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Senate

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 Father, thank You for the stirrings in our minds and the longings in our hearts that are sure evidence that You are calling us into prayer. Long before we call, You answer by creating the desire to renew our relationship with You. You allow that feeling of emptiness in the pit of our being to alert us to our hunger for fellowship with You.

Our thirst for Your truth, our quest for Your solutions to our needs, and our yearning for Your answers to our problems are all assurances that before we articulated our prayers, You were preparing the answers. It is a magnificent, liberating thought that all through this day when we cry out for Your help, You have already been waiting for us to give up our persistent self-reliance and start drawing on the supernatural strength and superabundant wisdom You are so eager to give us.

Thank You for a day filled with serendipities of Your intervention. In the name of our Lord and Saviour. Amen.

RECOGNITION OF THE ACTING MAJORITY LEADER

The PRESIDENT pro tempore. The able acting majority leader is recognized.

SCHEDULE

Mr. JEFFORDS. Mr. President, this morning the Senate is immediately resuming consideration of S. 830, the FDA reform legislation. In a moment we will begin two consecutive rollcall votes on or in relation to the pending amendments offered by Senator DURBIN. Following those votes, additional

amendments are expected and therefore rollcall votes will occur throughout the day.

Under the consent agreement there are 5 hours remaining for debate prior to a vote on the pending substitute amendment. I hope that once the debate time has expired, the Senate will be able to proceed to a vote and then passage of this important legislation.

The majority leader has also stated that this week the Senate will consider the D.C. appropriations bill and any appropriations conference reports that become available.

I yield the floor.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The PRESIDING OFFICER (Mr. HUTCHINSON). Under the previous order, the Senate will now resume consideration of S. 830, which the clerk will report.

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 consideration of the bill.

Pending:

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.

Durbin amendment No. 1140 (to amendment No. 1130), to require that entities and individuals accredited to conduct review of device notifications be subject to the conflict of interest standards that apply to employees of the Food and Drug Administration.

Durbin amendment No. 1139 (to amendment No. 1130), to eliminate provisions relat-

ing to the discretion of the Secretary of Health and Human Services to track devices or to conduct postmarket surveillance of devices.

AMENDMENT NO. 1140

The PRESIDING OFFICER. The Senate will now resume consideration of the Durbin amendment No. 1140 with 2 minutes of debate prior to the vote.

The Senator from Illinois.

Mr. DURBIN. Mr. President, thank you for recognition this morning and the resumption of our consideration of this important bill.

Amendment No. 1140, which I have offered, is an amendment that I think is absolutely essential if this bill is to be airtight. We are giving to outside laboratories the authority to review and approve medical devices, medical devices which literally could mean life or death for millions of Americans.

When these approvals are given, these companies stand to make substantial profits because of FDA approval. The Durbin amendment corrects a serious error in this bill by making certain that there will be no conflict of interest by the third-party reviewers. We say in specific terms that those reviewing the medical devices cannot receive gifts from the company that is the owner of the medical device, they cannot receive or own stock of the company that they are reviewing, they cannot have been offered a job or solicited a job from the company that they are reviewing, and there must be a full financial disclosure.

If we are going to maintain the integrity of the process, protect American consumers, and avoid this sort of conflict of interest, I urge my colleagues to adopt the Durbin amendment.

Mr. JEFFORDS. Mr. President, the Senator's amendment at best duplicates the third-party conflict-of-interest protections in the bill and at worst unnecessarily constrains the agency. The ranking minority member, Senator KENNEDY, and the FDA join me in opposing this amendment.

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



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Section 204 of the bill provides a full statutory directive to the agency adopt measures within 180 days of enactment 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 provides full discretion to the agency to develop appropriate standards. The agency will not be limited in any way in developing these guidelines. In fact, the agency has already developed extensive conflict-of-interest guidelines as part of its existing third-party program, including protections from situations such as if the third party or any of its personnel involved in 510(k) reviews has any ownership or other financial interest in any medical device, device manufacturer, or distributor.

The Senator's concerns have caused us to reexamine the important issue of preventing conflicts of interest. We commend him for doing so, but I urge a no vote.

Mr. FEINGOLD. Mr. President, I am pleased to join my friends and colleagues, Mr. DURBIN of Illinois and Mr. JOHNSON of South Dakota, in cosponsoring amendment No. 1140. This amendment will ensure that private, third-party reviewers of class I and II medical devices will be subject to the same conflict-of-interest restrictions that federally employed reviewers are.

Under current law, employees of the Food and Drug Administration who review drugs and medical devices are subject to strict regulations governing their interaction with the companies whose products they are reviewing. They are not allowed to accept gifts from such companies. In addition, they cannot designate other persons to accept gifts on their behalf. Another important restriction prohibits reviewers from having a financial interest in any company whose products they are reviewing.

Mr. President, these are common-sense measures which help to maintain the public's confidence in the safety of our Nation's drugs and devices. The pharmaceutical and medical device industries command billions of dollars every year. We live in a world in which FDA approval can mean immediate and enormous profits for investors. In such an environment, it is absolutely critical that the Government be vigilant in its responsibility to ensure that applications are reviewed thoroughly and in an unbiased manner.

We all know people—family members and friends—whose health, and even lives, rely on important medication and devices. There are few jobs more significant than assuring the safety and efficacy of these items. In my mind, Mr. President, this is a role—protecting health and safety—that is best served by Government, rather than by the private sector. However, the bill before us takes a different view, and establishes a large-scale pilot

project to allow private sector review of medical devices. If we are to take this step, it is absolutely critical that we subject those private sector reviewers to the same conflict-of-interest restrictions that Government reviewers are subject to.

The amendment sponsored by the Senator from Illinois would do just that. It would say to private sector reviewers, "You cannot own stock in any company whose product you review. You cannot accept any gifts from a company whose product you review, and you cannot designate any other person to receive such a gift." That's it. Pretty simple and straightforward. But very important.

As one of the lead sponsors of the Senate gift ban several years ago, I feel strongly that the public has a right to know that elected officials are working in the best interests of their constituency, and cannot be bought or sold over lunch provided by high-paid lobbyists. Just as politicians should not be trading on their influence, neither should private sector medical device reviewers be swayed in their decision process by gifts from industry representatives or the promise of huge profits derived from a recommendation for FDA approval.

I hope my colleagues will do the right thing, and limit the potential for corruption in this bill by voting for this important amendment.

The PRESIDING OFFICER. The yeas and nays have not been ordered.

Mr. JEFFORDS. I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. The question is on agreeing to the Durbin amendment No. 1140.

The yeas and nays have been ordered.

The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. NICKLES. I announce that the Senator from North Carolina [Mr. HELMS] is necessarily absent.

The PRESIDING OFFICER (Mr. ROBERTS). Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 40, nays 59, as follows:

[Rollcall Vote No. 252 Leg.]

YEAS—40

Akaka	Feingold	Lieberman
Baucus	Feinstein	Moseley-Braun
Biden	Ford	Moynihan
Bingaman	Glenn	Murray
Boxer	Graham	Reed
Breaux	Harkin	Reid
Bryan	Hollings	Robb
Bumpers	Inouye	Rockefeller
Byrd	Johnson	Sarbanes
Cleland	Kerry	Torricelli
Conrad	Landrieu	Wellstone
Daschle	Lautenberg	Wyden
Dorgan	Leahy	
Durbin	Levin	

NAYS—59

Abraham	Bennett	Burns
Allard	Bond	Campbell
Ashcroft	Brownback	Chafee

Coats	Hagel	Murkowski
Cochran	Hatch	Nickles
Collins	Hutchinson	Roberts
Coverdell	Hutchison	Roth
Craig	Inhofe	Santorum
D'Amato	Jeffords	Sessions
DeWine	Kempthorne	Shelby
Dodd	Kennedy	Smith (NH)
Domenici	Kerrey	Smith (OR)
Enzi	Kohl	Snowe
Faircloth	Kyl	Specter
Frist	Lott	Stevens
Gorton	Lugar	Thomas
Gramm	Mack	Thompson
Grams	McCain	Thurmond
Grassley	McConnell	Warner
Gregg	Mikulski	

NOT VOTING—1

Helms

The amendment (No. 1140) was rejected.

AMENDMENT NO. 1139

The PRESIDING OFFICER. Under the previous order, we will resume consideration of amendment 1139 by the Senator from Illinois with 2 minutes of debate equally divided.

Mr. JEFFORDS. Mr. President, the Senate is not in order.

The PRESIDING OFFICER. The Senator from Vermont is correct. The House is seldom in order and the Senate is not in order. The Senate will come to order.

We will not resume consideration of the amendment until the Senate comes to order.

Will the Senators to my left please cease audible conversation?

The Senator from Vermont.

Mr. JEFFORDS. Mr. President, I would defer to the Senator from Illinois, and I reserve my time.

The PRESIDING OFFICER. The Senator from Illinois is recognized for 1 minute in behalf of his amendment.

Mr. DURBIN. Mr. President, if you buy a car in America the manufacturer keeps a record of your name and address, or if there is a defect they can recall the car. This bill removes the requirement for medical device manufacturers to keep a record of those people who receive pacemakers and heart valves. Why is that important? Because, if there is a defect in that life-saving medical device, they can't find the patients. What results?

Just a few years ago 300 Americans died. They had the Bjork-Shiley heart valve that was defective and they couldn't be found. Does it make sense for us to remove this responsibility of medical device manufacturers?

Take a look on your desk at a letter from 27 different organizations representing patients across America who say it is only sensible to make certain that we track and keep track of those who are receiving these medical devices.

I urge my colleagues to vote for this amendment. It is not too great a burden on a medical device manufacturer to keep a record of those receiving pacemakers and heart valves.

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

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont is recognized to speak for 1 minute.

Mr. JEFFORDS. Mr. President, I disagree entirely with the statement made by the Senator from Illinois. The Senator's amendment strikes the agreement reached on these provisions among the bill's sponsors, the FDA, and Senator KENNEDY. The FDA should have the discretion to decide when it makes sense to require device tracking or surveillance for a product.

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

The FDA is overburdened. We want to free them up to do the things that need to be done.

The FDA has publicly stated that it is unnecessary for all devices in the mandatory category—postmark and surveillance category—to be subject to its postapproval evaluation.

I urge defeat of the amendment.

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

The question is on agreeing to the amendment of the Senator from Illinois. The yeas and nays have not been ordered.

Mr. JEFFORDS. I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. The question is on agreeing to the amendment of the Senator from Illinois. On this question, the yeas and nays have been ordered and the clerk will call the roll.

The bill clerk called the roll.

The result was announced—yeas 39, nays 61, as follows:

[Rollcall Vote No. 253 Leg.]

YEAS—39

Akaka	Feinstein	Levin
Baucus	Ford	Mikulski
Bingaman	Glenn	Moseley-Braun
Boxer	Graham	Murray
Breaux	Harkin	Reed
Bryan	Hollings	Reid
Byrd	Hutchison	Robb
Cleland	Inouye	Rockefeller
Conrad	Johnson	Sarbanes
Daschle	Kerrey	Shelby
Dorgan	Kerry	Specter
Durbin	Kohl	Torricelli
Feingold	Leahy	Wellstone

NAYS—61

Abraham	Brownback	Cochran
Allard	Bumpers	Collins
Ashcroft	Burns	Coverdell
Bennett	Campbell	Craig
Biden	Chafee	D'Amato
Bond	Coats	DeWine

Dodd	Jeffords	Roberts
Domenici	Kempthorne	Roth
Enzi	Kennedy	Santorum
Faircloth	Kyl	Sessions
Frist	Landrieu	Smith (NH)
Gorton	Lautenberg	Smith (OR)
Gramm	Lieberman	Snowe
Grassley	Lott	Stevens
Gregg	Lugar	Thomas
Hagel	Mack	Thompson
Hatch	McCain	Thurmond
Helms	McConnell	Warner
Hutchinson	Moynihan	Wyden
Inhofe	Murkowski	
	Nickles	

The amendment (No. 1139) was rejected.

The PRESIDING OFFICER. Under the previous order, the Senator from Rhode Island is recognized to offer an amendment.

AMENDMENT NO. 1177

(Purpose: To ensure that determinations of the Secretary with respect to the intended uses of a device are based on the proposed labeling only if such labeling is not false or misleading)

Mr. REED. Mr. President, I have an amendment at the desk, amendment No. 1177. I would like to call up my amendment at this time.

The PRESIDING OFFICER. The clerk will report.

The bill clerk read as follows:

The Senator from Rhode Island [Mr. REED] proposes an amendment numbered 1177.

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

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

The amendment is as follows:

On page 30, line 16, insert before the first period the following: "if the proposed labeling is neither false nor misleading".

The PRESIDING OFFICER. The Senator is recognized.

Mr. REED. I ask unanimous consent Senators KENNEDY and BINGAMAN be added as cosponsors of this amendment.

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

Mr. REED. Mr. President, today we are debating very important legislation, important for the country in the reformation and reauthorization programs at the Food and Drug Administration. Particularly important in this legislation is the prescription drug user fee program, which has proven to be a remarkable achievement that has speeded the approval of drugs, getting these necessary medicines to the American public.

S. 830 includes a number of provisions that will include and streamline the regulation of prescription drugs, biological products and medical devices, and we have made great progress over the last several weeks and months in reaching this position today. This bill is a result of ongoing renegotiations, both prior to and subsequent to the markup of the legislation. Through this process, a number of provisions that could have threatened the public health and safety have been dropped or otherwise reformed in such a way that we have made, as I said, remarkable and very effective progress.

However, this legislation still contains provisions which could jeopardize the public health. I rise today to address one of these areas and that is the elimination of an important consumer protection against unsafe or ineffective medical devices. The bill, as it is proposed today, as we deal with it today, would limit the FDA's authority to ask device manufacturers for safety data. It prohibits the FDA from considering how a new device could be used, if the manufacturer has not included that use in the proposed labeling.

As a general matter, the FDA does not typically consider uses that the manufacturer has not included in its proposed labeling. However, there are instances where the label does not tell the whole story. In these instances, when the label may be false or misleading—it is in these instances that my amendment would give the FDA the authority to look behind the label. In fact, this is such a critical issue that the administration has made it clear that this provision could put the whole bill at risk, including, I might add, the reauthorization of the PDUFA, the prescription drug user fee amendment, because they have threatened, if this provision does survive, to veto the legislation. And that would, I think, derail a great deal of very positive work that we have done today.

A great deal of discussion has taken place on the medical device provisions of this bill. I certainly want to compliment Senator JEFFORDS and Senator KENNEDY and all my other colleagues on the committee for resolving most of these issues and doing so in a very reasonable, very thoughtful, and very responsible manner. However, the provision regarding device labeling still raises substantial concerns, as I have alluded to, and it could be corrected very simply by my amendment without, I believe, undermining the attempt of this bill which is to provide for a streamlined, effective process so that new medical devices, new pharmaceuticals can reach the market and be used by the American public for their health and well-being.

Let me preface discussion of my amendment by briefly describing the process of how the FDA regulates and clears medical devices for market. Under current law, manufacturers of new class I and class II devices can get their products onto the market quickly by showing that they are substantially equivalent to devices already on the market. For example, the manufacturer of a new laser can get that laser onto the market if it can show the FDA that the laser is, again, "substantially equivalent" to a laser that is already on the market. Similarly, the manufacturer of a new biopsy needle can get the biopsy needle onto the market by showing it is substantially equivalent to a biopsy needle already on the market. And the manufacturer of new patient examination gloves can get the same expedited market clearance by claiming substantial equivalency.

Under current law, manufacturers are required to demonstrate this substantial equivalency to the FDA by showing that the new product has the same intended use as the already-marketed product; and that the new product has the same technological characteristics of that already-existing product in the marketplace. If the new product has certain different technological characteristics, these characteristics must not raise new types of safety and effectiveness questions in order for the product to still be substantially equivalent to the older product. The logic of this process for moving medical devices onto the market is quite simple. If a product is very much like an existing product, it can go to market quicker. But if it raises new safety or effectiveness questions, those questions should be thoroughly answered before the product is made available to the public.

The process for getting new medical devices on the market is commonly known as the section 510(k) process or the 510(k) process. It's considered to be the easiest route for FDA approval. In fact, 95 percent of all medical devices that come onto the market come through this 510(k) process. In a sense, because of this, because of this ease, this is the process that is most used by manufacturers. There is, in many cases, an incentive to bring your new product through this 510(k) procedure. It has the lowest thresholds for approval, if you will, and this incentive requires, essentially, the manufacturers at times to look about in the marketplace and say this is going to do just what this item does currently, even though the new technology or the new innovation or new design might be adaptable to other purposes. But there is, I believe, a regulatory incentive to try to speed things through the FDA by saying: No, no, this is substantially equivalent, that's all we are going to do, this is it. As a result, I think the FDA has to seriously look at, not just the labeled use, but in certain circumstances—not common circumstances but in certain circumstances—look behind the label.

The bill as it is currently proposed would compromise the FDA's existing ability to do that and this change could raise substantial risks to the public health. My amendment addresses this bill that would prohibit the FDA from considering how a device would be used if the manufacturer has not included the use in its proposed label. My amendment would add 9 simple words to the bill. Let me first show you the existing language that is under discussion, and that is:

The determination of the Secretary under this subsection and section 513(F)(1) with respect to the intended use of a device shall be based on the intended use included in the proposed labeling of the device submitted in a report under section 510(k).

Essentially, what this says is if a manufacturer says, "This is what we are going to do," on a label, this is all

we can consider in our application process, even if the FDA considers the possibility of other uses or even, some would argue—even if the FDA felt that the label was misleading or, indeed, false.

My language would be added at the very end, and it would simply say, "if the proposed labeling is neither false nor misleading." In a sense, it would give the FDA the opportunity to look at a proposed use on a proposed label and say, "This is consistent with the device, consistent with use, let's get this onto the market through the 510(k) process expeditiously." But if they thought there was another possible use, another likely use, or that the intended use was really perhaps a subterfuge for other uses, they could challenge the application at that juncture.

I believe this is something that the FDA should have the authority to do. In fact, I would assume the American public believes that the FDA has this authority, that they can look very closely, very carefully; that they don't have to take as the final authority the characterization of the device by the manufacturer. And they can, by simply examining the device, using their experience, conclude that there might be other uses which should be evaluated before this device gets on the market.

As I indicated, my amendment would allow them to effectively look behind the label, look behind the characterization that was proposed by the company.

It is also important to note that this is not a particularly novel or startling approach to legislation. Because if you turn to the other major approval process, that is for a class II product, a new product that has to do extensive pre-market review, in this case they do have the explicit authority, under present law, to look beyond the label. Because even if the manufacturer indicates one use on the label, they do not have to accept that use if they determine that it is false or misleading. So this is not a novel concept. In fact, I think it represents what should be the normal practice for the FDA, to be able to look behind the label.

My amendment would give the Food and Drug Administration this authority. It would give them the authority, and does so for new information, additional information, additional data. This is not an attempt to frustrate progress, to slow up the process, to impede the rapid deployment of new technologies into the marketplace. This is, I hope, an attempt to protect the public health and safety, protect the consumers of these devices; and, hopefully, to delineate the authority of the FDA which typically they would use only in rare circumstances so we don't have a battle at the FDA about whether this device is technologically different. So I hope, by using this approach, this language, we could conform the 510(k) process in this respect to the existing process and we could move forward

with good, sound public policy regarding the Food and Drug Administration and medical devices.

Let me give just a few examples, because this is not just a legal, academic issue. This is a very real issue. There has been one example that has been discussed on the floor by my colleagues and that is the use of biopsy needles. Biopsy needles are approved for one use, principally. That is, as the name implies, to take a biopsy to remove tissue from a breast lesion, for example. Typically, these needles will remove a very small bit of tissue, about the size of the tip of a pencil. But a manufacturer could present a device that could remove 50 times that—not a typical pencil, but the width of a hot dog. And that would obviously raise questions about how this new device is going to be used.

But under the language in the legislation, there is a very strong argument that the FDA could not look to possible other uses because the manufacturer said simply, "We're going to use this for the traditional biopsy of tissue, a small biopsy of tissue. That's all. We're not going to use it or suggest it be used for the removal of tumors, the removal of tissue, just the biopsy." Then they would be essentially prevented from looking at this other use which may in fact be the actual use of the device in the marketplace.

So we have to be very careful about that. The FDA should be able in this case to say, "Well, this could be used for something beyond a simple biopsy. If that's the case, show us some data about its success rate, show us some data about the effects if it's used in this way and not the precise label use."

This is something that I believe we should have. There are proponents of the existing language which say that the FDA can get at that simply by saying this is a new technology, it is not equivalent to the old one. But the manufacturer could argue that there are no questions of safety or effectiveness even if it was a new technology. Essentially this new language designed to streamline the process could lead us right back to the contentious issues about whether or not this new technology endangers health and safety. It could lead us back, I think, in a way in which the FDA has the weaker hand in the argument.

I believe that the American public would like to see the FDA with the authority and the ability to ensure that these devices are thoroughly reviewed before they get to the marketplace.

As we go forth, there are other examples. In fact, my colleague from Massachusetts, I think, will talk specifically about one example of a biopsy needle which went on the market. Before this device went on the market, it was tested only on two cows and, I am told, 13 roast beef. Now we hear that the device marketed as a biopsy needle has in practice been used for other surgical procedures. Now, this is an example of

how something, even if it was not deliberately designed by the manufacturer, can be changed in its use in practice. And, again, I think the FDA should be able to anticipate those rare circumstances where it might happen and take effective action to protect the public health.

There are other examples. Another good example is a surgical laser. Lasers have been used for decades for the removal of tissue. Several years ago a manufacturer added a side-firing mechanism to their laser to improve its use for prostate cancer. While the manufacturer did put that specific use in the proposed label, it was very, very clear that this new side-firing design was intended solely for this purpose of treating prostate patients. As a result the FDA, using its current authority, its ability to look beyond the actual labeling use, was able to require the manufacturer to submit data demonstrating the laser's safety and effectiveness in treating prostate patients.

This is precisely how the approval process should work. In rare circumstances, when the device obviously looks different than the label use, the FDA should be able to say, this could be used in ways that you are not labeling. We have to look at all the likely, obvious ways beyond the label. Let us do that. Let us get beyond the label. Under the present language, without the Reed-Kennedy-Bingaman amendment, the FDA would have a difficult time looking behind the label, looking at actual uses and requiring the data and the analysis which should be done beforehand, before the goods get on the market.

I do not think you have to do this simply because there are people out there who would have a malignant motive. This is a situation where, if we create through our legal structures opportunities to get products quicker to the marketplace, then companies, with their expert legal counsel, will exploit those ways. It is our responsibility to ensure that we have a process that protects the public health.

Whatever process we develop here today will be used by the companies in a way which, if we were executives of companies, we would use in the same way. But we have to take into consideration not the benefits or the position of the manufacturer, but the position, I think, of the general public that would use the devices.

So, I believe we have to have standards that are sufficient to give the Food and Drug Administration the authority they need to do the job. I believe that my amendment does this. I believe we have to have these procedures in place before a device gets into the marketplace. There are those who would argue that the FDA has the power to recall an item, has the power to intervene, but then of course it is too late because obviously the public has already suffered in some way.

Indeed, it is not as easy as it may appear for the FDA to step into the marketplace and get goods off or an item off the market that has already been

approved. So I think the idea that this can be corrected after the fact is not sufficient weight to preclude us from taking effective steps before a device gets in the marketplace.

What I would like to do in my amendment is simply give the FDA the authority to look at a proposed use, a labeled use, make a determination that this device and this label is consistent and get it through the 510(k) process quicker. But in those rare circumstances where the device itself and the label do not appear to be consistent, coherent, where there is the possibility of a false label or a misleading label, or the possibility that the company may indeed in most cases in very good faith be insisting this is how they want to market it, this is how they propose it be used, but the medical profession itself would adapt this very quickly for other uses, in those circumstances I believe the FDA should have the authority.

I hope that my colleagues will recognize this, will support this amendment, support giving what the FDA has today: the authority to look behind the label and to require that companies provide data for the likely uses of the product they intend to market.

Before concluding, I ask, Mr. President, unanimous consent that Senator DURBIN be added as a cosponsor to this amendment.

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

Mr. REED. I thank the Chair.

The PRESIDING OFFICER. Who seeks time?

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. My colleague from Rhode Island is a welcome addition to the Labor Committee. He has been active and has made some good suggestions for improving this legislation, but this is not one of them.

This amendment sounds like simple good Government but in fact would gut the provision and 20 years of effective medical device regulation.

Mr. President, I yield 15 minutes to the Senator from Connecticut.

The PRESIDING OFFICER. The Senator from Connecticut is recognized.

Mr. DODD. Thank you, Mr. President.

Let me begin by commending the chairman of the committee, Mr. President, for the work he has done on this bill and for others who have been involved in it.

We are arriving at the point here where we have a 211-page bill put together in the past 2½ years, where we are, hopefully, down to its last provision, which has been the subject of some discussion over the last number of days.

I want to just at the outset commend those who have been involved in it, explaining what the purpose of the intent here is. We have passed this bill out of our committee 14 to 4. There was some disagreement over a number of provisions, but I believe we produced a very fine product which is going to assist tremendously in making this even

more secure in the quality of products we are getting but also the efficiency with which those products become available to patients and people in this country. I thank my colleague from Rhode Island for the explanation.

This has become an arcane subject matter when we talk about paragraphs and titles and how the FDA process works. That is the reason the committee has spent so much time going back over this material, to try to sort out exactly what would work best and how it would apply.

Contrary to how it has been portrayed thus far, the provision in the bill which is the subject of this amendment—what it does, Mr. President, is it shrinks back to current law an authority that the FDA has been stretching, in our view, past the bounds of fair practices.

So the effort here is to try to get back exactly to what the intent has been. All we, the authors of the bill, are asking is that the FDA not force manufacturers to supply information on other than the imputed uses for which the manufacturer is not seeking approval and could not market the product even if they wanted to.

You can see how the FDA in the current practice of second-guessing manufacturers can certainly create uncertainty not only in terms of the manufacturer but also in terms of consumers. A manufacturer, Mr. President, can spend years designing a product for a specific purpose only to be told by the FDA that it should go back to the drawing board and test the product for uses other than those for which the product was created in the first place. That creates tremendous uncertainty.

Let me, if I can, Mr. President, try to describe this process and what we are talking about. That is where it gets a bit arcane. The Senator from Rhode Island, I think properly, characterized some of the differentiations here, but I think he gets lost on some people. What we are talking about here are not high-risk devices but lower risk devices.

Ninety-five percent of the products that come out of the FDA for approval in this area are lower risk devices. What is a lower risk device and what is the process that exists today that allows for the approval of these products to be marketed?

Well, the lower risk device goes through, as the Senator from Rhode Island has described, a 510(k) process. That is the applicable provisions at the FDA. Under that provision, if a manufacturer wants to bring out a lower risk medical device, they must prove that the new device is "substantially equivalent"—I am quoting here—"to a device already on the market," the so-called predicate device. That is why it is called a lower risk device. There already then has been the approval of a

product that is substantially equivalent to a product that the manufacturer wants to bring out.

So the decision was made, instead of having a manufacturer go through a de novo process, which can take years, as it should, that we are going to expedite that process as long as there is a predicate out there—there is a predicate out there—there has already been a product that is “substantially equivalent,” to quote the FDA. If that exists, then you can go, for the lower risk device, to the 510(k) process.

There are two tests—two tests—that you must meet if you are going to get FDA approval under that provision—the lower risk device, not the higher risk device. No one is debating that. We are talking about the lower risk device. The two tests are the following.

The first is that the device has the same intended use as the predicate device. That is a subjective test. Does it have the same intended use? Does the label say that? Does the marketing, does the information the company is putting out have the same intended use? That is a subjective test. And if a manufacturer puts on the label some other use, then they would fail that test—the intended use.

To say that a manufacturer must also now have some imputed use that you could not imagine, that you did not design, that you did not think about, that some doctor may decide they want to use it for, is not what that paragraph is all about. That is the first test.

But the second test is far more important. This bill does nothing to the second test at all. The second test is that the new device's technological differences do not raise new questions of safety and efficacy. That is an objective test, Mr. President. That is an objective test. Nothing in this bill changes anything in that second test.

What we are trying to do is to get back to that first test and say it is the intended use of that predicate device, the intended use of the predicate device. If the manufacturer does not meet both of these tests, then the FDA does not have to clear the device.

