all right, it must be safe.''

But no doctor is able to give that kind of assurance to a woman who is going to have this particular medical device utilized to excise a tumor, because it has not been done. How would our amendment change that? Our amendment would say that if the advertising is false or misleading, that anyone would be able to see that this particular device is going to be used to excise a tumor—U.S. Surgical, show us your studies, show us your information that would indicate that this is safe for American women. Show us where you have tested it to show that it does the job. Show us that it will do what you are advertising will be done. Let us examine that. And if that is the case, we approve it for that particular purpose.

This provision is unconscionable, Mr. President, when you look at the tragedies that have resulted from device disasters. We are not talking about Band-Aids and tongue depressors. We have seen medical device disasters which have cost the lives of hundreds and thousands of American consumers.

I was here and chaired the hearings on the Dalkon shield IUDs, which injured tens of thousands of women. Their injuries included pelvic inflammatory disease, sterility and perforated uteruses. That is because, Mr. President, with the Dalkon shield we found out that bacteria crept through the string of the device and caused infections in American women.

As a result of this disaster in the mid-1970's we set up protections for the American consumer with regard to medical devices to ensure that they would be safe and efficacious. Prior to the mid-1970's we did not test for safety and efficacy. We want to be able to make sure that the FDA is going to be able to test for safety and efficacy on a product that is going to be the predominant use of a particular medical device.

In another example of a human and public health tragedy involving a medical device, the firm Telectronics marketed a pacemaker wire for use in the heart. Twenty-five thousand of these pacemakers were marketed, beginning in 1994, before it was discovered that the wire could break, cause damage to the wall of the heart, or even destroy the aorta.

Why are we being asked in the U.S. Senate to deny the FDA adequate authority to protect the American people? Safe and effective medical devices is what the American public deserve and it is what Senator REED's amendment to section 404 would ensure.

Mr. President, another example is patients with defective Shiley heart valves who died, underwent painful and dangerous surgeries to remove the valves.

The company increased the degree of a particular vent from 60 degrees to 70 degrees. But because FDA had the power to examine whether this presented any additional health hazards to the American people, the modified valve was not marketed in the U.S. The company sold them in Europe. And the modified valve had six times the amount of disasters in the hearts as a result of that 10-percent increase. Hundreds of deaths resulted in Europe and thousands and thousands of people put at risk.

Then we have the angioplasty catheters that failed causing dozens to suffer emergency coronary bypass surgery, cardiac damage and death.

Mr. President, this is what we are talking about. We are talking about S. 830 which allows false and misleading labels for medical devices. S. 830 could result in the surgical needles that do not safely remove the breast cancer tumors.

FDA has been asked to clear surgical lasers for marketing despite the lack of safety data submitted to support the clear intent of the manufacturer—to cut prostate tissue. What we have are laser manufacturers that say, ''Well, all right, we want to use lasers in the operations on the prostate. And a certain amount of cutting is going to be necessary.'' They effectively say, ''Our laser is substantially equivalent to lasers that are already approved for general cutting,'' when the intention of the company is to use the newer designed laser not just in the ordinary cutting of tissues but for use in a prostate operation. Therefore, through this loophole, a device may be used for a purpose for which it was clearly designed but not adequately tested.

We have also, Mr. President, the example of contact lenses that may cause blindness. FDA can tell by the materials and design of a contact lens that it will be used for extended wear. But a company could submit data only on a labeled use of daily wear and FDA would be prohibited from asking for additional information on extended wear. Extended wear lenses that are not adequately tested may cause ulcers on the cornea and can be sight-threatening.

Mr. President, we may see in the future digital mammography screening machines that may misdiagnose breast cancer. We have seen enormous progress being made in terms of mammography with all the benefits of early detection of breast cancer which permits early treatment and saves lives.

These advanced technologies, Mr. President, may be able to perform diagnostic mammography but not mammography screening. There is an important difference. The screening is used to find out whether there are tumors as compared to examining a tumor for diagnostic purposes to make a determination of the appropriate kinds of medical treatment. A mammography instrument labeled for use as a diagnostic machine could have features specific to mammography screening and the safety data should be submitted to support that use.

Why do we have to take a chance on it? What is the compelling need to take a chance on women's health? Why shouldn't we say to FDA that if they have reason to believe that the primary purpose of this new machine is going to be for screening and the label is false and misleading that they can ask for safety data for the intended use.

Why should we hamstring the FDA when we know that the purpose for these new kinds of medical devices are not consistent with what is being labeled by the manufacturing company?

(Ms. COLLINS assumed the chair.)

Mr. KENNEDY. Under this legislation, the FDA, even though they know this might provide an important safety question for the American people, are handcuffed from doing anything about it. Why are we doing this to the American people? For what purpose? Are we that far behind in terms of online medical devices? We are not.

I can put in the RECORD the various publications of the medical device industry that show they have been making important progress over the past several years, and the profits have gone up, and a different atmosphere is out there to bring the various products on the market. A GAO report has shown that medical device review times are down.

So if that is the case, why, now, are we going to rush these devices on through when their purposes are clearly different from the labeled use and for which we do not have adequate safety data? This is a major step back, and puts the public at risk.

Madam President, we can go through what some of the dangers are when we find various devices are used for one purpose and then changed and altered for another purpose. In this diagram we have the long bone screws that are used effectively to mend bones. I have a member of my family that has had those implanted and they have been enormously effective. A member of the family had a broken shoulder, and I went back to see her 5 days later and she was able to move her arm, move her shoulder. It was unbelievable when you think of what most of us understood would be a recovery time of several months.

We have seen how, when used properly, how they can help mend a bone, give stability to bone, and be effective in helping and assisting those people with that kind of a break to long bones. Then what happened? We found out the screws were being sold to back surgeons for another purpose. They were marketed for use in the spinal column to give stability to the spine.

What happened? Madam President, the screws broke, and they were disasters for many Americans who had the operation. Those screws were not adequately tested for use in the back and should not have been used in that manner.

These examples are what is happening every day. We have the biopsy needle, the contact lenses, we have the long bone screws, and the list goes on. We ought to be very careful about denying the Food and Drug Administration needed information in terms of their safety and effectiveness.

Now, Madam President, we cannot prohibit off-label use of medical devices. We are not doing that in the proposed amendment. What we are saying is that when you have on the face of it a clear intention that the new proposal that is being submitted to the FDA is going to be used clearly as a dominant use for another purpose, such as the breast biopsy instrumentation, that the FDA ought to be able to look at the safety and efficacy of the device.

Why are we going through this, Madam President? Why are we tying the hands of the agency that has the skill and the knowledgeable people to try to protect the public?

All we are saying is when there is a clear record on the use of a device, make sure the American public's interest is going to be protected and not denied. All our amendment says is when the label is false and misleading, the FDA is going to be able to look behind it. That does not seem to me to be a very dramatic or radical kind of resolution to this particular issue.

We have indicated four or five different types of compromises to this particular measure to try to protect the public's interest. We are ready to look at different language to protect the public's interest. But the guiding light is, when we know a medical device is being submitted with false or misleading information and that the device is clearly designed for another purpose, the FDA should be able to look at the safety and the efficacy of the device.

We have seen in recent years the dangers of simple changes like the absorbency of tampon material. It looked like it was just a very modest kind of alteration or change. But women were injured, and subject to infections that caused toxic shock syndrome sometimes leading to death.

Why are we doing less for the protection of our consumers? Why are we restricting the protections of the American consumers? We are going to have a difficult enough time trying to make sure that when medical devices go through vigorous requirements for safety and effectiveness that they are indeed safe and efficacious. Some mistakes may very well be made. At least we will know we have given it our best shot. At least we will know we have given to the American people the best we have, in terms of scientists and researchers, to try to make sure those products are safe.

On this particular provision, for the first time in 23 years, we will be effectively rolling back public health protections at FDA. We will be effectively handcuffing the FDA on a major matter that affects the health and the safety of the American people. It is unwise. It is unjust. There is absolutely no rationale or justification for this provision other than the profits of the medical device industry.

Madam President, I cannot help but believe as the American people understand this issue, understand the health implications, understand on the one hand we are risking the public health of the American people in favor of the profits of the medical device industry, that they will be heard on this issue. This provision puts at serious risk the health of the American people—that is what the HHS says, that is what the Women's Health Network says, that is what the principal consumers groups that are out there to protect the American people say.

What is the benefit on the other side? The profits of unscrupulous medical device manufacturers. It is not only going to be the profit of those individual companies like U.S. Surgical, but it will be an invitation to other medical device companies to go through a loophole, because otherwise they will be put at a competitive disadvantage. It makes absolutely no sense.

I hope very much, that when the Senate addresses this issue in the next week, we can have the support of our colleagues and we will have the support of the House of Representatives and we can move forward with an otherwise reasonable bill.

I see my friend and colleague, Senator DURBIN, here on the floor. I yield the floor.

The PRESIDING OFFICER. The Senator from Illinois is recognized.

Mr. DURBIN. It is my understanding under the unanimous consent I am allotted 30 minutes, 15 minutes on each side, on two separate amendments, amendments 1139 and 1140. Is that correct?

The PRESIDING OFFICER. The Senator has the right under the agreement to call up either amendment 1139 or 1140. When he does so, he will have 30 minutes on each amendment, equally divided.

Mr. DURBIN. I thank you, Madam President.

AMENDMENT NO. 1140

(Purpose: To require that entities and individuals accredited to conduct reviews of device notifications be subject to the conflict of interest standards that apply to employees of the Food and Drug Administration)

Mr. DURBIN. I call up amendment 1140.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Illinois [Mr. DURBIN], for himself, Mr. FEINGOLD, and Mr. JOHNSON, proposes an amendment numbered 1140.

Mr. DURBIN. Madam President, 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:

In section 523 of the Federal Food, Drug, and Cosmetic Act, as added by section 204, strike subsection (b) and insert the following:

''(b) ACCREDITATION.—

''(1) IN GENERAL.—Within 180 days after the date of enactment of this section, the Secretary shall adopt methods of accreditation that ensure that entities or individuals who conduct reviews and make recommendations under this section are qualified, property trained, knowledgeable about handling confidential documents and information, and free of conflicts of interest.

''(2) STANDARDS.—In adopting the methods of accreditation, the Secretary shall ensure that the entities and individuals—

''(A) are subject to—

''(i) the conflict of interest standards applicable to employees of the Food and Drug Administration under subpart E, H, and I of part 73 of title 45, Code of Federal Regulations (as in effect on January 1, 1996); or

''(ii) if the standards described in clause (i) would be inappropriate for the entities and individuals, conflict of interest standards developed by the Secretary that are—

''(I) based on the standards described in clause (i); and

''(II) modified, as appropriate, to apply to the entities and individuals; and

''(B) are not subject to the conflict of interest standards under subpart J of such part.

''(3) PUBLICATION.—The Secretary shall publish the methods of accreditation in the Federal Register on the adoption of the methods.''.

Mr. DURBIN. Before proceeding, I ask unanimous consent Senators FEINGOLD and JOHNSON be added as cosponsors of amendment 1140.

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

Mr. DURBIN. Madam President, the bill before the Senate is one of the most important we will consider during the course of this Congress. I don't believe that is an overstatement. This bill addresses the future of the Food and Drug Administration, an agency which we literally entrust with the safety and efficacy of thousands of drugs and prescriptions which we keep in our home and give to members of our family.

This agency has to be above reproach, it has to be efficient and responsible. This amendment No. 1140 that I am offering is an attempt to make certain that the integrity of the Food and Drug Administration is not compromised by this bill. I think overall this is a good bill. There are some areas Senator KENNEDY and I and others feel need to be addressed. But the one part of this bill that I address with this amendment is one of great concern.

We are now going to say that we will take outside of this Federal agency, outside of the Food and Drug Administration, the review of medical devices. We will say to third parties, which are hired for the purpose of making these reviews, that they will decide whether or not a medical device is safe for the American people and whether it's effective; and having made that decision,

that company will then have an opportunity to sell that device across America. We as consumers will believe, as we should, that we can trust that judgment.

The purpose of amendment No. 1140 is to address the question of whether or not the third-party reviewers are credible. This bill dramatically expands the ability of medical device companies to purchase their own third-party reviewers. Senators FEINGOLD and JOHNSON and I are offering this amendment so that it's clear that it's only reviews and not approvals themselves that can be bought under this system.

Up to 60 percent of medical devices going through the premarket notification process could utilize the outside reviewing system. A program of this magnitude will not permit the same level of close monitoring and oversight by the FDA as is currently undertaken. There are fewer than 10 firms that are credited for this purpose. That is why explicit anti-conflict-of-interest standards need to be laid out in the law. We should not cut corners when it comes to the question of conflict of interest. If we are going to give to these companies the authority to review and approve medical devices to be used across America, let us have no question that they are doing it in a professional way.

The Project on Government Oversight, a nonpartisan, nonprofit Government watchdog group, described the bill's provisions in this area as grossly inadequate, and the Government Accountability Project, which is another watchdog group, described the current FDA regulations for their pilot program as ''inadequate to guard against conflict of interest.'' Both groups, along with a long list of consumer and patient groups, urge the Senate to adopt this Durbin amendment.

Given the importance to the public of keeping the approval process untainted by monetary influence, we must ensure that there are strict anti-conflict-of-interest standards for product reviews.

Only the vaguest language possible on the issue of preventing conflicts of interest is currently contained within the bill. Let me tell you what it says on page 16:

> The Secretary shall adopt methods of accreditation that ensure that entities or individuals who conduct reviews and make recommendations under this section are qualified, properly trained, knowledgeable about handling confidential documents and information and free of conflicts of interest.

Nowhere does the bill mention what we mean by ''free of conflicts of interest.'' What are the standards that we will use? No reference point is given for a basic minimum that would satisfy and ensure unbiased review.

Senator HARKIN was successful in adding language that allows the FDA to look at contractual arrangements between an outside reviewing laboratory or entity and the company whose product is being reviewed. We would like to go a step further and add more protections against approval peddling.

FDA employees themselves are subject to a wide range of anti-conflict-of-interest regulations. This amendment seeks to establish basic requirements, and it is very simple. It merely asks that outside reviewers not be allowed to have a financial interest in the company they review.

Think about what I just said. The outside reviewer, which will decide whether a medical device should go on the market, should not have a financial interest in the company that he is reviewing. That seems rather simple to me. Nor should they be allowed to receive gifts from a company that has products being reviewed, and they should not be actively looking for a job with that company while they are in the process of making their review. No gifts, no job offers, no stocks. It seems simple.

It is amazing to me that we are arguing over this provision. I would have thought this would have been accepted long ago by the majority. But instead, there is a fight as to whether or not we are going to demand the highest level of integrity and honesty when it comes to these third-party reviewers.

Let me tell you why this is critically important. The approval by the FDA of a device can have a dramatic positive or negative economic impact on a company. If the FDA rejects a device and doesn't approve it, a stock can languish for months, if not years. If the FDA approval goes through, it is the seal of approval, and that company knows that there is money to be made.

Look at this chart indicating what happened in four different instances with medical device companies when there was an FDA approval. QLT Phototherapeutics, Inc. Look at how the stock shot right up with FDA approval. ATL Ultrasound. After FDA approval, it skyrockets. Thoratec Laboratories Corp., the same story; the stock is moving along slowly, and then, after FDA approval, it climbs dramatically, 50 or 60 percent in 1 day. It was the same thing with Integra LifeSciences Corp.

What we are trying to say is, the people making the decision on behalf of us, as consumers, should make that decision without any concern about the bottom line of that company. Would you think twice about giving to a reviewer the decision to approve a product if you knew that reviewer owned a thousand shares of the company that made the product? I think most of us would. What if that reviewer and his family had just come back from a Caribbean vacation, paid for by the company that submits the medical device for approval, or if that reviewer happens to have sent his resume to that company a week before, saying, ''I would like to have a job with you and, incidentally, I am working on your FDA approval,'' with a wink and a nod? That doesn't make me feel any better about what we are dealing with here.

The Durbin amendment basically says, let's get rid of the doubt as to whether or not people are going to use the highest professional standards. We should not cut corners here when it comes to conflicts of interest, when it comes to these outside laboratories. We have to demand the highest standards of professionalism.

Time and again, companies have been shown to make dramatic profits with FDA approval. Dr. Kessler, a former head of the FDA, said, ''Make no mistake, they talk a lot about approvals in Europe and in other countries. They can be lucrative, they can be profitable. But if you can get the approval of the Food and Drug Administration of the United States of America, it is a seal of approval recognized worldwide. The product you are trying to sell becomes a winner overnight.'' Shouldn't the people making the decision as to whether or not this product is safe and efficacious be doing it on the basis of science, rather than on the question of their own financial interest?

The medical device industry produces over $50 billion annually in sales. In fact, in a recent article in Medical Economics entitled ''Why Medical Stocks Belong in Your Portfolio,'' the medical device industry was described as ''a hot market that's only getting hotter.'' It doesn't take much imagination to see why we would not want to allow a reviewer to have stocks in the company they were reviewing. The connection between FDA approval and stock gain is just too clear. The money stakes are high for investors; however, the stakes are even higher for the patients who rely on these devices.

The approval of an unsafe drug or device can have a devastating impact. Doctors, hospitals, nurses, and families rely on these decisions. If a corner is cut, if this reviewer has a financial interest and decides, well, I am just going to tip it a little bit toward my own stock portfolio here, the losers ultimately are the innocent people. Reviews must be of the most stringent nature and must be carried out without any outside corrupting influence.

Surely, it is not too much to ask that a reviewer be prevented from accepting a gift or a loan from a company that he or she is reviewing. I can't imagine we are debating this. Should we allow the reviewer to take a gift from the company he is reviewing? That is an obvious conflict of interest and one that we can address explicitly. The language in the bill, unfortunately, is loaded with ''weasel'' words—weasel words about what a conflict of interest might be. We should make it crystal clear. It would give this bill more stature. It is an important bill and it should have that.

Furthermore, a reviewer or their spouse or minor child should not be allowed to have a financial interest in the company being reviewed. That means owning stock or a mutual fund that has more than 10 percent invested in the company. This is all laid out in subpart H of the regulations that we refer to in our amendment. A final restriction that we are asking for is that

the reviewer may not be actively soliciting future employment within the company they are reviewing.

Our amendment, which sets out guidelines to prevent tainted reviews, allows the Secretary to modify such guidelines where it would be appropriate for outside reviewers.

Therefore, if any provision included in these regulations would clearly not apply or not be appropriate, the Secretary can modify it. We have that flexibility built into our amendment.

I have heard some of my colleagues argue for more flexibility. I believe our amendment gives enough. It sets out specific standards. I challenge any of my colleagues to suggest that a gift ban or a financial interest ban would be unreasonable. It would be a sad day in America if reviewers expect a gift, or a job offer, or some other financial gain in order to review a medical device and, worse, that we were not willing to categorically repudiate a potential for such ''approval peddling.''

This industry and their products are too important to the American people. These are literally life-and-death products. We should take a firm stand and specifically enumerate these basic standards within this legislation to prevent even the potential for the corruption of this process.

Madam President, I yield the remainder of my time on this amendment.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. JEFFORDS. Madam President, first, let me very briefly review where we are. There has been considerable debate up to this point. I think it is important for me as the chairman of the committee to remind people as to where we are.

We have before us a 152-page bill, which is the first real overhaul of the Federal Food, Drug and Cosmetic Act in the last 30 years. We have taken little tweaks here and there, but it has not been thoroughly reviewed and brought into the modern world.

Out of that 152 pages, we are now spending most of the time debating on 2 or 3 pages. That is why the minority ranking member has praised the bill, but then picked on one—basically, we are here because of one provision, which is 404. On some standards, we cannot agree on the precise wording.

So everybody agrees on almost all of this bill. The amendment that is being offered by the Senator from Illinois does get into a very, very important area, and we do not disagree with that. We praise him for having given us the opportunity to review, to restudy, and determine as to whether or not the provision he is striking with his amendment and replacing is necessary or appropriate. We have concluded—I say ''we'' because I am sure that Senator KENNEDY joins me in this statement—that we adequately take care of the conflict of interest in this bill.

Let me go through what his amendment attempts to do and what the bill provides. First of all, the Senator's amendment, at best, duplicates the third-party provision that we have in the bill now and, at worst, it unnecessarily constrains the agency.

Section 204, conflict of interest protections, which is being stricken and replaced, provides a full statutory directive to the agency to prevent conflicts of interest that may be involved with both an individual reviewer and with the reviewing organization. As with Senator DURBIN, this was a critical concern for members of the committee.

Section 204(b) reads:

> Within 180 days after the date of enactment of this section, the Secretary shall adopt methods of accreditation that ensure that entities or individuals who conduct reviews and make recommendations under this section are . . . free of conflicts of interest.

Section 204 provides full discretion to the agency to develop appropriate standards. The agency will not be limited in any way in developing these guidelines.

We believe the FDA is the one that can best understand what will be effective in this regard. The agency has already developed extensive conflict of interest guidelines as a part of its existing third-party program. The notice of April 3rd, 1996, has almost a full page of Federal Register type laying out the standards, including restrictions if ''the third party, or any of its personnel, involved in 510(k) reviews has any ownership, or other financial interest, in medical device, device manufacturer, or distributor.''

That is a quote from the wording.

The agency has not identified any difficulties in the implementation of the conflict of interest guidelines, and it has expressed no concern about the conflict of interest provisions, as drafted. We have reviewed the FDA standards that appeared in the Federal Register on Wednesday, April 3, 1996, at page 14794, and believe that they adequately and appropriately address the problems which we are reviewing here. The agency's strict guidelines resulted in the elimination of 30 of the 37 applicants that originally sought accreditation. That means, obviously, that the FDA policy is effective, and it has outlined and again recognized—as the Senator from Illinois is aware—that there are problems that must be protected against. And we agree with him on that.

The Durbin amendment attempts to set standards but in fact may constrain the agency. In fact, the standards cited are reportedly outdated and do not reflect recent revision. This may explain why in the second part of the amendment Senator DURBIN effectively gives the agency discretion to craft appropriate guidelines. Section 204 provides a full statutory directive to the agency to prevent conflicts of interest that may be involved with both an individual reviewer and the reviewing organization. Therefore, it appears to us that the amendment, although well-intended, may even make it more complicated than necessary, and that we will end up perhaps with a less effective system than is already contained in the bill.

Madam President, I ask, if we yield back time, what happens to that time? May we be advised on that?

The PRESIDING OFFICER. The time would just lapse. I believe the Senator from Illinois has yielded his time on this amendment. If the Senator from Vermont yields the remainder of his time, then the Senator from Illinois could call up his second amendment.

Mr. JEFFORDS. If at the end of the time we, for instance, end up instead of using an hour on the Durbin amendment using half an hour, does that time fall into the same category as the last half-hour of this unanimous consent? So we have an hour in that last part of the unanimous-consent request.

The PRESIDING OFFICER. The Chair is not clear about the Senator's question. We would proceed to the next amendment, and there would be 30 minutes equally divided on that amendment. Then we would stay on the bill, if that is the wish of the managers.

Mr. JEFFORDS. Madam President, I believe I understand the ruling of the Chair. I appreciate that.

The PRESIDING OFFICER. Regardless of the amount of time we use today, on Tuesday we will have 5 hours on the bill itself equally divided.

Mr. JEFFORDS. I appreciate that clarification because this does get a little bit complicated as we move forward. This is an important issue.

I think at this time I will just again restate that we believe that the bill as written adequately covers the problems of the conflict of interest situation.

We commend the Senator from Illinois for really focusing attention on this and bringing it to our attention again so that all of my colleagues hopefully will understand that the bill—this is agreed to I believe also by Senator KENNEDY—is effective in accomplishing the goals of the Senator from Illinois.

So, again I commend him for what he has done.

Madam President, I yield the remainder of my time.

The PRESIDING OFFICER. All time on the amendment has been yielded.

AMENDMENT NO. 1139 TO MODIFIED COMMITTEE SUBSTITUTE AMENDMENT NO. 1130

(Purpose: To eliminate provisions relating to the discretion of the Secretary of Health and Human Services to track devices or to conduct post-market surveillance of devices)

Mr. DURBIN. Madam President, under the unanimous-consent request, I would like to call up my amendment 1139.

The legislative clerk read as follows:

> The Senator from Illinois [Mr. DURBIN], for himself, Mr. HARKIN, and Mr. JOHNSON, proposes an amendment numbered 1139 to the modified committee substitute amendment numbered 1130.

The amendment is as follows:

On page 46, beginning on part 5, strike sections 605 and 606.

Mr. DURBIN. Madam President, I ask unanimous consent that Senator HARKIN be added as a cosponsor of amendment No. 1139.

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

Mr. DURBIN. Madam President, the conflict of interest provision which we have just discussed is a very important one, but the one which I am addressing with this amendment may be even more important.