This provision does not change that in any way whatsoever. You have to meet both tests. All that we are asking in this bill, among other things that we have tried to reform here, is that we be able to draw some lines around the first and very subjective test of the intended use while retaining FDA's full discretion on the much more objective tests of the technological differences. Now, in our view, with all due respect, the FDA has been stretching its authority by trying to impute uses that the manufacturer has no intention of doing.

We have been given some examples over the past week of how the act would only test the intended use on the label. In fact, as I said, there are two tests under 510(k). In each of the examples that have been given, the FDA had the ability to stop the devices from

going on the market because they failed the second test. No reference has been made to that. They failed the second test, not the intended purpose, but the technological differences.

All the examples that have been given, of course, are tragic ones, deaths and injuries resulting from the Dalkon shield, a woman who contracted toxic-shock syndrome from superabsorbent tampons, disfigurement caused by artificial jaw joints, and faulty plastic eye-lashes that led to blindness.

These are all tragic examples without question. But in every single case it was not because they failed the first test, the intended use; it was because they failed the second test. They were technologically flawed. It was not somehow that the manufacturer produced a product that was used for some different purpose than the intended use on the label, but that the product was faulty, technologically it was faulty.

So we cite these examples and then say the reason that people lost their lives or were disfigured was because the manufacturer used it for some purpose or someone used it for a purpose other than was labeled. That is not the case. It just is not the case. So I urge my colleagues when looking at this, as technical and as arcane as it may be—and most Members do not follow FDA regulations, do not get involved in the details of it—but with lower risk devices there are two tests, all within this bill. This amendment we are dealing with is the first test, the intended use.

In every example cited, the horror stories cited, the tragic losses cited, in every single case it was the failure of the second test, which is not the subject of the amendment offered by the Senator from Rhode Island.

I urge my colleagues to pay attention to those of us who worked on this and understand what we are talking about. We are trying to see if we cannot narrow down the problem on the intended use sections.

Mr. President, let me talk here a bit about what our purposes are here. If we allow the FDA to have free rein in the sense of having to guess at what a lower risk product could conceivably be used for once it is in the hands of physicians, then there is no end, in my view, to the studies that could be required of manufacturers to produce.

Some suggest perhaps we need a threshold to that guessing; maybe the FDA is “kind of” sure that the doctors would not use the device for another purpose. That would be the right threshold. Maybe “really” being sure would be sufficient in some cases. Can you see how unworkable a concept like this would be? Anytime the FDA is told they can look into their crystal ball and guess how a doctor might use a product, the result is going to be uncertainty.

Mr. President, let me step back a second. There is not a single Member of this body that in any way wants to be associated with or part of an effort

that is going to endanger anyone's life at all. In fact, quite the contrary. We want to do everything we can to see to it that people are getting safe products, efficient products, effective products that will serve their interests and protect their lives. That is our purpose and intent. We also want to see patients able to get products and have them reach the market. Certainly there are going to be those who will be fraudulent, bad actors. No one is suggesting they do not exist. Nothing we will do here will stop that, I suppose.

But to suggest somehow that because we are trying to in some way tighten up the intended use or purpose on the lower risk devices, that those who support this idea are guilty of somehow jeopardizing people all across this country, I think is an unfair characterization. It is quite the contrary.

In fact, a major company in my State of Connecticut, U.S. Surgical, with 9,000 employees, has come up with some of the most creative, imaginative, and effective devices to reduce the risks of injury and to preserve lives. It is a very reputable company. The company has brought to the American people revolutionary technology.

They were leaders in creating minimally invasive surgery using laparoscopes. Patients used to be laid up for months, or weeks anyway, after a gall bladder operation. As a result of laparoscopic surgery, now a person can be back at work within days because of the technology developed by U.S. Surgical.

The breast biopsy, which has been discussed here, was developed 2 years ago by U.S. Surgical and has been received by surgeons with overwhelming support in this country. Women have benefited from its use in over 7,000 cases worldwide. It is a safe and reputable company. I think it has been unfairly labeled as otherwise. In fact, regarding the biopsy, in trying to approve technology that would improve the technology, they should have received plaudits for that. The FDA approved it. There were questions raised about whether or not this was actually being used as a surgery to remove tumors. Never did the manufacturer ever suggest that was the case. Having listened to some of the debate, that was the implication.

Mr. President, I think it is unfortunate that that becomes the manner in which we debate a question here about one provision we are trying to narrow a bit in lower risk products.

Mr. President, there are a few examples of instances where the FDA has attempted to second-guess the manufacturers of a device about the device's intended use. One was an endoscope, an example where a manufacturer was asked to submit data on how the materials of a device would hold up after multiple uses. The company, in fact, insisted the label clearly state the product should only be used once and then discarded. That is what the label said. That is what the company and the

manufacturer intended—one usage of this endoscope. In the second case, a manufacturer designed a hearing aid to reduce background noise. The FDA decided that the real intended use was better hearing, and required the manufacturer to submit clinical data to prove that the device helped hearing overall. In a third case, Mr. President, a manufacturer developed a catheter that was coated with a substance that enhances the integrity of the device materials when the device is implanted in the body. The FDA decided the coating was really intended to reduce infection, and required clinical data to prove it.

Mr. President, in each of these cases the manufacturer was not seeking to promote or market the device for the imputed use at all and would have been prohibited from doing so, and the FDA's authority in no way is eroded. If the FDA believes that the company is off on some imputed use they have the authority to deal with that problem. We don't change that in this law at all.

I also point out, Mr. President, in each case a useful device was delayed from reaching consumers in this country. That is what we are talking about here.

I talked earlier about the biopsy, the testing device developed by U.S. Surgical. U.S. Surgical received approval from the FDA for a breast biopsy needle to be used for diagnostic purposes only, diagnostic purposes only. After the product was approved and on the market, the FDA asked for more information about the efficacy and the safety of the device for taking adequate biopsy samples—an appropriate request. U.S. Surgical supplied the information, and the second approval for the product was given by the FDA. At no time was the device marketed for another purpose. At no time was the device marketed for any other purpose than for diagnostic purposes.

I come back to the section, the 510(k), the lower risk medical devices. Two tests—the subjective test of intended use based on the label; and the second test on the technological questions, which is an objective test. Had the manufacturer said on its label or in its information or its marketing packages, “By the way, this will be a good diagnostic device and it may just work in terms of dealing with the tumor,” you have immediately violated the first test because your intended purpose is other than what you are seeking approval. But that is a subjective case. That is the way this works.

If you want to scrap 510(k) and put everything on the same footing, why don't we have an amendment that does that? I don't hear anyone suggesting that. We are trying to get these devices out where there is a predicate; that is, there has been a product already approved, which is substantially equivalent, substantially equivalent, to the device seeking approval. I urge my colleagues to remember that when you are considering how to vote on this. This is

not high risk. This is low risk. Two tests—subjective test, intended purpose; second test, is it technologically faulty, is it safe?

In the case of U.S. Surgical's diagnostic test for breast cancer, which has been overwhelmingly received, by the way—in fact, I think we will hear later from a colleague of ours who is a beneficiary of this—overwhelmingly accepted. Had they thought to do something else with that biopsy, then they would be in violation of this test. That was not the case and to suggest otherwise is just not true.

If it had been, the FDA would have had full authority to request data on the safety and efficacy of the device for the unapproved purpose. It would still have that authority under this provision. At no time did the FDA request any data for U.S. Surgical regarding the use of the breast biopsy device for tumor removal. So when this case is cited now, twice I heard it cited, I hope my colleagues would understand what the facts are. This is a fine company and the suggestion somehow they are producing devices out there for purposes other than what was intended, risking consumers in this country, is unfair to that company and unfair to the people who work there.

Mr. President, I urge our colleagues when considering this amendment—and again I respect entirely the motivations behind it; certainly all of us want to see the safest possible devices on the market, but we also want to see a process that will allow the products to get to that marketplace and serve the people they are designed to serve. If we are talking about something new, the tests are different, and they should be. If it is substantially equivalent to a device already out there, we have made the collective determination 20 years ago that the test ought to be different. When you go beyond that, in effect, if you are trying to take a lower risk device and apply it to a standard that exists to a higher risk device you are defeating the very purpose for which 510(k) exists.

With all due respect to my colleague from Rhode Island, I urge this amendment be defeated. In my view, the responses here are not arguing this provision on its merits. Instead, we are hearing language that I don't think reflects exactly what the situation is, what the facts are. While appealing on the surface, because some horrible cases have been cited as I pointed out, in every single instance in those cases it was not a debate about whether or not the manufacturer was producing a product for one purpose and used for another. In every single case those devices failed the second test of 510(k), not the first test of the intended purpose.

By definition, the process of determining substantial equivalence, a label is neither true nor false. It is the same as the predicate. If it is not the same as the predicate, then it does not pass the first test. In effect, trying to

squeeze false and misleading language into a place it doesn't fit means all devices would be undergoing the PMA process, a process that can take up to six times longer, six times longer. When there are patients out there and families out there that want to see this material get to them, we don't need to be complicating a process on low risk devices, delaying that event occurring, causing more pain and suffering. There are people who suffer as a result of a regulatory process that is so overburdened and so complicated that people cannot get these materials when they need them.

Mr. President, again, with all due respect, I urge my colleagues reject this amendment.

I yield the floor.

Mr. JEFFORDS. I yield to the Senator from Indiana 10 minutes.

The PRESIDING OFFICER (Mr. SANTORUM). The Senator is recognized for 10 minutes.

Mr. COATS. I thank the Senator for yielding.

I want to commend the Senator from Connecticut, Senator DODD, for his statement. Much of what I was going to say he has articulated probably better than I could articulate, in terms of the purpose of the 510(k) approval process, the nature of the tests that are involved in approving the devices that are substantially equivalent, and the technicalities that are involved in this that I know not a lot of Members have had the opportunity to focus on or really even the necessity of focusing on.

The point the Senator makes about the fact that the work of the committee over 2½ years has been careful and thoroughly undertaken in a way that is designed to provide the very best of protection for the consumer, the very best of safety and effectiveness so that the drugs and devices that are approved by FDA are devices and drugs that we can have confidence in.

No one on the committee is attempting to undermine the essential function and the essential purpose of the Food and Drug Administration. We want a dynamic, vibrant, effective agency in this country that tests the safety and effectiveness of devices and drugs before they are brought to the market.

Now, no process is ever going to be perfect. There will be mistakes. But we want to ensure that this agency has the very best of what it needs to accomplish that essential purpose. What we don't want, and what we are attempting to do with this reform bill is to have a situation continue where the approval process cannot even begin to meet the requirements that the agency thinks are appropriate and that we have dictated by law, by statute.

Numerous examples have been cited here on the floor, whether it is for drugs, or devices, or even other products that the FDA reviews, of unconscionable delays, of unnecessary delays, of letters being lost, of material that has been misplaced, of the inability of FDA to have the personnel, the

manpower, the computer power, the administrative procedures in place that provides for effective, efficient approval. It is all of this that has led to a number of suggested reforms of FDA. And one, which has been working very successfully is the PDUFA, Prescription Drug User Fee Act, where the drug companies themselves put money into a fund that allows the FDA to hire individuals and to purchase equipment and speed up the approval of life-saving and health-improving drugs to the market. That has worked. We want that to continue. We are up against a deadline on that. Funding for that runs out on September 30, the end of the fiscal year. We have been pressing hard now for several months—in fact, all year—to try to move this process forward so we don't run up against this deadline. Yet, we have encountered delay after delay after delay because of disputes about very small portions of a 200-plus page bill, carefully undertaken by the committee over a 2½ year period.

This is not a partisan issue, as Members who have been engaged in this understand. The Senator from Connecticut; the Senator from Minnesota, Senator WELLSTONE; the Senator from Iowa, Senator HARKIN; the Senator from Maryland, Senator MIKULSKI, have joined with the majority, Senator JEFFORDS and others on the committee, to produce a very, very substantial majority in support of the original bill, a 14 to 4 margin. Since then, some of the concerns of those four have been addressed in ways that the vote margin and support for the bill has even increased. There were 30-some concessions, which I held up a list of on the floor last week—more than 30 such negotiations and concessions with those who had continuing concerns about the bill.

So it is not a matter of saying: we won, 14 to 4, and this is the bill, take it or leave it. We are open to producing the very best bill that we can, and we think we have. We have been open to negotiation. But every time we have met an objection, something new pops up. It is ironic that in the committee the amendment we have been talking about here, the amendment that Senator KENNEDY has been debating at length, the reason for the filibuster that has gone on, is over language that wasn't even brought up in committee. If this was such an important, egregious omission on the part of the committee, how come an amendment wasn't offered in the committee to debate it or to discuss it or to change it?

The language that we are talking about here was proposed by Senator WELLSTONE—hardly someone who is viewed as being anticonsumer or someone viewed as trying to open a loophole so that the health and safety of Americans is jeopardized. In the negotiations and discussions, postcommittee markup, this wasn't on the list. I have in my hand the memo from the Labor Committee, from David Nexon, suggesting

items that need to be covered and need to be discussed. This isn't even on the list. We went over these amendments. All of a sudden, when at one point, the only thing left, to our knowledge, was a resolution of the cosmetic portion of the bill, which was resolved, all of a sudden this then pops up. So you have to question what is going on here.

We have a bipartisan coalition, people from liberal, conservative, and in-between perspectives, politically—Democrats, Republicans, people who worked on the committee, delved into the issues and worked to ensure that we have the very best bill possible. Yet, we meet delay after delay after delay and obstruction after obstruction after obstruction. So I think it is important not just to look at the specifics of the amendment, but to ask the question: What else is going on? What is the true intent here? Is it to undo FDA reform? Is it to block any reform? Here we are up against this deadline for PDUFA, and I think it is important that Members keep all that in mind.

I was going to go through the technicalities of the 510(k) process, but Senator DODD did a marvelous job explaining it. As he said, it's the lower risk devices. We are attempting to find a way in which we can efficiently expedite the approval of devices that are designed for the same purpose, which, in the FDA language, are substantially equivalent, and give those devices the opportunity to come to market without having to go through the same lengthy, costly approval process that the original device—the device called the predicate device—is subject to. Sometimes that takes months; often it takes years for that original device to accomplish a specific purpose to be approved. Once that is approved, there are others that can market and make devices that are roughly equivalent—not roughly, substantially equivalent to that. If the FDA determines that it is substantially equivalent under their review procedures, then that device can be approved.

As Senator DODD has said, however, that is only one part of the test. The other part of the test is that if there is a technological difference that raises safety and effectiveness concerns, FDA can say, "not substantially equivalent." You have to go through the process. FDA retains that authority. Nothing in this bill changes that authority. Nothing in this bill alters one iota of that authority. Every example raised by the Senator from Massachusetts ignored totally and failed to acknowledge that the second part of the test gives FDA the authority that they said FDA doesn't have.

So that's what is at issue here. It is an issue that doesn't have to be here. It is an issue that we don't need to be talking about. No one raised it in committee. No one raised it in negotiations postcommittee. No one indicated that this was a bill stopper. The last indication of a bill stopper was the cosmetic concern, which was negotiated and an

acceptable compromise was reached. Then, all of a sudden, this provision, 404(b), the language offered by the Senator from Minnesota, Senator WELLSTONE, and accepted by the committee as part of the bill, without objection, all of a sudden this now becomes the bill stopper, the killer language, the language that is going to destroy the FDA and place 260 million Americans in jeopardy of their life and their health.

I think Senator DODD very effectively outlined why the examples used were not relevant examples. They are tragic examples. We all regret that they happened. But they have nothing to do with the language that we are talking about. They have nothing to do with the amendment offered by the Senator from Rhode Island. And so let's keep that in mind as we move forward here in this torturous process of getting a bill passed through the Senate that has been substantially delayed because of procedural practices, which enjoy no support from this body. We have had two votes. I think the opponents of the legislation got five votes on the first try and four votes on the second try. The other 95 of us, or 96, depending on how you count it, are still here attempting to move forward.

Now, we have the good fortune of having Dr. FRIST—Dr. Senator FRIST—on our committee. For those of us who don't have the medical training and expertise to fully understand all of this, we frequently—in fact, every opportunity we have on medical questions—turn to Dr. FRIST for the expert's view. I think it is a phenomenal addition to the Senate that we have this capability available to us. He will be commenting on this and, frankly, I put a great deal of reliance on his judgment. Some of us could be reading this the wrong way, could be not understanding certain aspects of the process. We represent companies that make these devices. We hear their side of the story and it certainly sounds reasonable, and we try to make sure there is a proper balance between the need to bring products to market quickly and a need to make sure they are safe and effective. So we turn to people like Dr. FRIST to give us the expert view in terms of what we are doing.

I know I have used my time here. I will have more to say about that, as I think we have considerable time left under the cloture procedures here.

At this point, I yield the floor.

Mr. LIEBERMAN. Mr. President, I rise to address Senator REED's amendment to S. 830, the FDA reform bill. The proponents of the amendment have failed to distinguish between devices that are substantially equivalent to devices the FDA has approved and devices for which no predicate exists. That distinction is central to the regulatory scheme for device approval.

Most medical devices brought to the market represent a small incremental change. Around 95% of medical device approvals granted by the FDA involve

devices that are substantially equivalent to a device already approved by the agency.

Most devices are not breakthroughs. They are not devices with bold new uses. They do not represent a sharp departure in medical science. They are devices with a foundation of testing, experience in the field, and most important, devices with a foundation in previous FDA approval.

Policies and regulations that are appropriate for devices without a predicate are not appropriate where devices are substantially equivalent to a device that has already received the FDA stamp of approval. If each new device represented such a break with the past, it would be sensible to fully reexamine safety and efficacy every time FDA was asked to grant approval.

But in a world of small changes, this unwarranted bureaucratic impediment would strangle progress, limit the benefits available to the public from technological advances, and yield little if any public health benefit.

To capture the public health benefits of small incremental change, such devices are approved by the FDA under special procedures called the 510(K) approval process. The critical test applied by the FDA in approving the device is demonstrating that the device is substantially equivalent to a device that has already been approved by the agency. The test of substantial equivalence is a flexible definition that includes both products that are identical to previously approved devices, and those with a certain degree of technological change.

In contrast, where the new device represents a major advance and is used in supporting life or avoiding substantial impairment of health, the FDA uses entirely different tests before approving the device. These breakthrough devices undergo extensive safety and effectiveness trials before marketing. They require extensive pre-market review because the FDA has no assurance the new device is safe and effective based on studies of a previous device, field experience, or FDA approval.

Approving substantially equivalent products expeditiously allows the FDA to concentrate its resources on those devices that involve new technologies or uses rather than waste time and staff conducting full-blown reviews of the equivalent device again and again.

In the example we have heard so much about over the last few days, U.S. Surgical Corp.—which is headquartered in my State—submitted an application for approval of an advanced breast biopsy instrumentation device in October 5, 1995. The application was granted by the FDA on February 1, 1996. The FDA based their approval on substantial equivalence in design, materials, methods of use, and intended use to biopsy needles the FDA had previously approved. Since that date the ABBI device has been used in over 7,000 cases worldwide.

In granting approval to U.S. Surgical, the FDA applied the two statutory tests of substantial equivalence. First, the device was shown to have “the same intended use as the predicate device” and second, “the same technological characteristics as the predicate device”.

Some Members have mistakenly stated that U.S. Surgical has marketed the device to remove breast cancer tumors, but the Members are in error.

A degree of technological variation is permissible and specifically envisioned in the statute. Where the device has different technological characteristics, it can still be approved under 510(K) if the manufacturer submits

* * * information, including clinical data if deemed necessary by the Secretary, that demonstrates that the device is as safe and effective as a legally marketed device, and does not raise different questions of safety and efficacy than the predicate device.

ABBI uses a larger cannula than previously approved biopsy needles. The wide cannula allows the physician to extract a broader sample of breast tissue. The wide cross section allows more accurate diagnosis of breast lesions that appear in the x-ray as clusters of tiny particles rather than discrete nodes.

U.S. Surgical's product insert states in boxed, large type “The ABBI* system is to be used ONLY for diagnostic breast biopsy; it is NOT a therapeutic device.” Its patient pamphlet on the device discusses biopsy uses to the exclusion of any other potential use.

In the ABBI example, the FDA requested clinical data from U.S. Surgical about impact of the new technology, broader cannula. U.S. Surgical submitted the data on September 23, 1996 and the FDA updated the 510(K).

The sponsors of the amendment state that manufacturers have an incentive to seek approval based on false and misleading statements of intended uses. Under the 510 (K) approval process, the device must have the “same intended use as the predicate device” but the amendment sponsors state that manufacturers are able to undercut this test. The amendment sponsors suggest that the FDA be allowed to establish a new intent test for 510(K) approvals that allows the FDA to impute new uses, demand new safety and efficacy tests, and ignore the manufacturers intended uses.

First, I would point out that U.S. Surgical specifically responded to the FDA's concerns by adding new labeling to its device clearly stating that the device was to be used “only for diagnostic breast biopsy”.

Second, the FDA already has ample power to confront potential problems in labeling. For example, they sent a warning letter to the U.S. Surgical Corp., on June 3, 1996, regarding labeling and advertising claims made for the ABBI. The warning letter led to the modifications in labeling and re-submission of the 510(K) application.

Finally, the FDA has a host of criminal and civil penalties to prevent the

marketing of mislabeled products including administrative detention and seizure, criminal and civil penalties, injunction, mandatory consumer and physician mandatory notifications, mandatory recall, and adverse agency publicity.

For example, FDA can administratively detain devices that are misbranded based on FDA's unilateral determination that a detention is appropriate, and can last up to 30 days to permit the agency an opportunity to either perfect a civil seizure through the courts or obtain injunctive relief.

Into the middle of this, the Reed amendment would throw a major change. The amendment does not state grounds or procedures by which the FDA would determine that the proposed labeling was “false” or “misleading”. The evidentiary basis by which the FDA will impute the manufacturers intent is unknown, as is the frequency of off-label uses that spurs additional FDA requirements or the adequacy of additional clinical trials necessary to satisfy their concerns. If the amendment passes, manufacturers have to be prepared to conduct trials of safety and efficacy for uses they are not seeking. Furthermore, the additional requirements only apply to the unapproved device—not to the predicate device previously approved by the FDA.

The 510(K) process is intended to provide an expedited basis for bringing new versions of previously approved products to the market. It employs relatively simple and easy to apply tests of substantial equivalence. The tests are straight forward and predictable in their application. We should continue to protect this path of technological innovation. The FDA has ample power to prevent mislabeled products from endangering the public health. If the amendment passes, many innovative devices will not be available to consumers and the public health will suffer.

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I would like to just respond briefly to some of the points that have been made and then to get into the substance of the argument. I want to reiterate the importance of this particular provision. There are those who are trying to dismiss it as a relatively unimportant part of this legislation, and saying that we really didn't bring this issue to the attention of the committee until the final hours, therefore, we could not have been serious about it. Of course, this is completely untrue.

I won't take the time to put in the RECORD the agenda for June 17 where this was listed in “items under discussion” on section 4 of the labeling claims. This was exactly the matter that was brought up in the markup in June. It was identified by the Secretary of HHS in the June 11 letter to the committee. It was repeated on September 5. Secretary Shalala identified

the very few items that she would recommend that the President veto this legislation about. She listed the environmental issue, the elimination of the environmental impact statement. Another one was a technical amendment dealing with PDUFA. A third item was the cosmetic provisions. But this is the provision that was identified by the principal protector of the American people's health as the most important provision in terms of adverse effects to public health, this provision. Let's understand that right from the beginning.

I know that my colleagues say, well, there are only a couple of Members of this body that are really concerned about this particular provision. Well, it is interesting that, time in and time out, the No. 1 person in the administration that has the principal responsibilities for protecting the American health has said this is it, this is the provision. With all due respect to those who say this is a low-risk issue that doesn't matter, that this is a technical question and we should just get through this business and get on with the vote, these arguments should be disregarded, because this is an enormously important issue. It was raised during the course of the markup back in June, and identified by the Secretary of HHS during the course of the summer. Many people were briefed by the Secretary indicating her priorities and this was right out there. It is in the papers submitted by her in September as being the primary technical concern in regard to safety for the American people. That might not make a difference to some Senators but it ought to make a difference to the American people. And it is not just the Secretary who is concerned about this provision. We have virtually every single group of health professionals charged with protecting the consumers' interests have expressed concern about this issue—the President of the United States, the Secretary of HHS, the Consumer Federation, the National Women's Health Network, the National Order for Rare Disorders. Who are these groups and individuals? They are the very people that benefit from innovations in medical devices. They are the people whose lives are enhanced. They are ones who are saying, "No, don't do this. Support the Reed amendment."

I am glad to listen to my colleagues. I am interested in the number of people employed by these companies. I am interested in what a great job a company does. I am interested in the opinion of some of our colleagues who say, "Well, this really isn't such an important measure because there are only a few people out there who oppose it."

Go down the list of the organizations that are out there protecting the people that will benefit most from progress in these areas, and they say, "Don't do this. Support the Reed amendment." Do they make the judgment that this is not important just because it deals only with class II de-

vices—the relatively low risk devices. There has been the suggestion here on the floor of the Senate that these are virtually low-risk devices.

These are some of the devices: Ventilators. Low-risk? Who has not been in the hospital with a member of their family and hasn't understood the importance of making sure that ventilators are going to perform as they are labeled?

You have digital mammography with possibilities of missing tumors in women with breast cancer. We want to make sure that these devices are going to be safe and do what they are represented and designed to do—not just what is listed on the label.

You have the fetal cardiac monitors that monitor infants.

I saw them working yesterday in Springfield at the Bay State Fetal Center in one of the greatest neonatal centers in this country.

Do you want to take a chance on fetal cardiac monitors? Or on surgical lasers?

The list goes on—these are class II devices, low risk. We are not talking about tongue depressors. We are not talking about bedpans. We are talking about the kinds of items where we need to make sure they are going to be safe and effective. That is why these organizations whose job it is to protect the public are concerned.

With all respect to my colleague and friend from Connecticut, who I heard state three times that these products, which have not been approved for safety and effectiveness for the uses for which they are being advertised, are not being mislabeled. And that we shouldn't dispute or cast aspersions on the good, legitimate name of the U.S. Surgical Corp.

Mr. President, I have right here the letter from Dr. Monica Morrow, professor of surgery at Northwestern University School of Law, dated September 22.

Dear Senator KENNEDY:

I am writing you to express my feelings regarding the importance of the FDA's mandate to evaluate behind the scene use of devices and drugs. The need for such evaluation is clearly exemplified by the marketing strategy of U.S. Surgical's breast biopsy device. This device was approved as a diagnostic instrument. However, the company video clearly depicts the use of the device for definitive breast cancer therapy with no clinical trial using the accepted technology for comparing cancer treatments that have been conducted to evaluate this claim, and without such trials the device could potentially pose a significant risk to patients.

In addition, other claims regarding approved cosmetic outcome and patient acceptance are similarly unsubstantiated. The indication for use of the devices and drugs should be determined by appropriate clinical and scientific data, and not by their appeal as a marketing gimmick. This video was dropped off at my office by a company representative as part of an effort to interest me in purchasing the company equipment.

I have it right here. For people who doubt it, take a minute and watch the video. Read the letter. Call Dr. Morrow.

It is being marketed out there today. This is what we are talking about. That is the issue. When colleagues get up and say, "Well, it has not been, and it won't be, and that is wrong if it is?" I say, "It is being done." And that is exactly the problem that we are attempting to address.

Mr. President, this is an enormously significant and important health issue. This body has taken many actions on medical devices since the mid-1970's to enhance public health the protections since the mid-1970's that enhanced protections for public health. This provision which will create a loophole through which unscrupulous manufacturers of a medical device will be able to drive a truck is the exception to that commendable history. This provision will make a mockery of the substantial equivalence requirement, and will allow irresponsible companies to go out, as this company has, and advertise and represent a particular product for a purpose and use that differs from the one they put on the label.

Mr. President, it was interesting that some of our colleagues addressing the Reed amendment pointed out that there are two ways of approving the medical device. Only about 5 percent medical devices use this particular provision, the premarket approval. That provision says, "In making the determination whether to approve or deny * * * the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all the material facts pertinent to the proposed labeling."

Mr. President, I daresay that there is probably a less compelling reason to use the proposed labeling as "neither false nor misleading" in this provision because you are going to have such a survey in an oversight for new materials as it is in the other provision.

What the proposal that is before us now, the one that is for 95 percent of all devices, says is, " * * * the determination of the Secretary under this subsection * * * with respect to the intended use shall be based on the intended use included in the proposed labeling."

I would like to point out to those that have suggested here on the floor that the intended use is a subjective decision to be made by the FDA, that isn't what the legislation says. It says, " * * * the determination of the Secretary under this * * * section with respect to the" * * * device " * * * shall be based on the intended use included in the * * * labeling."

Who makes up the labeling? The manufacturer has the labeling "submitted a report under this section."

The only thing the amendment of Senator REED is proposing is that the

FDA be restricted to looking solely at the labeled use only in instances where * * * the proposed labeling is neither false nor misleading."

How can anyone be opposed to that?

We have just seen the example of the approval of a biopsy needle for one particular purpose—taking the biopsy. Then we find that this similar machine is represented as being for the purpose of biopsies, here it is in their advertisement—the latest technique in minimally evasive breast biopsy. This device takes 50 times the amount of material as the other one. Here it is being advertised in Canada. Here it is being advertised in the United States—not for use in biopsies but to remove the tumor itself. And there is no information available to the Food and Drug Administration about how good or safe the device is for that use. Maybe it does work. We are not here to say it doesn't work. We just want the company to have to provide the information that says it does work. If that is what you are going to use it for, why should the Food and Drug Administration, which has the responsibility of protecting Americans, be limited by the language of this particular legislation that says you can only look at what is on the label? When, at the same time, they have letters from doctors and they have videotapes that show it is being used for an entirely different purpose.

That is the issue. The Reed amendment says, OK, we are willing to only look at the use on the label, but let's just make sure that we are not going to encourage false and misleading labeling.

Is the Senate of the United States going to say to the FDA that if even if they know that the labeling is false and misleading that they should be prevented from protecting the American public?

That is what you are going to do if you do not accept the Reed amendment. That is what this debate is about. It is as simple as that.

Here we have this extraordinary example, where you have a biopsy machine that is supposed to take a biopsy about the size of the lead in that pencil versus something that takes 50 times the amount and the purposes for it is intended to be used are quite different, as mentioned here in the letter which says, "I am expressing my feelings * * * the importance of the FDA mandate."

"The video was dropped off at my office" with the interest of purchasing the equipment.

When the FDA became aware that the company was promoting the device for this unauthorized purpose, it also became aware that it had made a mistake in clearing a device that was clearly designed for a purpose not stated on the labeling—tumor removal for clinical testing. The FDA then acted to require the company to include a strong label that the device was only to be used for tissue sampling; not tumor excision.

I cannot imagine why the company failed to give the full information on that. But, nonetheless, that is what is happening.

Mr. President, I listened with interest to many of our colleagues talking about how there really are no dangers in terms of medical devices, that my examples are not really what this issue is all about. They are mistaken.

We are committed to ensuring that these kinds of circumstances will not occur in the future. That is why we are out here. We don't have to go through another incidence similar to the Dalkon shield where 18 women died from a perforated uterus and 2,700 women suffered miscarriages. We don't want to go through another episode like the Shiley heart valve one where a change in the angle of the valve would have changed the way the device interacted with the heart raised questions as to its safety. The FDA discovered this and refused to let it go to market in the United States. But the modified device was marketed in Europe and 15 times the number of people died using the new device over the earlier one. With all respect to those who say how much better the system is in other countries—15 times the deaths. And the whole toxic shock issue that we raised and its impact on American women.

What we are pointing out is that there are dangers that can take place in our country, that affect our people, when you start fiddling around with safety and effectiveness and medical devices.

That is the issue.

There are those who say, "Look. We have a little loophole. But it really isn't quite the same as it is with some of these other terrible kinds of situations."

We have given the illustration of the kinds of challenges that are out there today.

There are the laser technologies, cutting tissue laser technologies, where you have submitted to the FDA a laser that, everyone who has really looked at it agrees, is going to be used for prostate surgery. But there is virtually no information as to the safety and effectiveness of that particular medical device for that use—none. That is what happens.

There are the various digital mammography devices that may be very good for obtaining diagnostic information and evaluating a particular tumor but may be questionable for screening purposes. Questionable as to their effectiveness in allowing women to know whether they are going to have the first indications of a small tumor. Don't we want to be sure that this isn't what it is going to be used for? Don't we know what they are out there marketing this for and how well it performs?

We have just seen in the period of the last 5 days, the example of the terrible events concerning the off-label use of the drug fen/phen—and the health haz-

ards and challenges faced by the people who have used it.

Are we here today saying we don't want to include language in this bill that will allow the FDA to be able to look at safety of medical devices if they find the labeling is false and misleading? We have offered five different compromises to work this out. It is the No. 1 concern of the Secretary of Health and Human Services, the No. 1 concern by the FDA. I have listened here in the Chamber, to those who oppose this amendment who say the FDA has all the authority in the world to protect the public. I have quotes here from Senators who have said, in effect, that we should not be bothered by this because the FDA has all the power it needs and that this is really not a problem.

I was tempted to take the language of their quotes and offer it as an amendment because their description of the FDA is not what the law is and will be if this legislation is passed. We would have taken the kinds of protections that were implied by their quotes. Where they say, look, they have the real right to go behind if they think there is some kind of question in terms of safety.

The FDA would not have that authority under this bill as written. But if it is your understanding and that is what you want, let's take an amendment and ensure that they do.

But we do not have that opportunity. We are faced with the real possibility for a situation where the FDA does not believe it has the power and the authority to protect the American consumer. The FDA does not believe it has authority. If they know that the predominant use is going to be other than that which is listed on the label and which could provide a substantial threat to the American people, the FDA will not have the power or the authority to protect the American public.

Members of Congress can come out here and say, "Oh, yes, they do." I have listened to that argument. "Oh, I don't know why everyone is getting so worked up about it. You know, they really do have the authority."

They do not have it. The FDA itself states they do not. They have testified they do not. The President does not believe it. The Secretary of HHS does not believe it. The consumer groups do not believe it. National Women's Health Network does not believe it, the Consumer Federation, the Patients Coalition.

We have had this discussion and debate for a number of days. We believe we are finally getting through. But where are all the consumer calls saying, "Look, let's go with what is proposed in the legislation. We have read the record. We have looked at the law. We believe the FDA is out there and can protect the American public. I don't know what everybody is getting worked up about."

But we aren't getting those calls because virtually every consumer group

that has looked at this issue, has discovered that the language in the bill will not provide adequate protection for consumers.

National Women's Health Network: "Women need the FDA to act as a safety sieve screening out drugs and devices that are hazardous and defective. If 404 is enacted, a device manufacturer could label its product for a very simple use. The FDA would be limited to ask for safety and effectiveness for that use only."

The groups understand this issue, and they are concerned. "Even if it were clear from the device's technical characteristics that it might be used for other more riskier purposes."

That is the biopsy needle. You have a needle that is 50 times larger than is necessary for a biopsy and you have the clear evidence from doctors, both in this country and abroad, who have seen the videotape that the company is out there marketing it for a different use. We have it right here—a slick promotion for this particular issue. All we are saying is if the FDA is able to show that the labeling is false and misleading, they can look at safety.

Mr. DODD. Will my colleague yield on that point?

Mr. KENNEDY. I yield, sure.

Mr. DODD. I would respectfully suggest to my colleague that U.S. Surgical is not marketing a video that promotes an unapproved use for this device. Now, there are clinicians out there who have put out videos and other educational materials on medical practice issues. U.S. Surgical is aware of that. It can happen. But the implication that U.S. Surgical is now actively promoting unapproved uses is not true.

Mr. KENNEDY. Has the Senator seen this video?

Mr. DODD. No, I have not, but I am told categorically that U.S. Surgical is not promoting or marketing this device other than for breast biopsies.

Mr. KENNEDY. I suggest the Senator take the time to see it because when you turn it on, the first thing that you are going to see is the U.S. Surgical logo on it. I don't see how you can say that it is not being promoted or advanced or whatever if that is exactly what you will see. I would suggest to the Senator, if you are saying that those of us who have represented that it is being promoted for other uses—and we have the doctors' letters and we have this video, which you haven't seen—I would think that perhaps you ought to check again with U.S. Surgical and find out what they are doing. We have just seen it.

Mr. DODD. Will my colleague yield?

Mr. KENNEDY. I will yield in a second. We have just seen what the medical companies were doing with fenphen. They weren't promoting it. All they were doing was paying the doctors thousands and thousands of dollars to go out and promote it. When we look at this promotion, it has "U.S. Surgical" on it, and it is a U.S. Surgical medical device—and we have the doctors' let-

ters on this that say, "The indications for the use of devices. . . it should be determined by appropriate—"

This video was dropped off in my office by a company representative—

Company representative—
as part of an effort to interest me in purchasing this equipment.

Now, there may be other information. I am glad to have it included in the RECORD but I find this convincing.

Mr. DODD. If my colleague will yield. This company is not engaged in promoting unapproved uses for this biopsy needle. And U.S. Surgical categorically denies any association with any materials produced by others where this might have occurred. The FDA has approved the breast biopsy needle. The FDA has approved it twice, in fact, only for breast biopsies. Accordingly, U.S. Surgical does not promote the device or market the device for tumor removal. It is aware now that articles and videos do exist which discuss other uses of the devices. It is very common, and completely legal, for physicians to explore other possible uses of both drugs and devices as part of the practice of medicine. But the suggestion somehow that the company is now actively promoting this device for something other than diagnostic purposes, with all due respect, is just not true.

And the question that we should be asking here—a very important question—is, if this obviously illegal practice is occurring, if U.S. Surgical is actively promoting this product for an off-label use, why hasn't the FDA gone after the company? Now, clearly, if it were true, the FDA, with all the force of law would go out and pursue them vehemently. Promotion of a device for unapproved uses is one of the most egregious violations a company can commit. Surely if this were the case, and evidence of it were so readily available, FDA would have acted. But there has been no FDA action, because there has been no violation. And to suggest otherwise is irresponsible.

I mentioned earlier, if my colleague will continue to yield, that U.S. Surgical has promoted this device for the purpose for which it was approved—to give women and their surgeons a useful option in conducting breast biopsies. There are good medical reasons that a larger size biopsy might need to be taken. In conducting biopsies you do can not always get a reliable tissue sample just with a small needle—some tumors are just too diffuse. Evidence shows that, with some types of tumors, taking a larger biopsy gives the surgeon a far better chance of determining the quality of the tumor accurately without the need to take multiple, painful biopsies.

That is why this device was developed. And as women who have been through this will tell you, it is important to have this device as an option for taking an accurate and safe breast biopsy.

Mr. KENNEDY. Mr. President, I would like to regain my time.

I say that that is a promotional document. I would suggest the Senator watch it before he represents that it is not. It has the U.S. Surgical logo on it. We have the doctors who claim this is the case. The FDA has been going after U.S. Surgical.

That is another issue. It is an important issue. FDA ought to be concerned about it, and they are. But that doesn't get away from what the FDA may not be able to do sometime in the future. They won't be able to do it in the future, because all the FDA will have the power to do is look at what is on the label.

Mr. COATS. Will the Senator yield?

Mr. KENNEDY. No. I would like to just finish my presentation on this part here, and then I will be glad to yield.

Mr. COATS. If the Senator will yield—

Mr. KENNEDY. That is just the part I am going to mention.

Let me quote some extracts because that is the issue that is before us—the extracts of the promotion. This is the promotion that some do not think is being promoted by U.S. Surgical, even though its logo is on it, even though doctors have said it is being distributed by company representatives.

This is the quote:

U.S. Surgical is entering a new millennium in breast surgery by combining advanced stereotactic technology with minimal invasive surgery.

Not biopsy, surgery.

Unlike needle biopsies where small samples of the lesion are removed for pathological analysis, U.S. Surgical removes the entire specimen.

That sounds like an operation to me.

If the specimen proves to be cancerous but pathology reports the entire margin is clear, it's up to the clinical judgment of the surgeon to decide to remove the additional tissue, or if the procedure can be considered complete.

Translated, if you use this device and you take out the tumor, then it is the doctor who removes the tumor who makes the judgment whether he has to do any other surgery. That is not a biopsy needle. It continues.

The U.S. Surgical system allows the surgeon to provide the benefits of the minimally invasive technique to breast surgery. Benefits to the patients include reduced physical and emotional trauma as a woman undergoes only one versus two procedures. Minimal invasive breast surgery, a new standard of patient care offered only by United States Surgical Corporation.

I rest my case on that, Mr. President, about advertising and promotion. I rest my case on exactly the words of that promotion. "Minimal invasive breast surgery, a new standard of patient care offered only by United States Surgical Corporation."

If there are Members in this body who want to say U.S. Surgical is not promoting it, that they are not associated with it, that they don't know anything about it, I suggest that they watch this videotape.

Now, Mr. President, I want to just come back to—how much time remains

because I know there are others who wish to speak.

The PRESIDING OFFICER. The Senator has used 33 minutes and 30 seconds.

Mr. KENNEDY. I yield at this point now. I would like to go on to just some other remarks.

Mr. COATS. Just briefly. Senator DODD asked the question, if this is such an egregious violation of FDA policy, why hasn't FDA acted on it? Why has it not acted?

Mr. KENNEDY. They have. As I understand, they have requested the additional information on safety and efficacy. They are demanding that kind of information now. I will be glad to provide that.

But that has as much relevancy as yesterday's score of the Green Bay Packers. They are out there now promoting this for unintended uses. I do not think they should be. FDA says they are looking into this. I will find out and give the Senator a more detailed description.

Mr. COATS. I have a copy of a letter. The Senator was handed a letter. I was handed a letter.

The letter was addressed to Senator KENNEDY thanking him personally for the assistance that he provided, for the "assistance provided by your staff" to U.S. Surgical "in our efforts to deal with the Food and Drug Administration on the matter of the certification of the Advanced Breast Biopsy Instrumentation."

That is what we are talking about.

Mr. KENNEDY. Sure.

Mr. COATS. It says here the Senator assisted in making sure the FDA did not withdraw it. It specifically cites, "Please convey my gratitude to Dr. David Nexon and Gerry Kavanaugh," who I believe are on the Senator's staff, "for their willing assistance." Maybe they are on the market because the Senator intervened to keep it on the market.

Mr. KENNEDY. Well, Senator, I will be glad, first of all, to have it included in the RECORD so the record is clear. But I will say to you that, if U.S. Surgical was distorting and misrepresenting to the American public, then I think they ought to be pursued to every extent of the law. That is my response on it.

I had no idea of that unfair kind of consideration at that time, but clearly they have misrepresented themselves in this instance. They practiced that kind of misrepresentation on me as they are doing it with the American public.

Mr. COATS. Will my colleague yield?

Mr. KENNEDY. Here is their—I will yield briefly on this point. But I want to get back to my theme.

Mr. COATS. Apparently they convinced your staff, Dr. Nexon, that this was a safe procedure and it should not be withdrawn.

Mr. KENNEDY. I will be glad to take a look at the letter.

Mr. COATS. I ask unanimous consent the letter be printed in the RECORD.

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

Thermo Electron,

Waltham, MA, October 8, 1996.

Hon. EDWARD M. KENNEDY,
U.S. Senate, Russell Senate Office Building,
Washington, DC.

DEAR TED: I want to thank you personally for the guidance and assistance provided by your staff to our representatives, and those of U.S. Surgical Corporation, in our efforts to deal with the Food and Drug Administration on the matter of the certification of the Advanced Breast Biopsy Instrumentation (ABBI) system technology. Our concern, simply stated, is that the FDA will call for the withdrawal of this product from the market without appropriate cause.

The ABBI technology, jointly developed and marketed by both companies, is today in the marketplace, and as a result of its success, represents a fast-growing opportunity for Thermo Electron's Trex Medical Corporation subsidiary and our Connecticut partners, U.S. Surgical. The technology is a non-invasive, cost-effective alternative to surgery. In over 500 cases in which it has been utilized, there has not been a single complaint. Indeed, because it does represent a significant advance in women's health care, it is fast becoming the treatment of choice.

Thermo Electron has made a significant investment in this technology, and with the recent acquisition of XRE Corporation of Littleton, Massachusetts, plans to expand production of the product. Along with one hundred new jobs, we are projecting revenue production in excess of \$50 million. Thermo Electron is proud of its responsiveness to societal needs. The ABBI technology is a step forward in the field of women's health care.

Thank you for your interest, and please convey my gratitude to Dr. David Nexon and Gerry Kavanaugh for their willing assistance.

Best regards,

GEORGE N. HARSOPOULOS,
Chairman of the Board.

(Mr. SESSIONS assumed the chair.)

Mr. KENNEDY. The Senator from Indiana introduced a copy of a letter from a Massachusetts constituent of mine dated October 8, 1996, which purports to thank me for the guidance and assistance my staff provided to U.S. Surgical Corp. in connection with the FDA certification of the advanced breast biopsy instrumentation [ABBI]. The Senator suggested that this letter was proof that I had intervened with the FDA to urge them to approve an off-label use for this device. The letter does not substantiate any such allegation, and it is untrue. I ask that the full text of the letter be printed in the RECORD.

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

Thermo Electron,

Waltham, MA, October 8, 1996.

Hon. EDWARD M. KENNEDY,
U.S. Senate, Russell Senate Office Building,
Washington, DC.

DEAR TED: I want to thank you personally for the guidance and assistance provided by your staff to our representatives, and those of U.S. Surgical Corporation, in our efforts to deal with the Food and Drug Administration on the matter of the certification of the Advanced Breast Biopsy Instrumentation (ABBI) system technology. Our concern, simply stated, is that the FDA will call for the

withdrawal of this product from the market without appropriate cause.

The ABBI technology, jointly developed and marketed by both companies, is today in the marketplace, and as a result of its success, represents a fast-growing opportunity for Thermo Electron's Trex Medical Corporation subsidiary and our Connecticut partners, U.S. Surgical. The technology is a non-invasive, cost-effective alternative to surgery. In over 500 cases in which it has been utilized, there has not been a single complaint. Indeed, because it does represent a significant advance in women's health care, it is fast becoming the treatment of choice.

Thermo Electron has made a significant investment in this technology, and with the recent acquisition of XRE Corporation of Littleton, Massachusetts, plans to expand production of the product. Along with one hundred new jobs, we are projecting revenue production in excess of \$50 million. Thermo Electron is proud of its responsiveness to societal needs. The ABBI technology is a step forward in the field of women's health care.

Thank you for your interest, and please convey my gratitude to Dr. David Nexon and Gerry Kavanaugh for their willing assistance.

Best regards,

GEORGE N. HARSOPOULOS,
Chairman of the Board.

Mr. KENNEDY. Obviously, if it is a biopsy needle and it was intended to do that, I had no idea they were out there promoting, as they have been, and representing it for an entirely different purpose. That is the issue we are talking about here, and that is what we want to do. We want to make certain that the FDA is going to be able to look beyond false and misleading information on devices labels.

Mr. DODD. Will my colleague yield?

Mr. KENNEDY. I will yield in just a moment now.

Mr. DODD. Just on this point, if I could, on the point of the needle.

Mr. KENNEDY. On the needle? All right.

Mr. DODD. I'd like to clear up for everyone why we are discussing the size of the needle for the biopsy. Let's put aside for a moment your question of what the company has or hasn't said since we have been told that the FDA has not found that they are promoting the needle for tumor removal.

Mr. KENNEDY. If I can reclaim my time, I cannot let that go by, that the FDA has said they are not promoting it. That is not the information on it. I cannot let the statement go by. It is your opinion that it is not promoting. I don't see how you can have that opinion in the face of the fact that this videotape has stated what it has, with this U.S. Surgical's logo right on it.

Mr. DODD. If my colleague will yield, as I said earlier, if U.S. Surgical were promoting for uses beyond those on the label, I think the FDA would be acting on it. But let me again get to the point of why a larger needle is useful in some biopsies situations. I am not a surgeon or a doctor, but I am just sharing with my colleagues here, and my colleague from Massachusetts, why this larger needle may be needed. This Advanced Breast Biopsy device, as it is called, does remove a larger amount of tissue

than a conventional biopsy needle. Why? Why does it need to do that? This difference in needle size is not related to tumor removal. Rather, it addresses clinicians' requirements for sampling different types of lesions. Why do they do that?

Mr. KENNEDY. If my colleague—

Mr. DODD. I will just finish the paragraph. Breast lesions exist not only as discrete nodules but oftentimes as clusters of tiny particles known as microcalcifications. These microcalcifications appear diffuse on an X-ray; similar to the Milky Way. That's how surgeons describe it.

Due to this fact, obtaining adequate amounts of tissue for biopsy is important in order to optimize accurate diagnosis, so that women don't have to go through surgery unnecessarily. This needle allows clinicians to take a larger single sampling, rather than many, painful, smaller samples that could perhaps miss the tumor tissue. That is why this product was developed. That is why it has been so supported by women and by surgeons.

My colleague from Massachusetts can talk about videos that promote purposes other than this one. However, if that is the case, the FDA ought to be in there this very minute. But, they have not acted because no violation has occurred.

Mr. KENNEDY. The Senator is not correct. The FDA is out there looking into this, and it doesn't do much good to try to cloud up the issue as to what the purported purpose of this particular medical device is.

Here is what is in the ad. I say again, I wish the Senator would look at the ad, rather than just reading the U.S. Surgical statements on it. This is what their ad says:

Minimal invasive breast surgery. A new standard of patient care offered only by United States Surgical Corporation.

That is what the ad says. It doesn't say minimal invasive biopsy; it says breast surgery.

Maybe that is a new way of doing it. Maybe that is the best way that has ever been devised for protecting American women in terms of breast tumors. But the FDA does not have one sentence of proof or evidence from U.S. Surgical that provides data on the safety and effectiveness on this method of removing a tumor that other medical devices should provide. They have the biopsy needle. It is effectively the size of this pencil. They want one that is 50 times larger. You don't have to have a lot of sense to know what this is all about.

Maybe U.S. Surgical convinced the Senator from Connecticut. But the documents and their promotional materials indicate what they are about, and that is to provide for removal of tumors from American women, one out of seven, who have breast cancer. And doctors who see, "Approved by the FDA," then tell their patient this has been approved by the FDA, that it must be safe, and so they undergo

tumor removal with this device. These women are entitled to adequate protection, to know whether that device was safe in removing that tumor. They do not know that today.

And that is just the tip of the iceberg. You know about all the other kinds of medical devices that can fall within this category. We have mentioned some, like the mammography screening machines that may misdiagnose breast cancer. All this amendment says is, you cannot, if you are a medical device company, submit false and misleading information. I can say it another way, "Do you want false and misleading information on the labeling?" If you vote against our amendment, that is what you are going to be pegged with. We are going to be characterized as not caring if labels are false and misleading.

Why can't we say we will support the labeling as long as it is not false and misleading? That doesn't sound like an extraordinary or revolutionary concept. This is basically what we are arguing about. Those who are opposed to us say, "All right, let them provide false and misleading information." That is the other side of this argument. If they are not going to go through this kind of loophole, to promote it for some other reason, what do they have to fear?

Mr. President, there are all kinds of technologies out there that are just on the cusp, ready to go on ahead through this particular kind of loophole. You have the mammography screening machines that have not been certified for use in screening. The manufacturers have not been provided information on that use. We know the difficulty we have faced in terms of mammography machinery and false negatives and false positives.

Are we going to come out on the side of protecting American women on breast cancer, or are we going to say we are going support whatever any medical device company wants to do, no matter how false and misleading that information may be? The vast majority of manufacturers won't use this loophole. But you don't hear the arguments here about what the financial benefit will be to those companies that will not have to conduct the exhaustive tests for safety and efficacy. They will be at a competitive advantage over the other medical device companies that are trying to do it right.

Mr. DODD. Will my colleague yield?

Mr. KENNEDY. In a second. Because there will be those in those corporate boardrooms who will say, look, our competitor is getting in through this particular labeling device loophole. All you have to do is change the label a little bit. We will be able to do it as well. We can avoid the time it will take to do it right, we will save a good deal of our resources. We will get on the market sooner, we will beat the competitor, we will be on the shelves sooner.

We can use what U.S. Surgical did, where they denied—denied—that they

were promoting it, and yet they had some other group that was putting promoting it with their logo, talking about using it for an entirely different purpose.

That is the issue. This is not a very complex issue. We heard earlier about sifting out the chaff and moving to the substance on this. This is it.

What woman in this country who is facing having a tumor removed from her breast by a medical device believes that device is a low risk device? What mother that looks over a sick child in the hospital and sees a ventilator, thinks that ventilator is low risk? That is the reason that the Secretary of HHS, the President of the United States, virtually every consumer group, every patients' group, every group that will benefit the most by this kind of innovative progress in terms of medical devices, are saying don't do this. Don't play with our future health, don't pass that provision without this language. That is what they are telling us here on the floor of the U.S. Senate.

We have been out here with five different sets of language ready to compromise. But, they won't compromise, they have the votes. They say, "We have the votes. We have the profits that are going to come from it." They will profit over their competition. Other hard-working, decent, ethical medical device companies that are trying to play by the rules, trying to get their product in—are going to think, "Why not? Why not go ahead and do it the other way? Our competitors are doing it and beating the pants off of us."

I have just a few moments and I will be glad to yield the floor.

The question is, will the Senate vote in favor of approving medical devices based on false or 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?

Section 404 of the FDA bill requires the FDA to approve a medical device based on the user claim on the label submitted by the manufacturer, even if that label is false or misleading. It prevents the FDA from requiring the manufacturers to show their product is safe and effective for the purposes for which it will really 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.

Nothing better shows the need for the Reed-Kennedy amendment than the recent history of the advanced breast biopsy instrumentation system, a device developed and marketed by the U.S. Surgical Corp. This attempt to mislead the FDA and foist an untested machine on women with breast cancer

shows why it is critical that section 404 not be passed in its current form.

The U.S. Surgical Corp. submitted their new machine to the FDA for approval based on a labeled claim that it was to be used for biopsying breast tissue suspected of being malignant. This is a common procedure used when mammograms or other diagnostic techniques identify suspicious looking areas of the breast that may indicate malignant tumors. If the biopsy of a small piece of the suspicious material indicates a malignancy, surgery would normally follow to remove the cancerous tissue.

But U.S. Surgical's labeled claim was false. One of the models of the machine was designed to excise a piece of tissue 50 times as large as previous biopsy instruments—the size of a piece of a hot dog as compared to the size of the tip of a lead pencil. It was clearly designed to be used to excise small tumors—not just to perform a biopsy. But the machine was not tested to see whether it was safe and effective for this purpose. The company was, in effect, proposing to subject women with breast cancer to surgery with a machine that might have been less effective in curing their illness than existing therapies.

Women ought to have a choice on existing therapies whether they want to take a chance on this.

It placed the company's profits first—and the patient's needs last.

In fact, the only clinical testing the company submitted to the FDA in support of their application had been performed on seven cow's udders and two pieces of beef.

Because FDA initially relied on U.S. Surgical's false and misleading label, the device was subjected only to an engineering review and was cleared for use on February 1, 1996. Had the product been honestly labeled, FDA would have reviewed it using a multidisciplinary team and required the company to present genuine clinical data in support of the application.

On March 29, 1996, the FDA obtained a copy of a promotional videotape that U.S. Surgical was distributing to physicians to try to sell their product. The videotape clearly describes the device as appropriate for surgically removing small lumps of cancerous tissue. Let me quote some extracts from this slick production:

U.S. Surgical is entering a new millennium in breast surgery by combining advanced stereotactic technology with minimally invasive surgery * * *.

Unlike needle biopsies where small samples of the lesion are removed for pathological analysis, the ABBI system removes the entire specimen * * *.

If the specimen proves to be cancerous but pathology reports the entire margin is clear, it is up to the clinical judgment of the surgeon to decide to remove additional tissue or if the procedure can be considered complete.

The ABBI system allows surgeons to provide the benefits of a minimally invasive technique to breast surgery. * * *

Benefits to the patient include: reduced physical and emotional trauma as a woman undergoes only 1 versus 2 procedures. * * *

Minimally invasive breast surgery. A new standard of patient care offered only by United States Surgical Corporation.

They have the audacity to suggest they are not promoting it.

It is clear that this company has designed this machine for breast surgery, not just biopsy. And it is promoting it for this purpose—despite the false and misleading label submitted to the FDA.

Here is what a distinguished physician, Dr. Monica Morrow, professor of surgery at Northwestern University, had to say about the company's machine—I referenced that—

I am writing to express my feelings regarding the importance of the FDA's mandate to evaluate "behind the label" uses of devices and drugs.