Consider this possibility. On Monday of next week you go out to buy a Pontiac. On Tuesday when you go to the doctor, he says, ''You are going to have to go to the hospital, and you are going to need a pacemaker.'' In 1 week you have a Pontiac and a pacemaker. What is the difference? When you bought the Pontiac, General Motors took note of your name and address. If anything went wrong with the Pontiac, they would contact you in 6 months, 1 year, 2 years, or even later, and say, ''Bring it in. It needs to be fixed.'' It might not be safe, if you didn't. However, under this bill the pacemaker that you are going to have implanted by the surgeon perhaps a few days later doesn't have the same kind of following. Why? Because we let that exist.

Why would we let people have lifesaving devices implanted in their bodies and not keep track of that fact? That is what this amendment is all about, because this bill, as good as it is, takes away the mandatory requirement that we have surveillance and tracking of these high-risk devices that can be implanted in people.

I am glad to be joined by Senators HARKIN and Senator JOHNSON in offering this amendment which strikes the sections of the bill that undermine many of the patient protections for medical devices put in place by the Safe Medical Device Act of 1990.

This act of 1990 instituted a mandatory surveillance program to identify quickly any potential problems with approved high-risk devices. A mandatory tracking system to locate patients in the event a safety recall was also added.

Sections 605 and 606 in this act are nothing more than a backdoor attempt to eliminate these programs that industry considers burdensome. Yes, they are burdensome. To keep track of the name and address of each person who is given a pacemaker is a big burden on industry. But what kind of burden is it on the patient when the pacemaker fails and the patient can't be found? I would suggest that it is a much greater burden. That is what this amendment addresses.

Proponents of sections 605 and 606 say that the FDA has not been vigilant with respect to overseeing these vital programs. Does anyone imagine they are going to be more vigilant in enforcing these safety protections when they are relegated to an optional or discretionary status? Especially given CBO's high estimate of this bill's additional costs to the FDA without any corresponding increase in funding. Pressure can only increase on the agency to curtail its efforts in discretionary programs.

Opponents of this amendment will point to the fact that the administration went along with this change. This point is in fact even more worrisome when you look at what types of devices we are talking about, and the tragedies that may occur.

Many of us remember the tragedies that resulted from the Bjork-Shiley heart valve failures. Extensive congressional hearings were held in the late 1980's examining what had gone wrong and how we might prevent future repeats of these terrible tragedies.

Over 300 people died in the United States from these heart valve failures, and over 1,000 worldwide.

After it was concluded that these heart valves were defective—after they realized the product had failed—over 50 percent of the patients with these heart valves couldn't be located.

One widow testified—and this is a tragic story—about how her husband, who had a Bjork-Shiley heart valve implant, suffered chest pains but had no idea that the heart valve was the cause of the problem. She was in a position to choose from two hospitals. She quickly raced to one hospital, and made the wrong choice. She went to the hospital that didn't specialize in heart surgery when her husband needed to live. She didn't know. Why didn't she know? She wasn't on the list. Her husband's name and address were not on the list to be notified that the heart valve he carried in his body was failing him.

What does tracking actually involve? It involves a patient—this is I don't think a burden from that perspective—filling out a registration form with their address so they can be located if there is a recall of a pacemaker, or high-risk device. Most companies make this request already.

What kind of devices are we talking about? Just about anything? No. There are 17 specific types of devices that require mandatory tracking. We are talking about heart valves; pacemakers and pacemaker leads; vascular stents; jaw, shoulder, and hip joint replacements; windpipe prosthesis; breathing monitors and ventilators.

It is hard to imagine the tracking of these high-risk devices could ever been made optional, and yet that is exactly what this bill does.

FDA has already complained that they find it extremely difficult to enforce this provision, and yet, instead of making it stronger and helping them with enforcement, this bill weakens it. It weakens the FDA's ability to make this kind of adequate tracking and surveillance available.

Automobile manufacturers are required to have a tracking system to notify those who buy cars. It even happens with motorcycles. Look at this. What a coincidence. In the Phoenix Gazette of Friday, January 11, 1991, there are two articles next to one another. Harley-Davison recalls its motorcycles. We have a problem here. It turns out that their brake calipers are defective and could cause their front wheels to lock while driving.

Right next to it, on Consumer Watch, jaw implants. It is found that the implants of Vitek of Houston caused bone degeneration. If we cannot track the people who bought the jaw implants through their surgeon, we can certainly find the owners of the Harley-Davidsons. Does that make sense?

I would like to submit for the RECORD a letter that I received from Victims Against Lethal Valves, a support group out of Pittsburgh for those who have suffered from defective heart valves. They urge the Senate to adopt my amendment. If you read this letter from the families of those who were caught unaware that they had a defective heart valve, you might think twice. I hope my colleagues will.

I ask unanimous consent that this letter be printed in the RECORD.

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

VICTIMS AGAINST LETHAL VALVES,
Pittsburgh, PA, September 16, 1997.

U.S. Senate,
Washington, DC.

DEAR SENATOR: As a Bjork-Shiley heart valve survivor and founder of VALV, a support group for people with the Bjork-Shiley heart valve, I strongly urge you to support Senator Durbin's amendment to S. 830 to maintain mandatory tracking and postmarket surveillance of high risk medical devices like heart valves.

The Bjork-Shiley heart valve experience was a major impetus to enacting these two provisions in 1990. Almost 1,000 people (world-wide, the device was marketed longer in Europe than in the U.S.) have died as a result of the fracture of the Bjork-Shiley valve. S. 830 makes tracking and postmarket surveillance of these very high risk devices discretionary rather than mandatory.

The Bjork-Shiley disaster highlighted the need to implement a systematic method for tracking the device recipients. When the FDA finally ''caught up'' with the significant numbers of Bjork-Shiley heart valve fractures and ordered the company to notify recipients of the valve's potential failure, what symptoms to look for, and what to do if these symptoms appeared, the manufacturer claimed that they had no record of how to find as many as half of the recipients. Should a defect in a device be identified, it is critical that device recipients be notified so they can seek medical attention.

The manufacturer knew that the Bjork-Shiley heart valve had a tendency to fracture very soon after it went on the market. But the firm conducted no systematic surveillance, and did not accurately report the information about problems it received to the FDA. Section 522 was designed to remedy this gap in reliable, verifiable information—so that the manufacturer would know, and the FDA could check—on problems with new post-1991 devices.

Most Market surveillance and tracking are consumer safeguards that were won with the lives of people like me and the members of

VALV. We urge you to adopt Senator Durbin's amendment and keep these consumer protections in place.

Sincerely,

ELAINE LEVENSON,
Founder.

Mr. DURBIN. Madam President, another key aspect of the Safe Medical Device Act, which this bill undermines, is the mandatory surveillance program for high-risk medical devices.

These surveillance programs are extremely important for early detection.

In some cases, the initial breakage of a device may not cause instantaneous harm. For example, in the case of the Telectronics Heart Pacemaker ''J'' Leads which are found to be defective in 12 percent of the patients with them, breakage didn't result in any harm until the next bout of heart arythmia. Surveillance of these leads identified problems in some patients. And this led to the notification of patients with these leads of the need to have them checked.

Likewise, in the case of the Bjork-Shiley heart valves, 300 Americans died when this tiny heart valve no bigger than a pen turned out to have a structural defect.

This is a blowup of a photograph of a heart valve. And it shows a crack in one of these struts on this heart valve. This crack alone wouldn't be lethal. But when the strut next to it cracks, it is too late. You are going to die unless you have immediate surgical relief.

We believe that once you know that the heart valve is in danger, you should know the people who have received it so that you can notify them so that they can go to a doctor and have the necessary test to see if they are in danger.

Early detection and correction could have prevented many of the 300 deaths that occurred when this Bjork-Shiley valve failed.

Let me tell you about another case, teflon jaw implants. People with the temporal mandibular problems—TMJ—have turned to these implants as a way of dealing with a maddening situation, and a very painful one.

In the case of the implants made by Vitek in the 1980's, early detection unfortunately wouldn't help. These implants splintered and caused massive corrosion of jaws and skull due to the triggering of inflammation and other immune responses. By the time the patients suffered pain, for many of them it was too late. Many of the patients required the removal of much of their jawbone structure because this implant had failed. Even some of their skulls were exposing their brain because of this subsequent surgery.

If a surveillance program had been in place prior to the Vitek jaw implant defect, many of the patients would have been able to have their implants removed prior to the full deterioration of their jaws. In fact, many individuals would have been saved altogether from ever having the implants inserted in the first place.

Vitek jaw implants were first marketed in 1983, but it wasn't until 1990 that FDA sent out a safety alert, and in 1991 issued a recall.

Think about that, 7 or 8 years later we finally realized that there was a problem with this implant.

At that stage, between 25,000 and 26,000 patients had received these implants. The rate of failure was nearly 100 percent.

Here on these charts you see some of the sad stories of the victims. These are troublesome to see, but think about these poor people and what they went through. Asking these companies to keep track of the people who received these implants is not unreasonable when you take this lovely young lady in this picture and look how she deteriorated after these implants started to fail. And the same thing, this lovely lady in this picture and what happened to her face as a result of the implant failure. On this one, look at this. After the implant failed, look what happened. It actually emerged from the skin.

Is this something that we want to think twice about? I would think that as a matter of just decency we should include in this bill tracking and surveillance to try to avoid this from happening to anybody in the future.

Some may try to argue we still have the medical device reporting system. That is no substitute for company surveillance. The medical device reporting system is basically a body count program. We hope that we could have a strong program to detect problems before death and injury. That is exactly what a surveillance program does. Many medical devices on the market are approved on the basis of data from trials of shorter than the lifespan of the device. Vascular stint, approved by the FDA this year, was approved on data after 6 months of use. FDA requires surveillance to check if the device will be safe for a longer period similar to the life expectancy of the device.

I would like to also bring to the attention of my colleagues a recent GAO report on the inadequacies of the medical device reporting system before anyone starts arguing that it is a substitute for surveillance programs. This report from the GAO states that between March 1994 and April 1995, a backlog of about 48,000 malfunction reports from manufacturers accumulated at the FDA. Many of the malfunction reports, according to GAO, were not entered into the adverse event reporting system until 1996—almost 2 years in some instances. In fact, the House device bill suggests eliminating even this report because of its inefficiencies.

In contrast to that system, the tracking and surveillance programs which I am pushing for are much more effective. This January a good example of this was seen in the case of a runaway pacing implantable cardioverter defibrillator manufactured by Ventritex. Due to their surveillance programs, Ventritex realized the clock in the defibrillator was running radically.

For those who are not familiar, it is a situation where a person has a heart problem where the heart beats irregularly. The defibrillator feeds a shock to the heart to stop the defibrillation and save the person's life. The company realized it was not working right. That kind of problem could be fatal for individuals with these defective devices implanted. On January 15, the company met with FDA and proposed a temporary fix that could set these devices straight. Within less than a month, over 97 percent of the 5,600 patients were found and their devices were reprogrammed. Thousands of lives may have been saved by this effective tracking and surveillance.

Shouldn't this be the case for every lifesaving device? Why does this bill water it down? Why does this bill take away the tracking and surveillance that would give us the necessary information to track this very sort of thing to save people's lives.

In the pretracking days, before we started doing this, I have a letter from a lady named Charlotte Evans. She only discovered this year that her teflon jaw implant might be defective even though the product has been off the market for over 7 years, but no tracking program had been in effect when she bought it. For 11 years since she had this device implanted, her jaw had been undergoing deterioration due to this defect, but she had no notice of any problems with the device.

I think the final chart says it all. Mandatory surveillance leads to early detection of problems, which results in fewer deaths and less serious injuries. Mandatory tracking gives us effective recall and saves lives. To rely only on the medical device reporting system is to treat American people as though they were lab rats while we wait for the body and injury count to mount.

Let me tell you who supports my amendment: Victims Against Lethal Valves, the TMJ Association, the National Breast Implant Task Force, NORD, AARP, Consumers Union, Consumer Federation of America, Bazelon Center for Mental Health Law, the American College of Nurse-Midwives, AMFAR, the AIDS Action Council, DES Action, Center for Medical Consumers, Committee for Children, Human Rights Campaign, National Women's Health Network, Public Citizen, and the Treatment Action Group.

I hope that it will also be supported by a majority of my colleagues. If any of us believed for a moment that someone we love, a member of our family, was about to undergo a surgery and have a device implanted in their body and then be lost so that if something is found wrong with that device later on and their lives are in danger, we would think twice about this provision in the bill.

Let us keep tracking and surveillance in the bill. The medical device manufacturers must accept the burden

of keeping track of the people who receive these devices. If something goes wrong, it is literally our only way to avoid injury and save lives.

Mr. President, at this point I yield back the remainder of my time.

The PRESIDING OFFICER (Mr. BURNS). The time of the Senator from Illinois has expired. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, I again commend the Senator from Illinois for focusing on some of the most critical problems that we have with respect to devices. However, I would only point out that the bill as is at this time is subject to a bipartisan agreement with full concurrence of FDA.

At this time I ask unanimous consent that Senator COLLINS be recognized for up to 10 minutes as if in morning business and that upon completion of her remarks the Senate return to the consideration of S. 830 and the Durbin amendment.

The PRESIDING OFFICER. Without objection, it is so ordered. The Senator from Maine is recognized for 10 minutes.

Ms. COLLINS. Mr. President, I thank the distinguished manager of the bill for yielding to me.

(The remarks of Ms. COLLINS pertaining to the introduction of S. 1199 are located in today's RECORD under ''Statements on Introduced Bills and Joint Resolutions.'')

The PRESIDING OFFICER. Who seeks recognition? The Senator from Vermont.

Mr. JEFFORDS. Mr. President, I now return to the Durbin amendment.

Section 605, is also the subject of bipartisan agreement, with FDA's concurrence. By way of brief explanation, device tracking is intended to facilitate a product recall.

Current law requires tracking for certain product types and also gives FDA discretion to require tracking for other products. It simply is not necessary for every device in the mandatory category to be subject to the tracking requirement. This provision allows FDA to affirmatively indicate which products in the mandatory category should be subject to tracking.

FDA may use its discretion to add new products to the list of products which must be tracked or put a product back on the list for tracking if evidence indicates the need.

This provision is needed because today, FDA will often indicate to a manufacturer that a product need not be tracked, even if it is in the mandatory category. While this many be good policy in the specific case, it puts both the FDA and the manufacturer in an undesirable legal situation. This provision allows FDA to exercise proper discretion and removes any potential cloud of legal liability which exists today.

It is inconceivable that FDA would not require tracking in the tragic cases identified by the Senator. The provision in the bill is logical, safe, and necessary. Further, the GAO report cited by the Senator refers to areas of FDA control totally unrelated to device tracking and surveillance.

SECTION 606: POSTMARKET SURVEILLANCE

Some have asked why we have made the FDA's postmarket surveillance authority discretionary. I am pleased to address that question and I think my colleagues will understand the good reasons for doing so. First, let me clearly state the FDA is in full concurrence with the appropriateness of this policy. I should add that FDA has actually required relatively few products to conduct postmarket surveillance. It is important to differentiate between this authority and the medical device reporting [MDR] and user reporting programs which are unaffected by this provision. The Medical Device Reporter Program is the keystone to the postapproval system for identifying hazardous or defective medical devices on the market place. The MDR Program, coupled with FDA's authority to force product recalls and the device tracking provisions are a strong web of protection for the consumer. User reports, submitted to FDA and manufacturers by hospitals and physicians, are an additional layer of information on the status of medical devices in the healthcare system.

Postmarket surveillance has a different purpose—to gather additional data to provide the extra assurance in the relatively rare situation where FDA has approved a product, yet still believes that the product should be subject to a limited period of postmarket evaluation. This is because for certain types of devices, problems may arise years after approval—problems which may not be detected in even the most elaborate clinical trial but could be dangerous to the individual, or even life threatening.

It is instructive to consider the history of this authority. The Safe Medical Devices Act of 1990 included a provision requiring a manufacturer to conduct postmarket surveillance for any device first marketed after January 1, 1991, that is a permanent implant the failure of which may cause serious adverse health consequences or death, is intended for use in supporting or sustaining human life, or potentially presents a serious risk to human health.

In other words, if you have something which can prevent death or serious injury, you certainly want to try it and use it, but you want to keep track of it to make sure if it proves to be the reverse in certain situations, that you at least know that and then can take appropriate action.

In addition to this mandatory surveillance, FDA was authorized to require postmarket surveillance for any device when the agency determined that surveillance is necessary to protect the public health or to provide safety or effectiveness data. All manufacturers subject to mandatory postmarket surveillance were required to submit protocols for FDA approval within 30 days of first marketing the device. The FDA was required to determine the adequacy of the principal investigator and the protocol and to approve the protocol after review by an appropriately qualified advisory committee.

In practice, the provision for mandatory surveillance, like the one for mandatory tracking, is so broadly worded that it is causing a good deal of uncertainty about those devices which are subject to this requirement. In some cases, companies and the FDA are technically exposed to unfair liability when the FDA does not require surveillance for products where it is, in fact, not necessary. We simply give FDA the discretion to require postmarket surveillance on any product it deems appropriate. This provision in no way suggests that FDA should cease to require surveillance for the types of devices it is currently covering under the existing authority. Indeed, we expect that FDA will by and large continue to require surveillance for most if not all of the products currently covered in the mandatory category. The committee and FDA believe this will be an appropriate way to bring clarity and efficiency to this important agency function. Indeed, FDA Director of Surveillance, Larry Kessler, recently said that he hoped Congress would join FDA in moving toward doing more discretionary and less required postmarket surveillance. They want to ensure that they can use their time as is most appropriate and most effective and efficient for their work, and not be required to do things which their judgment has found not necessary to take their time.

So, for that reason I must oppose this, and as I pointed out, Senator KENNEDY, as well as the FDA, would concur in opposition to this amendment.

I think now I will take some of the time to go back and discuss the 404 situation here, why we are here. Senator KENNEDY has taken extensive time last night and today. Certainly this is an important issue. It is an extremely important issue.

The PRESIDING OFFICER. The Senator has 5 minutes.

SECTION 404: LABELING CLAIMS FOR MEDICAL DEVICES

Mr. JEFFORDS. Mr. President, with the medical device amendments of 1976, Congress intended that device classification and approval decisions be made based on the intended use of devices as described in labeling. In the 20th century, major strides in medical technology have revolutionized the practice of medicine. Thanks to achievements in such fields as fiber optics, imaging, biomaterials, electronics, and biotechnology, today's medical technology is faster, more efficient and more productive than ever. These achievements have provided benefits to individual patients and to society at large—benefits such as better health, more cost-effective medical treatments and the return of patients

to productive lives more quickly. Today more than ever, medical technology is advancing at an astounding rate. Around the world, medical providers and device innovators are working together to bring better, more cost effective therapies to patients.

That is what we are involved with here. So we want to keep in mind, and this is why we sometimes have an interesting dilemma, where you have something which the patients' groups are plotting and which the consumer groups sometimes take an opposite position on, based upon their fears that this process may lead to something getting on the market which might cause a problem and they do not have the confidence that is built into the oversight part. I urge people to understand, the devices we are talking about are important to health. If we delay, as has been the case here, delay after delay after delay, unnecessarily so, then those who need it, those who are trying to improve their health, are denied it because some are so concerned that the delays which are deemed, really, unnecessary, lead to people having devices denied them.

Over the years, FDA has made premarket regulatory decisions based on uses for devices that are unrelated to the intended uses set forth in labeling. S. 830 includes two provisions that express the committee's specific intention to limit FDA's review of premarket submissions to the proposed labeling before the agency. Considerations like cost-effectiveness, relative effectiveness, or whether the product effects some improvement in a patient's quality of life, are irrelevant to a premarket review unless such claims are included in proposed labeling. Simply put, the FDA should not exceed its jurisdictional responsibilities by incorporating into the review process claims not before the agency for review consideration.

For premarket notification submissions, the labeling proposed in the submission will be controlling of a device's intended use. If the intended use is the same or sufficiently similar to the intended use of a predicate device, then the device may be found to be substantially equivalent to the predicate. No considerations outside of the proposed labeling for the 510(k) device should bear on the question of whether or not the proposed labeling of the newer device is compatible with the labeling of the predicate device.

For premarket approval applications, the determination of whether or not there is a reasonable assurance of device safety and effectiveness must be based on claims in proposed labeling if such labeling is neither false nor misleading. The FDA may fairly consider all facts which are pertinent to proposed labeling in PMA's in determining whether or not the labeling is false or misleading. Facts which are pertinent to proposed labeling are those which directly relate to claims in such labeling. For example, proposed labeling which states that a device is for use in treating atherosclerosis cannot be false or misleading because another device is more effective for that purpose. Nor can the proposed labeling be false or misleading because another device provides the same treatment benefits but is less expensive to purchase and operate. However, the failure to state a material fact about the device itself will make labeling in a pending PMA false or misleading.

This provision, which has strong bipartisan support, provides a much needed element of due process to product reviews. We preserve all of FDA's enforcement authority and leave the agency wide discretion in making judgments about new products.

What is at stake here? The ability of FDA to hold up a manufacturer's product on the basis of how a product might be used in the future—even if the company does not seek authority to market a product for those future uses.

I think it will be helpful to delve a little deeper into the technical issues related to this amendment dealing with one part of section 404—it is worth a brief explanation of how FDA clears for marketing new products which are similar to older, legally marketed products, this is the 510(k) process. The agency considers whether the new product is substantially equivalent to the older one. In this process, FDA asks two questions. First, does the new product have the same intended use as the older product? Second, are there issues raised by technological differences in the new product compared to the older one?

On the first question, FDA must not be allowed to second guess or impute new intended uses that the manufacturer does not claim—essentially acting as judge and jury on that question. That is what our bill does. This is simply too subjective a question to allow FDA broad latitude. This bill would not allow that. If the product before FDA claims a legitimate intended use and the product can perform that intended use, this part of the test is met.

But what if the new product has technological features not present in the older product which give rise to different safety and efficacy concerns? Under the bill, and it would certainly be my intent, FDA should and can demand data on those concerns or else not clear the product for marketing. That is what they do today, and that is what they would do under the bill. Further, if FDA determines that a manufacturer is promoting a product for a use that is not approved, all of its enforcement authority is available to correct that situation.

Section 404 simply establishes a proper balance in the product review process and focuses FDA's authority on the more objective ground of technological considerations.

Mr. MACK. Mr. President, I want to add my strong support for S. 830, which will reauthorize the Prescription Drug User Fee Act as well as provide much-needed reforms to the FDA, and the approval process for prescription drugs and medical devices.

I want to specifically address one area of FDA reform which has become one of the most controversial, and most often misunderstood, provision of this legislation. I'm referring to the issue of off-label information dissemination.

This is an issue I've worked on for more than 2 years. Joining me in this effort have been Senators FRIST, DODD, WYDEN, and BOXER. We come from different political parties. We have different political philosophies. But, there is one principle upon which we strongly agree.

Physicians, and other health care professionals, should have the ability to receive credible scientific information from reputable medical journals and medical textbooks in order to make informed treatment decisions with their patients.

However, because of an FDA policy—not a law, not a regulation, but a policy—that is not happening today.

Let me explain.

When the FDA approves a prescription drug or medical device, it does so for specific uses. Frequently, scientists find the FDA-approved prescription drug or medical device is also effective for other uses. Doctors are legally able to prescribe drugs or use devices for these new uses, which are called off-label uses.

According to the American Medical Association, between 40 and 60 percent of all prescriptions written are for off-label uses. For cancer patients, up to 80 percent of prescriptions are for off-label uses. For example, the prescription drug Intron A has been approved by the FDA for the treatment of melanoma, hepatitis B, and other diseases. Additional studies, which were published in such prestigious publications as the New England Journal of Medicine and the Journal of Clinical Oncology, have shown the drug is also effective for such diseases as kidney cancer, myeloma—cancer of bone marrow—and bladder cancer.

However, since 1991, the FDA has maintained a policy which prohibits manufacturers from giving doctors and other health care professionals scientific data about new uses of FDA-approved drugs and medical devices.

That's simply bad public health policy—and the bipartisan agreement we have reached will correct this intolerable situation.

The agreement will permit the dissemination to health care professionals of balanced, peer-reviewed articles from reputable medical journals and medical textbooks about new uses of FDA-approved prescription drugs and medical devices.

It will also ensure that the important research on these important new uses of prescription drugs and medical devices moves forward.

We ensure that only the highest quality of information can be disseminated

by defining the specific criteria for medical journals and medical textbooks. It is important to note this legislation does not permit the dissemination of marketing materials, brochures, promotional materials, newspaper or magazine articles, or other industry-generated materials.

Our legislation ensures that a balance of material about the use must be disseminated. Sixty days prior to dissemination, manufacturers must submit the article it desires to disseminate to FDA along with a bibliography of other medical journal articles about that off-label use. The Secretary has the option of adding an objective statement which describes additional scientific findings about that off-label use of the prescription drug or medical device.

The intent is that the statement be limited to objective and scientific information, and not present an opportunity to editorialize about independently derived scientific information. That statement, along with the required bibliography, must accompany the article or textbook. In addition, companies must also submit and disseminate a detailed statement which discloses that the article being disseminated describes a scientific study about an off-label use; any potential conflict of interest of the authors of the article; the source of funding for both the study and the dissemination of the article; and a statement which discloses if other products or treatments have been approved by the FDA for the use described in the article.

In other words, in addition to the article the company wants to share, the doctor will also receive: the disclosure statement; a statement of additional scientific findings from the Secretary of HHS; any previous FDA notices about that off-label use; a bibliography of other articles about that off-label use; and a copy of the FDA-approved labeling for the drug or device described in the article.

In order to disseminate the medical journal articles and textbooks, manufacturers must agree to conduct the required clinical trials in order to apply for a supplemental new drug application.

Companies must either certify they will file an SNDA within 6 months, or they must submit a clinical trial protocol and time schedule for conducting the needed studies to apply for an SNDA within 3 years. The Secretary of HHS may grant a 2-year extension to comply with this requirement if the company is acting in due diligence to conduct the studies in a timely manner. Periodic progress reports are required to be filed with the Secretary. Companies may apply for an exemption under very limited circumstances.

The manufacturer is also required to share with the Secretary new information about that same off-label use of the drug or device. If the Secretary determines the new information demonstrates that the drug or device may not be effective or may pose a significant risk to public health, then the Secretary shall, in consultation with the manufacturer, take corrective action to ensure public health and safety.

The provision provides the Secretary of HHS with strong oversight authority, including the ability to stop dissemination of articles and the ability to require manufacturers who violate the provisions of this legislation to either take corrective action or return to compliance. The Secretary can order a manufacturer to cease dissemination if the SNDA application is denied.

We also require that two future studies be performed. One study will examine the impact this legislation has had on FDA resources. The other study will assess the quality of the information disseminated and it will examine how useful the information has been to doctors and other health care providers.

It is important to note that this legislation will expire in 2006, unless Congress acts to continue it.

This legislation has earned the enthusiastic support of the American Medical Association. Let me quote from the AMA's Council on Scientific Affairs report:

> It is imperative that physicians have access to accurate and unbiased information about unlabeled uses of prescription drugs. Dissemination of independently derived scientific information about unlabeled uses by manufacturers to physicians can help physicians have access to the latest, scientifically credible information.

A Roper poll of oncologists released in July 1997 found that 70 percent of doctors believe FDA rules about off-label information stand in the way of doctors' efforts to get the most credible information about cancer treatments. The poll also found that 99 percent found peer-reviewed medical journal articles is a source they use when making prescription decisions.

In addition, numerous patient organizations also support the dissemination of scientific information regarding off-label uses of prescription drugs and medical devices. These organizations include the American Cancer Society, the Leukemia Society of America, the American Osteoporosis Foundation, the American Society of Clinical Oncology, the Cystic Fibrosis Foundation, the A–T Children's Project, the American Liver Foundation, and the National Alzheimer's Association.

Mr. President, for the past 2 years, this bipartisan group of Senators—myself and Senators FRIST, DODD, WYDEN, and BOXER—have worked together to craft legislation which will permit health care professionals to receive important scientific information while ensuring consumer safeguards.

This bipartisan effort is based upon the belief that health care professionals should be able to receive scientific data while ensuring patient protections.

Most importantly—and this is key—from a patient's point of view, this legislation will greatly increase one's odds of getting state-of-the-art treatment which could cure a disease, slow the progression of a disease, or, at minimum, improve one's quality of life.

It is simply wrong to continue this policy which denies the ability of a health care professional to receive an article from a medical journal or medical textbook.

Doctors, nurses, and other caregivers help patients make life or death decisions every day. They need access to credible scientific information to discuss with patients. We must take this commonsense step to make sure they are able to receive accurate, unbiased information, including information about off-label uses, which will help them make informed treatment decisions with their patients.

I am very pleased to report this agreement has received the support of our colleague, Senator TED KENNEDY, the ranking member of the Senate Committee on Labor and Human Resources. It also has the support of the Secretary of Health ad Human Services, Donna Shalala.

I would like to thank them, along with Richard Tarplin, Assistant Secretary of HHS, and Bill Schultz and Dianne Thompson of the FDA, for their cooperation in reaching this historic agreement on what has been a very contentious issue.

Finally, I want to thank my colleagues who worked with me on this agreement, Senators FRIST, DODD, WYDEN, and BOXER. It's been a pleasure to work with each of you, and I look forward to working with you on other public health issues in the future.

Mr. President, I suggest the absence of a quorum

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

Mr. JEFFORDS. I understand the Senator from Georgia has time, and I ask if he would yield me 5 minutes.

Mr. COVERDELL. I yield up to 5 minutes to the distinguished Senator from Vermont.

The PRESIDING OFFICER (Mr. HAGEL). Without objection, it is so ordered.

Mr. JEFFORDS. I am sorry to have to report, we have been trying in this last 45 minutes to see if we could move some amendments that everybody has agreed to and to show that we are really trying to bring this bill before this body and to make progress so we can decrease the amount of time that will be needed at the end as we move through the cloture process.

Unfortunately, we have not been able to get that agreement. So such amendments as those of Senator MURRAY, Senator DEWINE, and others, that would have been approved by unanimous consent by will have to wait for

some future time in hopes that we can get agreement.

I want to point out there are a large number of amendments pending on this bill, many of which are agreed to, others that probably will fall by the wayside, it should not be that difficult to finish work on this bill. However, if we continue to have this delay, without any cooperation to move the process forward, then it is going to foul up our very crowded calendar. That is unfortunate, as we all want to get the legislation done, get the conference reports on appropriations bills passed, and other pending legislation which is essential, so that we do not have to shut the Government down. If we fail to get the cooperation of the minority in even agreeing to things that everybody agrees to, it is unfortunate.

Let me point out some of the Senators we would have helped today: Senator DEWINE, for instance, and Senator DODD; their amendments should have been agreed to. They have shown great leadership in advocating greater research into pediatric uses of new and existing drugs. Their amendment reflects Senator DEWINE's successful effort to marry the mandated approach in the administration's regulations with the incentive-based approach underlying Senator DEWINE and Senator DODD's provision. Senator MURRAY has worked diligently to protect the health and safety of children. Her amendment, which everybody agrees should be approved, modifies the national uniformity provision clarifying that the exemption requirement is applicable to the health and safety of children.

Other amendments by other Members that we could have adopted today will have to be done at some later time as long as the minority continues to block progress on the 152-page bill, of which 150 pages are agreed to. That does not make much sense. Why do we have this delay over a provision on which there is a disagreement, and general knowledge that the disagreement will have to be taken care of in the conference committee. The White House will insist that we come up with something different than is in the bill and the House has already taken a different position. Why should we delay the meeting of that conference committee?

I urge the minority to let us vote—they are holding up an extremely important piece of legislation. The only advantage in doing this is to raise more public attention to one issue—that the minority is willing to tie up the Senate over one sentence in this bill in full knowledge that further work will be done on the issue in conference.

So let's move this bill along, get it to conference. The House is moving expeditiously, so we can go to conference probably at the end of next week if we can get this bill done. I urge the minority to change the tactics of delaying any progress on this bill.

I yield the floor.

The PRESIDING OFFICER. The Senator from Georgia.

EDUCATION REFORM

Mr. COVERDELL. Mr. President, this Congress began its deliberations in a very interesting way. Our conference, our side of the aisle, met before the convening of the 105th Congress and concluded or defined 10 major issues they thought should be brought before the Nation.

The first issue, which resulted in the first piece of legislation for this Senate, for this Congress, was education. It was unanimous agreement in the conference that our first expression in this Congress on our side of the aisle would be about education and its importance. Not long after that the President of the United States announced that education would become a centerpiece of his activities during this Congress, and he actually visited Georgia, he visited various locales across the country, and he talked about, by and large, the requirement or need that people have some relief from the costs of higher education.

It is interesting, and in a sense in a bipartisan way, we had key leaders in both parties focusing on this issue. It is certainly exactly what ought to have happened. I believe the genesis of American glory is that we have been a free people. I have said more than once that an uneducated people cannot be free. An uneducated people cannot be free.

So as we, the custodians of this great democracy, prepare for a new century, we have to be asking ourselves the question over and over: Are we preparing the generation that will lead that century with the tools that they will need and require to be ready to do that job? Unfortunately, the news is not altogether comforting when you review the data.

Despite the intense interest in the last tax relief proposal on costs of higher education, that higher education is not where America is in trouble in its education. America is in trouble in its elementary and high school level.

I was reading just the other day a prominent survey of the condition in elementary schools. It is fairly alarming. It suggested that 4 out of 10 students in elementary school today are frightened by some aspect or fearful of violence in the school. Mr. President, the survey concluded that 3 out of 10 students in elementary school will have property stolen from them in the schools. It suggested that 1 out of 10 will be confronted with a deadly weapon while they are in school.

When you look at the condition of our reading proficiency, our basic skills—reading, writing, adding and subtracting—we are not comforted by the data which, of course, has led to this massive debate about skills that students have to achieve by the time they are in the fourth grade, have to achieve by the time they are in the eighth grade, and how are we going to certify that it has happened.

I have spent the better part of the last 2 years talking about the fact that we have a drug epidemic in the United States, particularly among our younger teenagers. We have seen statistics that show that drug use has doubled in the last 36 to 40 months. These are schoolchildren, Mr. President. If you go to these schools—and I invite anybody to do it—the students are very savvy, they know exactly what is happening, and they know that there are drugs and violence surrounding their environment in school.

So, 4 in 10 are fearful; 3 in 10 are going to be robbed; 1 in 10 is going to face a weapon; and all of them will tell you the nature of drugs and the availability of drugs.

Three out of ten who come to college this September will have to take remedial training in reading. In other words, 30 percent-plus of the students that have gone through our elementary school system and our high school system are not ready for college and can't read well. So I guess the story is beginning to frame itself: We have a problem in K through high school. An American family ought to at least expect that when their child graduates from an American high school, they can do the ABC's, they can read, they can write, and they can do their arithmetic, and they are not behind. Society spends millions upon millions of dollars retraining these students by the time they get to college.

Well, I think this data and these statistics, Mr. President, are the reason that when you poll Americans, the vast majority of them now put education as the No. 1 issue. It is because they are reading the same data that we are reading. And, of course, it is the reason that leadership in both parties have come forward of late and have suggested that we need to make the Federal Government be the appropriate partner—the appropriate partner; not the governor, not the manager, but a good partner—in helping our States and our local communities get a handle on what is going wrong in public education at the elementary and high school level.

So, as a result, the first bill was introduced, S. 1, which contained three major initiatives. First, there was tax relief making employer-provided educational assistance tax free to help make up this shortfall, help these employers bring new educational opportunity to their employees. That is now law.

S. 1 allows State prepaid tuition plans to pay for both college tuition and room and board. That is now law.

S. 1, our first piece of legislation, made interest on student loans tax deductible. That is now law.

S. 1 provided education savings accounts for college. That is now law. That was a compromise and a coming together of the President's proposals and of our conference proposals.

S. 1 dealt with the Individuals With Disabilities Education Act and made a commitment to full funding for the Individuals With Disabilities Education Act because, while passed originally in the 1970's with a promise that about half of the cost would be borne by the Federal Government, it was never done. Congress had reauthorized the act earlier this year. It attempted to modify it, to make it more flexible, more suitable for local school boards. And that is now law. Everything that we wanted to achieve in S. 1 was not, but much was.

There were key provisions in S. 1 for school safety. I alluded to this data just a moment ago—that you have 4 out of 10 that are fearful, 3 out of 10 that will be robbed, 1 out of 10 that confront a deadly weapon, and all of the students will tell you of the problems with drugs in and around their schools. This is not yet accomplished, this key provision of S. 1, and we plan to come back and address these issues as we move through this 105th Congress. As an example, we currently offered an amendment to the Labor-HHS appropriations bill that provides funding, Mr. President, for student hot lines to report acts of violence in school or for witness protection programs that would allow students additional protections if they would ever become a victim of a serious crime.

Now, Mr. President, in the course of the debate on tax relief, I introduced an amendment, cosponsored by many, that tried to make the tax relief proposal reflect more concern about the problems that we are having in elementary school and high school. As I said, if there is a criticism about the education components of the tax relief proposal, a constructive criticism, it is that it all focuses on higher education. But as I have just alluded to, Mr. President, the problem is not there. Yes, the problem of costs are associated with it, but it is an effective system, the envy of the world. Our elementary schools are not the envy of the world, and they are a source of great worry for us in the United States.

So we introduced in the Senate, in the debate on tax relief, a proposal that would empower parents to deal with education deficiencies, whatever they happen to be, for their children. We created and passed in the Senate, by a very powerful vote, 60 to 40, an education savings account for students, grades kindergarten through high school. It allowed parents to save up to $2,000 per year per child in after-tax dollars, but the interest buildup would not be taxed if, at the time the account was used, it was used for an educational purpose for that child.

Mr. President, the savings account has a very unique feature to it. It allows sponsors to contribute to the account. So the parents can contribute to the account, obviously, but the grandparents could as well, or an aunt, an uncle, a neighbor, a friend, an employer, an organization, an association—all of these could become partners to that family to help produce an account that that family could use on behalf of the child's education. Mr. President, this would result in billions of dollars over the next decade coming to the assistance of education where it really needs it—elementary and high school.

Mr. President, these new dollars, these billions of new dollars, I call the smart dollars. They are the most intelligent dollar investment that will occur in education. Why is that? Because they can be used for any education deficiency; whether the child needed a home computer or some other new technology, or the child might need a tutor because of a math deficiency, the child might need to be prepared for an SAT test, it might be necessary for an after-school program, or transportation, or uniforms, or whatever. But these dollars would be directed, like a bullet, right to whatever the problem was.

Now, vast public spending doesn't accomplish that. It sets up the broad parameters, but it has a difficult time getting to that child's specific deficiency. It may be medical, like dyslexia, or some other problem. But who knows best about those deficiencies? The parents. This arms those parents with an ability to go right to the problem, right on target.

So these billions of dollars would be the most intelligent invested dollars we could envision or imagine in education. Mr. President, these education savings accounts have created an enormous outpouring of support. There is some opposition, and I am going to deal with that in a minute. But the account could also be used for home schooling. The account could also be used for tuition, if the parents had decided that they needed to put that child in another learning environment, for whatever reason.

Mr. President, last week, we held a press conference here in Washington on behalf of two proposals that are part of our side's education initiatives. One was the proposal to provide funding for Washington, DC, public school scholarships, to allow students that are trapped in the most difficult schools an opportunity to have the resources, up to $3,200 per student, to move to a school that was either safer or was producing a quality education.

The other proposal that the press conference gathered to support was the education savings account that I have just described. It was one of the most moving press conferences I have seen in Washington, Mr. President. The Presiding Officer and all of us have been to one press conference after another, and you can almost cite the routine. But this one broke the routine. I knew the Speaker would be there, and the majority leader from the House, and myself and Senator COATS from Indiana, a leading spokesman for education reform. We walked into the room and were joined by Alveda Celeste King, a native of my home city; Congressman FLAKE of New York, an eloquent spokesperson who decided that he will resign from Congress and return to his ministry; a young woman named Starr Parker, who had written a book, ''From Welfare Mother to Work.'' It tells the story of her life, freeing herself from the entrapment of dependency, and the independence she has gained by moving to regular work; a great spokesperson and a single mother of four from Cleveland, OH, giving an elongated story of her work to free her four children, who were in violent situations in public schools. They were in schools that were not teaching her children, and she told her story of freeing them from these schools and getting them to a new environment.

They were all there speaking on behalf of ideas like the education savings account and how important it would have been to them to help them deal with the particular problems that their children had faced and the entrapment that they were confronted with when no options were made available to them. The education savings account would have been a tool that they could have used to free themselves of these environments and get their children into the proper school environment that they sought.

It reminded me, Mr. President.

I see that we have been joined by our good colleague from Alaska, and I am going to turn to him in just a moment.

But my sister was a single mother of four with two sets of twins. I remember my father and I meeting many, many years ago and deciding that their education was going to be a major issue. We didn't have a lot to spare in those days. We opened up a savings account, and he and I both started contributing every month a little bit, and then a little bit more so there was a little nest egg available by the time these children were trying to deal with their college education.

If the education savings account had been in place, that nest egg would have been twice the size it was when it was ready for use because the interest would have built up, and it wouldn't have been taxed. We could have used those assets to help further and even do more than was done on behalf of their education. There is not a family in America—no matter whether their child is in school—that this concept wouldn't be applicable to, and no one knows more what the peculiar or particular deficiency is than the family.

So this is a powerful tool that will stand behind education wherever it is occurring—public schools or private schools or a home school or an employer environment.

Mr. President, I am going to turn to the Senator from Alaska, who has just joined us. He has been an eloquent spokesman in terms of our educational issues. I yield him up to 15 minutes, if that is appropriate.

Mr. MURKOWSKI addressed the Chair.

The PRESIDING OFFICER. The Senator from Alaska.

Mr. MURKOWSKI. Mr. President, let me first commend my good friend from Georgia for his efforts to bring attention to the significance of the current education situation in the United States, and in particular, for emphasizing some of the shortcomings in our educational system and what we can do to change them. I am very pleased to join him in this effort.

Mr. President, I would like to talk about issues concerning education and the attitude of constituents with regard to what they see as insensitivity by the Federal Government. They look upon education as a responsibility that should be shared, with the primary concern resting with the parents, the educator, and then moving into the community as a whole and the school boards, as opposed to a centralized dictate from faceless and nameless bureaucrats in Washington, DC, dictating an educational system which suggests, ''one size fits all''.

When I go back to my State of Alaska, I consistently hear about the state of education—not only in my State but as it applies in our country today. I think it is fair to say that the American people are extremely concerned that, despite annually spending hundreds of billions of dollars at the Federal, State, and local level, our education system to a large degree is failing. The simple fact is that 78 percent—I am astounded at this—of all 2- and 4-year colleges offer remedial courses in math, reading, and writing; 78 percent. We would assume that our high school students have these skills when they get to the university. But that is not the case. Seventy-eight percent of all 2- and 4-year colleges now offer remedial courses in math, reading, and writing.

What does that suggest? It is pretty obvious that many high school students are being shortchanged in their academic preparations for adulthood.

Is that a responsibility of the parents, the educators, the school board, or the system? Well, I would have to say, it is pretty much the system.

As my friend from Georgia recently stated on this floor, the educational savings account offers relief. The recently enacted balanced budget bill contained nearly $40 billion in tax incentives to help parents and students defray college education costs.

In addition, the new law provides individuals a $2,000-per-year lifetime learning tax credit that can be used by an individual throughout his or her life, to enhance professional skills or complete graduate or undergraduate degrees.

I strongly support these tax incentives because in the globally competitive 21st century our Nation's economic success—our very future—will depend on a highly educated and high-skilled labor force.

It is so disturbing today as we look at some of the areas, particularly the inner-city areas of this country, where, unfortunately, many young people come from homes in which they spent little time with either parent, and oftentimes with a relative trying to do the best he or she could in raising those children as a single parent. Some of these children are involved at a very young age in simply transporting narcotics, a trade made easier because law enforcement agencies might not initiate any significant sentencing on these young people. Some of them become addicted as teenagers and young adults and thus depart on this trail which leads to dire consequences. Others may be incarcerated from time to time as teenagers. The fact is when they are looking for a job, their skills are very limited. Many of them can't read and can't write. They have a very bleak future. Oftentimes that future leads to crime, drugs, and ultimately, a burden on society.

It is just not the inner-city areas where we have this exposure. We have it in other areas of the country also. Obvioulsy, we need to alleviate this situation. To do so, we should assist families instead of offering a Federal solution which more often than not will not work.

So I go into this area to elaborate a little bit on the dilemma facing society today. Some of the solutions that have been proposed, and the tax incentive for higher education that was supported by the President along with the majority of Democrats and Republicans in Congress, do not contain restrictions that condition the incentives on students attending a public university. So families at the college level can take advantage of incentives whether the children attend State school or private universities.

But I think it is ironic that while the Congress and the President work so well together on promoting higher education incentives, the President, as we know, had threatened to veto the entire tax bill because a bipartisan group of Senators, including myself and the Senator from Georgia, sought to give parents with children in grades kindergarten through 12 basically similar tax choices.

Why is it that it is all right to provide incentives for attending private universities but similar incentives are deemed inappropriate while students are attending kindergarten through 12? The White House has not offered much of an explanation.

As important as a university education is this day and age, the best assurances that a child will do well in college, let alone be admitted to college, is the quality of education that student receives between the ages of approximately 5 through 18. When are study habits developed? When are reading, writing, and math skills developed? Everyone in this Chamber knows that children do not suddenly develop these disciplines when they enter college. The foundations for educational development begin at the early stages of kindergarten, preschool, and evolve as the student moves up in grades through junior high and high school.

As we look at other societies, particularly Japan, I have often been struck by the commitment of parents. Many times the mother will study with the child. As a consequence, a family unit takes a significant interest in the learning process. When those youngsters who are in the Japanese system want to go on to school, they must take an exam. There is a great deal of family excitement around the test as the student studies for the exam and the family experiences a great deal of anticipation as to whether or not the child will pass the exam. But it is a system, if you will, that is supported by strong parental association.

Sixty Senators voted in June to allow parents to establish educational savings accounts, proceeds of which could be used to offset the cost of private schools or home schools in the K through 12 grades. This would have given parents of young children a very modest tax subsidy if they choose to send their children to private school. Contributions to such accounts would not have been tax deductible. The only benefit of these accounts would have been that earnings could be withdrawn tax free.

Although modest in scope, these accounts could have given real choices to low- and middle-income families who believe their children's best chance for the future lies in gaining an education in a private school.

Income limits ensure that the benefits of these educational savings incentives would have been focused on middle-income families. Wealthy families most often do not need to use these educational accounts because they can easily afford the cost of private K through 12 tuition and because the tax base in wealthy communities often provides the best possible public education in the Nation.

But middle- and low-income families don't have the same choices that the wealthy have when it comes to education because they don't have the adequate resources to pay private tuition. Allowing these families the choice of using funds from educational savings accounts for grades K through 12 would enable families with modest incomes to send their children to the schools where they believe that the child will get the best preparation for college.

What is wrong with that?

Mr. President, if the education savings accounts can be justified for college tuition, shouldn't they also be allowed for the educational expense that gives the child the opportunity to apply to college?

Mr. President, Congress and the President will again have the opportunity to debate this aspect of educational choice in front of the American public.

I am pleased to be a cosponsor with my good friend, Senator COVERDELL, who is with me on the floor today, of

his bill, PASS A+ Act—and I think that is an appropriate name, PASS A+ Act—which would allow parents to make contributions to education savings accounts that can be used to finance K through 12 education.

I hope we can pass this legislation before the end of the year. I hope that President Clinton will reconsider his opposition to helping families finance the cost of sending their children to the primary and secondary schools of their choice.

Mr. President, while I am a strong supporter of giving families a choice of where they send their children to school, I believe a vibrant and dynamic public school educational system is a strong bulwark of a free society, and I totally support it in this Nation.

That is why I supported an amendment to the Labor-HHS bill offered by Senator SLADE GORTON that will award all funds appropriated to the Department of Education for K through 12 programs directly to local school districts.

Let the local school districts bear the responsibility associated with the education process and let them be responsive to the parents of those children entrusted to the local boards of education for performance. That is the concept, the very basis of the accountability concept. It is pretty hard to hold nameless bureaucrats in Washington, DC, under a dictate one-size-fits-all. I think Senator GORTON's amendment puts the responsibility down at the local area, with the local school boards, by giving them, if you will, the necessary funding. His amendment I think reflects my fundamental belief that education policies and procedures are best determined by those who are the closest to the student. That means shifting decisionmaking to parents, teachers, and local school boards and away from Washington bureaucrats.

By simply block granting education dollars to local school boards, each of the thousands of communities in this country will have the flexibility to improve their education system at the local level, putting the responsibility on the people.

And by consolidating Federal education funds into a block grant we can assure that almost every school district will receive more funds for actual education rather than having the funds lost in a bureaucratic administration mire that exists here in Washington.

Under the Labor-HHS appropriations bill, more than $11 billion would be distributed under the block grant approach. Currently, the costs of administering the programs that would be block granted represent nearly 15 percent of the $11 billion. The block grant approach would free up the administrative dollars, meaning nearly $1.5 billion more—$1.5 billion more—could be used for students instead of filling out forms to be sent back to Washington, DC.

Mr. President, there are 788 Federal education programs that spend nearly $100 billion a year. How many of these are necessary? These programs are administered by 40 departments and agencies of the Federal Government. These agencies, I assure you, are not supportive of our proposal because they would not have anything to do.