The need for such evaluation is clearly exemplified by the marketing strategy for the U.S. Surgical breast biopsy device (ABBI). This device was approved for use as a diagnostic instrument. However, the company video clearly depicts the use of the device for definitive breast cancer therapy.

No clinical trials using the accepted techniques for comparing cancer treatments have been conducted to validate this claim, and without such trials, the device could potentially pose a significant risk to patients. In addition, other claims regarding improved cosmetic outcome and patient acceptance are similarly unsubstantiated. The indications for the uses of devices and drugs should be determined by appropriate clinical and scientific data, and not by their appeal as marketing gimmicks.

This video was dropped off in my office by a company representative as part of an effort to interest me in purchasing this equipment.

When the FDA became aware that the company was promoting the device for this unauthorized purpose, it also became aware that it had made a mistake in clearing a device that was clearly designed for a purpose not stated on the label—tumor removal—without adequate clinical testing. The FDA then acted to require the company to include a strong cautionary label that the device was only to be used for tissue sampling, not tumor excision. And it required it to submit clinical data on its use for the original claimed purpose of biopsy. Based on this revised label and the new clinical data, the FDA recleared the machine for breast biopsy on September 24, 1996.

That is what the FDA has been doing, effectively denying them the opportunity to use it for these other purposes, and permitting them to use it only for biopsy.

And it further required the company to conduct studies on the safety and effectiveness of the machine for tumor removal, studies which are ongoing.

Evidently, the company, when asked to provide the additional studies, they agreed. That is interesting, isn't it? Now, once they have gotten caught they say, "OK, we'll supply the data."

If section 404 is passed in its current form, the FDA will be handcuffed in its efforts to protect the public against untested and potentially harmful—even fatal—devices. Under current law, the FDA is able to require that the company develop data to show that the new device was safe and effective for

removing tumors—the real use intended by the company, not the false and misleading use submitted on their proposed label. When the FDA made a mistake and inappropriately cleared the device, it had the authority to go back to the company and warn that it would revoke their approval unless adequate warnings were placed on the label and necessary clinical testing was performed.

I hope our colleagues will listen to this.

But under section 404 of the FDA reform bill, the FDA would be forced to approve the new device without such evidence. Unscrupulous companies will not only be allowed but encouraged to submit misleading labels, because they will gain a competitive advantage over companies that play by the rules.

American women do not want to die from breast cancer because companies are allowed to sell devices that may be unsafe and ineffective. No Senator would want their own wife or mother or daughter to be subjected to such an untested device, solely because a greedy company wanted higher profits.

The issue goes far beyond products to excise breast cancer. If applies to lasers to treat prostate disease, stents to be placed in carotid arteries, imaging systems to detect breast cancer, and a host of other treatments for dread diseases.

The FDA believes those numbers will increase dramatically as the new technologies come into play.

If allowed to stand, this provision will give unscrupulous companies a license to lie to the FDA. It will penalize ethical companies who are truthful and do the necessary testing to prove that their products are safe and effective. Most of all, it will put the health of American people at risk so that a greedy few may profit.

Companies that hope to benefit by weakening the FDA are powerful and profitable. They believe they have the votes to push this disgraceful provision through the U.S. Senate. Later today, we will see if they are correct. But 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, 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 labeling. And let me make very clear that this vote will not be the end of the story, whichever way it ends up. We will continue to fight to keep this provision from becoming law, and I believe we will ultimately succeed.

The FDA reform bill has many constructive elements. But this disgraceful provision should be eliminated. False or misleading labels should have no place in approval of medical devices. Unscrupulous manufacturers do not deserve a free ride at the expense of public health.

The Reed-Kennedy amendment will protect Americans against dangerous

machines and unethical practices. It is a simple amendment. It says that the FDA should not be bound by the company's label if the label is false or misleading. Every Member of the Senate should support this simple, common-sense change. I know that the American public supports it.

And I know that every patient and every physician deserve to know that the FDA has had a fair opportunity to assure that the devices on which lives and health depend are safe and effective.

I yield the floor.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. Let me try to remove some of the confusion that I think must exist. Certainly the Senator from Massachusetts most eloquently has expressed his feelings, but his feelings and the law are not necessarily the same.

I point out, first of all, that false statements, all these kinds of problems, are certainly reachable. Let us get back to where we are. Let us remove first a couple of the things that have been invoked here in the discussion. Fen/phen, for instance. Fen/phen deals with drugs, not with devices. So do not get that confused with this particular situation here.

In addition to that, I point out that because of the off-label use of drugs, this committee appropriately put in place a system which would have probably even prevented fen/phen but at least would have made it possible for the FDA to intervene through the knowledge that they might not have had. So I want to take that completely out. That just raises insecurities in people which is inappropriate under this legislation.

Second, with respect to the debate on devices, I think it is important that we take a look at what we are talking about here. Devices are different from drugs. Devices have to do with things which are implanted in you or are used like the neck collar, whatever else, which do require approval.

There are two ways to approve these matters. One is the PMA, the premarketing approval.

The amendment that they are asking for would require not only the premarketing analysis but would move the same kinds of standards which are in the premarketing approval process over to the 510(k) process.

Why is that? First of all, the premarket approval is the one which requires all the clinical trials and tests and which makes it very clear as to whether a device is going to create a threat.

Let us put that into dimension here. Just in the 510(k) process, there were over 5,000 a year. Over the last 6 years that has been about 30,000 devices. There have only been five or six that have created any problem which required mandatory recall.

So that evidence is with respect to two points: First, these are rare things

and, second, there is the present ability to handle those situations.

So by putting in these words "false and misleading," you take this device basically and move it back in under the premarketing approval process because, if you have to approve everything, if you have the duty of going out and inquiring among doctors, "Are you using this device which has already been approved?" and you say, "I have something which is substantially equivalent to be used for that purpose," they would have the burden of going out among the doctors and finding out what the practice of medicine is and whether their device was being used for something other than what it was approved for under the premarketing approval process.

That means a huge increase in costs to each of these companies that are trying to get something on the market to compete with the one that is already on the market. This creates huge delays. And for what reason? For no real purpose because it is only going to be used for that use intended unless somebody decides to use it otherwise.

So I think we have to remember here there is authority under the law for those people who abuse the process. But one of the purposes of the 510(k) was to reduce the time so that competition can get out there with a better device and bring the costs down because there would be no longer a monopoly in that situation.

The second purpose is to relieve the FDA from having to recheck and reexamine a device which is substantially or equivalent to the one that has already been studied and require the FDA to go out and examine all the doctors, all those kinds of things and create a huge burden on the FDA.

So our purpose here in the bill is to make sure that we have an efficient, effective FDA with adequate resources to do their job. So I want to make it clear as to what the discussion is supposed to be about. I also remind you that the 510(k) process only applies to those devices which are not life threatening, so they are not the devices that would do the kind of horrendous things that the Senator from Massachusetts has alluded to.

I yield to the Senator from Connecticut.

Mr. DODD. I thank my colleague for yielding.

Mr. President, may I ask—the hour of 12:30 is going to arrive here. I think there has been an earlier order that would have us recess.

Mr. JEFFORDS. I ask unanimous consent that we be allowed to proceed until 12:40.

Mr. DODD. I thank my colleague for yielding.

Mr. President, I sat here and listened to this debate this morning. A good part of it has been focused, not on the merits of the provision, but on one individual company in the State of Connecticut, U.S. Surgical Corp., and a device which they developed for diag-

nostic purposes related to breast cancer.

I think it is unfortunate that there have been so many misleading statements made about this company, who not once, but twice, received full FDA approval for this diagnostic device.

I would like to make the fact extremely clear—just for the purposes of the RECORD. The company's original application was submitted to the FDA on October 5, 1995 and was cleared by the FDA 119 days later, on February 1, 1996.

The company resubmitted their medical device under the 510(k) on September 23, 1996, with additional clinical data requested by the FDA. This resubmitted 510(k) was cleared by the FDA on December 20, 1996, 88 days later. The process works.

I cite for the RECORD here, Mr. President, what is on the label.

Indication: For diagnostic sampling of breast tissue where large diameter incisional breast biopsies are desired.

Contraindication: The device is used for diagnostic breast tissue biopsies; it is not [in bold letters] intended for therapeutic excision of tissues.

Now, I don't know what could be more clear than that. I ask unanimous consent this be printed in the RECORD.

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

ABBI biopsy device chronology

<i>Original 510(K)</i>	<i>Indication: Transection of tissue during a surgical biopsy procedure</i>
October 5, 1995 through February 1, 1996	Original 510(K) Premarket Notification submitted to FDA. Minor questions answered. FDA clears 510(K) and issues Substantial Equivalence letter. (119 days)
May 8, 1996 through June 6, 1996	FDA raises questions regarding the ABBI device. FDA states they made a mistake in clearing the original 510(K) without asking for clinical data. FDA states USSC has done nothing wrong; it was FDA who neglected to request data.
	FDA issues Warning Letter to USSC, 6/3/96, regarding labeling and advertising claims made for the ABBI.
	FDA meeting held, 6/6/97, with USSC, Dr. Barbara Schwartzberg and Dr. Bill Kelly to review data demonstrating the safe and efficacious use of the ABBI as a diagnostic biopsy device. USSC agreed to work with FDA to gather retrospective clinical data from ABBI users to address FDA safety and efficacy issues stemming from larger core needle design.
<i>510(K) Resubmission</i>	<i>Indication: For diagnostic sampling of breast tissue where large diameter incisional breast biopsies are desired</i> <i>Contraindication: The device is used for diagnostic breast tissue biopsies; it is NOT intended for therapeutic excision of tissues</i>

**ABBI biopsy device chronology—
Continued**

September 23, 1996	USSC resubmits 510(K) for ABBI including modified labeling, 39 clinical case reports and commitment to submit additional clinical case reports over the next several days. USSC submits additional clinical case reports to supplement the original 9/23/96 submission for a total of 312 ABBI clinical case reports. On 10/16/96 FDA requested that no more data be sent while they analyze what has been submitted. USSC responded to numerous FDA questions regarding clinical data and labeling.
December 20, 1996	FDA clears 510(K) resubmission and issues Substantial Equivalence letter. (88 days)
December 23, 1996	FDA rescinds original 510(K), dated October 5, 1995, so no other substantially equivalent device will have a basis for submission without corresponding clinical data.

Mr. DODD. This is the chronology of the events. This device is being used to try and improve biopsy and diagnostic purposes and reduce, hopefully, the need for unnecessary surgery—something most people applaud. And the label clearly limits the product to that purpose.

The Senator from Massachusetts suggests that this is somehow a rationale for us to reduce or change the language of this bill that deals with the approval process for less riskier medical devices. He cites a lot of examples that has nothing to do with this issue. Fen/phen has nothing to do with this amendment. The Dalkon shield has nothing to do with this amendment; that was a failure of technology that had nothing to do with the intended purpose of the device.

The examples cited, one after another, do not address the issue at hand. The issue at hand is how the FDA interprets intended use in making a substantial equivalence determination—the first test a lower risk device undergoes. That is what we are dealing with here.

If you have to say to a company that it must try and imagine what a device conceivably could be used for by some surgeon out there, and on that basis FDA can hold up its 510(k), you might as well scrap 510(k) and make every new device, even low-risk ones, go through the PMA process. You can make a case for that, I suppose. But I don't hear anyone advocating that. But if you really believe that we ought to so change this process, then get rid of 510(k) altogether—that is the safest way to go. But again, I don't hear anyone suggesting that.

All we are saying here is, the FDA ought to look at the intended purpose listed, and ought not try and go beyond that, particularly when they have full authority to apply the second test of reviewing technological differences. All we are trying to do here is to expedite

the process a bit so we do not delay further the ability of very worthwhile devices to get approved by the FDA and get to the marketplace.

I regret deeply that a very fine company with a tremendous track record that has produced some wonderful devices has been the subject of an attack here on the floor. It is not deserved. It is not deserved. They produce a very worthwhile product, the breast biopsy needle, that has been approved by the FDA and is making a difference in women's lives. There are thousands of examples of where this device and other products made by this company have made a difference in people's lives. This company, U.S. Surgical, has been manufacturing medical devices in Connecticut for over 30 years now and has an excellent track record for producing safe, effective, and innovative products. In addition to setting the gold standard for the laproscopic surgery devices, as I mentioned earlier, I should also note that U.S. Surgical pioneered the technique of closing wounds with staples, rather than sutures—a revolution in everyday medical practice. The thousands of Connecticut workers who help create these products, ought to be applauded by our colleagues rather than used as an irrelevant example, somehow, of some attempt to limit the protections that the FDA offers.

For those reasons, Mr. President, I urge our colleagues, with all due respect, to reject the Reed-Kennedy amendment and to support the provision we have included in this legislation which we feel not only adequately protects people, but does even more than that. It allows them to get the materials they need to see they have a healthier and safe life.

Mr. JEFFORDS. I yield 5 minutes to the Senator from Indiana.

The PRESIDING OFFICER. The Senator from Indiana.

Mr. COATS. Mr. President, again I want to tell Members I think it is important to keep their eye on the goal here and on the facts. Senator DODD went through part of the chronology of the approval of the device that Senator KENNEDY was talking about.

I say to my colleagues, the system is working the way it is supposed to work. FDA has the authority. The company submitted the application, FDA cleared the device, then questions came up about it, and the FDA responded and asked for some additional material, and then they acknowledge that, yes, we had the material, you sent it to us, but we didn't get a chance to review it. We have now reviewed it.

Mr. KENNEDY. Will the Senator yield?

Mr. COATS. I will be happy to in a moment.

They made a change in the "indication" and "contraindication" in accordance with what FDA asked them to do. They resubmitted for a new 510(k). FDA, with the help, apparently of Senator KENNEDY and his staff, ap-

proved the 510(k) and then the new 510(k) was applicable.

So that is exactly how FDA is supposed to work and it did work under the existing procedures.

Again, over and over and over, what has not been described and discussed is the authority that the FDA has regarding changes in technology that raised questions of safety and efficacy, effectiveness of the predicate device.

Mr. KENNEDY. Will the Senator yield?

Mr. COATS. Happy to yield for a question.

Mr. KENNEDY. If you would be willing just to maintain the current law, we could move very quickly toward final passage.

The Senator has just given an excellent explanation about how the FDA works at the present time. That procedure is being halted dramatically in this law. So if the Senator would support—

Mr. COATS. Reclaiming my time.

Mr. KENNEDY. I had yielded—

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

Mr. COATS. I think the Senator from Massachusetts knows exactly what it is we are attempting to do and why we are doing it. It is part of the two-part test. The second part, which the Senator admits on every example he uses and every example he uses does not apply to the situation as it exists. Dalkon shield has nothing to do with this; fen/phen, as the Senator knows, has nothing to do with this language. This whole thing was supposedly prompted by the fen/phen scare, and the Senator failed to admit that fen/phen is a drug and not a device.

Most of us are trying to keep some level of patience and some level of perspective on this whole process and procedure. I don't know of anybody at U.S. Surgical—they may have visited my staff. I have never talked to anybody that I know of from U.S. Surgical. I didn't even know they made that device. All I know is when they got in trouble they went to Senator KENNEDY, and the very device he is talking about that is so dangerous to women's health, he intervened, or at least participated in the process of clearing U.S. Surgical.

I had printed in the RECORD the letter citing specifically Senator KENNEDY's help and the help of Dr. David Nexon, Senator KENNEDY's staffer and Gerry Kavanaugh. There was no explanation of that minor omission in the Senator's presentation. I would be interested to hear what that might be.

So, the Senator criticizes the Senator from Connecticut for supporting this company and not being objective with the facts, when the Senator, who is raising the issue in the first place, has been the person to provide that support.

What we are attempting to do is to return to past law which sets in place a reasonable procedure whereby devices that are substantially equivalent under FDA's determination to devices

that have already gone through lengthy premarket approval processes, where those devices can be expedited into the system because there is no difference and the question is on the label what the intended use is, not on what somebody tries to make the intended use to be. It would be impossible for anybody, any company, anybody to possibly speculate and list all the ways in which people might think up of using devices. The company produces it for a specific purpose, it provides an indicator for a specific purpose, and a contraindicator for how it is not to be used, and if there is in any way a technological change in that device, then FDA has full and complete authority to deny the substantial equivalency label.

Let's keep our eyes focused on what we are attempting to do here and not be confused by egregious examples that don't even fit the issue, that don't even go to the core of what we are debating. It makes for good theater. It makes for lousy legislation.

Mr. JEFFORDS. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll. The bill clerk proceeded to call the roll.

Mr. 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.

UNANIMOUS-CONSENT AGREEMENT

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the Senate stand in recess until 2:15 p.m., and when the Senate reconvenes, there be only the following time remaining, limited in the following fashion: 20 minutes under the control of Senator KENNEDY, 20 minutes under the control of Senator JEFFORDS, 10 minutes under the control of Senator HARKIN, and 10 minutes under the control of Senator FRIST.

The PRESIDING OFFICER. Is there objection?

Mr. HARKIN. Mr. President, reserving the right to object. I ask the manager of the bill, would the 10 minutes under my control occur prior to the vote on the Reed-Kennedy amendment or after the vote?

Mr. JEFFORDS. After the vote.

Mr. HARKIN. I appreciate that. I have no objection.

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

RECESS

Mr. JEFFORDS. Mr. President, I ask that the Senate now stand in recess under the order.

Thereupon, the Senate, at 12:53 p.m., recessed; whereupon, the Senate, at 2:15 p.m., reassembled when called to order by the Presiding Officer (Mr. COATS).

Mr. JEFFORDS addressed the Chair. The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. JEFFORDS. I yield 2 minutes to the Senator from Iowa.

The PRESIDING OFFICER. The Senator from Iowa is recognized to speak for 2 minutes.

LANDMARK HEARINGS

Mr. GRASSLEY. Mr. President, today was a landmark day for the American people in hearings before two Senate committee on which I serve.

As chairman of the Special Committee on Aging and the request of my colleague, Senator SHELBY, I assembled several panels to raise the awareness of the second-leading cause of cancer death for men: prostate cancer.

In the Finance Committee, we opened up 3 days of unprecedented oversight hearings into systemic abuses of power by the Internal Revenue Service.

The telephones were ringing off the hook in my office as these hearings were underway. That's how much these issues struck a chord with the American people.

And suddenly, the hearings were canceled. Why? Was it a national emergency? The death of a colleague? An international crisis? Hardly.

Instead, the Democratic leadership used the Senate rules to shut down the public's business.

They shut down important policy debates on prostate cancer and IRS abuses. And that's only in the two committees I was involved with. Other committees were affected.

What's apparently more important to the Democratic leadership than these issues is a partisan political issue in Louisiana. It's an issue involving campaign irregularities in a campaign in Louisiana involving one of our colleagues.

Certainly, this is an important issue, although political. But is it important enough to systematically close down the public's business?

The hearing before the Committee on Aging this morning was called at the urging of Senator SHELBY. He is a prostate cancer survivor. The hearing was designed literally to help save lives.

This year alone 335,000 American men will be diagnosed with prostate cancer. The ranking member of the Committee on Aging—Senator BREAU—and I worked to put together a healthy policy debate about treatment options.

This productive debate, a debate that could help save lives, was cut short this morning because of politically motivated maneuvering through Senate rules. We were therefore unable to engage in a full debate about when to screen and how to treat prostate cancer.

Among the 10 witnesses scheduled to testify this morning was the distinguished former Senate majority leader Bob Dole. I'm happy we were able to hear his statement before the shutdown.

Senator Dole's testimony this morning was his first official event on Capitol Hill since he left the Senate in June 1996.

No better way, in my view, to get the message out.

Today, I think this legislative body would be well-served to remember the productive, bi-partisan leadership of Senator Dole. The people's business was always Bob Dole's first concern as he presided over the work of the Senate for many years.

The second very important effort stopped by this maneuvering today was landmark hearings of the Finance Committee to expose the excesses and abuses of the American taxpayer at the hands of the Internal Revenue Service.

The fair-minded and very capable chairman, Senator ROTH, spent 8 months preparing these hearings to talk about the specific problems and to consider specific solutions on how the IRS can be restructured to work for taxpayers, not against them and at the expense of the civil liberties of individual Americans.

All of this was disrupted by the Democratic leadership who put petty politics ahead of the public's health. I'm very disappointed. And I wouldn't be surprised to learn of the public's disappointment as well.

The Democratic leadership needs to explain to the American people why partisan politics seems more important than No. 1: raising the awareness of the second-leading cause of cancer death for men, prostate cancer. No. 2: exposing abuse and mistreatment of hard-working taxpayers at the hands of the IRS.

If you don't like the investigation into campaign irregularities in Louisiana, fine. But should the priorities of the American people be shoved aside for the partisan concerns of a political party? I don't think so.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. JEFFORDS. I yield 2 minutes to the Senator from Iowa.

The PRESIDING OFFICER. The Senator from Iowa is recognized to speak for 2 minutes. copy

ORDER OF PROCEDURE

Mr. JEFFORDS. Mr. President, I yield the Senator from New Hampshire 5 minutes.

The PRESIDING OFFICER. The Senator from New Hampshire.

Mr. GREGG. Mr. President, I appreciate the Senator yielding. I wanted to speak on another item.

Mr. JEFFORDS. We have a very limited debate time.

Mr. GREGG. Can I ask unanimous consent that I be allowed to proceed for 5 minutes under morning business?

The PRESIDING OFFICER. Is there objection?

Mr. KENNEDY. Reserving the right, I apologize to the manager. Could I hear that request again?

Mr. GREGG. The request was to proceed for 5 minutes as if in morning business.

Mr. KENNEDY. I have no objection.

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

The Senator from New Hampshire is recognized to speak as if in morning business for up to 5 minutes.

U.N. ARREARAGES

Mr. GREGG. Mr. President, I understand we are in the middle of debate on FDA which has been going on for some days. I did want to talk briefly about the President's comments in New York yesterday relative to the United Nations.

The President went to the U.N. General Assembly and made a very eloquent speech, as he often does, in which he promised that he would be paying what is represented to be the arrears of the people of the United States that we owe to the United Nations, arrears which is somewhere around \$1 billion. I think that was generous of the President to do that. But he should have made it much clearer what the conditions are for our paying those arrears.

As chairman of the committee that has the authority over the spending of the money relative to the U.N. accounts, I have been working with Senator HELMS and Senator GRAMS, along with the administration and with House Members, and we have developed a package which makes that payment to the United Nations conditioned. Unfortunately, the way the President expressed it, the conditions were mentioned only in passing, and hardly even mentioned at that. But the conditions are critical.

The American people simply are not going to send another \$1 billion to the United Nations unless the United Nations cleans up its act—unless they reduce the patronage; unless they put in place accounting procedures that are trackable—so that we when we send \$1 there we know where it goes.

Today the American citizens pay 25 cents of every \$1 spent at the United Nations and the United Nations has no idea where that money is spent. Not only do they have no idea where most of that money is spent—they may have an idea but they certainly don't know specifically where it goes—but, more importantly than that, they don't have any systems in place to assess whether or not the money is getting anything for the dollars that are being spent.

What we are seeing is an institution which is rampant with mismanagement and inefficiencies. Regrettably, the President didn't point that out. He had an excellent opportunity to stand before that body and say, "Listen, if you expect the American taxpayers to pay for a quarter of the cost of this institution then the American taxpayers expect adequate accounting. And the American taxpayers expect that it will be spent on programs that work. And the American taxpayers do not want to have their money spent on patronage. And they don't want to have it mismanaged, and do not want to have it inefficiently used."

The new Secretary General of the United Nations has given a significant

number of talks on this topic. He has pushed forward an agenda for reform. But his agenda for reform doesn't go as far as the agreed to package, which passed out of this Senate with an overwhelming vote.

The simple fact is that I have come to the floor today to restate the obvious, which is that we are not going to send \$1 billion to the United Nations until the conditions of that package are met, until we know that the dollars are being spent effectively, and until we know that there is in place a reform effort which is going to work.

I regret that the President did not take the opportunity to express that thought to the membership of the United Nations. But I think the point should be clarified before the people who are expecting to get their billion dollars think they have a blank check, because they don't. We are not going to tolerate it.

I yield the time.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The Senate continued with the consideration of the bill.

AMENDMENT NO. 1177

The PRESIDING OFFICER. Who yields time?

Mr. KENNEDY. Mr. President, I understand we have 20 minutes to each side.

The PRESIDING OFFICER. The Senator from Massachusetts has 19 minutes remaining.

Mr. KENNEDY. I yield 10 minutes to Senator REED. I will take 9 minutes.

Mr. REED. I thank the Senator. Thank you, Mr. President.

Mr. President, we debated this morning the Reed amendment, which would give the Food and Drug Administration the authority to look behind the labeled use in evaluating a class 1 or class 2 medical device before that device would be sold on the marketplace. My amendment is very simple. It would allow the FDA, if they felt the label was misleading or false, to ask for additional information with respect to possible uses other than the labeled use. This is consistent with their current practice. And it would protect the public health dramatically.

I urge all of my colleagues to support this amendment.

I heard opposition on the floor this morning to the amendment—first, not so much opposition but an attempt to diminish the importance of this amendment by saying, "Well, class 1 and 2 devices are just simple little medical devices. They are low-risk medical devices." I don't know about you. But, like many Americans, I think the definition of a low-risk medical device is a device that is being put into someone else's body, not my own. Because, if there is any type of device that is coming into a person's body, they expect and anticipate that the FDA would thoroughly review it, ask

all the questions, and look at all the possible uses that are reasonably discernible from the device itself.

The other objection which has been made to the amendment is that it is unnecessary because the FDA can step in and ask for this type of information. But, in fact, that is not the case.

As some have explained here today, there is a two-prong test to get 501(k) approval under current. First, the device must be substantially equivalent to another device already on the market, and this device performs essentially the same task that the other device does. If there are technological differences in the device, then the FDA can make an evaluation of this technology to determine its effectiveness.

But all of these different tests collapse into one point. The question is, what is the device being used for?

That is where the current language in the bill is so restrictive of FDA responsibility and the obligation we expect them to discharge. Because, according to the language in the bill, the FDA and the Secretary of HHS reviewing any of these proposals could only do so with respect to the intended use of the device based on the intended use included in the proposed labeling of the device.

You have to evaluate these devices for safety and health, and efficacy based upon some use. And if the FDA is restricted solely to the use indicated on the label, then they will not be able to look behind the label to other possible uses—look beyond the label to other possible ways—in which the device could be used and ask for supporting data to justify those uses.

We have seen and heard examples today on the floor with respect to biopsy needles, with respect to lasers, with respect to a host of very important medical devices. The American public I hope would demand that these devices be evaluated thoroughly for all reasonable uses—not only the use that a manufacturer would suggest as a way to take advantage of this expedited procedure for review and entry into the marketplace.

One does not have to repute ill will or bad motives to the manufacturers of these devices. Simply stated, they have a tremendous incentive to get these items into the marketplace. Once they are in the marketplace, there are different uses that could be promoted.

Also, in terms of marketing, there are scores of salesmen and women who are zealous in trying to promote these goods. They might not be as scrupulous with respect to these uses as intended by the manufacturer.

All of these factored together suggest strongly that if we do not initially have a good approval process which allows the Food and Drug Administration to look behind the label, to look at likely uses other than the ones presented by the company, we could run the risk of introducing medical devices into the marketplace that would be harmful to the American public.

We have made great progress on this legislation. We have done so because we all feel sincerely that our chief responsibility is to protect the public health. My amendment would do so.

My amendment would give the FDA the authority to request additional safety information in the rare circumstances in which they have suspicions that the labeled use is either false or misleading. The FDA could look behind that label and require additional data before they would release a device onto the marketplace.

I hope that we all support this concept. I hope we can all rally around the principle that when in doubt, and when confused about the different interpretations of various sections, that we will ultimately allow the FDA to use its judgment and its discretion to protect the public health of the American people.

I yield our time.

The PRESIDING OFFICER. Who yields time?

Mr. JEFFORDS. Mr. President, I yield to the Senator from Tennessee 10 minutes.

The PRESIDING OFFICER. The Senator from Tennessee is recognized for 10 minutes.

Mr. FRIST. Mr. President, thank you.

Mr. President, the issue that we are facing in the next several minutes on which my colleagues will be voting appears very simple on the surface. Why would anybody oppose an amendment that really strikes at the heart of what so much of the FDA is about—that is, a medical label that is maybe false or misleading?

So, on the surface it seems simple. But it really is not. The larger bill, the underlying bill, is about strengthening the FDA, and making sure that we fulfill that mission to the American people of having products, drugs, and devices that improve health and not huge barriers that push over the great new technological advancements that we see—push them off into the future so that we cannot benefit from the technology that is out there today.