Well, it is time to do a top-to-bottom review of how we could streamline the delivery of education dollars to local communities, and I think Senator GORTON's amendment is the first step. It is my hope the President will support this approach through educational funding that puts children and teachers ahead of bureaucrats and program managers in Washington.

So I think it is time for Washington to catch up with the American people on how to improve the educational opportunities of our children.

Mr. President, I wonder if I could defer and make a short introduction of a resolution that would follow as opposed to interrupting the presentation by my colleague.

Mr. COVERDELL. I will be glad to yield whatever time to deal with the resolution, and it is perfectly appropriate. The Senator is asking unanimous consent it follow this.

Mr. MURKOWSKI. I ask unanimous consent, Mr. President, the resolution follow the debate on education we are having here today.

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

(The remarks of Mr. MURKOWSKI pertaining to the submission of Senate Concurrent Resolution 53 are located in today's RECORD under ''Submission of Concurrent and Senate Resolutions.'')

The PRESIDING OFFICER (Mr. COVERDELL). The Chair recognizes the Senator from Nebraska.

Mr. HAGEL. Mr. President, I thank the Chair. I rise to support the Coverdell bill, of which I am a cosponsor.

Mr. President, we have been debating several pieces of legislation on education here in this body over the last few weeks. It is important to clearly understand how all of this legislation fits together and why. This is about restoring the fundamental belief that education policy and curriculum belong at the local level; they are best determined by those closest to the students, who care most about the students, and who have the most to win or lose—the parents, the teachers, the local school boards, not Washington. As well-intentioned, as well-motivated, as the Department of Education is, as are the President and the Congress, who all care about education, it is those at the local level who understand it best.

The Gorton amendment, which has been referred to by my friend and colleague from Alaska, was passed last week during the debate on the Labor-HHS appropriations bill. This amendment block grants funds from several K–12 education programs in the Department of Education. It sends that money back to the States, back directly to school boards.

The Coverdell bill, another piece of the fundamental education philosophy debate in this body, is the Parent and Student Savings Account Plus Act. This legislation, as has been referred to many times this morning, allows parents to make up to a $2,000 per year contribution in after-tax dollars to an education IRA, or you could refer to it as an expanded education savings account for primary and secondary education. Parents would be free to choose how this money and where this money would be used on behalf of their own children's education.

The Coverdell bill helps families, especially lower-income families, exercise the same rights as wealthy people when it comes to deciding where their children go to school.

Mr. President, I always start with this premise: Whose money is this? Whose money are we talking about? It is not my money. It is not the President's money. It is not the money of the Secretary of Education. It is the parents' money, the taxpayers' money. My goodness, should they not be empowered with some responsibility, since it is their money, as to how they use that, where they focus to help educate their children? I think so.

Our education problems begin not at the college or postsecondary level. Somehow we glide over that. Our problems in education begin at the beginning, at the elementary and secondary levels. This is where we must capture these young people. This is where they learn to read and write and discipline themselves and develop logic and work through problems—at the beginning. Not in college; it is too late. This is where we should focus. This is where the choice should be. This is where students and parents desperately need a choice in education.

We will probably soon have the opportunity to vote on a third education reform measure in this body, that being the District of Columbia Student Opportunity Scholarship Act, another fit, Mr. President, in the overall education debate, the overall education philosophy.

It is no great secret that the District of Columbia school system is deeply troubled. It is not the parents' fault. It is not the students' fault. But this bill that we will debate would create a tuition scholarship fund that would allow 2,000 low-income students in the District to attend public schools, private schools, or parochial schools, but schools of their parents' choice. It would also provide direct aid to an additional 2,000 public school students who want to improve their academic skills through afterschool tutoring.

As Alveda King recently wrote, ''Is it moral to tax families, compel their children's attendance at schools and then give them no choice between teaching methods, religious or secular education, and other matters?'' I do not think it is. ''Is it consistent to proclaim, meanwhile, that America is a

Nation that prides itself on competition, consumer choice, freedom of religion, and parental responsibility,'' yet, in fact, we don't give our parents a choice where they send their children to school?

The Gorton amendment, the Coverdell bill and the DC Student Opportunity Scholarship Act are not an attempt to destroy public schools. My goodness. And that is an important point, Mr. President. I hear my colleagues on the other side of this debate saying, ''Oh, you will destroy public schools. You will take funds from public schools.'' Nonsense. This Nation is a rich, great Nation because we have always had diversity. From the first days of the people who settled this Nation, it has been about diversity. People from all over the globe have made America great and continue to make America great. It is about diversity. It is about choice. It is about competition.

Americans should want their public schools to be the very best, to be the absolute best school systems that they can make, they can provide, they can develop. I have a daughter in a public school system in Virginia. It is a good school system. I am not standing in this Chamber today to do anything that would deteriorate, take away or harm the public school systems. But we must enable all people to choose the best education for their children, whatever their circumstances are in life. And we must restore the fundamental belief that education policy and curriculum are best determined by those closest to the students—parents, teachers, school boards—not Washington.

Mr. President, I strongly encourage my colleagues to support the Coverdell bill, and I yield my time. I thank the Chair.

Mr. GORTON addressed the Chair.

The PRESIDING OFFICER. The Chair recognizes the Senator from Washington.

Mr. GORTON. Mr. President, on Monday, millions of American children will board schoolbuses all across the country.

But when they get off those buses, will they be walking into schools that challenge them to learn and grow, or into empty shells of missed opportunities and lost hopes? Are we doing the best possible job of educating our children, or can we do better?

For decades, the conventional wisdom in our Nation's Capital has been that Washington, DC, knows what's best for our schools. I disagree. I think teachers, parents, principals, and school boards know what's best for our children.

Earlier this month, the U.S. Senate passed school reform to restore the traditional role that parents and teachers play in education.

The reform adopted by the Senate sends Federal education funds for kindergarten through high school directly to school districts.

Bypassing Federal and State bureaucracies, which siphon millions of dollars and attach regulatory strings, means more authority and more money for local educators.

All of us want the best education possible for our kids. We all want them to succeed.

A good education unlocks the future, provides a lifetime key to open doors of opportunity and helps our children reach their dreams. We can provide that opportunity to our children by restoring the role that parents, teachers, and principals need to play in education.

Unfortunately, Washington, DC, takes a different view—the President and Democrats in Congress have denounced this proposal.

Education should not be a partisan issue, but when this school reform measure was approved by the Senate, not a single Democrat voted for it. And the President has said he will veto this reform when it comes to his desk.

Apparently, he prefers a system that has Washington, DC, deciding what's best for schoolchildren in Chehalis, WA; New York City, and every place in between. By taking this position, I think the President is telling parents and teachers: ''I don't trust you.''

While I believe the President has taken the wrong position, I know that he and I share the same goal—we both want what is best for our children. The debate is not over who cares more for our children's future—the debate is about how to achieve our shared goal of doing the best we can for children.

There is nothing more important than our children's future. There are few issues as troubling as the state of our educational system. The next century will demand a lot—advanced technology, the global marketplace, an ever-changing American society—and I am concerned that our children aren't going to be completely prepared for their upcoming challenges.

There was a time in America when parents and teachers had more say in their children's education. Over time, Washington, DC, gradually took responsibility for education from our home towns, and put it in the hands of Federal bureaucrats. What have we gotten for allowing Washington, DC, to run our local schools?

Since 1960, education spending has risen 200 percent, but SAT scores are down. Teachers used to make up two-thirds of the full-time school staff—now it is barely half. And schools are more dangerous than ever.

The Washington, DC-knows best approach to education has also taken us away from the ''back to basics'' approach long-favored by parents. Skim through your daughter's American history book. Does it instill her with hope? Is it the story of how incredibly diverse people came from all over the globe to pursue boundless opportunities? Or is it a visionless narrative of American failures and shortcomings?

Those who oppose this measure argue that it's somehow dangerous to entrust parents and teachers with more control over our children's education. Those in Washington, DC guard their power jealously, and they won't give it up easily.

The President says this proposal will reduce funding for schools, and eliminates the Department of Education—it will not.

Under this proposal, local schools get more money, and the Department of Education plays a more modest role.

While fewer bureaucrats and a weakened Department of Education are valuable byproducts of this effort, they are not my primary concern—giving parents and teachers more control over their children's education is my single most important goal.

One Senator who opposes school reform said he actually thought that parents would build more swimming pools, instead of buying more books, if Washington, DC stops telling our schools how to educate our children.

I disagree. It's offensive to suggest that parents and teachers don't have the children's best interests in mind.

I believe that with the additional authority and funding schools would receive from this reform, our teachers, parents, principals, and school boards will be inspired to do even more—not to build swimming pools—they will be inspired to make sure that every child receives the best education possible.

It comes down to this—will local schools be improved through more rules from Washington, DC, or will they be improved if we restore the authority for education decisions that parents, teachers, and principals once had?

On this issue, I believe the answers are best left to our parents, teachers, and communities, not Washington, DC.

Mr. LOTT. Mr. President, I commend the Senator for what he has done with the education issue. I am really excited about the prospect of having, in fact, more education funds available for my State but decisions made about those funds going to the States and local governments. I commend him for doing that.

UNANIMOUS-CONSENT REQUEST—CAMPAIGN FINANCE REFORM

Mr. LOTT. Mr. President, I ask unanimous consent that the majority leader, after consultation with the Democratic leader, must turn to S. 25, the McCain-Feingold campaign finance reform bill prior to the close of the 1st session of the 105th Congress, and Senator MCCAIN be immediately recognized to modify the bill, and it be in order for the majority leader to immediately offer an amendment relative to campaign finances. I further ask unanimous consent that it not be in order for any Senator to offer any legislation regarding campaign finances prior to the initiation of this agreement.

The PRESIDING OFFICER. Is there objection?

Mr. DASCHLE. Reserving the right to object.

The PRESIDING OFFICER. The Chair recognizes the minority leader.

Mr. DASCHLE. Mr. President, I am very disappointed on what I thought was an understanding the majority leader and I had about the way we were going to do business around here. I worked very closely with him all day yesterday. We were able to get quite a bit done legislatively on Interior appropriations, and work through an agreement on FDA that required my cooperation. Yet I am presented with this about 30 seconds ago—no consultation, no discussion, no deliberation, no way with which to discuss whether this makes sense for either side; an ultimatum, take it or leave it.

That is not the way to do business around here. It is an affront to the Democratic Caucus, to me personally, and it begs the question about how sincere this offer really is. If it were sincere I would think the majority leader and I would have a chance to sit down and talk about it together, work it through. No effort was made to do that.

So, it is enlightening, it is instructive, and it will be reciprocated.

I am delighted that the Republicans have finally seen fit to recognize the importance of dealing with this issue this year. I am pleased that at long last they have agreed at least to taking the bill up, the McCain-Feingold bill, that 45 Democrats have said they support. It only takes 2 more Republicans and we will have the 50 votes necessary to pass McCain-Feingold as it was introduced, as S. 25. So we are looking for two more Republicans. We are hoping that 5 Republicans and 45 Democrats will pass this legislation sometime this year.

What the majority leader is asking in this unanimous-consent request is that at some point between now and the time we adjourn—it could be the last day of this session—that we give consent to go onto this legislation.

Before the majority leader leaves the floor, I will have a question for him, if I could pose it? At least I would appreciate that respect.

Is it the intention of the majority leader to bring this bill up at a point that will allow a deliberation and consideration of the legislation well before the adjournment of the session in order to afford us the opportunity to have a good debate about the bill? Mr. President, I would ask the majority leader that question.

The PRESIDING OFFICER. The Chair recognizes the majority leader.

Mr. LOTT. In response to the question under the Senator's reservation to the unanimous consent, this agreement says that it would be done prior to the close of the 1st session of the 105th Congress. Certainly, there would be notification of what date that might be. I think, you know, we would have to talk to a lot of people on both sides of the aisle, including Senator MCCAIN, among others, who could not be here at this hour because he has had a commitment and had to leave by airplane. It depends on a lot of other circumstances that we would have to take into consideration. We might want to do it early. We might want to do it later. But it would not be my intent to do it right at the end of the session. But I don't have a date in mind. We will have to look at what is happening with other bills all the way from FDA to appropriations conference reports.

Next week, for instance, the focus has to be on getting the appropriations conference reports agreed to. It would depend on what is happening with other major legislation like the transportation bill, the administration's proposal with regard to fast track—all of these will be taken into consideration. We want to do it in a time when it can be fully debated. I think it is important that we have a chance to look at different proposals and see if a consensus can be reached, see if there is some way that we can deal with the way the laws were broken in 1996 but see if it can be done without another big Government gag of free speech.

So, we fully intend to have notification of the date and an adequate discussion on all sides of the issue.

Mr. DASCHLE. Is it the majority leader's intention to adjourn on or about the date of November 14?

Mr. LOTT. I beg your pardon, repeat the question?

Mr. DASCHLE. Is it the intention of the majority leader to adjourn on or about the date of November 14?

Mr. LOTT. As we have discussed in the past, at the beginning of the year we sort of laid out a schedule for the whole year of the times that we would be in and out in each month. At the beginning of the year we had talked in terms of having a week in October off for the Jewish religious holidays as well as the Columbus Day period, and that we would—you know, our target day to adjourn was the 14th.

There has been some consideration of it being earlier than that. Senator DASCHLE and I, as you recall, we did discuss the possibility of November 7. So I don't think we can at this point fix a specific date. I think more important is to get the work done that we must get done before we leave. But I think we are sort of shooting now for the 7th of November. But at the beginning of the year we said we would be out no later than the 14th.

Mr. DASCHLE. Well, if it is the 7th, or the 14th, somewhere in there, Mr. President, I ask unanimous consent that the request made by the majority leader be amended to say that ''at a date no later than the 31st of October.'' That would leave, according to the Senator's answer, at least 1 week for us to debate this and not make a sham of this request.

Obviously, if he has no intention of bringing it up until the last day, this isn't a meaningful request. If we have at least a week to debate it, it is a meaningful request. So I would propose that we take S. 25 up before the Senate at a date no later than the 31st of October.

The PRESIDING OFFICER. Is there objection?

Mr. LOTT. Mr. President, I do not intend to have this issue come up the last day or the last week of the session, because I think we will have other issues that we would have to deal with or want to deal with and I assume the administration wants to deal with at that point. I presume that we would probably want to look for a date earlier in the month of October, maybe even the end of October.

But I think this consent request is an honest one and a fair one for now. I would like to leave it the way it is so that we will have a full panoply of options to make sure we have it brought up at the right time and we can have a full debate and look at all the other things that we need to consider.

So I object at this time to changing that date. Let's leave it for the end of the session. I do not intend to bring it up the last day. I don't want to do that. I don't want to go out and be cramped on this issue. I would like to have a free discussion much earlier, but I would like to have a chance to talk to Members who have worked it on both sides—Senator MCCAIN, Senator MCCONNELL, Senator FEINGOLD, the leadership on both sides, the committees that are involved—and come to an understanding and agreement that everybody is comfortable with.

Mr. DASCHLE. Mr. President, can I just request for the record why the majority leader has seen fit not to share this unanimous-consent request with me until we came to the floor? This is a highly unusual matter. I would be interested in the leader's response.

Mr. LOTT. If I could address that question, if the Senator is surprised, he is the only person in the room, in the building, in the media that is surprised by this. This has been a running discussion for quite some time. In fact, yesterday——

Mr. DASCHLE. Has the majority leader shared the language——

Mr. LOTT. Let me respond to the question, if I can, and give a full response. We were working on the language of the UC. I believe a copy was given to Senator MCCAIN, perhaps a copy to Senator FEINGOLD. I understand Senator DASCHLE saw it. It is not a complicated UC. Basically, all it says is we are going to bring this up and how it will be brought up and it will be done before the end of the session.

As a matter of fact, Senator DASCHLE and I sat right there yesterday, and we talked about the parameters of this agreement, and I had the impression he knew full well what was in it.

The only difference in it now to what happened yesterday was to clarify that we are not going to have this popping up all the time while we have an agreement to get it brought up at a specific time.

So that is why it was done the way it was. He was notified I was going to make a unanimous-consent request. We don't have, usually, necessarily hours or days of running discussions. This was very simple and clear. I thought

everybody would be delighted with this. Senator MCCAIN is comfortable with it. I had the impression Senator FEINGOLD is comfortable with it. Senator MCCONNELL is here ready to comment on it. He is comfortable with it.

If this is a sneak attack, there hasn't been such a well-covered sneak attack since Pearl Harbor. So everybody knew what was going on. I think it is a fair agreement. If we want to get this issue up in a way everybody understands and deal with some of the changes that we can make legitimately in campaign finances, including allowing employees and union members to have some say in how their dues and their fees are spent in campaigns, then we can do that.

Mr. DASCHLE. Well, the Senator from Mississippi is a smooth sell. Let me just say this. Senator MCCONNELL ought to be very happy with this, because this plays right into the hands of the opponents of campaign finance reform. Senator FEINGOLD didn't know about this. I didn't know about this. There is no Democrat I am aware of who has seen any of this language.

So, I am very disappointed. We are not going to relegate our right to offer campaign finance reform in some form to other bills prior to the last day of this session, and that's really what the majority leader is asking here. He is asking us to forgo the opportunity to debate campaign finance reform until what could be the very last day of the session, and we will then be under the terms of this agreement, an agreement that I have not seen. And yet, yesterday we worked through several unanimous-consent requests, back and forth, in detail, in direct consultation, he and I working together to get an agreement on Interior appropriations, to get a deal, as difficult as it was, on FDA reform. We worked through that because he knows it is one thing to say we are going to schedule FDA next week, it is another thing to come up with an arrangement that brings about the unanimity of all 100 Senators that takes care of all the concerns raised by Senators who have issues and concerns that they want to raise.

That's how you work through unanimous consent requests. You don't bring it to the floor and say, ''Here it is, take it or leave it.'' You negotiate it.

If there was a real intent, a sincere intent to negotiate a real unanimous-consent agreement, do you suppose I would have been presented with it 2 minutes ago on the floor with no discussion, no negotiation?

We did have a discussion here on the floor a couple nights ago, or whenever that was. But it was, ''You know what, we may actually bring up campaign finance reform and we may actually have an agreement I would like you to look at.'' I am looking at it, but this is the very first time.

In all the time I have been leader, every single time when there has been a sincere effort to resolve a unanimous-consent request, guess what happened? Senator Dole and I worked on it together, Senator LOTT and I worked on it together, and jointly we presented it to the body because we wanted to get it passed, we wanted everybody to agree.

This is designed for disagreement. This is designed to surprise. This is designed so all the people up there will write, ''Democrats objected to a unanimous-consent request.'' That's what this is about. He knows it; I know it. We are playing a game this afternoon. We object.

The PRESIDING OFFICER. Objection is heard.

Mr. LOTT. Mr. President, I think we have made a very fair unanimous-consent offer here that we would bring this issue up before the end of this session of Congress, that we would bring up McCain-Feingold and then the latest iteration of that, which I believe is the McCain bill, and that I would have the opportunity, as majority leader, which I have anyway, to offer an amendment or a substitute for that. A very clear, understandable, fair process.

Now, if the Senator is surprised, I thought he had been talking to his own Senator FEINGOLD. I have in my hand a press release from yesterday that went out from Senator FEINGOLD's office announcing that Senators MCCAIN, FEINGOLD, and LOTT, much to my surprise, ''will discuss the McCain-Feingold campaign finance proposal in coordinated statements on the Senate floor this afternoon.'' That was yesterday. ''Attached is an outline of the new proposal.''

I thought if it had gone that far—which I thought was certainly jumping the gun because we were trying to make sure everybody had an opportunity to know how this unanimous-consent agreement was being constructed and what was in it, and Senator FEINGOLD, to his credit, apologized that it was done in the way it was. I said, no problem. I understand how sometimes we get a little carried away, maybe staff got a little exuberant and released it before it was completed.

For instance, I felt like I ought to at least talk to Senator MCCONNELL and make sure he was aware of what we were developing here. I thought this was a very good proposal. This is a fair way to get the issue up, have a full discussion, for us to offer proposals that would correct some of the problems and abuses of union members, abuse of their dues, to deal with the illegal foreign contributions that we have seen over the past year in 1996, to deal with the other abuses of the law, tighten up the law and make it clear, or clearer if we need to, about the President and Vice President should not do certain things while on Federal property. Whatever.

It seemed like a fair proposal to me. And I was ready to go with that. And my intent is to try to get an agreement where we could do this some time early in October. But if the Senator feels constrained to object, that is certainly his right.

Mr. DASCHLE addressed the Chair.

The PRESIDING OFFICER. The Chair recognizes the minority leader.

Mr. DASCHLE. We will do it in October. I guarantee the majority leader of that. But we will do it either the easy way or the hard way. We will do it the easy way, by scheduling Democrats and Republicans in a way that makes sense in getting a unanimous consent that works, or we will do it the hard way, we will do it the way we had to do on Kennedy–Kassebaum, we will do it the way we had to do it on minimum wage, we will do it the way we did it on disaster. But we will do it and do it and do it until it is done. That is a promise.

So we can play games on schedule and we can position ourselves and talk about how much we are in favor of campaign finance reform, but the bottom line is it is going to be more than rhetoric. We are going to get this job done the hard way or the easy way. It is going to get done.

I yield the floor.

Mr. FEINGOLD addressed the Chair.

The PRESIDING OFFICER. The Chair recognizes the Senator from Wisconsin.

Mr. FEINGOLD. Mr. President, the road to campaign finance reform is obviously a long, hard one. But we are going to keep on it. I just want to say, because I am involved in a bipartisan effort here, that I believe the majority leader was engaged in the last couple of days in a good-faith effort, negotiating with Senator MCCAIN, of course, with members of his own caucus, to try to resolve this issue.

I believe there has been a relatively small misunderstanding here with regard to the specifics that sounds a lot worse than it actually is. What we are down to here is merely a difference, based on the conversation I just heard, as to whether the bill will come up in early November or whether it might come back some time in October.

Surely, we will not allow such a difference to make the difference between whether we debate campaign finance reform or not.

I just had the opportunity to speak with Senator MCCAIN briefly. He and I share the view that I think most of the American people share, that too much has happened with regard to this scandal in this area to not address this matter.

I think we need to work a little more on the UC. I had not seen the UC. I want that noted in the RECORD. I had not seen the UC, but I am not complaining. That is not my role in this institution to be the main person reviewing an agreement of that kind.

But I am confident, once this small matter is resolved, that we will have an agreement very much like the one that was just propounded. That agreement would be a historic agreement. I think it would be the first time in memory that the leaders of both parties in this body had agreed to bring up bipartisan campaign finance reform.

The nature of the proposal was quite reasonable. The proposal suggested

that there would be full and open debate on this issue without a time limit, that there would be an opportunity to amend. We can fix the bill with amendments. We can accommodate Members' concerns. We can improve the bill or we can even defeat the bill, as my colleague from Kentucky may choose to do. But that is different than last year when we were given only 2 days, no amendments, and a cloture vote.

The agreement that was just propounded was significantly better in that regard. The agreement would give the American people the opportunity with some certainty to know about when this issue was going to come up so that the people across the country could write their Representatives, call their Representatives, e-mail their Representatives, and say, ''We'd really like this bill passed'' or ''We'd like it killed'' or ''We'd like it changed.'' I think all of this is embodied in the proposal.

So I say, on behalf of myself and Senator MCCAIN, if I may do so, that, apart from this small issue of the exact timing, that this agreement, once agreed to, will do what we want it to. It is what we want. It is what we worked for for a long time, while all the pundits, especially in this town, have said that the issue will never come up. Most importantly, when we have this debate—and it will be in the near future—I am confident it will be done in an orderly manner. And it will give the American people what they deserve, an opportunity to have a real debate on this issue instead of just an endless stream of reports of abuses with regard to campaign financing throughout their Government.

So, Mr. President, I am very optimistic that this brief conversation here was merely a blip and that we will not be forced to use the tactic of having to try to attach this legislation to other bills and in fact S. 25, which of course is still the McCain-Feingold bill, will in fact come before this body in the relatively near future.

I want to thank the majority leader for his cooperation on this. I want to thank my leader for his efforts to try to resolve these differences at this point. I want to thank all 45 members of my caucus, all the Democrats for having signed on to the McCain-Feingold bill. Of course I want to thank the other cosponsors of the bill, Senator THOMPSON and Senator COLLINS on the other side of the aisle.

I want to thank the President. The President has been very steadfast in trying to move this legislation forward. His staff has worked closely with us on a day-to-day basis to try to see if we could resolve the very difficult differences between the parties so we could have this matter debated.

Mr. President, we will get there. We are getting there. I hope we can today begin to tell the American people they are finally going to be able to participate in, hear and understand the debate about whether big money is going to continue to control the Government of the people of the United States.

Mr. President, I yield the floor.