The amendment is unnecessary. The amendment we are going to be voting on right now is unnecessary, and a little bit worrisome because if it were to pass, there is a possibility that we hurt the system. In other words, we disallow improved devices which can benefit heart disease or lung disease, we put up barriers and push them off into the future. So if the amendment passes, it may be harmful. It clearly is unnecessary today.

The bottom line is this. The Food and Drug Administration is required to deny premarket approval for a device if the proposed label is false or misleading—current law—and that is why it is unnecessary.

To really understand the overall process, we talk about 510(k) and PMA, premarket approval. It is really pretty simple. You have a device today that goes through the FDA system that has

all sorts of standards that have to be met in terms of safety, efficacy, and false and misleading labels. That device goes through that process, what is called the PMA, premarket approval of the device. Then with technology and science new devices, better devices are developed; for example, a stint in the heart after a heart attack. Over time you improve the stint. That is the great thing about science today. That improved device may be almost exactly like the earlier version of that device. The FDA has to make a decision. Does it go through a process which says they are so similar that there is no reason to make it go through all the other standards or is it different enough it has to go through all the initial requirements and jump through the hoops and standards, and the FDA has to make that decision. Premarket approval initially, an improvement on that device or a new device, is it similar enough. Now, the words are used, is it substantially equivalent to the initial device itself. FDA has to make that decision.

What we really have not talked very much about is how they make that decision. It is written in the current law. We do not do anything about current law today, whether or not this new version is “substantially equivalent.” Those are the words.

What is the requirement? What is the current law? They are substantially equivalent if, No. 1, the new device has the same intended use as the earlier device and—and it has the same technological characteristics as the predicate device.

Now, that is a pretty good standard because the idea is, if you get a little stint that you put in the heart and it is improved, it works better, same principles, technologically equivalent, same intended use, then you go through this process of the 510(k).

Now, the amendment we are going to be voting on says we have to put it back again through the false or misleading label requirement. Remember, this improved device going through this process has already met the criteria of false and misleading labeling when it was in the PMA, the initial approval. That is very important to understand because we all are against anything in terms of labeling that is false or misleading. It is very important to understand the process.

So what we are debating right now is not whether a label is false or misleading but whether the FDA will have the ability to compel a manufacturer to produce clinical data to prove safety and efficacy for uses that are not included on the label. This brings me to the worrisome part of this amendment. Again, I am very comfortable that the FDA has standards today to make sure that the labeling is honest, is truthful. The worrisome thing is about just what if the FDA came in and said that this device, which is medically equivalent to an earlier device, technologically improved but the equivalent device,

what if the FDA says, “No, let’s make people go back and jump through all the initial hoops once again.”

We already know for a device that we are not meeting device approval or disapproval over the time required in statutes. Already it takes months and years to go through the approval process. So with every improvement, when it is substantially equivalent to the earlier device, if we take all those improvements, make them meet all these new criteria again, what are we going to do? We are going to push off the great advancements today to save lives, to improve the quality of life to some time in the future where we and maybe even our children cannot benefit from that device.

Now, a key question that I think we all have is, if a device is determined by the FDA to be safe and effective for the labeled use, should the FDA—for the labeled use that has been approved—should the FDA be able to force a manufacturer to produce a clinical device that is safe and effective for other uses, other uses. Remember, it is approved for what is on the label. I would answer no. We do not do that for pharmaceuticals today. We do not do it for drugs today. Should we do it for devices? I say no.

My real fear is that when the FDA reaches outside of the proposed labeling, it is going to require a very subjective decision in determining what goes through those initial PMA, premarket criteria.

Finally, let me also step back and look at the enforcement procedures that the FDA already has. My colleagues make it sound as if the FDA is unable to protect the public health by keeping unsafe products off the market. In fact, the FDA today has the enforcement authority which allows the agency to remove devices that endanger public health from use and availability immediately, even if the device is on the market and the manufacturer’s intended use for a device changes over time.

Any device which the FDA has, and I quote, “a reason to believe is misbranded or adulterated in any way” can be detained today under law. FDA has a long list of remedies to protect consumers against persons who violate device laws including criminal prosecution, injunctions, civil seizures, and civil penalties.

Claims were made earlier by some of my colleagues that manufacturers will market and advertise for uses other than those approved by the FDA. That is illegal today.

Under the proposed bill—not the amendment, the underlying proposed bill—it is illegal. Again, let me say claims have been made over the course of the morning by some of my colleagues that manufacturers will market and advertise for uses other than those approved by the FDA. That is illegal. The Reed amendment does not change the fact that manufacturers cannot do this today, and it does not

change the fact that the FDA has enforcement authority today.

With that, I urge my colleagues to oppose the amendment. Again, I think it is unnecessary and worrisome in the sense that it would raise the barriers sufficiently in an unnecessary way for approval of devices that are substantially equivalent to devices that already have jumped through the hoops. I yield the floor.

The PRESIDING OFFICER. Who yields time? The Chair informs the Senator from Vermont there are 8 minutes 32 seconds remaining under his control and the Senator from Massachusetts has 12 minutes remaining under his control.

Mr. JEFFORDS. Mr. President, I yield 2 minutes to the Senator from Indiana.

The PRESIDING OFFICER (Mr. FRIST). The Senator from Indiana.

Mr. COATS. Mr. President, I am going to repeat points that have already been made, because I think it is essential to the understanding of what we are about here just before we are ready to vote.

Section 404, the section under debate, preserves a very key premarket statutory authority to the agency. It is important for Members to understand that the agency can call, still call for a premarket action requiring full data on the safety and effectiveness whenever there is a technological difference arising, and I quote from the statute, "that raises different questions of safety and effectiveness in the earlier approved device."

This authority is premarket. In other words, the product is never cleared for marketing. It is never distributed before the agency has an opportunity to act.

The authority is extremely broad. As soon as a product raises a question about safety and effectiveness, the agency can require the filing of a premarket authority, PMA. The agency retains full discretion to control the showing of safety and effectiveness. There are no words of limitation on that statutory authority. I point out that that authority has never been challenged successfully by a company in court.

It was Senator KENNEDY's own committee, as chairman of the committee, his own committee report on safe medical devices in the 1990 Device Act that confirmed the breadth of this authority, and I quote from that report.

However, notwithstanding data that may demonstrate comparable performance, the agency will not find the device substantially equivalent to a predicate device where the newer device raises different safety and effectiveness considerations than the predicate device. Under these circumstances, a finding of not substantially equivalent is made, necessitating a class 3 designation and the requirement of an approved PMA before the new device is marketed.

This is the language that was—

Mr. REED. Will the Senator yield?

Mr. COATS. Incorporated in the 1990 Medical Device Act, demonstrating in

the Senator's own committee report the breadth and scope of this particular authority.

The PRESIDING OFFICER. The Senator's 2 minutes have expired.

Mr. REED. Will the Senator yield?

Mr. COATS. My time has expired.

Mr. REED. Will the Senator yield?

Mr. KENNEDY. Two minutes.

Mr. REED. I concur with the Senator's notion that the FDA could look at safety and effectiveness but the critical question is safety and effectiveness to do what? To do what the labeled use is or to do something else. And the language of the bill restricts the answer to that question, to do what, statutorily to simply say whatever the company puts into the label. And that seems to be the crux of this debate. Yes, they can look at safety and effectiveness; yes, they can look at technological change, but only in the context of what the company purports in the label to say is the intended use. They can't look beyond it.

I yield back to the Senator from Massachusetts.

The PRESIDING OFFICER (Mr. COATS). Who yields time?

The Senator from Massachusetts.

Mr. KENNEDY. How much time, Mr. President?

The PRESIDING OFFICER. The Senator has 11 minutes 15 seconds.

Mr. KENNEDY. I yield myself 8 minutes.

Mr. President, my good friend from Rhode Island has put his finger on exactly the problem and the issue. Now, I listened to our friend, Senator FRIST, who believes that the FDA doesn't really have a problem if the information is going to be false and misleading, that the FDA has the authority to look behind the label itself and find out if that information is false and misleading.

If that is the case, we do not have a problem. We can accept an amendment that would restate what he has just said, or we can drop this whole provision.

It is interesting to listen to those who are opposed to the Reed amendment say, well, look, the FDA can do this and that and protect the public, while at the same time they are emasculating the very safety valve with this new provision—restricting the FDA in its ability to judge on the issues of substantial equivalence.

Now, Mr. President, before we move to the vote, I want to reiterate where we are so that those who have been listening to the debate for these last few minutes understand where we are.

We are talking about the preeminent issue identified by the administration's principal spokesperson charged with protecting American health. This has been identified as the one provision in the whole legislation that is of central concern to the public health of the American people. They mentioned the issues of cosmetics; they mentioned the fact that this eliminates environmental impact statements; they men-

tioned technical issues dealing with PDUFA; but there was only one public health issue that the Secretary of HHS has recognized, and it is this particular provision which Senator REED has tried to address.

It is of such importance that the Secretary of HHS indicated that if that provision remains unchanged, she would recommend that the President not sign the legislation. And it is not just the Senators from Rhode Island and Massachusetts who are concerned about this provision. Every single consumer group is concerned about it as well. All of the groups that speak for patient rights, all of the groups that are concerned about women's health issues, all of the various consumer groups—I have listed them before—all of them say that we ought to support the Reed amendment, if we are truly interested in protecting the American consumer. We have, over the last few days, talked about why this is so important.

Those who are opposed to this amendment keep repeating their assertions that the FDA has the authority to protect the public. That is hogwash. They may believe it. I have yet to see a Member of the Senate who is opposed to our amendment take out this legislation and thumb through it and point to the specific language that states the FDA will have authority to protect the public if this amendment is not carried by the Senate of the United States. They have not done it because they cannot do it. They cannot point to a provision in here that says, "OK, if we defeat the Reed amendment, FDA will still have the authority." They have these assertions on the floor of the U.S. Senate. But they have not pointed to specific language in this legislation, and that is what counts. They cannot point to it because it is not there.

We are talking, as the Senator from Rhode Island has pointed out, about medical devices submitted to the FDA for approval, which a company would say is "substantially equivalent" to an existing device. But which, in reality, is a device which has significant technological changes in its design and in fact, is designed for another use. However, when the new device is submitted for approval, the label will still maintain that the device will be used for the same purposes as the original device. That is what is happening. That is the danger and that is what the Reed amendment is attempting to prevent.

We have discussed the example of this that is currently unfolding. The biopsy needle that was supposed to be substantially equivalent to a biopsy needle the size of your pencil lead but which actually removes an amount of material the size of a hot dog. This device is used to take the place of surgery for women, but it is untested and untried for that purpose. We don't know if it's safe. The company hasn't submitted evidence as to whether it is

safe. But we know that this device developed by U.S. Surgical was not designed for the narrow biopsy; it was designed for another purpose. It takes out 50 times the amount of material necessary for a biopsy.

We know what it was designed for, we have the promotion tape. We have the statements from doctors saying they were being solicited to use it for surgery, not biopsy.

You can claim that these are low-risk devices. You can claim that is really just a technical issue, that its not important. But we know that is not the case. We are talking about anesthesia machines which are used for major surgeries. We want those to be able to perform the way they should and to meet safety and efficacy standards. We are talking about fetal cardiac monitors. We want to make sure that children who need that kind of monitoring have a device that will be safe and do the job. What mother wants to discover that her child is using a fetal cardiac monitoring system that has been approved for some other use and here the hospital or clinic is using it for a different purpose without knowing that it is safe and effective for that use?

The list goes on. We have had the situation where surgical lasers are being submitted as general cutting tools when it is clear that the intention is to use them for surgeries for prostate cancer and no information about how safe or effective they are for that purpose has been submitted to the FDA. Why are we risking the health of the American people over this issue? What is the benefit?

I have cited examples where we have been called on in this body to make decisions about whether we are going to use a limited amount of money to feed the elderly people—how much will we use in congregate sites? How much will we use for home delivery? If you use more in home delivery, you will be able to feed fewer people. It's a painful issue, and whatever we do some are going to benefit, some are going to lose. We can understand men and women of good judgment differing on that issue.

But not on this issue. What is the balance? The balance is that the protections of American consumers are weakened in the area of medical devices—significantly weakened for the first time in 25 years. And the profits of the medical device industry go up. And they have a competitive advantage over the other companies who do the right thing and conduct the tests to provide health and safety information on their devices.

Why are we doing that? What is the rush? Why aren't we hearing from the other side that, "We have 10 consumers' groups that believe we can get the information much more rapidly and their health needs will be advanced and we don't need the Reed amendment." Where are those statements, why haven't we heard them. Because they are not there.

We have to decide whether we are going to retain, for the Food and Drug Administration, the ability to deal with labeling. The ability to look beyond the label when they find it to be false and misleading. That is a pretty high standard. FDA has to find it false and misleading. Only then can they look to safety. Some of us wish it was a lower standard, but that is the standard we have here, false and misleading.

We have given examples, ads have been used to promote medical devices for other purposes. That is happening now. We have also spelled out the human tragedies that occurred when medical devices malfunctioned, when we did not have all the necessary information to assess safety.

Are we going to deny the principal health agency charged with protecting the American public, the authority to ask for more data if they find that the label on a medical device is false and misleading. Are we going to say your hands are cuffed?

The PRESIDING OFFICER. The additional 2 minutes of the Senator have expired.

Mr. KENNEDY. How much time do we have?

The PRESIDING OFFICER. The Senator has 1 minute remaining.

Mr. KENNEDY. I yield that to myself.

Are we going to tie their hands, tell them that they cannot do a thing? Are we going to tell them that we understand that they have done the scientific review? We understand that the label is false and misleading, but you are not allowed to protect the consumers or the American public from it."

I think that is the wrong position for this body to take, and I hope the amendment is accepted for the reasons I have outlined and for the splendid reasons outlined by the Senator from Rhode Island. I withhold the remainder of my time.

Mr. JEFFORDS. I yield to the Senator from Connecticut 2 minutes.

Mr. DODD. Mr. President, let me say briefly to my colleagues that what I believe is false and misleading is to suggest what we are trying to do in any way is something injurious to the American consumer. What we are doing is saying that we shouldn't create roadblocks in a process that has been in place for more than 20 years and that has worked well for lower risk devices. To prove a device is substantially equivalent to a product that has already been in the marketplace there are tests which must be complied with, but you don't force the product to prove itself all over again. That negates the process that was set up to be quicker and more efficient and makes patients wait too long to get access to devices which can change their lives, even save their lives.

If you want to scrap the process altogether and require that every new variation of the predicate product begin this process all over, then let's do that. I don't hear anyone calling for that.

What the law says is that if it's substantially the same product and if the intended purpose as stated is the same, you don't ask the company to try to guess how someone may use that product for some purpose that the company has not supported. To suggest that a company is going to have to guess as to what other ideas someone may have for the use of that product, and develop data to support those uses—that would make this process null and void. We might as well scrap the entire section and 25 years of effort here.

The purpose of this bill is to take advantage of new technologies, to see to it we have safe and effective products that are going to reach consumers. To allow an agency to cause a company to have to guess and guess again as to what some other intended purpose would be, I think would be a mistake.

So I urge, with all due respect, this amendment be rejected and the committee bill be supported.

The PRESIDING OFFICER (Mr. KEMPTHORNE). The time of the Senator has expired. Who yields time? The Senator from Vermont.

Mr. JEFFORDS. Mr. President, as we close debate on this issue, I want to say if I listened to this and didn't understand the law and the protections in it, I would go home and be depressed that I was backing such legislation. However, knowing the law and knowing the process, I still come away totally opposed to this amendment.

First of all, let's take a look. We have had about 36,000 devices approved over the past 6 years. Out of that, there would have been six recalls. So this is not an issue that is something which has proved to be a failure in the law.

Second, what we are dealing with here is the definition of false and misleading. Actually, the regulations cover the important aspects of it. But false and misleading means if you knew or should have known. They want to get into the practice of medicine. They want to say if this person has this device, and it is the same as the device with the premarket approval, they should be looking around and deciding and finding out all the possible and conceivable uses out there, and then they could be required to run clinical trials on all these.

The purpose of the 510(k) process is to allow something that is identically the same, having gone through all this, not to have to go through it again. This would send fear through the device industry because it may know it is impossible to get anything improved again without expending thousands and thousands of dollars and waiting 2 or 3 years. That is totally unnecessary. The law fully protects the consumer now. This is totally unnecessary and will increase the cost to consumers and decrease the availability of devices to them in a timely manner. That is why I am opposed to it.

It has been greatly overexaggerated as to what kind of problem is created here.

Mr. President, I move to table the amendment.

The PRESIDING OFFICER. The time of the Senator from Massachusetts has not yet expired. If the Senator will withhold his motion? I recognize the Senator from Massachusetts.

Mr. KENNEDY. Mr. President, as I understand I have 30 seconds?

The PRESIDING OFFICER. That is correct.

Mr. KENNEDY. Mr. President, I list those who support the Reed amendment: The administration, the President, Patients' Coalition, Consumer Federation of America, National Women's Health Network, American Public Health Association, National Organization for Rare Disorders, the Consumers Union, and the Center for Women's Policy Studies. I believe my time is expired. I ask for the yeas and nays.

Mr. JEFFORDS. Mr. President, I move to table the amendment. Mr. President, I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. The question is on agreeing to the motion to table the amendment of the Senator from Rhode Island.

The yeas and nays have been ordered.

The clerk will call the roll.

The bill clerk called the roll.

The result was announced, yeas 65, nays 35, as follows:

[Rollcall Vote No. 254 Leg.]

YEAS—65

Abraham	Frist	McConnell
Allard	Gorton	Mikulski
Ashcroft	Gramm	Murkowski
Bennett	Grams	Murray
Bond	Grassley	Nickles
Breaux	Gregg	Roberts
Brownback	Hagel	Roth
Burns	Hatch	Santorum
Campbell	Helms	Sessions
Chafee	Hollings	Shelby
Coats	Hutchinson	Smith (NH)
Cochran	Hutchison	Smith (OR)
Collins	Inhofe	Snowe
Coverdell	Jeffords	Specter
Craig	Kempthorne	Stevens
D'Amato	Kyl	Thomas
DeWine	Landrieu	Thompson
Dodd	Lieberman	Thurmond
Domenici	Lott	Warner
Enzi	Lugar	Wellstone
Faircloth	Mack	Wyden
Ford	McCaain	

NAYS—35

Akaka	Durbin	Lautenberg
Baucus	Feingold	Leahy
Biden	Feinstein	Levin
Bingaman	Glenn	Moseley-Braun
Boxer	Graham	Moynihan
Bryan	Harkin	Reed
Bumpers	Inouye	Reid
Byrd	Johnson	Robb
Cleland	Kennedy	Rockefeller
Conrad	Kerrey	Sarbanes
Daschle	Kerry	Torricelli
Dorgan	Kohl	

The motion to lay on the table the amendment (No. 1177) was agreed to.

UNANIMOUS-CONSENT AGREEMENT

Mr. JEFFORDS. Mr. President, I have a unanimous-consent request which I will offer.

I ask unanimous consent that immediately following the cloture vote with respect to S. 830, if invoked, there be

only the following time remaining in the following fashion: 4 hours equally divided between the chairman and the ranking minority member or their designee for use during today's session only; 4 hours equally divided between the chairman and the ranking minority member or their designee for use during the session of the Senate on Wednesday, September 24, beginning at noon.

I further ask, notwithstanding rule XXII, that following the conclusion or yielding back of time, the Senate proceed to vote on S. 830, as amended, without further action or debate.

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

AMENDMENT NO. 1137

The PRESIDING OFFICER. Under the previous agreement, we now have 20 minutes equally divided on the Harkin amendment numbered 1137, 10 minutes under the control of the Senator from Iowa and 10 minutes under the control of the Senator from Tennessee. The Senator from Iowa is recognized.

Mr. HARKIN. I yield myself 5 minutes.

Mr. President, there are many positive provisions in this bill that I am pleased to support. However, I am disappointed that an essential element has not been included in this bill. A major goal of FDA reform is to ensure that the public has access to medical innovations without compromising public safety. But the multimillion-dollar cost of obtaining FDA approval often excludes from the review process all medical therapies not promoted by major corporations, those that are non-patentable or low cost.

Very few sponsors of alternative medicines and treatments have the resources to go through this process. Unfortunately, this means that millions of Americans are denied access to important alternative medicines and treatments every day. In committee, I proposed and withdraw an amendment that would improve the access to medical care. It was called the Access to Medical Treatment Act. It was introduced this spring by Senator DASCHLE, cosponsored by the majority leader, Senator LOTT, Senators HATCH, INOUE, myself, and many others. It would allow greater freedom of choice and increased access in the realm of alternative medical treatments, while preventing abuses of unscrupulous practitioners.

However, it appears that we may not be ready to move on this important consumer reform. Mr. President, while we may not be ready for this, we cannot delay in moving to assure and improve and expand rigorous scientific review of alternative and complementary therapies. That is the purpose of my amendment.

Mr. President, increasingly Americans are turning to alternative medicine. A study done by Harvard University showed, in 1990, American consumers spent over \$14 billion on these practices. In that year, there were over

425 million visits to alternative practitioners, more than visits to conventional practitioners.

In light of that, in 1992, the Congress passed a bill setting up the Office of Alternative Medicine at the National Institutes of Health. We now have 4½ years' experience with that office operating. It has done some good things, but it has been severely hampered by the fact that it must go through the entire process at NIH, through the institutes at NIH, for its peer review and for its grant-making authority.

The amendment I have before the Senate now would simply change the status of the Office of Alternative Medicine from an office under the Director to a center for complementary and alternative medicine. It would not be an institute but a center. As such, that center could set up a peer review process and make its own grants.

Now, why is that important? Mr. President, every year since we established the office, we put in the legislation that the office's responsibility was to investigate and validate treatments, practices and medicines. That has been in there every year—to investigate and validate—because what we want is scientific analysis done of these treatments. Now, I have always heard, "There are a lot of quacks out there practicing alternative medicine." While that may be true, there are a lot of good people out there doing good things with alternative medicine. We need the review and the science to let us know what is good and what is working.

I asked the Director of NIH a few months ago, who was in my office, how many treatments, or practices, or medicines they had investigated and validated since 1992. I was met with a deafening silence. The answer is, none. Yet, next year we are putting \$13 million into the Office of Alternative Medicine. One might rightly ask, where is it going? What is happening?

So the purpose of my amendment was to set up a center to elevate its status so that that center could do its own peer review and have its own grant-making authority. That way, we can cut through and save a lot of money and save a lot of time, without in any way compromising rigorous scientific review. That is what this amendment does. It also incorporates within that center the Office of Dietary Supplements, which was also set up at NIH, to bring the two of them together in a new center which would provide more independence, assure economies of scale and efficiencies without in any way denigrating good scientific research. That is the purpose of the amendment.

Now, I understand that the Senator from Tennessee is going to raise a point of order that this amendment is not germane. Under the rules of cloture, I admit that it is not germane. That doesn't mean it is not important. It is very important. It is critically important. It should be passed.

Mr. President, I understand my 5 minutes are up. I yield 2 minutes to one of my chief cosponsors, the Senator from Maryland.

The PRESIDING OFFICER. The Senator from Maryland is recognized.

Ms. MIKULSKI. Mr. President, I rise to cosponsor Senator HARKIN's amendment to establish the Center of Alternative Medicine. I helped him establish the Office of Alternative Medicine in 1993 at NIH. Why did I do that? One, because I want everyone who is sick in the United States of America to have access to all possible means of treatment that are safe and have efficacy. At the same time, I wanted to prevent quackery. I also was aware of the Harvard study by a Dr. Eisenberg that said one out of three Americans was using alternative or complementary medicine, but we were not aware of scientific investigation to establish its efficacy or its safety. Yet, many of us have enjoyed those practices.

Some years ago, I had some very severe illnesses. Western medicine was of limited utility for me and I turned to acupuncture. Acupuncture helped me get well and has helped me stay well. I am pleased about that. But there are many other modalities out there being utilized by the American consumer. I want to make sure they are safe. I want to make sure they have efficacy. I want NIH to investigate it, and then I want them to validate it. I believe there is merit in this.

I am puzzled why NIH wants to continually try to submerge this Office of Alternative or Complementary Medicine. The hallmark of NIH is to have an open mind and to pursue scientific investigation. I believe Senator HARKIN is on the right track. Though this amendment might not be germane, it is certainly relevant to the American people. If we don't find a way to move it on this bill, let's explore other ways.

I yield back such time as I might have.

The PRESIDING OFFICER. Who yields time?

Mr. JEFFORDS. I have a unanimous-consent request, Mr. President.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

UNANIMOUS-CONSENT AGREEMENT

Mr. JEFFORDS. Mr. President, I ask unanimous consent that following debate and disposition of the Harkin amendment, Senator MURRAY be recognized for 5 minutes to offer her amendment No. 1161, and that following her remarks, her amendment be agreed to.

I further ask unanimous consent that the following amendments be called up, considered en bloc and agreed to: A Jeffords amendment No. 1174; a Jeffords amendment No. 1175; a Kennedy amendment No. 1152; a Wellstone amendment No. 1156, and Senator DEWINE's amendment No. 1136, as modified in the amendment I send to the desk.

The PRESIDING OFFICER. Is there objection?

Mr. HARKIN. Reserving the right to object, Mr. President. I was hard-

pressed to hear the numbers. Was amendment No. 1131 included in that?

Mr. JEFFORDS. There are no non-germane amendments in the unanimous-consent request.

Mr. HARKIN. I appreciate that.

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

Who yields time?

Mr. FRIST. Mr. President, I yield myself 9 minutes.

Mr. President, I rise today to respond to my colleague from Iowa with regard to an amendment to the Food and Drug Administration [FDA] reform bill, to establish a new national center for complementary and alternative medicine at the National Institutes of Health [NIH].

Again, remember the debate today and the past several days, and maybe through tomorrow, is on the FDA. Yet, we have introduced an amendment on another agency—the NIH. I oppose the offering of this proposal as an amendment to the FDA bill for that very reason.

Comments have been made earlier about the importance of complementary and alternative medicine to the public and to this country, the importance of science, and the importance of peer review—all of which I support. I have been in the field of medicine, in a broad sense, for the last 20 years. I have been involved in many medical fields, including a great part of which has been designated as alternative therapies—at least initially, because when I first started doing lung transplants, very few had been done in the history of this country before. Therefore, I, as a scientist, a medical professional, and a U.S. Senator, do feel that alternative medicine and complementary medicine is vitally important to the health and the well-being of Americans and people throughout the world.

What I do oppose, however, is dealing with this issue of elevating an office to the level of a center when most of our colleagues do not even know what a center in the NIH really means. What are the responsibilities of a center? What are the authorities? What is the difference between an office and a center and an institute? As I talk to my colleagues, they do not know. Why? Because we have not addressed the issue in the appropriate environment—that is, through the committee structure.

I am the chairman of the Subcommittee on Public Health and Safety, which oversees the reauthorization of the NIH. We are, right now, looking at the reauthorization of the NIH. We have held two hearings in the past examining how you set biomedical and medical research priorities. It is a process where we have people come in and testify, and we discuss and debate back and forth. This amendment, as proposed by the Senator from Iowa, has not been taken through that process. It is being brought to the floor on a bill that does not have anything to do with the NIH, but rather the FDA bill. Therefore, I do believe it is not germane.

I believe we should not be placing NIH authorizing legislation on an FDA bill. Rather, the more appropriate process would be to take it through the committee structure. I should also add, for the benefit of my colleagues, most of whom have not addressed this issue at all because it has not been through the committee process, that no legislative bill to establish a center of alternative medicine has been introduced into the Senate. Therefore, a bill has not been referred to the appropriate committee, it has not been vetted, it has not had hearings. There has been no formal debate. This would create a huge center within the NIH without that debate. Therefore, I object to bypassing this process, again, with a tremendous amount of respect for alternative medicine.

My colleague from Iowa is a senior member of the subcommittee, and he and I have had the discussion that we do need to look at the appropriate role for alternative medicine at the NIH. We have scheduled a hearing in early October. It has been mentioned on the floor of the Senate that one of the panels should address the issue of alternative medicine.

We have a 4-year history with the Office of Alternative Medicine. Let's debate and look at the results of that history. Let's see the results of peer review and see what advances have been made.