Mr. MCCONNELL addressed the Chair.

The PRESIDING OFFICER. The Chair recognizes the Senator from Kentucky.

Mr. MCCONNELL. Mr. President, I listened with interest to the comments of the Democratic leader and Senator FEINGOLD. I would just like to say briefly in response, there is no reluctance to debate this issue. Those of us who oppose McCain-Feingold look forward to the debate. We relish the debate.

My colleague in the chair remembers when we stayed up all night to debate this about 5 weeks before the 1994 election, which was the greatest victory for my party in congressional races in this century.

So let me just disabuse all of my colleagues of the notion that there is any reluctance on the part of those who oppose putting the Government in charge of political speech of individual groups, candidates, and parties in this country, any reluctance to debate the merits of that proposal. There is no reluctance whatsoever.

What the majority leader was trying to do here today was to structure that debate in such a way as to provide minimal inconvenience to Members of the Senate. The Democratic leader said we can get there the hard way or the easy way. We have no reluctance to get there the hard way, Mr. President, no reluctance whatsoever.

The majority leader was simply trying to accommodate all of the Senate by providing an orderly, structured way to have a debate that we relish, look forward to making. My experience with this issue over the years is the more colleagues and the American people and, yes, the press learns about the issue the better, the greater likelihood the first amendment will be protected.

So bring on the debate. We are ready for it. But, obviously, it will be a lot easier on everyone if we did it an orderly, structured way. That is what the majority leader was seeking to do. I commend him for that, and look forward to the debate that will be forthcoming. We will be happy to do it either the hard way or the easy way, whichever seems to suit the Senate the best.

Mr. President, I yield the floor.

The PRESIDING OFFICER (Mr. GORTON). The Senator from Georgia.

EDUCATION REFORM

Mr. COVERDELL. Mr. President, we have spent the better part of the morning talking about our initiatives to begin to get at the core problems in elementary education in America. We have talked about creating an education savings account that allows every family the opportunity to save and build resources to deal with whatever deficiencies are troubling their children.

We talked about the Presiding Officer's amendment which would move $11 billion or $12 billion to local school districts without the strings and encumbrances that Washington cannot ever seem to free itself of. Just put the resource at the local level.

We have talked about a proposal to create scholarships in the District of Columbia to try to allow these families in certifiably troubled schools a way out.

Three things, all of which are addressed where the real problem in American education is occurring: Elementary and high school.

Now, what has been the opposition? What is the opposition? It began when the savings account was put in the tax relief proposal. The President told the Speaker that if it was left in the proposal, the savings account for families to help kids in elementary school, he would veto all of it, all the tax relief would be vetoed.

So obviously it was removed. But we have not retreated. We have brought the proposals back. The Speaker introduced the education savings account on the House side, and myself and the majority leader on this side.

Now, what is the reason? Why would the President go to such lengths to clamp down on an education savings account? Well, he and the Secretary of Education say it would undermine public education—remove resources from public education.

Mr. President, I have to assume they are just misinformed by their own staffs. I can come to no other conclusion—that they just have become so accustomed to the status quo and to beating down any new idea that there is a knee-jerk reaction. They always try to infer that these ideas will somehow impair or undermine public education. Wrong, wrong, and wrong.

In fact, it is the reverse, the exact reverse. The savings account will infuse public education with new money. The vast majority of students are in public schools and the vast majority of students will stay in public schools. The savings accounts that the parents of those children create will come to the aid of—there is not a single dime, Mr. President, not 10 cents, that will be removed from public schools.

Conversely, billions—billions—of new dollars will come to the support of public schools. The child in a public school who needs a tutor, the child in public school—which, incidentally, will be a public schoolteacher. If I was a public schoolteacher I would be rushing in support of the education savings account because it will give them a vast, vast new opportunity to teach, which they love to do, and earn compensation, which will help them. Not one dime is removed.

Every family that opens this savings account will continue to pay their property tax for the public school—every one. They will set up the savings account. They will hire tutors from the public school system. They will be tutoring children in the public school

system. They will be buying home computers for children in the public school. And if the President's proposal is adopted sometime for uniforms, they will be buying uniforms in the public school system. They will be transporting students to afterschool programs or whatever in the public school system.

Now, Mr. President, it will also help private schools because those parents that have made that decision can also open up savings accounts, and all the things I have just said that would augment public education will augment private education.

Now, I guess this is the rub for the President. There will be some families who will use the savings account to change schools. They might leave a troubled school and go to another one, and he doesn't think they should have that right. He can say that. He can say it is good sound public policy for us to order families where they must go to school, but he may not assert that it undermines public schools, because it just isn't true. It is the reverse. It augments and brings vast new resources to all elementary education, public and private.

As I said when these remarks began, they are going to be the most intelligently spent dollars in all education because they are dollars being directed like a rifle shot to the exact problem the child has.

Vast public moneys, which do great good, cannot do that; parents do it. And we are giving them the tools to do it. That is a fact, Mr. President.

I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, as I understand the situation we are now under a time control of the minority leader?

The PRESIDING OFFICER (Mr. HAGEL). The Senator is correct.

Mr. KENNEDY. I thank the Chair. I yield myself such time as I might use.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

Mr. KENNEDY. Mr. President, the underlying piece of legislation that we have before the Senate is S. 830, which is the drug reform legislation. Earlier in the course of the debate and discussion, I pointed out one of the most serious proposals in that particular piece of legislation that puts the future health care of all at serious. I also pointed out the bewilderment the President of the United States and I share, which every consumer group shares: Why in the world are we providing the kind of change in protections for the American consumer that are included in this legislation?

I am reminded, Mr. President, that 30 years ago this Nation was faced with a thalidomide tragedy, and all the implications that that terrible situation had for hundreds of mothers and children. Twenty years ago, we had the Dalkon Shield tragedy, where 18 women died from perforated uteruses, 2,700 women had miscarrages, and millions of women were adversely affected with great illness and sickness and, in many instances, were unable to have children in the future. Why? Because we had a medical device that wasn't safe for American women.

Ten years ago, we had the Shiley heart valve. A certain part of that heart valve that was found to be unsafe here in the United States, but it was advertised and used overseas and resulted in hundreds of deaths.

We know that some medical devices can be dangerous. We have to ask ourselves, as we are coming into the final consideration of this legislation, why in the world we are retreating from protecting the American public in this area? That is what we are doing. We are putting the interests of the medical device industry ahead of the public health of the American people. For what reason? For the profits of those medical device industries.

The provisions of the legislation are clear and simple. S. 830 says:

> . . . prohibits FDA from reviewing the safety of a device for uses not listed by the manufacturer.

If the manufacturer labels a device as substantially the same as another device that has already been approved, the Food and Drug Administration cannot look at that medical device, beyond the use listed on the lablel, in terms of its safety and effectiveness in protecting the American consumer.

We are effectively handcuffing the Food and Drug Administration with this language. The amendment, which will be offered by Senator REED—on which I will join him, says:

> . . . prohibits FDA from reviewing the safety of a device for uses not listed by the manufacturer unless the label is false and misleading.

Who could defend a medical device manufacturer that knowingly submits false and misleading information? Anybody who is listening to this would say, we can't believe that, Senator. We can't believe that is really happening. Well they should believe it because that is what is happening.

The clearest illustration of this development is the use of a certain biopsy needle that has been manufacture by U.S. Surgical Co. A biopsy needle used to excise tumor tissue to see whether it is cancerous or not. The biopsy needle is maybe the size of the lead in a pencil. It is used to remove sufficient amount of material to be analyzed. Now, along comes U.S. Surgical Corp., which develops medical devices, with a new medical device that can take 50 times more material than the earlier biopsy needle. U.S. Surgical says: Look, this new device is the same purpose as the other medical device. It is substantially the same. It is for taking material that can be a biopsied. We have been approved previously in terms of safety and effectiveness. According to our label, this new device is a biopsy needle and, according to the law, under S. 830, FDA cannot look beyond that use and into the real purpose of this new device to determine whether or not the device is safe and effective for that new use.

Well, Mr. President, unfortunately for U.S. Surgical Corp., a number of us have seen their ads and promotions for this particular medical device. What is U.S. Surgical Corp. promoting? It is promoting this new device as a device that is going to remove the tumor, not just take the biopsy, but remove the tumor from a woman's breast. Now, it may be very good in removing that tumor. It may be able to get all the cancerous material. It may do the job better than any other medical device we have had before. But we don't know that. The patient won't know it. The doctor won't know it. The family of the patient won't know it. Why? Because U.S. Surgical Corp. would not have to provide one paragraph of information demonstrating that this medical device is safe and effective for removing tumors. The doctors will see it and say, well, this has been approved by the FDA, it must be safe. I think I will use it, especially after reading about, hearing, or watching the promotion film used in Canada to promote this device.

The FDA would be prohibited from looking behind the labeling of the device to determine whether it is safe and effective. The FDA can say, look, we know the manufacturer is out there day in and day out promoting this device for tumor removal. They can hardly wait to get approval to go out and sell that medical device for the purposes of removing the tumor. According to the proposal under S. 830, if the label says that it is substantially equivalent to the biopsy needle, the Food and Drug Administration cannot require U.S. Surgical Corp. to provide information demonstrating that the device is safe and effective for its marketed purpose. That is wrong.

We are taking an important step backward in protecting the American people. And it is not just this particular medical device. The real concern is all the other medical devices that are out there now being considered. It is the mammography screening machines that are being used for breast cancer screening. The mammography screening machines may be very good in terms of the diagnostic evaluation of tumors, once the tumor is detected. They may be even better as screening tools to look for such a tumor. But we don't know because the FDA wouldn't be able to ask for safety and effectiveness data for its use in breast cancer screening. So we have examples of mammography machines coming into the FDA that will be approved because they are effective in terms of evaluating and diagnosing tumors, but have not been studied in terms of their effectiveness in screening. Yet we find the machine is being used for screening purposes. American women will say that they have been screened with

mammography machines, and they have been found to be free of any kind of cancer. They will be very happy about that. Since we have no data on how effective this device is for screening, they may find later, maybe too late, that they have some kind of a tumor. They may find out that this machine didn't do what it was represented to do because it had not been tested in terms of effectiveness. That should not be the case.

That is true with regard to the surgical lasers that haven't been tested for safety and effectiveness in cutting cancerous prostate tissue. It has been demonstrated that the lasers are safe and effective in cutting general tissue. But, the manufacturer changes the design and puts another laser in that also cuts tissue. But the purpose of that new laser is to cut through tissue in the prostate area, whether it is a cancerous tissue or noncancerous tissue. The laser has not been approved for that purpose. We do not have safety information to know that it is effective in dealing with this particular kind of operation. The manufacturer doesn't have to provide it. All they have to do is say it is a laser that cuts tissue and they get approved. The FDA can be fully aware that they are going to promote it for prostate cutting, but they will not be able to ask the manufacturer to provide safety information for that use.

The same is true with contact lenses that get approved though this loophole channel—saying that the lenses are substantially equivalent to equipment that has already been approved. But those lens manufacturers are intend to promote these new lenses for long-term use rather than short-term use like the ones that have been approved. The FDA can know about the advertising—and can even tell from the change in materials used to make the new lenses that they are designed for long-term use. But they cannot evaluate the new lenses for safety and long-term use. We can see the dangers that could result—maybe even blindness.

Mr. President, we shouldn't be taking a risk with the health of the American people in this way. It is fundamentally wrong. The only reason to do so is to give a competitive advantage to unethical medical manufacturing companies. Those are the ones that will use this loophole. And when they do, they will gain a competitive advantage over the ethical manufacturers that take the time and spend the money to conduct the safety and effectiveness studies to show that thier devices are safe. They will be at a financial and competitive disadvantage because less ethical companies will use this loophole for approval.

That is why each and every one of these consumer groups are opposed to this provision—why we have recommended five different alternatives to address this issue over the past weeks. The medical device industry has turned those down because they say they have the votes. They can roll over the public health concerns of the American people. That has happened in the past. But I hope it will not happen next Tuesday. This issue is too important. It is important for our wives, our daughters, our sons, our fathers, our grandparents—to be sure that when they have to use medical devices, those devices are going to be safe and effective. We have the ability to ensure safety in so many new ways—ways that were unimaginable years ago.

But with this provision, we are effectively tying the hands of the FDA. If there is an appropriate title for the provision, it is the false-claims provision of the medical device and pharmacy legislation, S. 830. And it is the wrong way to go.

We look forward to debating this issue next week. I am hopeful that we can address it in a way that will provide the real protection the American people deserve.

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

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

BANNING ANTIPERSONNEL LANDMINES

Mr. LEAHY. Mr. President, earlier this week, the President of the United States announced that the United States would not sign the landmine treaty that was just negotiated in Oslo. This treaty is the culmination of a process begun a year ago in Ottawa, Canada, by the Foreign Minister of Canada, Lloyd Axworthy, who invited nations around the world to sign a treaty that would be a comprehensive ban on the use and the export and the manufacture and stockpiling of antipersonnel landmines.

Antipersonnel landmines are these weapons that destroy the lives—either by maiming or killing—of 26,000 people a year. There are approximately 100 million landmines in the ground of the 65 nations—or more—around the world. And more are being put down every day. As one person from one of the nations most severely impacted by landmines told me once, they clear the landmines in their country ''an arm and a leg at a time.''

Thanks to the leadership of Canada, and Minister Axworthy, this effort gained support around the world. Close to 100 nations joined together in Oslo to put the final pieces together on a comprehensive landmine treaty that would be signed in Ottawa in December.

The United States had basically boycotted this process, preferring a much slower and less effective one in Geneva following a very traditional route, the one that showed absolutely no movement. To the administration's credit, they finally did join the process, although at the 11th hour. Unfortunately, when they went to Oslo, they went to Oslo saying that the United States would need some major changes in the treaty to accept it, that they would have to have the treaty rewritten to accommodate the United States, and that these positions were not negotiable.

I applauded the United States for going to Oslo, but I was disappointed in the steps they took once they were there. I went to Oslo for a few days and met with many of the delegates, including the chairman of the conference. Then it became clear to me—I also spoke to the American delegation—that the United States had come with basically a take-it-or-leave-it attitude and that other countries were not going to agree.

The President said that we had obligations in Korea that were unique to the United States. We do have special obligations in Korea. But that was not an insurmountable issue. In fact, those who went there had said almost a year before, if the United States made an effort, they would help accommodate our security interests in Korea, but the United States ignored the entire process.

Finally, hours, literally hours before the conference was to end, the United States became engaged and said, well, we need some changes. If you will give them to us, we can sign. The first change is to have a treaty that would not take effect for 9 years, plus the 10 years as provided for in the treaty to remove existing minefields. That is 19 years from this December. We would actually be in the year 2017 before the mines would be removed. The United States asked for a 19-year period even though countries far less powerful than us were willing to act much quicker. The United States was saying that even though we are the most powerful nation on Earth, we want the ability to be able to use our antipersonnel landmines all over the world for another 9 years, and the antipersonnel mines we use near antitank mines, forever. And, lastly, of course, accommodate us on Korea. It became a bridge too far for the other nations. They said we were asking too much. They were, after all, the nations being hurt by landmines and they would go forward with the treaty with or without the United States, and that is where we now stand.

After that, the President of the United States announced a number of steps that he is willing to take unilaterally, and I commend him for these steps because he has said that he also wants to see, as we all do, this scourge of landmines to end.

Interestingly enough, many of the steps that he talks about are in legislation pending before the Senate—legislation sponsored by both the distinguished occupant of the chair right

now and myself. So I ask this: If, indeed, the main problem the administration has is our obligations, treaty obligations, defense and national security obligations in the Korean Peninsula, especially the defense of South Korea from a country that has proven its belligerence before, North Korea, a country that has an unstable political system today, faces drought, famine, and flooding—it is amazing it could have all those going on at once. It faces the consequences of its own secrecy and belligerence. If that is our main concern, they should look at the legislation we have before the Senate, similar legislation before the House of Representatives, the Leahy-Hagel bill in the Senate, the Evans-Quinn bill in the House.

I urge the administration, disappointing as it is that it has not joined the Ottawa process, disappointing as it is it has lost this golden opportunity, to work with the Congress, the Congress which has driven the debate in this country on banning landmines—not the executive branch—the administration should now come and work with the Congress and continue forward, because, after all, the ultimate goal is to end the scourge of landmines. There is only one way to do that, and that is for the United States to join in the Ottawa Treaty. If not in December, then in the future. We need to get there, one way or another. There is no other treaty, and without the United States, we will never see the worldwide ban we all seek.

We are coming to the close of the bloodiest century in history. It is a century where we have seen the world torn by wars, great and small, but wars that more and more saw their greatest toll in innocent civilian populations. Whether in Rwanda, in Angola, in Bosnia, in Mozambique, in Central America, or anywhere else, it is usually the noncombatants who suffer the most. And more and more those noncombatants suffer from the scourge of landmines.

Peace agreements are signed at some time, and someday armies march away and someday the guns grow silent, but in more and more of these countries, after that happens, landmines stay in the ground and continue killing and continue maiming long after all hostilities have otherwise ceased. Sometimes long after people can remember what they were fighting about, a child walking to school is blown apart, a farmer going with his or her animals into a field is blown apart, a mother, following a child down a road, is blown apart; and nobody knows who put the landmine there. They may not even remember what the war was about. But they know—that person knows—that their life is changed forever.

We have used, now, for several years, the Leahy war victims fund. We spend $5 million of our taxpayers' money each year for artificial limbs, for men, women, and children who have been injured by landmines.

My wife, who is a registered nurse, has gone with me to some of the clinics where we use the fund. We have seen people our age get their first wheelchairs, even though they lost their legs in wars long gone by. We have seen children who have lost half their body from a landmine. We have seen a child who went to pick up what she thought was a shiny metal toy on the side of the road and lost her face and her arm.

Mr. President, people talk about one type of landmine versus another type of landmine. They talk about the technical capabilities of one army or another. But what is often forgotten is the face of the victims. Some of those victims may no longer even have a face. When she was alive, I told the Princess of Wales that the greatest difference she made in the battle against landmines was to focus the world's attention on the faces of the victims. Because when she visited a hospital for landmine victims, the whole world visited that hospital with her. Those victims are still there. Just because the TV camera turns off, the victims don't disappear. They are still there. Their lives are still ruined. And in the time that I have been speaking, there have been two more victims of landmines. By the time we go home tonight, there will be a dozen more victims of landmines—26,000 this year alone.

I commend the effort begun by Canada, and Foreign Minister Axworthy. I commend those nations that came together in Oslo to sign the treaty. Not in my lifetime has there been an arms control issue that so many nations have moved so quickly on, to sign a treaty so comprehensive. Never before have so many nations responded so urgently, and so effectively, to a humanitarian problem such as this.

I regret very much that the United States was not among those who agreed to sign the treaty. Not because we are causing the problem. Other nations never even went to Oslo. Russia, China, Pakistan, India, others, who are part of the problem, they weren't even there. And that should be noted. But the United States is the most powerful nation history has ever known. The United States could be a moral beacon. Instead, the United States said: Notwithstanding our power, we want to keep our landmines, but you less powerful nations, you should give up yours.

We should join them. We should be willing to set an example. Not to pretend that we are giving up our landmines when in fact what we are doing is calling them by another name. Let us use the steps that we can, through congressional action, which will be taken, I am sure, because there is an ever-increasing number of Members in both parties who want to see stronger U.S. leadership.

Let us take that step here as a nation. But then let's give guidance to the rest of the world. Let's not have Russia, China, and others stay out of the process because the United States is staying out. Let us be wholeheartedly a part of this process and put pressure on other nations to join us, until the day arrives when we do with landmines what we have done with chemical weapons, and make their use a war crime.

Throughout this process, the U.S. position has been driven primarily by the Pentagon; not by the State Department, not by the White House. I think back to the 1920's, to the First Geneva Convention, when Gen. Blackjack Pershing, no theoretical dilettante he, said we should give up poison gas. But the Pentagon said no, not so fast, because there are some instances when it could be very helpful in protecting our troops. Fortunately, our civilian leaders understood that the humanitarian disaster that could result from using poison gas outweighed whatever military utility could be got from using it. And so over time, poison gas was stigmatized so that anyone who used it risked being branded a pariah. And it was virtually never used, even though in the Korean war, or in Vietnam, there were any number of instances when it might have been militarily advantageous.

Today we have a similar situation, where many of our best known, most decorated generals say let's give up landmines. Again, we hear the Pentagon saying, as General Pershing heard, ''No, there are instances when landmines can help us.'' Of course there are. There are instances when any nation would want to use landmines. But earlier this week, 89 nations made the moral decision to put the lives of innocent people first.

The balance of power throughout the world would still be the same as it is today. The only thing that would change is there would not be the thousands of innocent civilian casualties every single year.

Again, my prayer for the next century is that armies of humanity remove and disarm landmines, and no armies, no armies, put any new landmines down. What greater gift could we give to those in the next century, than a world without landmines?

PARTISAN ATTACKS ON THE INDEPENDENCE AND INTEGRITY OF THE JUDICIAL BRANCH

Mr. LEAHY. Mr. President, I think it is regrettable that this week the Senate has failed to consider and confirm judges necessary to fill vacancies that are leading to a crisis in the Federal courts. Instead, this is going to be remembered as the week that the Republican leadership in the House and the Republican leadership in the Senate talked openly about seeking to intimidate—their word—to intimidate the Federal judiciary.

I regret that any Senator or any Member of the House of either party would speak of a desire to intimidate the Federal judiciary. One of the greatest hallmarks of the United States of

America is that we have an independent Federal judiciary of the highest integrity. We are the envy of the world in that respect. To hear Republican leaders in the House and the Senate talk about intimidating that Federal judiciary was disheartening. It indicates our system of government showing disrespect to the intelligence of the American people and sends a signal of shame throughout the world.

These partisan attacks threaten the independence that the Founders created to insulate the judiciary from politics. These attacks threaten the checks and balances on the political branches of our Federal Government that have served us so well for over 200 years. These bedrock principles have helped preserve our freedoms for two centuries and has helped make this country a model for emerging democracies around the world.

Not since Congress and the American people rejected the Court-packing scheme over 60 years ago have we faced such a threat to our third branch of Government and its ability to act as the guardian of our constitutionally guaranteed rights.

On Sunday, Congressman DELAY of Texas was quoted in the Washington Post openly asserting that ''The judges need to be intimidated.'' We have heard Republicans clamor for impeachment when a judge renders a decision with which a Republican Member of the House of Representatives disagrees. We have heard demands that Congress destroy the orderly process of appellate court and Supreme Court review and, instead, assume the role of a supercourt and legislatively review and veto decisions on a case-by-case basis as it may suit Congress' passing political whim and fancy.

We have seen proposals to amend the U.S. Constitution to eliminate the independence and tenure that the Founders understood were essential if judges were to act impartially and in the interest of justice in each case rather than worry about partisan intrigue.

This extreme rhetoric and outlandish proposals have contributed to a poisonous atmosphere in which the Federal justice system is overloaded. We have heard testimony in the Judiciary Committee from judges around the country who fear that the quality of justice they will be able to provide in our Federal courts will be adversely affected. More and more courts around the country are being forced to rely on senior judges, retired judges, and visiting judges to hear cases. The Second Circuit Court of Appeals expects to include an outside visiting temporary judge on 80 percent—80 percent—of its panels over this year.

Other appellate courts have had to forego oral arguments in more and more cases, and litigants, the people who are paying the bills, the taxpayers of the United States, are denied any opportunity to see the judges who are deciding their causes and to have any reassurance that judges are personally considering their arguments and concerns. Court clerks and attorney staff are being used more and more extensively in the determination of cases as judges become overburdened and backlogs grow.

These are not the way to engender confidence in our system of justice or acceptance of the process and decisions being rendered or respect for courts and the Government.

The chief judge of the eleventh circuit has testified about ''crushing workloads.'' He has noted that Federal courts are ''no longer able to provide the public with the same standard of excellent service that [they] did in the past.'' The Chief Justice of the U.S. Supreme Court, William Rehnquist, has called the rising number of Federal judicial vacancies ''the most immediate problem we face in the Federal judiciary.'' He warned at the end of 1996 that ''filling judicial vacancies is crucial to the fair and effective administration of justice.''

The second shoe dropped on Wednesday when it was reported that the Republican leader of the Senate echoed the sentiments of Mr. DELAY and defended the idea of Republicans plotting to intimidate the Federal judiciary and said, ''It sounds like a good idea to me.'' I can only hope that the reports of this exchange with the majority leader of the Senate were in error. For the Republican leader in the Senate to join Republican leaders in the House in an acknowledged effort to undercut the independence and integrity of the Federal judiciary would be a sign of grave danger for the American people and would be a sign of danger for the system of government that has protected this democracy for over 200 years.

Wednesday marked the 210th anniversary of the signing of the U.S. Constitution. Rather than commemorating the principles that helped make this country great, the Republican leadership's statements this week undermined the separation of powers on which our charter is based.

Last Congress, the Republican leadership was bent on shutting down the executive branch of the Government. I remember being on the floor of the Senate arguing against that, but they shut down the Government. The American people rose up and rejected that effort outright, as the American people should. In my State, Republicans and Democrats alike roundly condemned what was done.

So now, these Republican forces have turned their fire on the branch of Government most protective of the people's rights but least equipped to protect itself from political attack.

They might not be able to speak up, but I will, because this year's continuing attack on the judicial branch, the slowdown in the processing of the scores of good women and men the President has nominated to fill vacancies on the Federal courts around the country, and widespread threats of impeachment are all part of a partisan ideological effort to intimidate the judiciary. Judges cannot take the floor of the U.S. Senate and defend themselves. I will.

I have felt privileged to serve in the U.S. Senate representing the State of Vermont for 23 years. I have served twice in the majority in the Senate and twice in the minority in the Senate. I have served with Republican and Democratic Presidents, and I have worked alongside great majority leaders, like Senator Mansfield, Senator BYRD, Senator Baker, Senator Dole and Senator Mitchell. I have never known a time when the leadership of the Senate would tolerate partisan and ideological politics so diverting this institution from its constitutional responsibilities with respect to the third constitutionally coequal branch of Government. If Wednesday's reports are accurate, sadly the American people must know that not only is the Senate leadership allowing these efforts, it is condoning them.

Mr. President, the United States is a great democracy, I believe the greatest democracy history has ever known. Something that sets our great country apart from virtually all others in the world is the independence of our Federal judiciary and the respect that it commands among all of us.

Every nation in this century that has moved from a dictatorship toward democracy has sent observers to the United States. Why? To see how they can emulate our judiciary.

Those working for democracy in countries that are still struggling to adopt democratic principles know that one thing that is holding them back, one thing that allows crime and corruption and economic breakdown, is a lack of a truly independent judiciary. They know that unless they can come close to something like our independent judiciary, they will never become truly great democracies or truly free.

We have the greatest judicial system in the world. We are the envy of people around the world who are struggling for freedom. Independence of our third coequal branch of Government helps allow it to act fairly and impartially. It is our judiciary that has for so long protected our fundamental rights and freedoms and served as a necessary check on overreaching by the other two branches that are so easily susceptible to the gusts of the political winds of the moment.

This is a sad week for America because it is a week in which a campaign to intimidate Federal judges was acknowledged and condoned.

Mr. President, I call upon the U.S. Senate to reject that effort and go forward to fulfil our constitutionally mandated duty to advise and consent on the nominations of judges that the President has sent to us. Vote them up or vote them down, but show that we are united, whatever party we belong to, in protecting the integrity and, most importantly, the independence of our Federal judiciary.

MORNING BUSINESS

(During today's session of the Senate, the following morning business was transacted.)

THE VERY BAD DEBT BOXSCORE

Mr. HELMS. Mr. President, at the close of business yesterday, Thursday, September 18, 1997, the Federal debt stood at $5,374,488,603,408.56. (Five trillion, three hundred seventy-four billion, four hundred eighty-eight million, six hundred three thousand, four hundred eight dollars and fifty-six cents)

One year ago, September 18, 1996, the Federal debt stood at $5,193,857,000,000 (Five trillion, one hundred ninety-three billion, eight hundred fifty-seven million)

Five years ago, September 18, 1992, the Federal debt stood at $4,036,814,000,000. (Four trillion, thirty-six billion, eight hundred fourteen million)

Ten years ago, September 18, 1987, the Federal debt stood at $2,353,225,000,000. (Two trillion, three hundred fifty-three billion, two hundred twenty-five million)

Twenty-five years ago, September 18, 1972, the Federal debt stood at $436,926,000,000 (Four hundred thirty-six billion, nine hundred twenty-six million) which reflects a debt increase of nearly $5 trillion—$4,937,562,603,408.56 (Four trillion, nine hundred thirty-seven billion, five hundred sixty-two million, six hundred three thousand, four hundred eight dollars and fifty-six cents) during the past 25 years.

SMITHSONIAN INSTITUTION AND THE BOY SCOUTS

Mr. ABRAHAM. Mr. President, I rise today to note a recent injustice done to one of America's most valuable associations, the Boy Scouts, by one of our most valued institutions, the Smithsonian. I also rise to express my appreciation to Smithsonian Secretary I. Michael Heyman for his assurance that such an injustice will not occur again in the future.

Mr. President, in January of this year the Smithsonian Institution denied an application from the Boy Scouts of America to use the National Zoo's auditorium for a Court of Honor ceremony for District of Columbia area Scouts.

Why would the Smithsonian deny such an application from a group known for its commitment to environmental conservation? According to Robert J. Hoage, Chief of the Smithsonian's Office of Public Affairs, the Smithsonian's policy prohibits co-sponsoring events with any organization that exercises bias on the basis of religious beliefs.

Asked about this decision, the Smithsonian's communications director, David Umansky, explained: ''Our lawyers have documented cases of the Boy Scouts denying membership to atheists, and that violates our non-discrimination code.'' The Smithsonian also claimed that the honor court event was not sufficiently relevant to the National Zoo's mission. But that claim stretches credulity because of the Boy Scouts' myriad programs devoted to environmental education and conservation. Indeed, the Scouts' highest honor, awarded to only about 1,000 Scouts since 1914, recognizes exceptional work for environmental conservation.

In a letter to my colleagues dated September 12, I expressed my dismay that the Boy Scouts, an organization that has helped literally millions of American boys reach responsible manhood, should be denied access to a federally supported institution because it exercises its constitutional right to free exercise of religion. I also expressed concern that the Smithsonian Institution should enforce a policy diametrically opposed to the principles on which our nation was founded. The Smithsonian, our premier teaching museum, is entrusted with, among other treasures, the Star Spangled Banner, the flag that Francis Scott Key saw flying when he penned our national anthem. I recently sponsored legislation appropriating $8 million to the Smithsonian for restoration of that flag. I was frankly disturbed to see that the institution to which it has been entrusted was acting in this manner.

However, Mr. President, I am now relieved to report that Secretary Heyman, in a September 15 letter to my distinguished colleague, Senator FRIST, who serves as a regent to that Institution, has apologized for this action. Further, Secretary Heyman's letter expressed his conviction that ''our special events policy clearly allows the sponsorship of events by all groups, including religious groups, that are consistent with the mission and tradition of the Smithsonian.''

Recent events at the Smithsonian, including the proposed *Enola Gay* exhibit, with its misleading and inaccurate treatment of the Second World War, and a number of new exhibits distorting history to cast America and American values in a bad light, have caused me to worry about the future of this distinguished and crucially important institution. I thank Secretary Heyman for his courageous statement of fundamental policy and hope that it heralds a new, more positive era at the Smithsonian.

Mr. President, I ask unanimous consent that the full text of my September 12 letter to my colleagues and the September 15 letter from Secretary Heyman to Senator FRIST be printed in the RECORD.

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

U.S. SENATE,
Washington, DC, September 12, 1997.

Smithsonian Snubs Boy Scouts

DEAR COLLEAGUE: I want to bring to your attention the latest in an unfortunate series of decisions made at the Smithsonian Institution, America's premier teaching museum. It has come to my attention that in January of this year the Smithsonian denied an application from the Boy Scouts of America to use the National Zoo's auditorium for a Court of Honor ceremony for District of Columbia area Scouts. The application was denied on the grounds that the scouts require members to believe in God and that the event supposedly did not meet the ''relevance requirement'' needed for Smithsonian cosponsorship.

In a letter to T. Anthony Quinn, president for District Operations for the National Capital Area of the Boy Scouts of America, Robert J. Hoage, Chief of the Smithsonian's Office of Public Affairs stated that ''the Smithsonian's policy prohibits co-sponsoring events with any organization that exercises bias on the basis of religious beliefs.'' Asked by a reporter from the newsweekly Human Events to explain this decision, David Umansky, communications director for the Smithsonian responded: ''Our lawyers have documented cases of the Boy Scouts denying membership to atheists, and that violates our non-discrimination code.''

I find it deeply disturbing that the Boy Scouts, one of America's most important private organizations, which has helped literally millions of American boys reach responsible manhood, should be denied access to a federally supported institution because it exercises its Constitutional right to free exercise of religion. I also am disturbed that the Smithsonian Institution, the repository of so many objects central to our heritage as a people, should enforce a policy diametrically opposed to the principles on which our nation was founded.

In an August 14 follow-up letter to Mr. Quinn, Smithsonian Under Secretary Constance Berry Newman failed to so much as mention the ''anti-discrimination'' motivation behind this rejection. Instead the Under Secretary detailed two Smithsonian events involving Boy Scouts, both of which took place several years ago. Her argument was that Smithsonian ''policy emphasizes that the activity or event proposed by the outside organization should have some Smithsonian involvement and participation in the proposed activity or event.'' That an event put on by the Boy Scouts, an organization devoted to outdoor activities and knowledge of the natural world, should be found ''irrelevant'' to the National Zoo stretches credulity to the limit. Further, recent events at the National Zoo clearly have had little to do with that institution's mission. Events have included a naturalization ceremony by the Immigration and Naturalization Service and a Washington Singers musical concert.

I urge you to contact Smithsonian Secretary Michael Heyman and/or members of his staff to express your deep concern that the Boy Scouts, an institution of long-standing importance to our culture, traditions and public life, is receiving such inappropriate treatment. Further questions on this matter can be directed to Bruce Frohnen of my office at extension 4–8841.

Sincerely,

SPENCER ABRAHAM,
U.S. Senate.

SMITHSONIAN INSTITUTION,
Washington, DC, September 15, 1997.

Hon. WILLIAM H. FRIST,
U.S. Senate, Washington, DC.

DEAR SENATOR FRIST: As was discussed in this morning's meeting of the Board of Regents, and knowing of your concern on this issue, I am writing to apologize for an unfortunate decision that denied the use of facilities of the National Zoo to District of Columbia Boy Scouts last February. In a letter

denying the request, a determination was made that the event did not comply with a requirement that all events be relevant to the mission of the Smithsonian and further that the Boy Scouts violated standards of non-discrimination with regards to religion. I have reviewed this determination and reversed it. Scouting is an important American institution that helps in educating young men and women about the outdoors with special emphasis on protection of the environment, a mission relevant to and shared by the National Zoo.

Further, as I mentioned in our meeting, I believe that our Special Events Policy clearly allows the sponsorship of events by all groups, including religious groups, that are consistent with the mission and tradition of the Smithsonian. This event certainly complied with that standard and its denial on that ground was in error.

The Smithsonian and the Scouts have over the years jointly sponsored many events too numerous to mention here. I apologize for this unfortunate mistake and look forward to continuing our long standing and mutually productive relationship with the Boy and Girl Scouts of America.

Sincerely,

I. MICHAEL HEYMAN,
Secretary.

MESSAGES FROM THE PRESIDENT

Messages from the President of the United States were communicated to the Senate by Mr. McCathran, one of his secretaries.

EXECUTIVE MESSAGES REFERRED

As in executive session the Presiding Officer laid before the Senate messages from the President of the United States submitting sundry nominations which were referred to the appropriate committees.

(The nominations received today are printed at the end of the Senate proceedings.)

ENROLLED BILL PRESENTED

The Secretary of the Senate reported that on September 19, 1997 he had presented to the President of the United States, the following enrolled bill:

S. 910. An act to authorize appropriations for carrying out the Earthquake Hazards Reduction Act 1997 for fiscal years 1998 and 1999, and for other purposes.

INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second time by unanimous consent, and referred as indicated:

By Ms. COLLINS (for herself, Ms. SNOWE, Mr. HOLLINGS, and Mr. ROBB):

S. 1199. A bill to amend the Higher Education Act of 1965 regarding income protection allowances for certain students; to the Committee on Labor and Human Resources.

By Mr. CAMPBELL:

S. 1200. A bill to provide that countries receiving foreign assistance be conducive to United States business; to the Committee on Foreign Relations.

SUBMISSION OF CONCURRENT AND SENATE RESOLUTIONS

The following concurrent resolutions and Senate resolutions were read, and referred (or acted upon), as indicated:

By Mr. MURKOWSKI:

S. Con. Res. 53. A concurrent resolution commending Dr. Jason C. Hu, Representative of the Taipei Economic and Cultural Representative Office in the United States; to the Committee on the Judiciary.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Ms. COLLINS (for herself, Ms. SNOWE, Mr. HOLLINGS, and Mr. ROBB):

S. 1199. A bill to amend the Higher Education Act of 1965 regarding income protection allowances for certain students; to the Committee on Labor and Human Resources.

THE WORKING STUDENTS' INCOME PROTECTION ACT

Ms. COLLINS. Mr. President, today, I am introducing the Working Students' Income Protection Act, a bill to increase the number of working students who are eligible for Federal Pell grants. I am pleased to have Senator SNOWE, Senator HOLLINGS, and Senator ROBB as cosponsors.

This bill will correct a problem created by the 1992 amendments to the Higher Education Act that unfairly denies aid to hundreds of thousands of deserving students. Let me explain the problem.

The formula used to determine the eligibility for Federal financial aid includes an income protection allowance, known as an IPA, which enables working students to retain a portion of their earnings to pay their basic living expenses. This allowance is not counted in determining eligibility for student aid. A portion of earnings above the IPA is used to calculate the contributions students can make to their education expenses. As students' incomes rise above the IPA, their eligibility for Federal student aid, especially for Pell grants, declines.

The 1992 amendments to the Higher Education Act dramatically and drastically lowered the income protection allowances. For single students, financially independent of their families, the IPA was reduced from $6,400 to $3,000. The IPA for working dependent students was lowered from $4,250 to $1,750. As a result, the amount a typical independent student can receive under the Pell Grant Program begins to decline when his or her income exceeds $3,000, and the student becomes completely ineligible at an income level of $10,000.

Because of this decrease in IPA's, the number of independent students receiving Pell grants declined from over a million in 1992 to about 750,000 in 1993—a loss of over a quarter of a million grants to independent working students.

This change has three unfortunate consequences:

First, many nontraditional students are not able to pursue post-secondary education. Typically these are older individuals with jobs who are attempting to improve their skills. Because the IPA is not enough to meet living expenses, independent students find themselves unable to pay tuition and meet their basic living expenses. They are forced to defer or even forgo higher education.

Second, the current law creates a disincentive to work. If a student knows that earning more than $3,000 will reduce the size of his or her Pell grant award, the student can easily conclude that there is no reason to try to earn more than $3,000 a year.

Third, it penalizes students who are trying to pay for their education through work rather than by borrowing. This is particularly unfair to the almost 75 percent of dependent undergraduates who are working while studying to pay college expenses. When earnings result in lower grants, these students must turn to larger loans to finance their education.

The Working Students' Income Protection Act will make great strides toward correcting these problems. It will allow single independent students to retain $6,000 of their earnings for basic living expenses, married working independent students to retain $9,000, and working dependent students to retain $4,200 before they begin to loose their Pell grants. This will not only make higher education more affordable for these students, it will also encourage and reward work, a worthwhile objective.

Moreover, these changes will correct an injustice by providing benefits to a segment of the student population that has been largely overlooked by the changes in student aid recently passed or currently under consideration. Increasing Pell grants by $300, for example, a move that I strongly support, which was included in the budget agreement, will not help the working students who are ineligible for these grants because of the inadequate level of the current IPA. Similarly, the tuition tax credit will not help them because they are not earning enough to pay taxes. By increasing the IPA, these students will be able to share in the government assistance available to those seeking to pursue a higher education.

I would like to give you some examples from the University of Southern Maine, a State-supported institution serving 10,000 students. These students have an average age of just under 30 years. They are largely independent students and they are balancing jobs, school, and often family responsibilities. When these students have incomes above the IPA, which they must have to survive, they are not eligible for Pell grants under the current law. Let me describe two of these students to you.

Both are single students. The first is a 25-year-old junior recreation therapy

major. She has worked as a nurses aide since graduating from high school, and she continues to work full time during the summers and part time during the school year. The second is a 31-year-old social work major. He works year round in a variety of part-time restaurant and clerical jobs. Both have total gross earnings of about $15,000 per year.

The current income protection allowance permits each of these students to retain only $3,000 for basic living expenses. It assumes that the remainder is available for calculating the family contribution toward educational expenses. The Working Students' Income Protection Act will allow each of these students to retain $6,000 for basic living expenses and will restore their eligibility for Pell grants. It will allow them to complete their education without incurring significant amounts of debt.

The president of the University of Southern Maine, Richard Pattenaude, has often noted that the mission of a public university is to help people of diverse backgrounds achieve their goals. These citizens, including recent high school graduates, adult learners with jobs and families, and single parents, all come to us, he says,

> With dreams of becoming more than they are. I am always moved and inspired by how hard our students work to realize those dreams and how deeply they care about their educations. These students underscore the significance of maintaining support for higher education if we are to enter the 21st century with an educational system ready to meet the needs and challenges of the people we serve.

By increasing the income protection allowance, the Working Students' Income Protection Act will take a major step toward meeting this challenge by helping working students afford college and encouraging them to pursue higher education.

Later in this Congress, the Senate Labor and Human Resources Committee, whose chairman is here today, will mark up the Higher Education Act reauthorization legislation. It is my hope that this legislation will be incorporated into the committee's bill.

Enacting this modest change will make a significant and positive change in the lives of thousands and thousands of students in the United States I urge my colleagues to show their support by cosponsoring this bill.

Mr. President, I ask unanimous consent that a letter from the American Council of Education on behalf of seven higher education associations which support this bill be included in the RECORD.

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

AMERICAN COUNCIL ON EDUCATION,
Washington, DC, September 4, 1997.

Hon. SUSAN M. COLLINS,
U.S. Senate,
Washington, DC.

DEAR SENATOR COLLINS: The higher education associations listed below, representing the nation's 3,700 colleges and universities, strongly support the legislation you are sponsoring to correct current inequities in the need analysis formula for the Pell Grant program. Your legislation parallels the reauthorization proposal we have advanced to reinstate or expand eligibility for single independent students and for dependent students who work.

A broad-based consensus exists among students, campus officials, and higher education policy analysts, as well as the Clinton administration and many members of Congress, that the 1992 Higher Education Act (HEA) amendments made it overly difficult for single, independent students and dependent students with earnings to receive Pell Grants. These changes were felt immediately and had a substantial, negative impact on access to higher education. For example, at least 200,000 single independent students lost their Pell Grants as a result of these changes in the first year they were implemented.

For a number of years, the cost of providing greater grant access for these extremely needy students has been cited as a reason against acting to assist them. However, the President has requested funds for this purpose this year, and the House Appropriations committee has included funds that will make a substantial contribution toward addressing this problem in its version of the FY 1998 Labor, Health and Human Services and Education appropriations bill. Securing these funds, along with passage of authorizing legislation such as yours to permit the funds to be spent, will provide tremendous relief and benefit to students on campuses across the country.

Again, we are grateful for your leadership on this important issue. Prompt consideration and passage of your bill immediately following the August recess will pave the way for appropriations to follow, enabling students and their families to make financial plans for the next academic year. We are eager to assist you in any way to secure passage of your legislation.

Sincerely,

STANLEY O. IKENBERRY,
President.

By Mr. CAMPBELL:

S. 1200. A bill to provide that countries receiving foreign assistance be conducive to U.S. business; to the Committee on Foreign Relations.

THE INTERNATIONAL ANTI-CORRUPTION ACT OF 1997

Mr. CAMPBELL. Mr. President, many of my colleagues and I have received complaints from constituent companies, or from constituents who are affiliated with companies, which are encountering unfair and illegal business practices in other countries. What is especially disturbing is that many of these countries are receiving significant amounts of U.S. foreign assistance.

Ukraine, for example, is the fourth largest recipient of United States foreign aid, receiving approximately $228 million in 1997. Yet, despite this generous U.S. assistance, corrupt government officials cheat and threaten U.S. businesses and investors.

In March of this year, the Motorola Corp. pulled out of a $500 million investment because of arbitrary decisions made by powerful bureaucrats. News reports indicated that Motorola's decision came less than 2 weeks after the consortium it was leading was selected as one of three winners in a tight competition to install cellular phone networks in that country. As reported, the government kept changing the rules up to the last minute which drove Motorola to its startling decision to pull out. The Wall Street Journal called Motorola's experience ''a case study of the pitfalls faced by investors in Ukraine.

The Foreign Operations Subcommittee of which I am a member held a hearing on May 6 regarding the Ukraine, Russia, and the New Independent States. The hearing considered the administration's request for millions of dollars in new funding for these countries. A number of subcommittee members and I raised with the witnesses specific examples of United States companies and American investors who are victims of corruption and dishonesty by the Ukrainian Government.

I would like to take a minute and highlight some statements made by AID Assistant Administrator Thomas Dine at that hearing which underscore how serious the situation is in the Ukraine. Mr. Dine testified that ''there are real problems in the Ukraine. The perceived level of official and unofficial corruption is pervasive and deep.'' He also testified that ''the Deputy Prime Minister, the country's leading reformer, recently resigned.'' And, ''major and small U.S. companies, faced with harassment, intimidation, and bribery are leaving the country.'' Mr. Dine further testified that ''we cannot expect American investors to do business in Ukraine or any of the NIS countries if they are not going to be treated fairly.'' I fully agree with this last statement, and believe we in Congress should act to ensure American investors are treated fairly, especially in those countries which are receiving millions in American tax dollars.

Corruption is a major problem for companies around the world. The World Bank recently surveyed international executives who identified corruption as the biggest problem they face in doing business in Latin America, the Caribbean, and sub-Saharan Africa.

And, we have seen disturbing news reports of the extent of corruption and illegal practices which are adversely affecting U.S. businesses abroad. A New York Times article of May 24, 1997, cited a Commerce Department finding that U.S. companies lost approximately $11 billion in contracts since mid-1994 because of bribery by their foreign competitors of foreign officials. And, this staggering loss is attributed only to those high-profile cases which were identified. Another report cited in the June 2, 1997, Economist Intelligence Unit, cited a loss of $45 billion to American companies because of corruption.

How many more millions of dollars have U.S. companies lost because of corrupt practices by foreign officials?

Mr. President, corruption in foreign countries hurts the U.S. economy. Trade with foreign countries creates and supports American jobs. Trade helps keep prices low, provides a greater selection of goods, and creates a larger market in which American companies can sell their products. Corruption limits the possibilities for U.S. investment and exports. It increases the risk and costs of doing business to the detriment of U.S. businesses and consumers.

Some important steps are being taken on the international scene. In May 1997, the 29 member nations in the Organization for Economic Cooperation and Development [OECD], which is composed of the world's largest industrialized nations, reached an agreement to fight corruption. This agreement is the first international accord which makes it a crime to bribe foreign officials.

And, on July 31, the International Monetary Fund decided to end its $216 million loan agreement with Kenya because of corruption and governmental mismanagement in that country.

But, more needs to be done.

The United States, in effect, is subsidizing other countries which are harassing U.S. companies and American investors abroad. This is unfair to U.S. businesses and unfair to U.S. taxpayers. And, this practice should stop.

That is why I am introducing today the International Anti-Corruption Act of 1997. This legislation requires the State Department to submit a report and the President to certify by March 1 of each year that countries which are receiving U.S. foreign aid are, in fact, conducive to American businesses and investors. If a country is found to be hostile to American businesses, its aid from the United States would be cut off.

The certification would be based on whether a country is making significant progress in, and is committed to, economic reform aimed at stemming corruption. The specific factors of economic reform which the State Department would consider include: market principles, private ownership, equitable treatment of foreign private investment, adoption of a legal and policy framework necessary for such reform, protection of intellectual property rights, and respect for contracts. The certification also would determine whether that country is making significant progress to eliminate corrupt trade practices and become integrated into the world economy.

Based on the State Department's findings, the countries would be assigned to one of three categories regarding their business climate: Conducive for U.S. business; not conducive to U.S. business; or hostile to U.S. business.

If the President certifies that a country is hostile to U.S. businesses and investors, the U.S. Government would immediately cut off foreign aid to that country. The United States also would vote against any loans to this country in the multilateral development banks. The aid would remain suspended until the President certifies the country is making significant progress in implementing the specified economic indicators and is no longer hostile to U.S. business.

If the President certifies that a country's business climate is not conducive for U.S. businesses, that country will, in effect, be put on probation. The country would continue to receive U.S. foreign aid through the end of the fiscal year, but aid would be cut off on the first day of the next fiscal year unless the President certifies the country is making significant progress in implementing the specified economic indicators and is committed to being conducive to U.S. business.

This probationary period is similar to the one in S. 457, which I introduced on March 19, 1997, regarding the drug certification process. This new approach would provide a specific time period during which the country on probationary certification would be expected to comply with certain conditions stipulated by the administration. If these conditions were not met at the end of this period, the United States would act firmly and cut off aid.