The issue of whether to elevate an office to a center—again, as I talked to my colleagues over the last few weeks about taking an office at the NIH and elevating it to a center—is one that I think we need to discuss, but not today on the FDA bill, not over the course of a few minutes, but look at it through the appropriate hearing process. What does it mean to elevate an office to center status? What is a center at the NIH? I hope my colleagues ask themselves right now, do I really know what a center at the NIH is? Most will say no. The role of the current Office of Alternative Medicine, the office—as outlined by the Senator from Iowa, my colleague, who basically defined what the office is—is to coordinate and foster the conduct and support of alternative medicine research at the NIH. Right now, the office provides a central focus for a research area that is germane to all NIH components. In other words, the office can work with all the various institutes.

I understand that the majority of complementary and alternative research is performed and supported by those 24 centers and institutes and divisions within the NIH, and it is integrated within the scientific research portfolio of each of those institutes. My colleague is arguing—and he may be right, and that is why we need to discuss it—that we must consider alternative medicine being a center in and of itself. But that would mean that the scientists and researchers who are responsible for broad areas of science may not have the opportunity to integrate alternative medicine into their

respective research portfolios as they do today. It needs to be discussed. It needs to be debated in the appropriate forum.

I recognize that the Senator from Iowa has concerns about whether the current approach is working or not. Again, I look forward, through our reauthorizing committee, to the Subcommittee on Public Health and Safety, on which he serves, to address this very issue.

I do know that when you elevate an entity like an office to an institute or to center status, the scientific potential of the field should be sufficiently demonstrated so that the new institute or center can support a thriving intramural and extramural program. Are we at that point today? I do not know. I daresay that most of my colleagues have not studied this specific issue yet.

I will have to say that as I have reached out to people, many others in the scientific community have raised concerns about establishing a new center at the NIH. Let me read to you a portion of a letter sent to me from the Association of the American Medical Colleges expressing their concerns:

This is the AAMC, Association of the American Medical Colleges:

Any change in the organizational structure of the NIH of this magnitude raises significant scientific and administrative questions. . . .

Further, the AAMC believes all members of the research community should have the opportunity to address these issues in a full and public manner during a hearing conducted by the subcommittee.

Mr. President, I ask unanimous consent that the letter by the AAMC be printed in the RECORD.

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

ASSOCIATION OF
AMERICAN MEDICAL COLLEGES,
Washington, DC, September 16, 1997.

Hon. BILL FRIST,

*Chairman, Subcommittee on Public Health and Safety,
Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.*

DEAR CHAIRMAN FRIST: The Association of American Medical Colleges (AAMC) opposes efforts to attach to the pending FDA reform bill, S. 830, a proposal creating a National Center for Complementary and Alternative Medicine at the National Institutes of Health (NIH).

Any change in the organizational structure of the NIH of this magnitude raises significant scientific and administrative questions. The AAMC believes that research into complementary and alternative medical practices is best conducted by the individual disease-based institutes, and that creating a separate office will isolate and impede rather than promote and coordinate ongoing research activities in these areas. Moreover, it appears that the additional administrative costs associated with the creation of a new organizational entity at the NIH are not justified at the present time.

Further, the AAMC believes all members of the research community should have the opportunity to address these issues in a full and public manner during a hearing conducted by your subcommittee. The necessarily limited floor debate that would occur if this proposal is considered as an

amendment to S. 830 would not afford sufficient time or opportunity for such deliberations.

The AAMC urges the Senate to reject the effort to attach this proposal to the FDA bill and instead consider it during the upcoming NIH reauthorization legislation.

Sincerely,

JORDAN J. COHEN, M.D.

Mr. FRIST. Mr. President, raising the Office of Alternative Medicine to a center at NIH greatly increases its statutory authority. Has the field of alternative medicine demonstrated that track record to date? Again, let's review these issues in the committee process. The Office of Alternative Medicine today clearly does not have the organizational structure or the necessary budget to support this proposal—creating a national center for complementary and alternative medicine would require setting up a whole new administrative structure and a whole new research infrastructure to support this activity.

Are we ready for that today? Possibly.

Let's ask the scientists around the country. Let's have alternative medicine researchers come forward and testify. Let's ask the National Institutes of Health. Before we go out and create another center, which again is a new entity, we need to look at the proposal about its administration, and about how it will be paid for.

Again, the watchwords today are "consolidation and coordination," not proliferation.

Mr. President, I would like to reserve the remaining minute of my time.

The PRESIDING OFFICER. Who yields time?

Mr. HARKIN. Mr. President, I have a couple of minutes.

The PRESIDING OFFICER. The Senator from Iowa has 2 minutes and 45 seconds.

Mr. HARKIN. Mr. President, I will respond to my friend from Tennessee who made the argument. He said it would create a huge center at NIH. I am sorry. The Office of Alternative Medicine has 14 employees, the last count I had, and its budget next year is \$13 million out of \$13 billion at NIH. That is one-tenth of 1 percent. Huge? I beg to differ.

There are only two changes under this amendment. It provides that it could make grants, that it could do its own grants, and could have peer review. That is the only difference. We are not creating anything new and huge. It is up to the Congress to decide later on if they want to expand it or not. I am just changing its status.

Also, Mr. President, I want to say that if it were not for this point of order this amendment would pass. The cosponsors are Senators HATCH, DASCHLE, CRAIG, MIKULSKI, LUGAR, SPECTER, GRASSLEY, DURBIN, WELLSTONE, MOSELEY-BRAUN, and a number of others. I am not going to read them all.

This amendment would pass, if the point of order were not raised.

The Senator says it should go through the committee structure, that we have not had hearings, and stuff. I say in all friendship—and he is a great friend of mine, the Senator from Tennessee—that just a couple of weeks ago the Senator voted on the Gorton amendment that cut out title I—vocational education, safe and drug-free schools, education technology, bilingual education—knocked it all out. And, yet, we never had one hearing on it. It never went through our committee, of which the Senator and I both sit. We never had any hearings on that. Yet the Senator from Tennessee says fine. He stepped up and voted to abolish all of those without going through the hearing process.

But I would say to my friend from Tennessee, you want more testimony. Look at the Record. Our subcommittee on both the appropriations side and on the authorizing side have had hearing after hearing after hearing on this. We have had all kinds of testimony come in.

But the most compelling testimony, Mr. President, for this amendment is that more and more Americans are using alternative practices in medicines than they are using with mainstream doctors. They are spending billions of dollars a year. At last count it was over \$13 billion in 1 year.

It is up to us to make sure that we do the adequate scientific research to find out what alternative medicines are working and what are not.

That is why this center is needed. It may not be germane to this bill. But I will tell you. It is needed. It is drastically needed today—not next year or 2 years or 3 years from now. We have had enough testimony basically from the American people.

Mr. President, I ask unanimous consent to have printed in the RECORD a letter from a number of organizations supporting the amendment.

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

To the Honorable Tom Harkin, United States Senate:

We write in support of the proposed amendment to Bill S. 830, the purpose of which is to increase the authority of the Office of Alternative Medicine by creating in its place a national Center for Complementary and Alternative Medicine at NIH.

It is our understanding that this amendment would assure that relevant projects are reviewed by scientists with expertise in the particular area of complementary and alternative medicine proposed to be studied, and the Center would have the ability to directly fund projects without oversight from other NIH Institutes. In addition, the Office of Dietary Supplements would be included within the proposed Center, thereby ensuring improved coordination of research and resource allocation.

These reforms will, in our view, facilitate and expedite the implementation of rigorous and scientifically based evaluation of complementary and alternative medical therapies. Patients and their families need and deserve responsible and authoritative advice concerning the use or avoidance of these therapies. We must therefore do more to distinguish useful from useless complementary and alternative medical interventions.

We thank you for your efforts in this area.
Sincerely,

DAVID M. EISENBERG, M.D.,
*Beth Israel Deaconess
Medical Center, Har-
vard Medical School.*

BRIAN M. BERMAN, M.D.,
*Complementary Medi-
cine Program, Uni-
versity of Maryland.*

WILLIAM L. HASKELL,
PH.D.,
*School of Medicine,
Stanford University.*

FREDI KRONENBERG, PH.D.,
*Center for Complemen-
tary and Alternative
Medicine Research
in Women's Health,
Columbia Univer-
sity.*

M. ERIC GERSHWIN, M.D.,
*Division of
Rheumatology, Al-
lergy, and Clinical
Immunology, Uni-
versity of California,
Davis.*

GUY S. PARCEL, PH.D.,
*Center for Health Pro-
motion Research and
Development, The
University of Texas,
Houston.*

SAMUEL C. SHIFLETT,
PH.D.,
*Research Department,
Kessler Institute for
Rehabilitation, Inc.*

ANN GILL TAYLOR, R.N.,
EC.D., FAAN,
*Center for the Study of
Complementary and
Alternative Thera-
pies, University of
Virginia School of
Nursing.*

LEANNA J. STANDISH, N.D.,
PH.D.,
*AIDS Research Center,
Bastyr University.*

THOMAS J. KIRESEK, PH.D.,
*Center for Addiction
and Alternative
Medicine Research,
University of Min-
nesota Medical
School.*

Mr. DASCHLE. Mr. President, I am pleased to cosponsor this amendment with my friend from Iowa. The amendment promotes the same fundamental goals that have fueled FDA reform—that is, to improve access to safe and effective medical treatments, and respond to the growing popularity of alternative health care options.

I commend Senator HARKIN for his dedication to breaking down barriers that are too often a function of ignorance, inertia or territorialism in order to increase the health care options available to all Americans. Senator HARKIN has advocated long and hard for openminded exploration of treatments outside the box of western medicine, and we owe him a debt of gratitude both for his common sense and his vision in promoting the safe and effective use of promising alternative treatments.

I would also like to thank Senator JEFFORDS and Senator KENNEDY for their commitment and leadership

throughout this process. I appreciate their willingness to work with us on reforms aimed at creating a more level playing field for alternative medical treatments.

And I would be remiss if I did not acknowledge my good friend Berkley Bedell, who represented Iowa's sixth congressional district so ably for 12 years. Berk has worked tirelessly, against strong odds, to give consumers more health care options, and the fact that we are here today, talking about the potential of alternative medicine, is largely due to his vision, conviction and persistence.

For those of us whose health and well-being may ultimately depend on these options, Berkley Bedell's contribution is an invaluable one. Thank you, Berk, for your time, energy and unyielding commitment to expanding consumers' choices.

The strategy outlined in this amendment—increasing the autonomy and authority of the NIH Office of Alternative Medicine—is a sorely needed and long overdue response to the obstacles hindering access to alternative medical treatments. Under this amendment, the role of the NIH Office of Alternative Medicine would be enhanced through the authority to conduct and support intramural and extramural research.

The Office would no longer be relegated to the second tier, placed in the untenable position of convincing other institutes within NIH to take on as part of their own resource-constrained agendas, projects the Office deems important. As a full research institute, the Office of Alternative Medicine could respond to the growing interest in alternative treatments by identifying research gaps and fulfilling those gaps on a timely basis.

Mr. President, as you may recall, in February Senator HARKIN and I re-introduced the Access to Medical Treatment Act, a bill intended to give consumers greater freedom to use alternative and complementary medical treatments. The bill provoked some controversy, as was expected.

There is no stronger opponent to change than the status quo, no matter how valuable. It has become abundantly clear that unless we shake things up a little, we will continue to tread water in our efforts to tap the full potential of alternative medical treatments. Like S. 578, this amendment definitely shakes things up, but it does so from a different angle.

S. 578 promotes the idea that consumers should be free to use nontraditional medicines. This amendment confronts the resource barriers that prevent essential research into the benefits and risks of alternative treatments.

Too often an alternative treatment is written off because, the traditional medical establishment claims, there is no proof of its effectiveness. In fact, untested does not necessarily translate as ineffective. It may mean that insuf-

ficient resources are available to definitively prove what has been demonstrated again and again on an anecdotal basis. A small firm or single practitioner may not have access to the resources necessary to conduct large-scale clinical trials in the U.S. to document the safety and effectiveness of a drug or device. If the treatment isn't patentable or profitable, it may be difficult to attract the interest of drug or device companies.

This doesn't mean the drug doesn't work or isn't safe. It means we don't know. How many beneficial alternative treatments gather dust because they are not "brand name" material?

Even more important is the issue of safety. Regardless of the obstacles hindering alternative medical treatments, they are increasingly popular. A 1993 article in the New England Journal of Medicine reported that more than one-third of Americans use alternative, nonconventional medical treatments.

In 1990 alone, Americans spent over \$14 billion on these treatments. Consumers are using these medical treatments, yet research on the safety and effectiveness of alternative treatments remains scarce, and the current regulatory system remains focused on large-scale, mainstream medicines.

This amendment is intended to open doors to alternative treatments so that they can be assessed for safety and effectiveness and, when they are found to be safe and effective, made widely available.

It's the right thing to do, and the longer we wait to do it, the more opportunities we forsake to make use of beneficial medical treatments. This amendment promotes the best interests of every health care consumer in the Nation, and I am proud to support it.

The PRESIDING OFFICER. Who yields time?

Mr. FRIST. Mr. President, how much time is remaining?

The PRESIDING OFFICER. The Senator from Tennessee has 1 minute.

Mr. FRIST. Mr. President, in closing, to go right to the heart of the matter, to increase and elevate the alternative medicine from an office to a center needs to be addressed, but not in this forum. To establish a center means you give it grantmaking authority, establish an advisory council, and you instruct the center to study the integration of alternative medicine, establish a new data system, establish research centers, all of which is something that is not just moving toward peer review.

We will address it in the future—hopefully actually in a panel 2 or 3 weeks from now, in early October.

POINT OF ORDER

Mr. President, I make a point of order that the pending amendment No. 1137 is not germane.

The PRESIDING OFFICER. The point of order is sustained.

The amendment falls.

Mr. COATS addressed the Chair.

The PRESIDING OFFICER. The Senator from Indiana is recognized.

Mr. COATS. Mr. President, I ask unanimous consent to speak for 2 minutes prior to the scheduled vote on the committee substitute.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. COATS. Mr. President, in 2 minutes we will be voting on the FDA reform bill.

This committee substitute has been legislated for a 2½ year period thoroughly and carefully and responsibly. It is a piece of work that has received a 14-to-4 vote in committee by Democrats and Republicans. People of different philosophical backgrounds have supported it. It is legislation that has survived two filibusters, and the cloture votes have been overwhelming to move forward. It is legislation that has been changed and modified 34 times to meet the objections of the Senator from Massachusetts and some others about its deficiencies; 34 modifications since that 14-to-4 committee vote.

There are 8 days left in this month before PDUFA—the tax on the drug companies that funds up to 600 employees at FDA to review and to expedite the review of drugs—8 days left before that authorization expires. The clock is ticking. FDA will be laying off more than 600 people in just 8 days unless we can move this legislation forward. We don't need more filibusters. We don't need more debate. It is time to move forward. If we do not, drug and device reviews will be delayed substantially, and reform will be stopped. Responsible people have legislated responsibly, and I urge my colleagues to support us on this vote coming up.

The PRESIDING OFFICER. Under the previous agreement, the Senator from Washington is recognized for up to 5 minutes on amendment No. 1161.

AMENDMENT NO. 1161

(Purpose: To modify the exemption requirements relating to national uniformity for nonprescription drugs to provide an exemption for a State or political subdivision requirement that protects the health and safety of children.)

Mrs. MURRAY. I send an amendment to the desk.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Washington (Mrs. MURRAY) proposes an amendment numbered 1161.

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

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

The amendment is as follows:

Beginning on page 117, strike line 24 and all that follows through page 118, line 10, and insert the following:

“(b) EXEMPTION.—

“(1) IN GENERAL.—Upon application of a State or political subdivision thereof, the

Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that—

“(A) protects an important public interest that would otherwise be unprotected, including the health and safety of children;

“(B) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and

“(C) would not unduly burden interstate commerce.

“(2) TIMELY ACTION.—The Secretary shall make a decision on the exemption of a State or political subdivision requirement under paragraph (1) not later than 120 days after receiving the application of the State or political subdivision under paragraph (1).

Mrs. MURRAY. Thank you, Mr. President.

Mr. President, I filed two amendments to this bill, the intent of which were aimed at what I believe is a serious problem with national uniformity. And that is the issue of poison control labeling to prevent unintentional exposure to dangerous over-the-counter drugs and cosmetics by children.

During markup of this bill, national uniformity for labeling of over-the-counter drugs and cosmetics was adopted as an amendment. At the time, I raised concerns that I have about the State of Washington's successful Mr. Yuk campaign which simply teaches children and parents about the dangers of many common household products. I was concerned at the time that this program, which I have personal experience with and know how successful it is, would be in jeopardy.

This is a Mr. Yuk sticker. It is a small green sticker that parents and teachers can put onto products—toxic household products. And kids across my State are taught if they see a Mr. Yuk sticker they don't swallow what is inside of it.

I was concerned that national uniformity would harm my State's ability to continue this very important program. I raised this point during markup, and I was assured that the objective of the amendment on national uniformity was not to impede a State's ability to protect their children.

Since the markup, I have become even more concerned about poison control labeling. I am well aware of the fact that Mr. Yuk is voluntary, and there is no State mandate involved. However, this is where I became concerned. Under the uniformity language that is contained in this bill, a State can petition the Secretary for a mandated labeling requirement on OTC's and cosmetics if they meet certain public health and safety standards, and if—and only if—the labeling requirement does not unduly burden interstate commerce. This standard is extremely high and the only way for a State to meet the threshold is for the Secretary to make the requirement a national requirement.

What does this mean for Mr. Yuk? If New York, based on a local health concern files a petition with the Secretary

for a symbol, like a skull and cross bones to be placed on mouthwash or hair coloring, and they make a strong and sound case, the Secretary can be convinced. However, in order to comply with the act and not unduly burden interstate commerce, she must make this a national labeling requirement. Now Washington State faces a situation where they have a Mr. Yuk Program and must also teach about the skull and cross bones warning. This would be extremely confusing to young children in my State. I can say that as a former teacher.

Both of my amendments that I put forward attempted to address this issue. My first amendment would add poison control efforts using symbols in the criteria a State can use to petition the Secretary and change the “and” to an “or” unduly burdening interstate commerce; giving the Secretary the opportunity to continue to allow States to have their own poison control programs if they decide that a voluntary effort has not worked. Only through a mandate requirement will they be able to protect young children. Simply changing the “and” to an “or” would give the Secretary the needed flexibility, and would at least guarantee that one State requirement would not become a national requirement if it was not applicable to all 50 States.

Mr. President, my amendments have strong opposition by the industry. They simply don't want to have 50 different State legislatures coming forward with 50 different proposals. And I certainly believe there is an argument for preemption in many situations. But I don't believe there is one in this case.

I am really at a loss as to why supporters of the uniformity language in one breath talk about the need to reform and revitalize the FDA to prevent unnecessary delays in approving drugs and devices and then in the next breath talk about how States must petition an already overburdened agency for the approval to do what they have been doing for years without any public threat of consumer confusion problems.

It is interesting to note that the managers' amendment does exempt one State from uniformity. Our State is going to be treated differently. One State, the State of California, will be allowed to bypass the petition process and have different health and safety labeling cosmetics.

Because of the strong opposition to my original amendment and the well-financed national campaign to defeat my amendment, I have revised my language. The new amendment which I am offering today will at least acknowledge the importance of protecting health and safety of children, and will require the FDA to act on a State's petition within 120 days. The new amendment does not address all of my concerns. But because there has been a strong lobby and I am only one Senator that seems to be concerned about poison control, I recognize that my original amendment does not have the

votes. But I cannot allow these uniformity provisions to go to conference without some recognition of the health and safety of children.

So I thank the chairman for working with me. I am pleased that he has recognized my efforts and has supported the pending underlying amendment which has already been agreed to.

I thank the Chair. I yield my time.

The PRESIDING OFFICER. Is there further debate on the amendment offered by the Senator from Washington? If not, the question is on agreeing to the amendment of the Senator from Washington.

The amendment (No. 1161) was agreed to.

The PRESIDING OFFICER. Is there further debate?

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

AMENDMENTS NOS. 1182, AS MODIFIED, AND 1183

Mr. JEFFORDS. Mr. President, I ask unanimous consent to call up and adopt Senator HATCH's amendment No. 1183, and 1182, as modified by the amendment, which I send to the desk.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

AMENDMENT NO. 1182

Mr. HATCH. Mr. President, the Hatch-Wyden amendment, number 1182, modifies FDA's mission statement contained in S. 830.

For the first time, this legislation puts into statute a mission statement for the Food and Drug Administration. Because of its important public health role, Congress needs to give FDA the proper mission.

In short, the Hatch-Wyden amendment charges FDA to act in partnership with the public, scientific experts, and regulated entities as the agency performs its critical public health mission. The language of our amendment simply makes explicit what is already implicit, proper, and, in fact, necessary: that FDA should work, "in consultation with experts in science, medicine, and public health and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products."

As longtime advocates of modernizing and reforming the FDA, Senator WYDEN and I are convinced that this amendment will help FDA improve and protect the public health. Regulators can increase their effectiveness if they act more closely in concert with the public that they serve.

As Vice President GORE, the leader of the administration's Reinventing Government initiative, has said:

We can put the days of almighty holier-than-thou, mister-know-it-all Washington behind us. We can become partners."

Business owners and local governments are noticing the changes, too, as the federal government becomes more of a partner and less of an adversary.

Regulatory agencies are on orders to make partnership with business their standard way

of operating. We have tested it long enough to know it increases compliance * * * Now we can move beyond pilot programs for partnership into the mainstream.

The purpose of the Hatch-Wyden amendment is to inject this spirit of partnership right into the FDA mission statement. Giving such prominence and visibility to the idea of partnership can help the agency better fulfill its public health mission.

In no way does the Hatch-Wyden amendment limit, or is intended to limit, FDA from carrying out its enforcement obligations. The Hatch-Wyden amendment does not concern itself with particular regulatory decisions, that is, product approvals, enforcement sanctions, etc., rather it simply clarifies that as part of the general manner in which the agency conducts itself, FDA should work closely with those affected by its regulatory actions.

We are informed that the FDA is supportive of this amendment so long as language is added to make clear that the Secretary has discretion to see that only appropriate interactions between FDA and outsiders take place. We have incorporated this change.

In order to fulfill its current statutory responsibilities FDA routinely solicits advice from dozens of standing advisory committees of outside experts and consults with its colleagues at the National Academy of Sciences, the National Institutes of Health, the Centers for Disease Control and Prevention and many others. Similarly, FDA works closely with consumer groups such as patient advocacy groups and various regulated entities such as manufacturers of foods, drugs, cosmetics and medical devices.

In fact, S. 830 contains many particular provisions that detail partnerships between FDA and others such as the reauthorization of the user fee provisions for new drug review, and the rules that grant access to experimental drugs for patients suffering from serious or life-threatening conditions.

In March 1997 testimony to the Senate Labor Committee, Dr. Michael Friedman, the highest ranking FDA official, observed:

One of the themes that runs throughout the Agency's efforts to improve its performance of involving all stakeholders both in defining the problems that exist and in developing appropriate solutions.

While this amendment is philosophical and exhortatory in nature, we believe this philosophy, if adopted, can achieve tangible benefits for the FDA and public alike. As Lead Deputy Commissioner Friedman testified:

This model of public participation . . . is most clearly delineated in the procedures the Agency has promulgated for the issuance and use of Agency guidance documents. Concerns about the absence of public input on guidance documents and the inappropriate application of such guidance raised in a Citizen's Petition . . . and were the subject of a [House] hearing. . . In response to these concerns, the Agency undertook a thorough review . . . We found inconsistencies and lack of clarity, and we set about to fix it.

As the FDA's testimony indicates, there is reason to believe that encouraging the agency to interact appropriately with the public can have practical benefits.

We firmly believe that if the Congress formally embraces the principle of partnership in the FDA mission statement we will help create an atmosphere conducive to improving the public health. Accordingly, I hope my colleagues will support giving the FDA a 21st century mission statement.

Mr. WYDEN. Mr. President, I am happy to join my colleague Senator HATCH in offering an amendment which will add strength, substance, and a new level of appropriate public accountability and involvement in the missions of the Food and Drug Administration.

Quite simply, our amendment provides for real access and participation by patients and consumer groups, science and health experts, and the regulated manufacturers in appropriate policy making functions within the scope of the agency's missions.

As my colleague Senator HATCH has pointed out, our amendment underscores the real partnership FDA must forge with all Americans as it conducts its work certifying the safety and effectiveness of so many products important to our everyday lives.

I certainly want to acknowledge and applaud the assistance and encouragement of our colleagues Senators JEFFORDS and KENNEDY with regard to the development of the FDA reform bill generally, and their work with us in perfecting the agency's mission statement in particular.

I believe this legislation will help create the dialog necessary between the agency and all interested parties in order to effectively exercise all of the other far-reaching elements of this reform bill. I was very pleased to have played some part in the development of that legislation and the broader reform effort, and I know that American citizens dependent on pure food, life-saving new drugs and medical devices, and safe electronic equipment will benefit for many years to come from the work we do here, today.

AMENDMENT NO. 1183, AS MODIFIED

Mr. HATCH. Mr. President, the second amendment we are considering, No. 1183, will encourage the prompt and complete reporting of potentially vital public health information to the FDA.

Essentially, my proposal codifies a rule that already applies to drugs and medical devices and makes it applicable to all FDA-regulated products.

Specifically, my amendment would codify the liability disclaimer provisions that appear at 21 CFR section 803.16, for devices; 21 CFR section 314.80(l), for new drugs; and, 21 CFR 312.32(e), for investigational new drugs.

My amendment is closely patterned after these three provisions of existing regulation.

The public health benefit and rationale for my amendment are simple: A rule that encourages reporting to the

FDA of any alleged adverse incident now and resolving liability issues later, helps the FDA achieve its public health mission.

The FDA is a public health agency, not an arbiter of tort liability. That is the job of the courts.

But what is important for the public health is that FDA be able to receive quickly and completely raw data pertaining to adverse experiences with products under its regulatory purview.

Please understand that my amendment, like the existing regulations, is tort neutral.

Nothing in my amendment, or in the existing regulations, increases or decreases an ultimate finding of liability.

The Hatch amendment simply says that the mere filing of an adverse reaction report or submission of other information to FDA does not necessarily reflect an admission of fault or a finding of liability on the part of a manufacturer or the Federal Government.

Of course, the actual information contained in the report may, or may not, justify a finding of liability but that is an entirely other matter.

What this amendment says is that the mere filing of a report does not automatically mean anything with respect to the issue of liability.

This is a public health amendment that encourages timely reporting and complete reporting to the FDA.

Let me give a little background into the amendment and the existing FDA rules that it builds upon.

Back in mid-1980's when FDA issued proposed and final rules governing mandatory reporting for adverse incidents with respect to medical devices, a concern arose among those subject to these new reporting requirements.

In particular, there arose concern about the tight reporting timeframe for reporting deaths and serious injuries.

The argument was that medical device firms should have an opportunity to conduct fully its own investigation into alleged malfunctions of its products before turning over these reports to FDA.

After all, went the argument, this information which may have come from interested third parties—such as doctors and patients—could place the manufacturing firm in a precarious position vis-a-vis liability.

Inevitably, some reports will contain inaccurate information but regardless of this it is clear that the FDA had an overriding public health interest in getting this information as quickly as possible to see whether a national trend was developing.

The way this matter was resolved in the final medical device reporting rule was with the inclusion of language that permitted manufacturers to disclaim liability based solely on the filing of the report with the FDA.

To be sure, the information contained in the report might be used to establish, or help establish, liability on the part of the manufacturer. That de-

pends on what is in the report and the veracity of that information.

What the rule says simply is that the mere filing of the legally required report in and of itself does not establish liability.

One can easily imagine a case where a device malfunctioned and the MDR report does, and should properly be used to, establish liability. An example would be a case in which a heart pacemaker short circuited and failed.

On the other hand, there will be occasions when required reports do not necessarily establish any fault on the part of the manufacturer. An example of this might include a case in which a medical scalpel is used as a murder weapon; an unfortunate, legally reportable event no doubt, but not one likely to establish fault on the part of the manufacturer.

Building on the success of the disclaimer statement in the medical device rule, the FDA later included similar language both for approved and investigational drugs.

Once again, the rule advances the FDA's public health mission by helping to get information to the FDA in a timely and complete fashion.

The Hatch amendment codifies the basic regulation that now applies to mandatory reports that device and drug manufacturers now must make and establishes this basic principle of "report now, resolve liability issues later" for all products under the FDA's regulatory domain.