I initially designed this alternative to put countries on notice that the United States had serious concerns about their lack of cooperation. But, I also wanted to provide a fair period of time during which those countries could address U.S. concerns.

I included the probationary period in the bill I am introducing today for those countries which fall in the ''not conducive for U.S. businesses'' category, because I believe it is important to provide adequate notice to these countries which may have important ties to the United States. And, access to more timely and specific information during this probationary period would assist Congress in exercising its legislative and oversight responsibilities.

The third category applies when the President certifies a country is conducive to U.S. businesses. Foreign aid continues without interruption.

My bill includes the customary waiver authority where the national interests of the United States are at stake. For countries certified as hostile to or not conducive for U.S. business, aid can continue if the President determines it is in the national security interest of the United States. However, the determination expires after 6 months unless the President determines its continuation is important to our national security interest.

The bill also contains a provision which would allow aid to continue to meet urgent humanitarian needs, including food, medicine, disaster and refugee relief; to support democratic political reform and rule of law activities; to create private sector and nongovernmental organizations that are independent of government control; or to develop a free market economic system.

Finally, the bill directs the Commerce Department to establish a corruption hotline. Through this toll-free number, U.S. businesses and investors will be able to report unfair and illegal practices they are encountering in foreign countries. The Commerce Department would use that information in its investigations and would pass the information along to the State Department to be included in its annual report.

At a time when we are working to balance the Federal budget and make tough spending choices here at home, we can no longer tolerate or afford to have our Government misdirect U.S. foreign assistance to corrupt countries, especially countries harassing American investors.

I urge my colleagues to support the bill I am introducing today to fight corruption, protect American investors and businesses abroad, and improve the allocation of U.S. foreign aid.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 1700

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''International Anti-Corruption Act of 1997''.

SEC. 2. LIMITATIONS ON FOREIGN ASSISTANCE.

(a) REPORT AND CERTIFICATION.—

(1) IN GENERAL.—Not later than March 1 of each year, the President shall submit to the appropriate committees a certification described in paragraph (2) and a report for each country that received foreign assistance under part I of the Foreign Assistance Act of 1961 during the fiscal year. The report shall describe the extent to which each such country is making progress with respect to the following economic indicators:

(A) Implementation of comprehensive economic reform, based on market principles, private ownership, equitable treatment of foreign private investment, adoption of a legal and policy framework necessary for such reform, protection of intellectual property rights, and respect for contracts.

(B) Elimination of corrupt trade practices by private persons and government officials.

(C) Moving toward integration into the world economy.

(2) CERTIFICATION.—The certification described in this paragraph means a certification as to whether, based on the economic indicators described in subparagraphs (A) through (C) of paragraph (1), each country is—

(A) conducive to United States business;

(B) not conducive to United States business; or

(C) hostile to United States business.

(b) LIMITATIONS ON ASSISTANCE.—

(1) COUNTRIES HOSTILE TO UNITED STATES BUSINESS.—

(A) GENERAL LIMITATION.—Beginning on the date the certification described in subsection (a) is submitted—

(i) none of the funds made available for assistance under part I of the Foreign Assistance Act of 1961 (including unobligated balances of prior appropriations) may be made

available for the government of a country that is certified as hostile to United States business pursuant to such subsection (a); and

(ii) the Secretary of the Treasury shall instruct the United States Executive Director of each multilateral development bank to vote against any loan or other utilization of the funds of such institution to or by any country with respect to which a certification described in clause (i) has been made.

(B) DURATION OF LIMITATIONS.—Except as provided in subsection (c), the limitations described in clauses (i) and (ii) of subparagraph (A) shall apply with respect to a country that is certified as hostile to United States business pursuant to subsection (a) until the President certifies to the appropriate committees that the country is making significant progress in implementing the economic indicators described in subsection (a)(1) and is no longer hostile to United States business.

(2) COUNTRIES NOT CONDUCIVE TO UNITED STATES BUSINESS.—

(A) PROBATIONARY PERIOD.—A country that is certified as not conducive to United States business pursuant to subsection (a), shall be considered to be on probation beginning on the date of such certification.

(B) REQUIRED IMPROVEMENT.—Unless the President certifies to the appropriate committees that the country is making significant progress in implementing the economic indicators described in subsection (a) and is committed to being conducive to United States business, beginning on the first day of the fiscal year following the fiscal year in which a country is certified as not conducive to United States business pursuant to subsection (a)(2)—

(i) none of the funds made available for assistance under part I of the Foreign Assistance Act of 1961 (including unobligated balances of prior appropriations) may be made available for the government of such country; and

(ii) the Secretary of the Treasury shall instruct the United States Executive Director of each multilateral development bank to vote against any loan or other utilization of the funds of such institution to or by any country with respect to which a certification described in subparagraph (A) has been made.

(C) DURATION OF LIMITATIONS.—Except as provided in subsection (c), the limitations described in clauses (i) and (ii) of subparagraph (B) shall apply with respect to a country that is certified as not conducive to United States business pursuant to subsection (a) until the President certifies to the appropriate committees that the country is making significant progress in implementing the economic indicators described in subsection (a)(1) and is conducive to United States business.

(c) EXCEPTIONS.—

(1) NATIONAL SECURITY INTEREST.—Subsection (b) shall not apply with respect to a country described in subsection (b)(1) or (2) if the President determines with respect to such country that making such funds available is important to the national security interest of the United States. Any such determination shall cease to be effective 6 months after being made unless the President determines that it continuation is important to the national security interest of the United States.

(2) OTHER EXCEPTIONS.—Subsection (b) shall not apply with respect to—

(A) assistance to meet urgent humanitarian needs (including providing food, medicine, disaster, and refugee relief);

(B) democratic political reform and rule of law activities;

(C) the creation of private sector and nongovernmental organizations that are independent of government control; and

(D) the development of a free market economic system.

SEC. 3. TOLL-FREE NUMBER.

The Secretary of Commerce shall make available a toll-free telephone number for reporting by members of the public and United States businesses on the progress that countries receiving foreign assistance are making in implementing the economic indicators described in section 2(a)(1). The information obtained from the toll-free telephone reporting shall be included in the report required by section 2(a).

SEC. 4. DEFINITIONS.

In this Act:

(1) APPROPRIATE COMMITTEE.—The term ''appropriate committees'' means the Committee on International Relations of the House of Representatives and the Committee on Foreign Relations of the Senate.

(2) MULTILATERAL DEVELOPMENT BANK.—The term ''multilateral development bank'' means the International Bank for Reconstruction and Development, the International Development Association, and the European Bank for Reconstruction and Development.

ADDITIONAL COSPONSORS

S. 484

At the request of Mr. DEWINE, the name of the Senator from South Dakota [Mr. JOHNSON] was added as a cosponsor of S. 484, a bill to amend the Public Health Service Act to provide for the establishment of a pediatric research initiative.

S. 1008

At the request of Mr. DURBIN, the names of the Senator from Nebraska [Mr. KERREY], the Senator from Missouri [Mr. BOND], and the Senator from Ohio [Mr. DEWINE] were added as cosponsors of S. 1008, a bill to amend the Internal Revenue Code of 1986 to provide that the tax incentives for alcohol used as a fuel shall be extended as part of any extension of fuel tax rates.

AMENDMENT NO. 1137

At the request of Mr. HARKIN the names of the Senator from Indiana [Mr. LUGAR] and the Senator from Pennsylvania [Mr. SPECTER] were added as cosponsors of amendment No. 1137 proposed to S. 830, a bill to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

AMENDMENT NO. 1139

At the request of Mr. DURBIN the name of the Senator from South Dakota [Mr. JOHNSON] was added as a cosponsor of amendment No. 1139 proposed to S. 830, a bill to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

AMENDMENT NO. 1140

At the request of Mr. DURBIN the names of the Senator from Wisconsin [Mr. FEINGOLD] and the Senator from South Dakota [Mr. JOHNSON] were added as cosponsors of amendment No. 1140 proposed to S. 830, a bill to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

SENATE CONCURRENT RESOLUTION 53—COMMENDING THE REPRESENTATIVE OF THE TAIPEI ECONOMIC AND CULTURAL REPRESENTATIVE OFFICE IN THE UNITED STATES

Mr. MURKOWSKI submitted the following concurrent resolution; which was referred to the Committee on the Judiciary:

S. CON. RES. 53

Whereas Dr. Jason C. Hu has served with distinction as Representative of the Taipei Economic and Cultural Representative Office (TECRO) since June 1996, and has ably represented the interests of the Republic of China on Taiwan;

Whereas Dr. Hu has been a firm and consistent advocate of democratic principles throughout his distinguished career;

Whereas Dr. Hu has established many deep friendships with Members of Congress and other Americans during his tenure in Washington; and

Whereas Dr. Hu has been asked to return to Taiwan to serve as the Minister of Foreign Affairs of the Republic of China: Now, therefore, be it

Resolved by the Senate (the House of Representatives concurring), That Congress hereby—

(1) commends Dr. Jason C. Hu for his service as Representative of the TECRO office; and

(2) expresses to Dr. Hu and his family its best wishes for his continued success in the future.

COMMEMORATING REPRESENTATIVE JASON HU OF THE REPUBLIC OF CHINA ON TAIWAN

Mr. MURKOWSKI. Mr. President, I rise today to offer a Senate resolution to commemorate Representative Hu of the Republic of China for his outstanding service as the head of the Taipei Economic and Cultural Representative Office [TECRO] here in Washington, DC. President Lee Teng-hui has called Dr. Hu back to Taiwan to serve as the Minister of Foreign Affairs. This new appointment is a tremendous honor, and I am sure that he will serve his government as ably as Foreign Minister as he has done in Washington, and in his other previous posts.

Serving Taiwan so well here in Washington, DC, has been no easy task. Dr. Hu must balance the needs of Taiwan with the difficult dynamics associated with the issues surrounding the Republic of China. Maintaining stability and peace in Southeast Asia while promoting democracy and strengthening our ties with our allies should be a top priority for both our governments.

I have spoken often on the floor of the United States Senate regarding numerous issues including our commitments under the Taiwan Relations Act, Taiwan's bid to enter the World Trade Organization, President Lee's visit to

Cornell in 1996, and military exercises by the People's Republic of China in the waters around the island of Taiwan on the eve of their historic Presidential elections. In all cases, Dr. Hu has provided valuable insights regarding these matters to me.

Throughout his career, Dr. Hu has distinguished himself among his countrymen. From his days as the ROC delegation leader at the U.N. World Youth Assembly in 1970 to his current post as the representative of the Taipei Economic and Cultural Representative Office here in Washington, DC, Dr. Hu has made a name for himself as an expert on foreign affairs. Obviously, President Lee recognizes Dr. Hu's abilities and has asked him to take the lead in foreign affairs. I hope Dr. Hu's replacement will be as helpful and knowledgeable about Taiwan issues.

Finally, I would like to wish both Dr. Hu, his wife Shirley, and their two children good luck and express to him my heartfelt thanks for a job well done.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON GOVERNMENTAL AFFAIRS

Mr. COVERDELL. Mr. President, I ask unanimous consent on behalf of the Governmental Affairs Committee special investigation to meet on Friday, September 19, at 10 a.m. for a hearing on campaign financing issues.

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

ADDITIONAL STATEMENTS

THE 50TH ANNIVERSARY OF THE DEPARTMENT OF DEFENSE

• Mr. STEVENS. Mr. President, yesterday I attended a ceremony to mark the 50th anniversary of the Department of Defense. It was a most impressive event to honor the men and women who serve in the defense of our Nation.

Our former colleague, Secretary of Defense Bill Cohen, highlighted the achievements of the Department over these past 50 years. He reminded us of the Department's great legacy and challenges that lie ahead in the future.

The Vice Chairman of the Joint Chiefs of Staff and my good friend, Gen. Joe Ralston, also spoke at this event. His remarks illustrated the significant changes that have occurred since the Department's inception and saluted our soldiers, sailors, airmen, and marines who so honorably serve our country.

Mr. President, I request that the text of the remarks of both Secretary Cohen and General Ralston be printed in the CONGRESSIONAL RECORD.

The remarks follow:

REMARKS BY WILLIAM S. COHEN, SECRETARY OF DEFENSE, ON THE 50TH ANNIVERSARY OF THE DEPARTMENT OF DEFENSE, SEPTEMBER 17, 1997

The poet Shelly called history ''a cyclic poem written by time upon our memories.''

Let me describe a certain pivot point in history: It is a time of daunting security challenges both at home and abroad. In Europe, the United States is proposing a bold plan to advance democracy, free markets and shared security. In the Pacific, America is the dominant power, but Korea remains dangerously divided and China is in a period of profound transition, its future uncertain, its intentions unclear. Meanwhile, breathtaking advances in technology are fueling a revolution in military affairs. And America's defense establishment is reorienting itself to confront the enormous security challenges of the new era.

I could be talking about September, 1997, for this picture captures our world today. But as history is ''a cyclic poem,'' this picture also describes September, 1947, when the Department of Defense came into being.

We have been marking many golden anniversaries of late. These are the days of remembrance, a time to recall the historic trials and triumphs of half a century. The hallowed days—D–Day, VE–Day, VJ–Day. The historic deeds—the Marshall Plan, the National Security Act. And the enduring establishments—the United Nations, the US Air Force, the Central Intelligence Agency, the Department of Defense.

Why do we recall these trials and triumphs? Because they can help us face the portents and possibilities of the century ahead. As we talk of tomorrow, we must be mindful to hold up the lamplight of history, so that we may walk with confidence on the footpath to the future.

We are here today to celebrate not the golden anniversary of a bureaucracy, or that of a building—but rather of a bold idea. That idea was for a National Military Establishment that unified all of our military services, land, sea and air, under a single Department with a civilian chief, the whole greater than the sum of its remarkable parts.

By 1947, it was an idea whose time had come. The generation that won the Second World War set out to win the peace. They understood that to win the peace, America had to be engaged in global affairs as a global leader. They had learned from personal experience—from their ''blood, toil, tears and sweat''—the central lesson of this century: That when America neglects the problems of the world, the world often brings its problems to America's doorstep. And so they created a Department of Defense that would engage the world with gathered strength and purpose.

To witness the wisdom of this bold idea and its historic achievements, you only have to walk the corridors of the Pentagon.

You will walk past George Marshall's desk. He was soldier who led our forces to victory against fascism; a diplomat who set forth a bold vision for a new Europe, healed, whole, free and linked to America in the spirit of help and hope; and a Secretary of Defense who helped to halt the columns of communism on the Korean peninsula.

You will walk past a section of the Berlin Wall, once a symbol of tyranny and peril, now a symbol of the triumph of freedom, and a triumph of the Department of Defense that trained, equipped and maintained the US Armed Forces—forces that gave America and our allies the power and the will to stand fast and stand firm through 40 winters of the Cold War, and gave us the opportunity to secure a lasting peace in Europe and Asia.

As you walk through the corridors of the Pentagon, you will see not only the artifacts of our trials and triumphs, but the individuals who endured the trials and ensured the triumphs.

You will see the portraits of the military leadership, and also those who led this Department—the Secretaries of Defense—some of whom have graced this ceremony with their presence today. Secretary Cap Weinberger, Secretary Frank Carlucci, Secretary Bill Perry: Each one of you has protected and defended those who protect and defend our nation. Each one of you has left the Department in better stead than when you arrived, and with a challenge to your successor to continue the legacy. I am honored and humbled to accept—and extend—this challenge.

But the legacy of leadership extends to those who were ready and willing to be led. And as you walk these corridors, you see the legacy of soldiers, sailors, airmen and Marines enshrined on our walls—from the Hall of Heroes that recall exceptional valor, to the exhibits that remember forgotten service—the Women's Military Corridor, the exhibits for Hispanic veterans and the Tuskegee Airmen.

To walk these corridors is to learn of courage and commitment; of service and sacrifice; of grit and greatness: From the frozen hills of Korea, to the twisted jungles of Vietnam; from Beirut to Grenada; Panama to Somalia; to the searing sands of Saudi Arabia and the mud and ice of Bosnia.

I dedicate our golden anniversary to their golden achievements.

In so doing, let me make a point which often becomes obscured in the reports which focus on our flaws: We have the best-trained, best-equipped and best-educated military in the history of the world, and we need to remember that despite our shortcomings, which we are eager to examine and confront openly, our forces are the envy of every other nation on this planet.

Finally, if you walk the corridors of the Pentagon, you will meet the backbone of this institution: The civilian employees who serve this Department and support the troops. The success of this Department is their success too.

But as we recall our trials and triumphs of the past, we face a new challenge: In 1997—as in 1947—we must build a Department of Defense that can face the dangers and the daring possibilities of the future. For a brave new world stretches beyond these lawns, past those shining monuments across the river. It is a world of momentous opportunity—of flourishing markets, stunning technologies, and new democracies. But it is also a world of startling new dangers—ethnic conflict, regional aggressors, and terrorism.

Fifty years hence, let those who look back on 1997 say that, we too, were not just a building or a bureaucracy, but that we too were bold. That we too were unafraid to think anew, to organize anew, to act anew. Let them say that by embracing the spirit of our era, we too were able to seize the challenges of our time: The challenge to shape the world; to respond to its threats; and to prepare for the future; to harness a Revolution in Military Affairs to give our forces the technology to dominate the battlefield; and to foment a Revolution in Business Affairs, to create a 21st Century Pentagon—a model of action, efficiency, economy and versatility.

Fifty years from now, let them say that our leadership, vision and courage helped catapult America into a new century. And 50 years from now, let them say that we bequeathed to them, what our predecessors bequeathed to us: The best trained, best equipped, best prepared military in history, the pride of our nation and the envy of the world.

I will close with the words from Daniel Webster, speaking at the dedication of the Bunker Hill Monument: ''And now let us indulge an honest exultation in the conviction of the benefit which the example of our country has produced and is likely to produce on

human freedom and happiness. And let us endeavor to comprehend in all its magnitude and to feel in all its importance the part assigned to us in the great drama of human affairs.''

REMARKS BY GEN. JOSEPH RALSTON, VICE CHAIRMAN OF THE JOINT CHIEFS OF STAFF ON THE 50TH ANNIVERSARY OF THE DEPARTMENT OF DEFENSE, SEPTEMBER 17, 1997

Secretary Cohen, Former Secretaries Weinberger, Carlucci, and Perry, Members of Congress, Gen. Jones, distinguished guests, ladies and gentlemen:

I am very proud to be here as the representative of the more than 3 million people currently serving in the defense of our nation as soldiers, sailors, airmen, marines, coast guardsmen—active duty, National Guard, Reserve, and civilians. It is an honor to be a part of this splendid anniversary; a celebration to commemorate fifty years of unwavering leadership to our armed forces.

Take a moment and put yourself back in time. Fifty years ago we had just won a world war and the country was still celebrating its victory. The might of the military machine was not broken, at least the American public didn't think so.

But we learned many lessons the hard way during that war and the leaders who fought that war knew we could and should do better.

These visionaries understood that to stand still would put the United States back where we were before the war . . . as isolationists.

Imagine if you can, the resistance these men faced as they attempted to reorganize our armed forces . . . a force that only a year prior had defeated a deranged dictator and an imperial army and navy.

These leaders, both civilian and military, realized the daunting task before them, but charged forward, amid intense debate, and agreed upon a ''unification'' course.

Although the reforms in 1947 were immense, ten years later the leaders of our country recognized the requirement for a course correction.

The Act of 1958, spearheaded by President Eisenhower, provided that course correction and called for the organization of all combat forces into unified commands and as he stated, ''singly led and prepared to fight as one, regardless of Service.''

With this new guidance our armed forces marched on for over 25 years. However, in 1986 a significant change occurred with the enactment of the Goldwater-Nichols Act. It not only reinforced our joint warfighting doctrine, but it also strengthened the civilian authority in the Department and increased the responsibility and authority of the Chairman. Today we have an armed force that is the envy of every nation on this Earth—and the pride of Americans.

Make no mistake . . . it is the magnificent men and women in uniform who make the sacrifices, who walk the jungles, fly over the deserts, sail on and under the seas, that provide the peace, freedom, and stability we enjoy as a Nation today.

But we must resist the temptation to relax and believe we have it just right. We must fight the complacency. We have much left to do as we revolutionize the way we do business, as we make the hard choices that will always put the needs of America's sons and daughters first.

Today I proudly salute the men and women of the Department of Defense.●

IN RECOGNITION OF HARRY BELL

● Mr. HOLLINGS. Mr. President, I rise today in recognition of Harry Bell, a man well known to the people of South Carolina. We salute him as he retires in December as president of the South Carolina Farm Bureau Federation.

Harry Bell is known throughout the State as a successful farmer. With his son, William, he operates a productive, 1,450 acre farm in Saluda County, on which he raises cattle and plants soybeans, cotton, small grains, and strawberries. But Harry Bell's activities extend far beyond farming. He also is a savvy and successful businessman, with a long career in banking and insurance.

In fact, he began his business career as a bank clerk, currently serves on the local board of First Citizens' Bank, and has been president of the Palmetto Casualty Insurance Co. and director of the Ridge Banking Co.

But it is for his work with South Carolina farmers that Harry Bell is best known. He has served as president of the South Carolina Farm Bureau since 1971; in that time, he helped South Carolina farmers weather droughts, high interest rates, and the increasingly overwhelming competition of large-scale commercial farms. During his tenure as president, Harry helped preserve the State's heritage of family-owned farms, while at the same time assisting farmers to mechanize and modernize their operations. It is partly as a result of his efforts that agriculture remains a key component of South Carolina's economy.

Harry Bell's involvement with agriculture has not been confined to the South Carolina Farm Bureau Federation. He also was president of the Saluda County Farm Bureau Federation for 4 years, and was vice president of the American Farm Bureau Federation from 1986–94. From 1967–85, he was the farm representative on the South Carolina Water Resources Commission.

Fortunately for us, Harry Bell has employed his prodigious talents and energies not just in the service of the farming community, but of the whole community. He must have filled his every waking moment with public service of one kind or another.

He is active in his church, Johnston Presbyterian, having served as an elder and former deacon. He responded to another kind of call when his country summoned him to fight, serving on active duty in the U.S. Air Force from 1945–47 and from 1951–53. Additionally, he served in the Air Force Reserves until 1974, when he retired with the rank of lieutenant colonel.

Harry Bell exemplifies the ideal of public service. His career has combined devotion to God, country, and community. Thanks to his stewardship, South Carolina farmers can look forward to many future harvests. It has been my good fortune to work with Harry Bell for over 20 years on important issues affecting the farmers and economy of our State. We in South Carolina are proud to call him our own, and I am honored to salute him today.●

DEPARTMENT OF THE INTERIOR AND RELATED AGENCIES APPROPRIATIONS ACT, 1998

OUTER CONTINENTAL SHELF LEASING PROGRAM

● Mrs. HUTCHISON. Mr. President, I would like to rise today, with my colleague, Senator JOHN BREAUX, to engage in a colloquy about a serious matter that has only recently come to our attention.

Mr. GORTON. I yield the floor for your colloquy.

Mrs. HUTCHISON. Mr. President, if these concerns are not addressed, one of our country's most successful programs, the Outer Continental Shelf Leasing Program, may be jeopardized. Under that program, the Federal Government has raised hundreds of millions of dollars in rents and royalties over the last 25 years, while at the same time developing safe and secure sources of energy for our country. Crucial to the success of that program is the ability of the private sector to conduct exploration of the Gulf of Mexico before submitting bids on the tracts offered for oil and gas leases.

I recently learned that the Minerals Management Service [MMS] has proposed changes to the rules under which that exploration is conducted. These changes would potentially jeopardize the continuity and success of the Outer Continental Shelf Lands Act [OCSLA] program.

Currently, geological and geophysical companies [G&G companies] conduct seismic surveys under MMS permits which require the permittees to provide the data they collect to the MMS under strict guarantees of confidentiality.

The G&G companies then provide the oil companies access to the data through nonexclusive licenses. The licenses allow the oil companies to use the data for any purpose including reprocessing the data using their own technology and data. These licenses are given on the condition that the licensee will not show or share the data with anyone else. In this way, the G&G companies are able to offer data to the largest number of possible users at the lowest cost.

Under the proposed regulations, MMS intends to extend its ability to obtain data from just the G&G companies to all of the companies who have licensed and reprocessed that data using their own technology. By requiring all industry to share reprocessed data with the MMS, the threat of disclosure of extremely sensitive business data exists. Under any number of situations, including appeal of fair market values, it is unclear if the proposed changes would protect the confidentiality of that data. This threat to sensitive business data could ultimately threaten the success of the OCS leasing program.

I understand and appreciate the need for MMS to have accurate data. However, I question the need of the Government to obtain reprocessed data that

belongs to the business community especially if it could potentially be released to competitor companies.

It is my understanding that my colleague, Senator BREAUX was an author of the original OCSLA. Do you believe the MMS' proposed regulations accurately reflect the purpose of that legislation?