This would include products like foods, cosmetics, and dietary supplements, as well as drugs and devices.

So, I have drafted the amendment to cover situations where there are no rigorous mandatory reporting requirements, such as those which now govern drugs and devices.

For example, we have heard a lot in the press recently about the Chesapeake Bay outbreak of *Pfiesteria*. Obviously, it would be in the public interest for the Government to have reports about the incidence of this toxic microbe. That is something we would want to encourage.

I believe that it is more likely this information, even sketchy third-party, unverified reports, would be transmitted to FDA if this disclaimer clearly applied in this situation.

What is good policy for drugs and devices, is also good policy for foods, cosmetics, dietary supplements, and other products under FDA's jurisdiction.

The Hatch amendment embraces the "report now/resolve liability later" rule that is already in place by regulation for drugs and medical devices and applies this principle for all FDA-regulated products, and further applies the provision both to mandatory and voluntary reports.

This is a consumer-friendly, FDA-friendly, tort-neutral provision and I urge its adoption.

Mr. President, I ask unanimous consent that letters in support of these two amendments from Brian H. Moss,

president of the Utah Life Science Industries Association, and Alan F. Holmer, president of the Pharmaceutical Research and Manufacturers of America, be printed in the RECORD.

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

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA,
Washington, DC, September 17, 1997.

Hon. ORRIN HATCH,
U.S. Senate, Russell Senate Office Building,
Washington, DC.

DEAR MR. CHAIRMAN: You have asked for comment on two proposed amendments to S. 830. We are pleased to offer our support for these amendments.

We particularly endorse Section 908, Safety Report Disclaimers, which would place into law a disclaimer that is currently found in FDA regulations. It should be noted that on page 2, line 3, the word "necessarily" is no longer found in the Medwatch disclaimer which was drafted more recently than the FDA regulation and pertains to the same circumstances which give rise to the need for the disclaimer. It would be an improvement if the word necessarily were deleted from the amendment, but in any case PhRMA companies support the need for the disclaimer in legislation.

We would also support the suggested amendment to the mission statement which sets forth a more collaborative and cooperative mission for the agency. PhRMA believes that the agency has responsibility to both protect and promote the public health. There are times when the pendulum has swung too far toward enforcement at the expense of the agency's mission to help bring safe drugs to patients sooner.

Sincerely,

ALAN F. HOLMER.

UTAH LIFE SCIENCE
INDUSTRIES ASSOCIATION,

Salt Lake City, UT, September 18, 1997.

Hon. JAMES M. JEFFORDS,
U.S. Senate, Hart Senate Office Building,
Washington, DC.

DEAR MR. CHAIRMAN: I am writing as President of the Utah Life Science Industries Association, concerning the two proposed amendments by Senator Hatch to S. 830. We are happy to extend our support for the two amendments.

We are pleased to support the amendment to the missions statement. We support the idea of a partnership between the FDA and the private sector, in such that the FDA will consult with experts in science, medicine, public health, and in cooperation with consumers and users. We believe that this will "help ensure" the public health.

We are supportive of the amendment to the Safety Report Disclaimer, and can see a need for this amendment. The amendment will encourage manufacturers to send safety data to the FDA, therefore, helping the FDA to protect the public good.

Utah Life Science Industries Association was formed three years ago by the Biotechnical, Biomedical and Medical Device industries in Utah. We represent the interest of these Utah companies on local and national issues. We are pleased that you and Senator Hatch have shown such great interest and concern for our industry.

Sincerely,

BRIAN H. MOSS,
President.

Mr. JEFFORDS. Mr. President, I ask for the yeas and nays on the adoption of the committee amendment.

The PRESIDING OFFICER. Is there a sufficient second?

At the moment there is not a sufficient second.

Mr. JEFFORDS. Mr. President, I make a point of order that a quorum is not present.

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 (Mr. GORTON). Without objection, it is so ordered.

Mr. JEFFORDS. Mr. President, I ask for the yeas and nays on adoption of the committee amendment, as modified.

The PRESIDING OFFICER. Is there a sufficient second? There is a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. Without objection, the two preceding amendments sent up by the Senator from Vermont are agreed to.

The amendments (Nos. 1182, as modified, and 1183) were agreed to, as follows:

AMENDMENT NO. 1182

(Purpose: To improve the mission statement.)

Beginning on page 4, strike line 11 and all that follows through page 5, line 6, and insert the following:

“(1) IN GENERAL.—The Secretary, acting through the Commissioner, and in consultation, as determined appropriate by the Secretary, with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products, shall protect the public health by taking actions that help ensure that—

“(A) foods are safe, wholesome, sanitary, and properly labeled;

“(B) human and veterinary drugs, including biologics, are safe and effective;

“(C) there is reasonable assurance of safety and effectiveness of devices intended for human use;

“(D) cosmetics are safe; and

“(E) public health and safety are protected from electronic product radiation.

“(2) SPECIAL RULES.—The Secretary, acting through the Commissioner, shall promptly and efficiently review clinical research and take appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability. The Secretary, acting through the Commissioner, shall participate with other countries to reduce the burden of regulation, to harmonize regulatory requirements, and to achieve appropriate reciprocal arrangements with other countries.”.

AMENDMENT NO. 1183

(Purpose: To provide for a disclaimer with respect to safety reports)

At the appropriate place, insert the following:

SEC. . SAFETY REPORT DISCLAIMERS.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 804, is further amended by adding at the end the following:

“SEC. . 908. SAFETY REPORT DISCLAIMERS.

“With respect to any entity that submits or is required to submit a safety report or other information in connection with the

safety of a product (including a product which is a food, drug, new drug, device, dietary supplement, or cosmetic) under this Act (and any release by the Secretary of that report or information), such report or information shall not be construed to necessarily reflect a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, serious illness, or malfunction. Such an entity need not admit, and may deny, that the report or information submitted by the entity constitutes an admission that the product involved caused or contributed to an adverse experience or caused or contributed to a death, serious injury, serious illness, or malfunction.”.

AMENDMENTS NOS. 1174, 1175, 1152, 1156, AND 1136, AS MODIFIED

The PRESIDING OFFICER. Under the preceding order, the Senate will consider the following amendments, numbered 1174, 1175, 1152, 1156, 1136, as modified. The question is on agreeing to the amendments en bloc.

Without objection, the amendments en bloc are adopted.

The amendments (Nos. 1174, 1175, 1152, 1156, and 1136, as modified) were agreed to, as follows:

AMENDMENT NO. 1174

(Purpose: To maintain authority of the Food and Drug Administration to regulate tobacco)

On page 30, strike lines 17 and through 20, and insert the following:

(c) RULE OF CONSTRUCTION.—Nothing in the amendments made by subsections (a) and (b) shall be construed to alter any authority of the Secretary of Health and Human Services to regulate any tobacco product, or any additive or ingredient of a tobacco product.

Mr. NICKLES. Mr. President, Members of this Chamber are well aware of the national debate on the question of the Food and Drug Administration's jurisdiction to regulate tobacco and tobacco products. To highlight the scope of this debate, I want to point out that this question is currently under review by the U.S. Court of Appeals. It is also a significant issue of debate between Members of Congress as well as Congress and the administration. I am concerned that the inclusion of this provision may be interpreted by some as an attempt by Congress to indirectly affirm FDA's authority to regulate tobacco.

It is my understanding that a recent report from the American Law Division of the Congressional Research Service stated that section 404 or any other provision in the FDA reform bill “would not interfere with or lessen the agency's authority to regulate tobacco products.” I notice that a rule-of-construction amendment has been included in the FDA reform bill that is intended to clarify further that section 404 of the bill will not affect any authority which the FDA may have to regulate tobacco. Is this the understanding of the Chairman?

Mr. JEFFORDS. Yes. This amendment I believe will address the concerns of several Senators who have a concern regarding the effect of this leg-

islation on FDA's authority to regulate tobacco. I believe we all have the same intent.

In drafting S. 830, my intent was and is to improve the efficiency and accountability of the product review process at FDA. In drafting section 404, we modified a provision in the FDA reform bill from the 104th Congress in an effort to more accurately capture our policy intent—my point is that the subject matter is section 404 has been under consideration in the Senate Labor Committee, as well as in legislation introduced in the House, for several years. The concern over FDA's tobacco authority came to our attention only after the markup of this bill in committee, in June of this year.

Section 404 introduces needed elements of due process to certain, very limited aspects of medical device reviews. None of the language in S. 830 is intended to address FDA's tobacco authority. Late in the course of negotiations on this bill, FDA raised the possibility that section 404(b) might be interpreted to limit the agency's future tobacco regulation authority. At the time we told the agency we did not agree with their interpretation but eventually offered to insert the rule of construction now before us in the substitute to make absolutely clear our neutrality on the tobacco issue. Subsequently, FDA and others have raised the possibility that section 404(a) of S. 830 could also affect FDA's authority in this area. As you mentioned, the Congressional Research Service, American Law Division, has evaluated S. 830 and determined that it, in fact, does not interfere with any tobacco authority FDA may have. This analysis was made part of the CONGRESSIONAL RECORD on September 5.

None of the provisions of S. 830 or the substitute should be interpreted as taking a position, one way or the other, on whether FDA has any authority under current law to regulate tobacco products, which as you know, is the subject of ongoing litigation in the Federal courts. The intention of the rule of construction in the substitute is to make clear that the Federal courts can continue to determine FDA's authority over tobacco without any interference from this act. Thus, the language in section 404 has no effect on whether or not FDA has authority over tobacco products, it only relates to a procedural aspect of reviewing 510(k) medical device submissions.

To sum up, I am pleased to offer an amendment extending the rule of construction to all of section 404 on the basis outlined in my preceding remarks—to keep the bill strictly neutral on the question of FDA tobacco authority, that is that we are not prejudging the outcome of any pending litigation on any tobacco authority the FDA may have. Further, it is my view that if this provision is included in the final FDA reform bill as reported by the conference committee, the conference report should include language which reinforces this point.

Mr. NICKLES. I thank the chairman for his explanation of this provision and his efforts to bring this important legislation to the floor. At some point in the 105th Congress, we may be considering the national tobacco settlement entered into by the State's attorney's general and the tobacco companies. At the appropriate time Congress will have the opportunity to fully examine what FDA's role should be in the regulation of tobacco products.

AMENDMENT NO. 1175

(Purpose: To provide that an environmental impact statement prepared in accordance with certain regulations of the Food and Drug Administration shall be considered to meet the requirements of section 102(2)(C) of the National Environmental Policy Act of 1969)

Strike section 602 and insert the following:
SEC. 602. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 402, is further amended by adding at the end the following:

"SEC. 742. ENVIRONMENTAL IMPACT REVIEW.

"Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this Act, shall be considered to meet the requirements for a detailed statement under section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C))."

AMENDMENT NO. 1152

(Purpose: To improve the standard for binding determinations with respect to the specification of valid scientific evidence with respect to the effectiveness of devices)

On page 24, line 19, strike "is" and insert "could be".

AMENDMENT NO. 1156

(Purpose: To provide for a study and report concerning the treatment of health care economic information)

Strike section 612 and insert the following:
SEC. 612. HEALTH CARE ECONOMIC INFORMATION.

(a) IN GENERAL.—Section 502(a) (21 U.S.C. 352(a)) is amended by adding at the end the following: "Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading if the health care economic information directly relates to an indication approved under section 505 or 507 or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a), 507, or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term 'health care economic information' means any analysis that identifies, measures, or compares the economic consequences, including the costs of

the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention."

(b) STUDY AND REPORT.—The Comptroller General of the United States shall conduct a study of the implementation of the provisions added by the amendment made by subsection (a). Not later than 4 years and 6 months after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to Congress a report containing the findings of the study.

AMENDMENT NO. 1136, AS MODIFIED

(Purpose: To improve the provisions relating to pediatric studies)

Strike section 618 and insert the following:
SEC. 618. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.

(a) GENERAL AUTHORITY.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following:

"SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

"(a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which may include a timeframe for completing such studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such timeframe and the reports thereof are accepted in accordance with subsection (d)(3)—

"(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

"(2)(A) if the drug is the subject of—

"(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

"(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

"(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions).

"(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE BENEFICIAL.—Not later than 180 days after the date of enactment of this section, the Secretary, after consultation with experts in pediatric research (such as the American Academy of Pediatrics, the Pediatric Pharmacology Research Unit Network, and the United States Pharmacopoeia) shall develop, prioritize, and publish an initial list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

"(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary makes a written request for pediatric studies (which may include a timeframe for completing such studies) concerning a drug identified in the list described in subsection (b) to the holder of an approved application under section 505(b)(1) for the drug, the holder agrees to the request, and the studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such timeframe and the reports thereof accepted in accordance with subsection (d)(3)—

"(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

"(2)(A) if the drug is the subject of—

"(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

"(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

"(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under subsection (c)(3) or (j)(4)(B) of section 505 shall be extended by a period of six months after the date the patent expires (including any patent extensions).

"(d) CONDUCT OF PEDIATRIC STUDIES.—

"(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request for studies, after consultation with—

"(A) the sponsor of an application for an investigational new drug under section 505(i);

"(B) the sponsor of an application for a drug under section 505(b)(1); or

"(C) the holder of an approved application for a drug under section 505(b)(1), agree with the sponsor or holder for the conduct of pediatric studies for such drug.

"(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder

and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance with the original written request and the written agreement referred to in paragraph (1). Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.

“(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly respond to the written request, whether such studies have been conducted in accordance with commonly accepted scientific principles and protocols, and whether such studies have been reported in accordance with the requirements of the Secretary for filing.

“(e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATIONS; PERIOD OF MARKET EXCLUSIVITY.—If the Secretary determines that the acceptance or approval of an application under subsection (b)(2) or (j) of section 505 for a drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent (including any patent extension) or market exclusivity protection, but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under subsection (b)(2) or (j), respectively, of section 505 until the determination under subsection (d) is made, but such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable period of market exclusivity referred to in subsection (a) or (c) shall be deemed to have been running during the period of delay.

“(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section.

“(g) LIMITATION.—The holder of an approved application for a new drug that has already received six months of market exclusivity under subsection (a) or (c) may, if otherwise eligible, obtain six months of market exclusivity under subsection (c)(1)(B) for a supplemental application, except that the holder is not eligible for exclusivity under subsection (c)(2).

“(h) STUDY AND REPORT.—The Secretary shall conduct a study and report to Congress not later than January 1, 2003 based on the experience under the program. The study and report shall examine all relevant issues, including—

“(1) the effectiveness of the program in improving information about important pediatric uses for approved drugs;

“(2) the adequacy of the incentive provided under this section;

“(3) the economic impact of the program; and

“(4) any suggestions for modification that the Secretary deems appropriate.

“(i) TERMINATION OF MARKET EXCLUSIVITY EXTENSION AUTHORITY FOR NEW DRUGS.—Except as provided in section 618(b) of the Food and Drug Administration Modernization and Accountability Act of 1997, no period of market exclusivity shall be extended under subsection (a) for a drug if—

“(1) the extension would be based on studies commenced after January 1, 2004; and

“(2) the application submitted for the drug under section 505(b)(1) was not approved by January 1, 2004.

“(j) DEFINITIONS.—In this section, the term ‘pediatric studies’ or ‘studies’ means at least 1 clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age-groups in which a drug is anticipated to be used.”.

(b) MARKET EXCLUSIVITY UNDER OTHER AUTHORITY.—

(1) THROUGH CALENDAR YEAR 2003.—

(A) DETERMINATION.—If the Secretary requests or requires pediatric studies, prior to January 1, 2004, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), from the sponsor of an application, or the holder of an approved application, for a drug under section 505(b) of such Act (21 U.S.C. 355(b)), the Secretary shall determine whether the studies meet the completeness, timeliness, and other submission requirements of the Federal law involved.

(B) MARKET EXCLUSIVITY.—If the Secretary determines that the studies meet the requirements involved, the Secretary shall ensure that the period of market exclusivity for the drug involved is extended for 6 months in accordance with the requirements of subsection (a), (c), (e), and (g) (as appropriate) of section 505A of such Act (as in effect on the date of enactment of this Act.).

(2) CALENDAR YEAR 2004 AND SUBSEQUENT YEARS.—

(A) NEW DRUGS.—Effective January 1, 2004, if the Secretary requests or requires pediatric studies, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act, from the sponsor of an application for a drug under section 505(b) of such Act, nothing in such law shall be construed to permit or require the Secretary to ensure that the period of market exclusivity for the drug is extended.

(B) ALREADY MARKETED DRUGS.—

(i) DETERMINATION.—Effective January 1, 2004, if the Secretary requests or requires pediatric studies, under Federal law other than section 505A of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), from the holder of an approved application for a drug under section 505(b) of such Act, the Secretary shall determine whether the studies meet the completeness, timeliness, and other submission requirements of the Federal law involved.

(ii) MARKET EXCLUSIVITY.—If the Secretary determines that the studies meet the requirements involved, the Secretary shall ensure that the period of market exclusivity for the drug involved is extended for 6 months in accordance with the requirements of subsection (a), (c), (e), and (g) (as appropriate) of section 505A of such Act (as in effect on the date of enactment of this Act.).

(3) DEFINITIONS.—In this subsection:

(A) DRUG.—The term “drug” has the meaning given the term in section 201 of such Act.

(B) PEDIATRIC STUDIES.—The term “pediatric studies” has the meaning given the term in section 505A of such Act.

(C) SECRETARY.—The term “Secretary” means the Secretary of Health and Human Services.

SECTION 807

Mrs. FEINSTEIN. Section 807 of the committee substitute for S. 830 pro-

hibits State and local governments from establishing or continuing—for nonprescription drugs, any requirement that is different from, in addition to or otherwise not identical to a Federal requirement; for cosmetics, any requirements for packaging and labeling that are different from, in addition to or otherwise not identical to a Federal requirement. This includes any requirement relating to public information or any other form of public communication relating to a warning of any kind for a nonprescription drug.

My State, California, has a long history of regulating nonprescription drugs and cosmetics and I would like to ask the bill manager's to engage in a colloquy with me to clarify his intent and the language of the bill.

The California Department of Health Services in a September 12 letter expressed their concern that they would have to request interpretations from FDA. They wrote: “For interpretation of Federal requirements, and in order to determine if a State conflict exists, it will be necessary for States to continually request from the Federal Government an interpretation of their requirements and both Federal and State legal review of those interpretations.”

Could you explain the bill's intent?

Mr. JEFFORDS. In most cases, it will be abundantly clear and States will not have to continually request written interpretations of Federal law. There should be no need to delay enforcement.

Mrs. FEINSTEIN. According to California officials, a number of requirements now in force in California could be considered to be in addition to Federal law under this bill and therefore could be preempted.

The first area relates to public warning requirements. The California Department of Health Services maintains that the bill would likely prohibit State-initiated public health warnings.

California DHS asked, for example, if point-of-purchase placards could be required.

Could my colleague comment on the intent of the bill with regard to State public warning requirements?

Mr. JEFFORDS. The public information and communication provisions of S. 830 would not prevent a State from issuing its own public statements to warn the public. But although the State is free to utilize the media and other such avenues, the State could not require point-of-purchase placards to be posted.

Mrs. FEINSTEIN. For both drugs and cosmetics, currently under California law, if DHS has probable cause to believe that a drug or cosmetic is adulterated, misbranded, or falsely advertised, DHS can embargo the product, remove it from commerce. In their letter, DHS says, “This power may be considered in addition to a Federal requirement.”

Could you clarify your intent in this area?

Mr. JEFFORDS. Enforcement authority is not covered by the preemption provision of the bill, so a State's embargo and other enforcement authority would not be affected.

Mrs. FEINSTEIN. For nonprescription drugs, California law requires comprehensive and annual inspections of manufacturers. Federal law requires limited inspections on no timetable. DHS maintains that the "State's requirements for drug manufacturer licensing and the annual inspections may be considered a requirement in addition to the Federal requirement."

What is the chairman's intent in this bill, as it addresses licensing and inspections by States?

Mr. JEFFORDS. As I said previously enforcement authority is not covered by the national uniformity provisions. Thus, drug manufacturer licensing and inspection in the States would not be affected.

Mrs. FEINSTEIN. My State has expressed concerns about advertising, saying that State law has advertising restrictions, that is prohibition on false and misleading advertisement, advertising of unproven remedies, that may be preempted. Could you elaborate on the bill's intent in the drug advertising area?

Mr. JEFFORDS. The national uniformity provisions would not affect traditional drug advertising laws because this bill does not address the authority of the Federal Trade Commission Act. State laws that prohibit false and misleading advertising or to prohibit unsubstantiated claims for non-prescription drugs, for example, would not be affected. Traditional advertising issues relating to claims substantiation, fair balanced and truth are outside the scope of national uniformity.

Mrs. FEINSTEIN. I thank my colleague. I hope that this discussion will clarify the true intent of the authors of this bill and provide some clarification of the State's authority to protect the public health under this bill.

VOTE ON AMENDMENT NO. 1130, AS MODIFIED

The PRESIDING OFFICER. The question is on agreeing to the committee substitute, No. 1130, as modified. The yeas and nays are ordered. The clerk will call the roll.

The assistant legislative clerk called the roll.

The result was announced—yeas 98, nays 2, as follows:

[Rollcall Vote No. 255 Leg.]

YEAS—98

Abraham	Bryan	Craig
Akaka	Bumpers	D'Amato
Allard	Burns	Daschle
Ashcroft	Byrd	DeWine
Baucus	Campbell	Dodd
Bennett	Chafee	Domenici
Biden	Cleland	Dorgan
Bingaman	Coats	Durbin
Bond	Cochran	Enzi
Boxer	Collins	Faircloth
Breaux	Conrad	Feingold
Brownback	Coverdell	Feinstein

Ford	Kerrey	Robb
Frist	Kerry	Roberts
Glenn	Kohl	Rockefeller
Gorton	Kyl	Roth
Graham	Landrieu	Santorum
Gramm	Lautenberg	Sarbanes
Grams	Leahy	Sessions
Grassley	Levin	Shelby
Gregg	Lieberman	Smith (NH)
Hagel	Lott	Smith (OR)
Harkin	Lugar	Snowe
Hatch	Mack	Specter
Helms	McCain	Stevens
Hollings	McConnell	Thomas
Hutchinson	Mikulski	Thompson
Hutchison	Moseley-Braun	Thurmond
Inhofe	Moynihan	Torricelli
Inouye	Murkowski	Warner
Jeffords	Murray	Wellstone
Johnson	Nickles	Wyden
Kempthorne	Reid	

NAYS—2

Kennedy

Reed

The amendment (No. 1130), as modified, was agreed to.

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

The PRESIDING OFFICER. Without objection, the motion to lay on the table the motion to reconsider is agreed to.

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. The majority leader.

UNANIMOUS-CONSENT AGREEMENT

Mr. LOTT. Mr. President, I ask unanimous consent that the scheduled cloture vote be vitiated with the previous debate limitation still in effect.

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

Mr. LOTT. In light of the earlier consent with respect to debate time on the FDA bill—I believe Senator JEFFORDS got the unanimous-consent request agreed to a few moments ago—there will be no further votes this evening. The Senate will begin, now, up to 4 hours of debate on the FDA bill. The concluding 4 hours of debate will begin at 12 noon on Wednesday. Therefore, final passage will occur at approximately 3:45 on Wednesday, of the Food and Drug Administration reform bill.

I guess I should put that in the form of a request, Mr. President.

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

UNANIMOUS-CONSENT AGREEMENT—CAMPAIGN FINANCE REFORM

Mr. LOTT. Mr. President, I ask unanimous consent the majority leader, after notification of the Democratic leader, must turn to S. 25, the McCain-Feingold campaign finance reform bill, prior to the close of the first session of the 105th Congress, and Senator MCCAIN will immediately be recognized, then, to modify the bill, and it be in order that the majority leader 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 Democratic leader.

Mr. DASCHLE. Mr. President, this is the same unanimous-consent request propounded last Friday. The difference is that I have now had the opportunity to consult with my colleagues, and also to consult with the President and those in the White House who have a great deal of interest in our progress on this legislation.

The President has just sent Senator LOTT and me a letter, indicating his desire to either keep us here or bring us back if we are not sufficiently successful in meeting the goals that we have all indicated we share with regard to the completion of the work on the McCain-Feingold bill.

Given his assurances that he will call us back or keep us here—and I certainly hope that that is not necessary because I think there is plenty of opportunity for us throughout the month of October to bring this legislation to the floor and have a good debate—we certainly would not object.

As I indicated on Friday, I had two concerns, one, that we would run out of time and, two, that I had not had the opportunity to discuss this matter, and we were precluded from offering the amendment to any other legislation in the event that we would have run out of time. Now there is no concern for running out of time because the President will see to it that we have whatever length of time we need to complete our work.

So Mr. President, I am very pleased that we have been able to make this progress, and we have no objection.

The PRESIDING OFFICER. Is there objection?

Mr. DASCHLE. I ask unanimous consent that the letter sent to me by the President be printed in the RECORD.

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

THE WHITE HOUSE,
Washington, September 23, 1997.

Hon. THOMAS A. DASCHLE,
Democratic Leader, U.S. Senate, Washington, DC.

DEAR MR. LEADER: Senators McCain and Feingold have pledged to bring their campaign reform legislation to a vote. When that happens, the American people will be watching. I encourage you to act responsibly and support passage of this long-overdue, bipartisan legislation.

This measure is of the utmost importance, and it deserves full consideration on the Senate floor. If any attempt is made to bring this bill up in a manner that would preclude sufficient time for debate, I will call on Congress to stay in session until all of the critical elements are fully considered.

There is a real need for reform. The amount raised by both political parties is doubling ever four years. And as candidates are forced to spend ever greater amounts of time raising every larger amounts of money,

the people's business suffers. We have an obligation to restore the public trust.

The bipartisan measure that Senators McCain and Feingold intend to bring to the floor is balanced and effective. It addresses many of the most pressing needs for reform. It does not include every reform that I believe necessary. But it is an important first step—and it represents the only real opportunity to enact meaningful reform in this Congress. Any attempts to attach amendments that would make it unpalatable to one party or another are nothing less than attempts to defeat campaign finance reform. And a vote to filibuster this measure is nothing short of a vote to maintain the system that favors special interests over the public good. For years, the special interests and their allies have filibustered reform. But this year, the American people will hold accountable those who vote to maintain the status quo.

Despite formidable odds, the Congress faces the best opportunity in a generation to enact campaign finance reform. Let us work together in a bipartisan spirit, as we have throughout this legislative session, to thwart special interests who seek to smother reform and deny the will of the people. I urge you to support the bipartisan efforts embodied in the McCain-Feingold proposal, permit the Senate to debate their bill, and vote to enact these needed changes to our political system.

Sincerely,

BILL.

Mr. LOTT. Mr. President, it is the same unanimous-consent request I offered last Friday. I thought it was a fair procedure within the bounds of the 105th Congress' 1st session to take up consideration of campaign finance reform. I still think it is a fair procedure. I indicated last Friday it was never my intent to try to have this come up on the last day or the last week. I do not think that would be in anybody's interest. And I did not intend to do that. I said at the time I did not intend to do that.

So I am glad we have this worked out. We will work now to try to determine a time to bring up consideration and debate of this issue in a way that will allow us to have time to discuss it freely but also give us time to look at other issues that we hope to have completed before the end of the session.

With regard to the President's letter, I have not had an opportunity to read the letter yet. I am always glad to have a communication from the President. I do not feel threatened or intimidated by the letter because we still have an awful lot of work to do together on appropriations bills. I am still hopeful that we can have the ISTEA follow-on transportation infrastructure bill passed. And we hope to even consider the fast-track legislation.

So the President has a lot of issues that he would like for us to work with him on. We would be glad to do that. And we intend to do that. However, we do not intend to be threatened or intimidated on this or any other issue.

The PRESIDING OFFICER. Is there objection?

Mr. MCCAIN addressed the Chair.

The PRESIDING OFFICER. The Senator from Arizona.

Mr. MCCAIN. Reserving the right to object, and I will not object, first of all,

I want to thank the majority leader for his willingness to take up this issue.

As I said on Friday when he made it very clear to all that we would take up this issue in a timely fashion under the conditions of the unanimous-consent agreement, as he stated, I thought it was eminently fair.

There are other issues that are before the Senate that need to be resolved. And over time I have great confidence that the majority leader will bring up this issue so that it can be adequately addressed.

As far as the letter from the President is concerned, let me just say, Mr. President, we all know that the President can call Congress into session all he wants to. He cannot make them act. And I see from time to time, as we address this issue, the seeking of some kind of political advantage and leverage here in this debate.