Mr. BREAUX. Mr. President, as one of the original authors of the Outer Continental Shelf Lands Act, I can advise the Senate that we spent a great deal of time and effort in developing a law that would result in the information, data, and interpretation remaining confidential. Any steps that would put that confidentiality at risk are contrary to the spirit and intent of what we were trying to accomplish in 1972.

At that time, geophysical contractors were particularly concerned about the data sharing and confidentiality provisions of the OCSLA because they felt any breach of that confidentiality would destroy the market for the data, which is the geophysical contractors' sole asset. To protect that confidentiality, provisions were adopted requiring MMS to make sure the agency obtained permission from the permittee and anyone to whom the permittee sold the data under promise of confidentiality before sharing any data obtained from the permittee with a State government.

Shortly after the amendment of the OCSLA, MMS promulgated regulations spelling out the mechanics of how data was to be made available to it and how it was to be protected once it had been turned over. Among those rules is one that mandates that the permittee, who had agreed to make its geophysical data available to MMS as a condition of the permit, require any party to whom the data is transferred to agree to the terms of the permit regarding data sharing as a condition of the transfer. Industry contends that when that regulation was proposed, MMS proposed to define the term ''transfer'' in a way that included nonexclusive licensees, but dropped that requirement from the final rule. Industry believes that MMS has now proposed to extend its data sharing requirements to nonexclusive licensees and to amend its regulations in several other significant ways.

MMS contends that, in the 25-year span of its statutory responsibility to hold geophysical data confidential, this confidentiality has never been breached. And, MMS believes its current rulemaking is fully consistent with its authority under the OCSLA. In other words, MMS is going forward with its rulemaking without further public input.

Mrs. HUTCHISON. I share your concerns regarding the intent of the original OCSLA and the effect of the MMS' actions.

MMS is threatening to implement regulations without adequate discussions between the agency, industry, and the original authors of the OCSLA. By utilizing a negotiated rulemaking, we have a unique opportunity to avoid the problems that MMS' current course of action will create. There are many stakeholders in this debate that have valid concerns which deserve to be addressed. The exploration contractors, the oil and gas companies and the MMS all have a lot to lose by pushing through regulations that will cause more problems than they will fix.

Each of the stakeholders can make significant contributions to a set of regulations that will accomplish the goals of the OCSLA, the MMS and the industry. I am frankly at a loss to understand why MMS has refused to engage in substantive negotiations on these issues when it is clear that substantive concerns remain unaddressed.

The notice and comment rulemaking that surrounded this proposed rule was insufficient. Significant disagreements continue to exist where solutions seem eminently reachable. It makes sense to get the interested parties together to see if they can find a mutually agreeable solution. I strongly urge MMS to abandon the current rulemaking proceeding and to negotiate immediately with the affected parties to avoid placing the OCS lease program in jeopardy.

Mr. BREAUX. Mr. President, I am very concerned about the tenor of these proceedings. MMS is the Federal agency charged with the responsibility to manage the mineral resources of the Outer Continental Shelf in an environmentally sound and safe manner and to timely collect, verify, and distribute mineral revenues from Federal and Indian lands. So, I want to know that this proposal is the best way to get at the objective that underlies it—a fair and reliable royalty system. But, I also want to ensure that the individuals and businesses affected by the MMS proposal are accorded every opportunity to have their concerns heard.

I agree that MMS needs access to G&G information to discharge its important duties. But, it ought to accomplish that duty in a way that does not risk disrupting one of the Federal Government's most successful revenue programs. The G&G industry estimates that the proposed regulations will, if adopted, require the renegotiation of thousands of existing license agreements and, until that renegotiation is complete, no data can be licensed. This renegotiation process may take several months, if not years. During that time, there will be no exploration. Thus, the process that recently led to another record oil and gas lease sale on the Gulf of Mexico Outer Continental Shelf, providing needed revenue to the Federal Treasury, will come to a grinding halt. This is an interruption we cannot afford.

For 50 years, oil and natural gas have been produced from the Outer Continental Shelf [OCS] underlying the Gulf of Mexico. This production represents more than 83 percent of total OCS oil production and more than 99 percent of all OCS natural gas production. In 1995, production from this area accounted for 15 percent of all oil produced in the United States and about a quarter of the natural gas.

Maintaining public trust in our royalty system is critical to the future of oil and gas leasing, both onshore and offshore. Federal royalty policy must balance the need to encourage public resource development with the need to ensure that the public gets its fair royalty share. That balancing act requires government and industry to work together. The OCS leasing program is one example of government and the private sector working together—reflected by the recent record leases, records bonus payments and increased exploration in the Gulf of Mexico.

I hope we can advance that partnership here. Let's take another opportunity to learn from each other what is working, what is not working under the current system—and how the MMS proposal addresses those problems. Then, we can move forward with a balanced policy that assures timely and accurate royalty payments for the people of the United States.●

TRADE NEGOTIATING AUTHORITY

● Mr. BAUCUS. Mr. President, I rise to discuss the administration's request for new trade negotiating authority.

Now, any discussion of trade policy should begin not with talk about new agreements. It should begin with a review of the basic facts, and of what we need to change in the international trade system to create jobs, raise wages, guarantee fairness, and create opportunities for Americans.

THE BASIC FACTS

So let's first look at the facts. We are enjoying what will soon be the longest period of economic growth in our history. Since 1992, our economy has grown from $6.5 to $8 trillion dollars. Inflation has fallen to 2 percent. We have added a net gain of more than 12 million jobs. And while from 1986 to 1993 real wages fell every year, since 1994 real wages have risen every year.

A lot of things go into that record. Research and development by companies and the Government. Deficit reduction from $290 billion in 1992 to $36 billion before the recent budget agreement. Improved competitiveness. Most of all, hard work and sacrifice by ordinary people.

But our trade policy in the past 4 years deserves some credit as well. Since 1993, Ambassador Mickey Kantor and now Ambassador Barshefsky, along with their staffs, have worked very hard, stood up for our workers and farmers, and achieved a great deal. And the result has been a nearly 50 percent jump in exports, from just over $600 billion in 1992 to nearly $900 billion this year.

FAR FROM FINISHED

That is a good record. But the work is far from finished.

Foreign countries routinely discriminate against our farm products. We can do more in high technology, where our telecommunications, computer hardware, and software firms are tremendously competitive. Subsidies and state trading companies in foreign countries distort trade tremendously. And our trade deficit remains unacceptably high. So we need to keep working to fix these things.

NEED FOR NEGOTIATING AUTHORITY

And the administration needs trade negotiating authority to do it. Granting negotiating authority—I do not call it ''fast track,'' because there is nothing fast about it—is a big step for Congress, but it is the right step. The fact is, big trade agreements are like base closing agreements. The best possible trade agreement will ask many different interests to give up a tariff, subsidy or other form of protection in exchange for an agreement that will help the entire country.

So I believe the Senate should approve a trade negotiating authority bill. And the one proposed yesterday by the administration is, I believe, a good start. It sets five general trade policy objectives: increasing market access; reducing barriers to trade; strengthening international trade rules; fostering economic growth and full employment; and addressing labor, environmental and other areas directly related to trade.

More specifically, the draft sets the following priorities: reducing tariff and non-tariff barriers; opening markets to services; protecting intellectual property; ensuring more transparency in international dispute settlement, which is extremely important to me; winning fairer investment rules, so countries no longer can force technology transfer or impose export requirements; and opening markets in agriculture. I am especially pleased by the inclusion of a specific negotiating objective of opening foreign markets to American farm products. The bill devotes appropriate attention to the problems we have with state trading enterprises like the boards which control grain trade in many of our trade competitors.

Finally, promoting internationally recognized labor standards and environmentally sustainable development.

LABOR AND THE ENVIRONMENT

Let me talk briefly about this last issue. This has become a source of controversy for reasons that I don't quite understand.

Since 1947 we have concluded five rounds of GATT. More recently, we have passed three so-called free trade agreements, the Information Technology Agreement, the Agreement on Basic Telecommunications and hundreds of other sectoral and bilateral agreements on trade issues. As a result, tariffs are lower, quotas have shrunk in number and scope, and other formal trade barriers have diminished.

As these agreements go into effect, we quite logically find that other policies—intellectual property enforcement, antitrust policy, subsidies, rule of law, transparency, technical standards, Government procurement, labor regulations, and environmental law enforcement all have some impact on trade.

Our trade policy should deal with these issues, and it does. Intellectual property is a top priority, as well it should be. Government procurement and subsidies are as well. To rule out labor and environmental standards is simply to make an arbitrary, ideological judgment that these are almost the only forms of policy whose trade effects we will refuse to recognize.

That does not mean treating them the same in all trade agreements. The trade agreement with Mexico, for example, was a unique case. There we negotiated an agreement with a developing country, with which we shared a long border and in which we had existing experience with a free trade arrangement—the maquiladora program—which had created very obvious and serious labor and environmental problems. So in my opinion, that agreement required pretty strict labor and environmental side agreements.

That is not necessarily true in all other agreements. We should look them over case by case. Some very important agreements authorized by this negotiating authority bill—for example, agreements on services, intellectual property and state trading companies in agriculture—probably don't require labor and environmental provisions at all. But it is simply wrong and unfair to American workers and companies to say that we should never consider these issues. And I believe that on the whole, the administration proposal strikes a reasonable balance by calling for negotiations on labor and environmental issues directly related to trade.

IMPROVING EXISTING AGREEMENTS

In one area, however, I think the proposal needs some additions.

That is, I consider it at least as important to enforce and improve existing trade agreements as to negotiate new ones. We now have a wide and complex web of agreements. Some work well. Others do not. Still others are bad agreements that ought to be improved or redone.

Let me offer an example. Ambassador Barshefsky recently scored a major success by opening Canada's market to our barley. That is a very good thing; but it also shows that NAFTA and the United States-Canada Free Trade Agreement are not perfect. They can be improved, and they should be. Likewise, the Uruguay round should have eliminated Japan's tariffs on wood products, but did not.

Thus I think we should also include language that reflects the importance of enforcing existing agreements and improving the ones we already have. And I hope to work with the administration to include such language.

NEGOTIATING AUTHORITY VERSUS AGREEMENTS

Finally, we should not confuse negotiating authority with actual agreements. By passing trade negotiating authority, we do not sign blank checks. I expect that the Congress and the public will be fully consulted as we decide which agreements to pursue,; and then as we negotiate those agreements. And we have the right to disapprove trade agreements that do not meet the standards they should. So by endorsing new negotiating authority, I do not promise support for any particular agreement.

To sum up, the country needs a tough and aggressive trade policy in the years to come. And the President needs negotiating authority for that policy. I support the effort and I hope the Senate will do so as well.

AMENDMENT NO. 1221

• Mr. McCAIN. Mr. President, I join with Senator INOUYE in expressing strong opposition to the amendment. Just a few months ago, Senator INOUYE and I introduced a bill to amend the Indian Gaming Regulatory Act of 1987. The Indian Affairs Committee, which has jurisdiction over matters involving native Americans, has scheduled the first hearing on this bill on October 8, 1997. This hearing has been on the schedule for over a month. This is the normal and proper procedure for making policy with respect to native American issues.

If I had been able to be on the floor, I would have fought against and voted against this amendment. In its modified form, as it was finally adopted by voice vote, the amendment does not affect any process or procedure that currently exists into law or in regulation. However, it does represent an unwarranted interference into the development of reasonable and appropriate approaches to the authorization and regulation of Indian gaming that have not been considered or approved by the Indian Affairs Committee, the administration, or, more importantly, the tribes.

The amendment, even as modified, represents an ill-advised action of the Congress to influence the future of Indian gaming. The mere fact of offering this type of amendment, which seeks to micromanage the regulation of Indian gaming, will have the effect of prejudicing the outcome of the Indian Affairs' Committee hearings on IGRA amendment.

The proponents of this amendment are seeking to override a carefully balanced procedure in the Congress. They are seeking to throw up new obstacles to prevent tribes from engaging in gaming and to disrupt ongoing negotiations between States and tribes who are cooperating in developing Indian gaming compacts.

The IGRA was carefully crafted to take into account the differences among the several States. IGRA is not perfect, and that is why Senator INOUYE and I introduced amendments to the bill. The Enzi amendment is premature. The Senate Committee on Indian Affairs hearing is the proper

forum to discuss these issues and for opponents of Indian gaming to express their concerns.

Mr. President, I join with my colleagues on the Indian Affairs Committee in urging the conferees on the Interior appropriations bill to eliminate this provision from the final conference agreement. ●

IN HONOR OF JUDGE LAWRENCE H. COOKE

● Mr. MOYNIHAN. Mr. President, this weekend a glorious and important event will take place in Monticello, NY. On Sunday, September 20, 1997, the Courthouse in Sullivan County will be renamed the Lawrence H. Cooke Sullivan County Courthouse. Judge Cooke, a native of Monticello, is one of our State's more distinguished jurists. His legal career spans almost 60 years and is highlighted by his tenure from 1979 through 1984 as the chief judge of the New York State Court of Appeals, our State's highest court.

While Judge Cooke may be best known for his time on the court of appeals and his many years as a judge, practicing attorney, and town supervisor in Sullivan County, he also served as a member of my Judicial Screening Committee from 1985 through 1993. During his 8 years on the committee he provided wise counsel in helping me select candidates for Federal judgeships to be nominated by the President. While not necessarily the most glamorous part of being a Senator, selecting individuals for nomination to a Federal judgeship is one of our most important responsibilities. Long after a Senator has left the body, the judges whom he/she helped select may remain on the bench for many more years to come with life tenure. Judge Cooke provided invaluable assistance to me in this endeavor and I am pleased to say that he is now lending his talents to New York Governor George Pataki by serving on the Governor's judicial screening committee for State judgeships.

When I travel around New York State, one of the things I like to do if I have a couple of free minutes is to visit the local county courthouse. In most places, the courthouse is a grand and beautiful old building, and the courthouse in Sullivan County is no exception. Sullivan County was founded in 1809 and the current courthouse is actually the third it has had. The original burned down in 1844 and the second was replaced by the current structure in 1909. The newly named Cooke Courthouse is an Ohio sandstone building which was designed by William Beardsley of Poughkeepsie and built by the Kingston firm of Campbell and Dempsey for $143,000. In 1979 the building underwent a major renovation. It is a beautiful and historic building well befitting of Judge Cooke's name.

Mr. President, 1997 marks the sesquicentennial of the New York State Court of Appeals. With the exception of the U.S. Supreme Court, this court is perhaps the most important court in our Nation's legal history. One of the greatest jurists of the 20th century, Benjamin Cardozo, was a chief judge of this court before being nominated by President Franklin Roosevelt to the Supreme Court. Even today, every law student must read several of Judge Cardozo's opinions as part of a legal education and his opinion in Palsgraff versus Long Island Railroad is still the seminal case on proximate cause in torts. The current chief judge, Judith Kaye, is nationally recognized as a leader in judicial reform, especially in the area of jury selection. It is a proud and important tradition with which Judge Cooke is associated, and he certainly is an important part of that tradition.

On this special day on which we honor Judge Cooke, I want to wish the Judge and his wife Alice the best and thank him for his many years of service to me, to Sullivan County, to New York State, and to our justice system.●

NORTH ATLANTIC FISHERIES RESOURCE CONSERVATION ACT

● Ms. SNOWE. Mr. President, yesterday Senator KERRY and I introduced the North Atlantic Fisheries Resource Conservation Act. Unfortunately, we neglected to specifically ask that the text of the bill be printed in the RECORD. In order to ensure that the public has easy access to the bill's language, I now ask that the text of this bill be printed in the RECORD.

The text of the bill is as follows:

S. 1192

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''North Atlantic Fisheries Resource Conservation Act''.

SEC. 2. HARVEST OF ATLANTIC MACKEREL AND HERRING BY LARGE FISHING VESSELS.

(a) PERMIT REQUIRED.—Nothwithstanding any other provision of law to the contrary, the Secretary of Commerce may not authorize or permit any fishing vessel (as defined in section 3(17) of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1802(17) that—

(1) is 165 feet in length or longer; or

(2) has an engine or engines capable of producing a total of more than 3000 horsepower,

to harvest Atlantic mackerel or Atlantic herring in a fishery unless the participation of such a vessel is specifically allowed under a fishery management plan developed and implemented for that fishery under the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 et seq.).

(b) EXISTING PERMIT TO BE REVOKED.—Within 5 days after the date of enactment of this Act, the Secretary shall revoke any permit issued by the Secretary before that date to a vessel described in subsection (a) under which the vessel would be permitted to harvest Atlantic mackerel or Atlantic herring in such a fishery.

(c) FISHERY MANAGEMENT PLAN.—

(1) IMPLEMENTATION OF PLAN.—The New England Fishery Management Council shall prepare and submit a fishery management plan for Atlantic herring no later than June 30, 1998. The Secretary of Commerce shall implement the plan no later than September 30, 1998.

(2) AMENDMENT OF PLAN TO PERMIT LARGER VESSELS TO HARVEST.—The Mid-Atlantic Fishery Management Council, in consultation with the New England Fishery Management Council, shall prepare and submit, no later than June 30, 1998, an amendment to the Fishery Management Plan for Atlantic Mackerel, Squid, and Butterfish Fisheries which specifically addresses the participation of vessels described in subsection (a) in the harvesting of Atlantic mackerel. The Secretary of Commerce shall implement the amendment no later than September 30, 1998.

(3) VESSEL LENGTH AND POWER CRITERIA.—The Council and the Secretary may include vessel length or vessel power limitations, or both, in any fishery management plan or amendment under paragraph (1) or (2). The limitations may be greater or smaller than the vessel length and vessel power of a vessel described in subsection (a).●

NATIONAL POW/MIA RECOGNITION DAY

● Mr. SMITH of New Hampshire. Mr. President, Friday, September 19, 1997, has been designated this year by President Clinton and numerous State Governors as National POW/MIA Recognition Day. This is a special day for paying tribute to our missing service members and civilians involved with our Nation's past military conflicts. It is a day for reaffirming throughout the United States our national commitment to obtaining the fullest possible accounting for America's POW's and MIA's.

It has been an honor and privilege for me, since my election to the Congress in 1984, to assist the POW/MIA families, our veterans, and their friends and supporters, with the many efforts that have been undertaken to try to achieve a proper accounting for so many of our Nation's bravest heroes still listed as missing. It has been a difficult and emotional task, complicated by on and off-again cooperation by foreign governments.

As many of my colleagues know, I served as vice-chairman of the Senate Select Committee on POW/MIA Affairs in 1992, and I currently serve as the U.S. chairman of the Vietnam War Working Group of the Joint United States-Russian Commission on POW's and MIA's. This past summer, I, along with Congressman SAM JOHNSON of Texas, himself a returned POW from North Vietnam, traveled to Russia, Poland, and the Czech Republic in our continuing efforts to open archives and interview people knowledgeable about the fate of American POW's. We both feel, as a result of our trip, that we have enhanced our Government's ability to further investigate POW/MIA leads. I have also continued my own efforts here in the Senate to ensure that U.S. Government records on this issue are declassified and made available to the public. I am pleased to report that I am making additional progress in that regard, specifically with respect to information from the Nixon administration that I hope will shed more

light on our own Government's knowledge about POW's and MIA's when the Vietnam war ended in 1973.

As a result of my direct involvement with this issue, I can report that, even though we have made some progress over the years, there is still much work to do. It is, therefore, my hope that this administration will take the opportunity National POW/MIA Recognition Day provides to rededicate itself to using all appropriate resources available to the U.S. Government to resolve the POW/MIA issue.

I personally believe that public awareness is critical to ensuring that the United States vigorously presses Communist governments abroad, especially North Korea, China, Vietnam, and Laos, to give us the complete answers that we deserve on this humanitarian issue. Indeed, the support of the public has enabled us to continue to push forward with legislative initiatives in Congress that can help to ensure the POW/MIA issue is pursued as a top priority with the governments I just referenced.

I want to assure my own constituents and the many concerned Americans who have contacted me through the years that I remain absolutely committed to doing everything I think is appropriate to resolve the fate of our missing soldiers.

Mr. President, I thank the American people for remembering our unaccounted for POW's and MIA's on this special day.●

EXECUTIVE SESSION

EXECUTIVE CALENDAR

The PRESIDING OFFICER. By unanimous consent, the Senate will immediately proceed to executive session to consider the following nominations under the Executive Calendar, Nos. 249, 250, and 251; by unanimous consent, the nominations are deemed confirmed and the motions to reconsider laid upon the table, and any statements relating to the nominations will appear at this point in the RECORD, the President will be immediately notified of the Senate's action, and the Senate will return to legislative session.

The nominations considered and confirmed en bloc are as follows:

SOCIAL SECURITY ADMINISTRATION

Kenneth S. Apfel, of Maryland, to be Commissioner of Social Security for the term expiring January 19, 2001.

DEPARTMENT OF THE TREASURY

Gary Gensler, of Maryland, to be an Assistant Secretary of the Treasury.

Nancy Killefer, of Florida, to be Chief Financial Officer, Department of the Treasury.

LEGISLATIVE SESSION

The PRESIDING OFFICER. Under the previous order, the Senate will now return to legislative session.

ORDERS FOR TUESDAY, SEPTEMBER 23, 1997

The PRESIDING OFFICER. By unanimous consent, when the Senate completes its business today, it will stand in adjournment until the hour of 9:30 a.m., Tuesday, September 23, and on Tuesday, immediately following the prayer, the routine requests through the morning hour will be granted and the Senate will immediately resume consideration of S. 830, the Food and Drug Administration reform bill, with 2 minutes of debate, equally divided in the usual form, on the Durbin amendment No. 1141.

At that point, there will be a series of stacked rollcall votes on Senator DURBIN's amendments Nos. 1339 and 1341. Members can anticipate additional rollcall votes on Tuesday in connection with the Food and Drug Administration legislation.

Following adoption of the committee substitute to that bill, the Senate will proceed to an immediate cloture vote on the Food and Drug Administration bill.

ADJOURNMENT UNTIL TUESDAY, SEPTEMBER 23, 1997, AT 9:30 A.M.

The PRESIDING OFFICER. Under the previous order, the Senate stands in adjournment.

Thereupon, at 2:37 p.m., the Senate adjourned until Tuesday, September 23, 1997, at 9:30 a.m.

NOMINATIONS

Executive nominations received by the Senate September 19, 1997:

DEPARTMENT OF THE INTERIOR

M. JOHN BERRY, OF MARYLAND, TO BE AN ASSISTANT SECRETARY OF THE INTERIOR, VICE BONNIE R. COHEN.

DEPARTMENT OF STATE

TERRENCE J. BROWN, OF VIRGINIA, A CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF CAREER MINISTER, TO BE AN ASSISTANT ADMINISTRATOR OF THE AGENCY FOR INTERNATIONAL DEVELOPMENT, VICE LARRY E. BYRNE, RESIGNED.

IN THE NAVY

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT IN THE U.S. NAVY TO THE GRADE INDICATED UNDER TITLE 10, UNITED STATES CODE, SECTION 624:

To be rear admiral (lower half)

CAPT. MARION J. BALSAM, 0000.
CAPT. BARRY C. BLACK, 0000.
CAPT. RICHARD T. GINMAN, 0000.
CAPT. MICHAEL R. JOHNSON, 0000.
CAPT. CHARLES R. KUBIC, 0000.
CAPT. RODRIGO C. MELENDEZ, 0000.
CAPT. DANIEL H. STONE, 0000.

THE JUDICIARY

MARY ANN COHEN, OF CALIFORNIA, TO BE A JUDGE OF THE U.S. TAX COURT FOR A TERM OF 15 YEARS AFTER SHE TAKES OFFICE. (REAPPOINTMENT)

DEPARTMENT OF JUSTICE

SETH WAXMAN, OF THE DISTRICT OF COLUMBIA, TO BE SOLICITOR GENERAL OF THE UNITED STATES, VICE DREW S. DAYS III, RESIGNED.

CONFIRMATIONS

Executive nominations confirmed by the Senate September 19, 1997:

SOCIAL SECURITY ADMINISTRATION

KENNETH S. APFEL, OF MARYLAND, TO BE COMMISSIONER OF SOCIAL SECURITY FOR THE TERM EXPIRING JANUARY 19, 2001.

DEPARTMENT OF THE TREASURY

GARY GENSLER, OF MARYLAND, TO BE AN ASSISTANT SECRETARY OF THE TREASURY.

NANCY KILLEFER, OF FLORIDA, TO BE CHIEF FINANCIAL OFFICER, DEPARTMENT OF THE TREASURY.

THE ABOVE NOMINATIONS WERE APPROVED SUBJECT TO THE NOMINEES' COMMITMENT TO RESPOND TO REQUESTS TO APPEAR AND TESTIFY BEFORE ANY DULY CONSTITUTED COMMITTEE OF THE SENATE.