Let me make one thing perfectly clear, the only way we are going to achieve meaningful campaign finance reform is by sitting down together in a bipartisan fashion. We do not need letters from the President of the United States now. What we need is meaningful and serious negotiations between all parties committed to meaningful campaign finance reform. I intend to work with my colleagues on both sides of the aisle to achieve that.

Again, I want to thank the majority leader because he told me a long time ago that this issue would receive the serious consideration that it deserves, and he has confirmed that confidence with the unanimous-consent agreement today.

Mr. KERRY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KERRY. Mr. President, I will not object either. I just want to ask the majority leader a couple questions.

Mr. President, I ask, is it possible for the majority leader to share with us any little bit deeper what his thinking might be as to when he thinks it might actually come? I know he cannot be precise, but is there some variation here in the course of the next 3 weeks, Mr. President?

Mr. LOTT. Well, we need to look at the conference reports on appropriations bills. We need to look at the continuing resolution, if one is needed. I presume it will be. We need to look at what progress is being made with regard to the ISTEA or the highway transportation bill. And we need to look at when we will need to schedule fast track. And we will need to consider when we are going to have an opportunity to take up serious product liability.

So there are several issues that we feel like, I think on both sides of the aisle, we must do this year, and one way or another—or should do—and we will look at all of that. It is not my intent to drag this out to the end of the session because I would like for us to be—if I had my way, I guess the last thing we would do would be probably

the fast-track legislation in one form or another and to deal with it up or down. That would be my thinking what we would do last, not because I am pushing it off to the end but because we have to have some hearings, it has to be marked up, go to Finance and I think Banking and two or three other Committees. That is what looks like will probably come up toward the end of October or early November.

So it is my thinking that we would want to do it before then. I will try to, you know, make sure everybody has an input here. We have Senators on both sides that have interest. We have chairmen that have interest. It is not my desire to have this come up in the congestion at the end.

I want to find a window. I can see a possibility of one before long where we can take this up and consider it for a period of time that everybody might be comfortable with.

Mr. KERRY. Mr. President, I thank the majority leader for the breadth of that. I think it is very helpful to have that on the RECORD.

Secondly, I want to ask him just with respect to my own understanding of the request, the first amendment is the amendment from Senator MCCAIN.

Mr. LOTT. The original McCain-Feingold.

Mr. KERRY. Followed immediately by an amendment from the majority leader; is that correct?

Mr. LOTT. No. Followed by the modified McCain-Feingold bill.

Mr. KERRY. With a second degree?

Mr. MCCAIN. Substitute.

Mr. LOTT. My amendment would be a first-degree amendment after the McCain-Feingold modification.

Mr. KERRY. Mr. President, if I could ask, in furtherance of the effort here to keep the bipartisanship and discussions going, would it be possible in the near term for us to learn the content of that other amendment, of the amendment of the majority leader, so that we might be able to have something competent to be able to meet on and discuss?

Mr. LOTT. We have not made a final decision. We have a number of options we are reviewing. It could be an amendment or it could be an amendment in the nature of a substitute. And we are looking at both of those possibilities. But before we bring it to the floor, we will notify the Members of what our intent would be on that.

Mr. KERRY. I thank the majority leader.

Mr. FEINGOLD addressed the Chair.

The PRESIDING OFFICER. The Senator from Wisconsin.

Mr. FEINGOLD. Let me take a moment, and reserve the right to object, to thank both of the leaders for coming together on this issue. It is of tremendous importance to everyone here in this body and to the American people. And I think they both have an extremely difficult task in dealing with an issue like this that is of such personal importance to each Member of the Senate.

It is very heartening to know that we have an agreement that will allow the open debate on this issue. Last year when the debate came up, there were no amendments and a cloture vote within 2 days. It was not a great opportunity for the body and for the members of the public to be involved in. So I think this is a great step forward.

I want to thank my leader, Senator DASCHLE, for his persistence on this. I want to thank the President for his absolutely relentless support of our legislation for over 2 years now. And I appreciate his involvement in this as well.

But overall, what I think we have seen here is a bipartisan ability to come together on timing. I hope it leads to a bipartisan ability to come together on a meaningful piece of legislation.

With that, I yield the floor.

Mr. MCCONNELL addressed the Chair.

The PRESIDING OFFICER. The Senator from Kentucky.

Mr. MCCONNELL. Mr. President, I too want to thank the distinguished majority leader for working with others who are interested in this legislation to create an atmosphere in which we can have an important debate on an issue of enormous significance to our country. I think it is a sensible and orderly way to give everyone an opportunity to have his or her say. I commend the majority leader and Senator MCCAIN as well for their good work to bring us to this point.

The PRESIDING OFFICER. Is there objection to the unanimous consent request of the majority leader? Without objection, it is so ordered.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNT- ABILITY ACT OF 1997

The Senate continued with the consideration of the bill.

Mr. JEFFORDS. What is the pending business?

The PRESIDING OFFICER. There is now to be 4 hours of debate equally divided on S. 830. The Senator from Vermont controls half that time.

Mr. JEFFORDS. I yield to the Senator from Utah 5 minutes.

The PRESIDING OFFICER. The Senator from Utah.

Mr. HATCH. Mr. President, I ask unanimous consent that the RECORD reflect the fact that amendment No. 1182, as modified, which was adopted was a Hatch-Wyden amendment.

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

Mr. HATCH. Mr. President, there is an old saying, "No good deed goes unpunished." And it applies only too well to those who tackle the job of shepherding the FDA legislation through Congress.

The legislation we are debating today has its foundation in the last Congress.

From my experience, I know that FDA bills are inherently contentious and complicated—and that would be true even if my friend from Massachusetts, Senator KENNEDY, was not on the Labor Committee. Sometimes I believe that it was this FDA bill that drove our good friend Nancy Kassebaum out of the Senate.

So we should all take off our hats and thank JIM JEFFORDS for his efforts in forging this important compromise bill. The overwhelming votes on cloture and on the motion to proceed are testament to the fact that S. 830 is a solid piece of bipartisan legislation that will benefit the American public for years to come.

Every Member of this body understands only too well the necessity of having good staff. Our staffs work long hours in order to resolve very difficult issues. I commend the work of all of the staff involved in the development of this bill. I will defer to tradition and allow the chairman and ranking member to single them out when the bill achieves its final passage.

However, I do want to depart from tradition for a moment to compliment the work of Senator JEFFORDS' point person on FDA reform, Jay Hawkins. It is always safe to bet against the passage of FDA legislation, but Jay joined the Labor Committee this past winter and hit the ground running and has helped the chairman in crafting and bringing S. 830 through the committee and onto the floor.

Jay has worked hard, listened patiently to diverse viewpoints, identified and solved problems, and has exhibited sound judgment and tremendous energy throughout this process.

Unfortunately for Jay and his family, on August 20, his mother, Mrs. Donna Lotz Hawkins, died after a long battle with cancer. Jay's mom was a mountain climber, ocean swimmer, and distance runner who had many friends that will deeply miss her.

The loss of a parent can never be replaced. While I never met Jay's mom, as a parent I know that she must have been extremely proud of her son for all of his important work in the Senate.

It is only fitting that this bill, which has so much of Jay's imprint, promises to speed the development of the next generation of cancer treatments.

I just wanted to take these few moments to salute Jay and the chairman for their considerable efforts on the FDA bill, and I want to extend my condolences to the Hawkins family on the loss of his mother.

I yield the floor.

Mr. D'AMATO addressed the Chair.

The PRESIDING OFFICER. Who yields time?

Mr. JEFFORDS. I yield 5 minutes to the Senator from New York.

Mr. D'AMATO. I thank the chairman and ask unanimous consent that I may proceed as in morning business.

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

(The remarks of Mr. D'AMATO pertaining to the introduction of S. 1203

are located in today's RECORD under "Statements on Introduced Bills and Joint Resolutions.")

Mr. KENNEDY. Mr. President, I yield such time as the Senator from Rhode Island might use.

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. REED. We have made great progress with respect to the Food and Drug Administration [FDA] bill. That is a tribute to Chairman JEFFORDS and the ranking member, Senator KENNEDY from Massachusetts, and all the members of the committee and the Members of the Senate participating in this debate.

However, there remains at least one issue of concern, one issue that was a subject of extensive debate today. That issue is a provision regarding the 510(k) approval process for class I and class II devices. As I mentioned previously, these class I and class II devices are serious medical devices. This is not a Band-Aid or gauze. These are lasers or biopsy needles or many other complicated, necessary medical devices.

As a result, we cannot, I think, assume that this is a small or inconsequential issue we are debating. It is a very important issue.

Essentially, the legislation that is before the Senate today limits the FDA from looking behind the stated use on the label presented by the manufacturer when they request approval to put a new product on the market. It is important, in certain cases, to make such a searching review beyond the proposed use by the manufacturer. It is particularly important in the case where there is strong suspicion that the label is either misleading or fraudulent or false. Although my amendment was not favorably considered earlier today, it would have given the authority to the FDA to look beyond the label in cases where they could show—and this is a very high standard of proof—that the label was false or misleading.

There is no other provision in this new legislation that would give the FDA such authority. Indeed, one could ask why the proponents of this legislation deliberately chose to remove the FDA's authority and to effectively prevent the FDA from conducting a thorough review of medical devices as they come on the market.

I have outlined, as many of my colleagues have, the detailed reaction of several sections of the FDA law. It is complicated, arcane legislative language.

I have tried to think of a more homely and mundane example which might illustrate the dilemma the FDA would be facing as it contemplates this new legislation. If the FDA were in the position of not approving medical devices but approving, for example, land transportation vehicles, they might be confronted with an existing model, perhaps a Ford Mustang. And say, for example, a new product such as an F-16 fighter plane is presented for review.

Both can move over the ground, both of them are fairly fast, and both of them have certain similar aerodynamic capacities. Both of them can carry passengers. So one could make the argument that the F-16 could be substantially equivalent in use as a ground transportation vehicle.

But I think anyone would have to say, upon looking at both of these devices, that there is a strong suggestion the F-16 can be used for something else. If the FDA, or in this example, the hypothetical agency, did not have the authority to ask the simple question: Will it be used to fly and can it fly? The hypothetical agency may not be doing the job.

That is a homely example to illustrate that the FDA is frequently confronted with devices that are presented as being substantially equivalent to existing devices. These new devices may be similarly labeled to that existing device, but they have the potential for other uses. If it is obvious that the device is for uses not listed on the label, the FDA should have the authority to make an inquiry into those other uses.

In fact, my suspicion is that in the development of new medical devices there is a long history of starts and stops. A history of contact with other individuals, many researchers working together, exploring different uses and alternatives, different materials. In that process, it is very likely that other issues are contemplated, evaluated and perhaps designed into the device.

Today we have a system where there is more incentive for approaching the FDA with a petition of a 510(k) approval because that is the fastest way to the marketplace. Even if there were uses that were discussed and contemplated, even if there are obvious uses that might become part of common practice, those may be dismissed in order to get this through the system quickly.

What we have done today by not adopting my amendment is effectively prohibit the FDA from making that searching inquiry into possible uses. The consequences can be severe to the public health.

Despite all of these issues we have discussed, this bill represents significant progress on many fronts. We are very, very close. I hope in the ensuing conference—or before we go to conference—that we could address this particular issue. It is an issue that has been highlighted by Secretary Shalala. It has been highlighted with respect to the potential for a Presidential veto. I hope we don't reach that point.

The hard work that has been done over many months by my colleagues, the hard work of many representatives of the industry, and the hard work of public health advocates I think will lead us, if we can get over this hurdle, to a bill that we will all be proud of.

In conclusion, today we have spent some time discussing the industry. We have spent some time discussing the

FDA. There have been criticisms by Members with respect to both the industry and the FDA. Our job at this point is not to demonize or deify anyone. It is to get good laws passed. I believe this legislation can be approved and can succeed.

I note the majority leader is standing by, and I yield back my time.

VISIT TO THE SENATE BY THE EUROPEAN PARLIAMENT

Mr. LOTT. Madam President, I am pleased to welcome a delegation from the European Parliament to the U.S. Senate. The parliamentarians are in the United States for the 47th interparliamentary meeting.

Europe continues to move forward with economic integration and the European Parliament's role is increasingly important. As the European Union—like the North Atlantic Treaty Organization—expands, the role of the European Parliament will become even more important.

The United States and the European Union have the world's largest commercial relationship, with trade and investment approaching \$1 trillion.

I believe increased interaction between our legislature and the European Parliament will serve the interests of both sides. I would like to add that I met with the U.S. Ambassador to the European Union, Mr. Vernon Weaver, earlier this summer and was impressed with the job he is doing to protect American interests in Brussels and across Europe.

I urge my colleagues to greet this delegation, led by Mr. Alan Donnelly of the United Kingdom.

Madam President, I ask unanimous consent that a list of all of the delegation be printed in the RECORD.

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

EUROPEAN PARLIAMENT DELEGATION FOR RELATIONS WITH THE UNITED STATES
(47th EP/US Congress interparliamentary meeting, 21–26 September 1997, Washington DC)

LIST OF MEMBERS (15)

Mr. Alan Donnelly, Chairman, PSE, United Kingdom.

Mr. Bryan Cassidy, 1st Vice-Chairman, PPE, United Kingdom.

Mr. Lucio Manisco, 2nd Vice-Chairman, GUE/NGL, Italy.

Ms. Nuala Ahern, V, Ireland.

Ms. Mary Banotti, PPE, Ireland.

*Mr. Jacques Donnay, UPE, France.

*Mr. Willi Görlach, PSE, Germany.

Ms. Ilona Graenitz, PSE, Austria.

Mr. Fernand Herman, PPE, Belgium.

*Mr. Mark Killilea, UPE, Ireland.

Ms. Elly Plooijs-Van Gorsel, ELDR, Netherlands.

Mr. Barry Seal, PSE, United Kingdom.

Mr. Michael Tappin, PSE, United Kingdom.

Mr. Josep Verde I. Aldea, PSE, Spain.

Rapporteur on Transatlantic Trade and Economic Relations, Ms. Erika Mann, PSE, Germany.

NOTE—Abbreviations:

PSE: Group of Party of European Socialists.

PPE: Group of the European People's Party (Christian-Democratic Group).

UPE: Union for Europe Group.

ELDR: Group of the European Liberal Democrat and Reform Party.

GUE/NGL: Confederal Group of the European United Left—Nordic Green Left.

V: Green Group in the European Parliament.

RECESS

Mr. LOTT. Mr. President, I ask unanimous consent the Senate stand in recess for 5 minutes so we may greet our guests from the European Parliament.

There being no objection, the Senate, at 4:58 p.m., recessed until 5:06 p.m.; whereupon, the Senate reassembled when called to order by the Presiding Officer (Ms. SNOWE).

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The Senate continued with the consideration of the bill.

Mr. KENNEDY. Madam President, we are making substantial progress on the FDA bill, and I applaud that progress. We have worked out a number of key issues on a bipartisan basis since the committee markup in June. We have worked out the issues on fast tracking some innovative opportunities for dealing with the special challenges we are facing. We built on the fast tracking that we have done on AIDS drugs, and we are trying to do more in the areas of cancer and Alzheimer's, following what has been an important initiative at FDA for getting drugs out faster. We have even worked out differences on the off-label uses of various pharmaceuticals and devices and what information and studies will be required in terms of safety and efficacy. We have worked out the early consultation between device manufacturers and the FDA.

We have been working toward reducing the total development time. A key element in our negotiations has been going upstream and working with the pharmaceutical companies, as well as the manufacturers, in shaping and formulating their applications so that they will move more rapidly through the approval process. Many of these initiatives were worked out by Dr. Kessler. We have put them into legislation under the leadership of Senator JEFFORDS and others on the committee. We have settled the issues of cosmetics, after good debate and discussion. We have also worked our third-party review pilot programs and timeframes for some of the drug approvals. Each one of these issues was worked out in a way that protects the public health.

This process continues now with further debate today and tomorrow on what I, and others with me, consider to be the most significant threat to the public health remaining in the bill. These other areas that are complex and difficult, where a wide variety of different positions had divided the committee in a significant way. We have

been able to make important and significant progress in ways that advance public health. I believe that we have advanced the interest in the public health. This final issue remains and has been identified by the President of the United States and the Secretary of HHS as being the No. 1 public health risk within this legislation. We had a good debate on that issue earlier today and a real engagement of the differing ideas. I find that we were able to make important progress. The Members realize and recognize what is really at stake. We were unable to win the majority of the Members, but we have a substantial group of Members who are likewise concerned about the public health issues.

We have heard from the various consumer groups and they are the ones that will benefit the most from breakthrough devices. If you read through their concern and opposition to the provision in the legislation and their strong support for the Reed amendment, you understand why we are so concerned about this particular provision.

The House is in the process of taking up legislation dealing with the same subject matter, although they have reached a stalemate with regard to the extension on PDUFA. PDUFA, which I certainly support, provides the additional resources for the FDA to get the kind of trained disciplined personnel that represents the top of our research technology to work very effectively in the evaluation of these various products.

As the prime sponsor of that proposal here in the Senate, with my friend and colleague, ORRIN HATCH, we are clearly strongly in support of PDUFA. We tried to take similar action with regard to the medical device industry, but we were unable to do that. But we were able to accomplish it with the pharmaceutical industry, and it is necessary to have this extension.

The House will take up the FDA. We will continue to work with the administration, and with the leaders of the Energy and Commerce Committees in the House to make sure the compromises reached in the Senate are retained or improved. We will work to make sure that the medical device issue that we have been debating on the Senate floor is fixed.

We believe that the Food and Drug Administration should not be faced with a situation where a device is submitted with a label that contains false and misleading information that would effectively deny FDA an opportunity to review the device on its real uses. And deny them the authority to require the medical device company to provide information relevant to the safety of that medical device.

There is nothing that we have heard that changes my very view that the interests of the American consumer and the American public are best protected by strengthening the lead agency for safety—the Food and Drug Administra-

tion. The agency to which all Americans turn when they find that there is tampering with pharmaceuticals, or they are concerned about the importation of pesticides on grapes from Chile, or they are concerned about drugs and medical devices. We saw that across the country this last week with the fen/phen tragedy.

Now we are being asked to reduce the protections for the American people by prohibiting this lead agency, with all its expertise, from protecting the public when it comes to medical devices. We are handcuffing them from being able to reach out and protect the American public when a medical device is falsely labeled. That is a serious error on our part.

A great deal of discussion has taken place in the committee and out here on the floor of the U.S. Senate as to the FDA's ability to approve medical devices in a timely manner. We heard it expressed this morning. We heard, "Just look how bad the FDA really is." We have to accept this provision because it is going to make such a difference to the patients that need these medical devices.

Let us look at what the record has been with regard to the FDA.

If you go through the GAO study on the FDA and its approval record, the progress that has been made in the recent time is truly remarkable. I have it here. This shows the review times that have been decreasing, starting in 1994, continuing 1995, and 1996. This is the General Accounting Office.

The premarket notification 501, the median FDA review time for notification as judged to be equivalent devices already on the market has dropped consistently from 199 days to 95 days in 1996. Look at that difference between 1993 and 1996. The time reduced from 199 days to more than half for the medical devices that are the substantial equivalent.

Here is the premarket approvals. Those take longer than the premarket notifications because the FDA reviews the substantial amount of evidence to determine if the devices are safe and effective. The median time for PMA has dropped from 766 days in 1993 to 280 days in 1996. Again, a 40 percent reduction of the time—a dramatic improvement in the most complicated medical devices that are new; to convince the FDA with the range of different new technologies that are coming and that are being implanted in people. We have reduced that time for clearance on the newest devices that have to be tested carefully and evaluated in terms of their safety. We have dropped the time by about 35 or 40 percent. Approval times have been reduced and we still have the best safety record. We are seeing dramatic improvement in approval time for the most complicated medical devices, and we are seeing dramatic improvement in approval times for the kinds of medical devices that are substantially equivalent. And we still have a strong safety record. But that isn't

enough for the medical device industry. They are refusing to support an amendment which would permit the FDA to look at the safety features of medical devices that ought to be looked at.

It would be an entirely different matter if these improvements had not been made. At least you would have an argument to say you needed dramatic changes in the approval process. But the time it takes for the newest kinds of medical devices are improving dramatically.

We heard on the floor of the Senate, "Well, we have to be able to get these devices out there because all of us are aware of how fast those devices are being approved in Europe. If we do not accept this provision, all our medical device companies are going to go abroad. We are going to lose jobs. This is an issue of jobs. We will take a chance with the health of the American people on this so we can keep our industry here and protect our public."

Well, let's look at the facts on this one. We have just had the GAO report of June 1997 showing the remarkable progress that is being made in terms of approving these devices while still doing comprehensive examinations of the complex safety issues. They can evaluate the new kinds of safety information provided by the medical device industry, and do it in a timely way, and protect the public. That is what Senator REED and myself believe should be done with regard to this provision.

Madam President, this is a May 12, 1997 document by the World Medical Device Diagnostic News.

This is April 21, 1997.

I will include the relevant parts in the RECORD. But I am reading now:

France calls on EU to tighten device controls. In a letter to the European Council of Ministers, the French government has called for tighter controls over high-risk medical devices. The government is particularly concerned about implantable devices and other products that fall into the high-risk categories, class 3, class 2.

The letter which was sent to other EU member states has not been released publicly. It forms part of the French campaign of ever-increasing intensity for more stringent relations on medical devices. France is also questioning the validity of the European approach to the regulation of products that pose a high risk to health.

Then in another section talking again about the European Union, industry experts speculate the French might argue on the basis of the results and the question of medical device directors being unable to cope with the high-risk products.

These are storm warnings with regard to the use of high-risk products—storm warnings from our European friends about what is happening over there with their medical device industry. Then we heard here, "Well, those may be high risk but we are only looking at low risk devices." Low risk? The list of the products that are being suggested as low risk: Ventilators, fetal

cardiac monitors, imaging devices, MRI ultrasound, x-ray. Who wants to take chances about whether the ultrasound that an expectant mother is having is going to do the job or not? We think that is a low risk? We don't think that mother ought to be able to get satisfactory information about the adequacy of the protection and the soundness of x rays and CAT scans and ultrasound and MRI's, imaging devices. Low risk? Anesthesia machines. Low risk? We have the storm warnings about what is happening in our own country.

Here is the February Business Outlook for the Medical Device Link. Here is their cover story February 1997:

With the improvements in FDA product review performance, despite an ever more challenging domestic market, device company executives are more optimistic than ever.

They talk about the FDA being cited by many as the leading source of their pessimism.

While nearly as many blamed the disconcerting restructuring of health care providers, two years later—that is now. This is going back to 1994 and 1995.

“* * * two years later device company executives report a substantial improvement in FDA's performance, particularly in the 510(k) product approval times.

This is the medical device industry document. It continues.

In fact, this year's survey conducted last October marks the highest business climate ratings ever in the 5-year history of the survey.

The highest degree of approval rating ever in the 5-year history.

It is going well, my friends. We do not have a Shiley Heart Valve tragedy today. We don't have a Dalkon Shield tragedy today. It is working in terms of protecting the public. But the industry is demanding changes in providing the protection. Why? This is what the industry is saying about the FDA. “The impact of FDA's internal reforms and review time is more significant than might appear. The agency has not only reduced the approval delays that slowed newer products but, perhaps more importantly, has greatly reduced uncertainty as to the timeliness of future product introductions.”

I will include the appropriate amount of this. I will not take up the whole record, although it is a fairly short document.

It continues along: Respondents' rating of the current business climate for the medical device. Here are the results. A substantial majority of medical device executives said, medical device industry, good or excellent.

Then it has executive ratings of device industry business climate, 1993 to 1997: 58 percent good or excellent. Last year it was 58 to 11. Find me an agency of Government where those who are being covered by the regulators are saying 58 percent approval, 11 percent disapproval. An examination of this review shows that it was down just in 1995, 37 to 23—37 percent approval, 23 percent disapproval. Now that dis-

approval has gone from 23 to 12 to 11 in 1997 and the 37 is up to 58 in 2 years. This is the reflection of those who are involved in medical device businesses.

“Expectation of respondents for business conditions in the medical device and diagnostic industry,” again, going up, enormously favorable.

“One important cause of this year's improved outlook is the clearly perceived improvement in relations with the FDA. As shown in figure 5”—that will be in the RECORD—“the decline in complaints about the agency mirrors the increase in positive business outlooks.”

You could not get a greater endorsement. You could not find better support for an agency that is being regulated. You could not see a more dramatic improvement in how that agency has been dealing with those that it is required to police. And all while still protecting the public health, all being done to protect the public health. As the Secretary of HHS and the President of the United States said, of all the different provisions, this is the one that puts the public health at risk. All against a background of a device industry that is saying things have never been better.

Several committee members have expressed concerns that the FDA will try to think of every possible off-label use for a device and harass the industry to death. There is no justification for that attitude. It is good rhetoric, but it just defies any kind of understanding about what is happening in the medical device industry today. The medical device manufacturers and personnel find that their relationship with the FDA is improving significantly in terms of how they are being treated, the times that are involved, the way that the agency has been considering various applications like the ones we have been talking about. The public health is being protected, but we are being asked to change it.

How many times around here do you hear, “If it is not broke, why fix it?” Well, this is the attempt to try to fix something that is not broke. And we are not talking about widgets here. We are talking about real health implications to the American public.

Why should we take a chance on people's health when those medical devices are being carefully tailored and designed technologically to do something that is different than is on the label? It just defies me. That is the issue.

So, as we go on through this survey report, talking about international markets: “Just as outlooks on business are influenced by market segments, so, too, they are affected by geographical markets. In fact, large companies have a clear advantage over small ones in entering foreign markets. Of the companies surveyed, 91 percent were selling to the United States, just over half were doing business in Europe and Canada, while 36 to 40 percent were in Latin America. Of the largest compa-

nies surveyed within the various”—\$50 million in annual revenues, 90 percent or more were involved in the survey and they show here when asked what markets offered them the best prospects in 1997, more respondents, 80 percent, named the United States than any other market. This are the medical device companies from Central and South America talking about what they believe the greatest opportunity for market expansion is in the United States, and they are going to have to meet the strict requirements that are being put out by the FDA. They think, even going through those requirements for safety and ensuring the public is going to be protected, that there is this dramatic opportunity for growth.

And it just continues. If we go through the Medical Economics magazine of this year, January, it talks about the enormous explosion of the various devices, talking of the demand for devices to treat arteriosclerosis, enlarged prostates, infertility and many others creates a worldwide market of \$120 billion, including about \$50 billion in the United States. That's growing by 8 percent annually. Feeding this demand are technologies that offer new ways to treat disease, allow doctors to treat illness more quickly, effectively and safely. The coronary stent, for example, created a submarket that exploded from \$220 million globally to more than \$1 billion in 1996. Sales of this device are growing 30 to 40 percent.

I used that as one of the examples here the other day. This is a \$1 billion industry. We are talking about the power of this industry to put pressure on Congress, with this kind of economic power, that pressure is dramatic. To resist that kind of pressure when it is contrary to the protection of the public health I think is enormously important.

What we are saying is simple and fundamental. That is, the proposal that is being advanced here will permit the medical device industry to submit various medical devices to the FDA and the FDA will be limited to examining only the uses listed on the label of the medical devices. If it is substantially equivalent to a medical device that's been approved, all the company has to be able to show is that it has the same kind of safety protections that the earlier device had, even though—even though—it is the intention of the medical device manufacturer to use that medical device for an entirely different purpose and market it for an entirely different purpose, the FDA is prohibited from examining the safety features.

Maybe those safety features are such that they will significantly improve the health and well-being of the person that is using the medical device, but we ought to make sure at least that the agency has the information that would justify that utilization. All this is happening against a background which demonstrates that the medical

device industry is happier with the FDA than at any time in the history of the 20 years, 23 years, of medical device legislation. Happier that there has been a dramatic improvement in approval timeframes, important improvement in terms of safety. We are taking that excellent record and risking it with this particular provision. It does not make sense.

This makes absolutely no sense at all. We strongly believe that this provision has to be altered or changed. We have missed the opportunity to do that on this particular legislation, but we will have further opportunities to do so in the near future.

It is amazing to me, as we went through consideration and as we were able to make progress on so many other items while advancing public health, but the medical device industry does not want to deal with this one. They felt they had the votes. They had them this afternoon. But this is a long road. It is a long road, the completion of this whole process, and we are going to fight every step of the way. We have seen a variety of different options that would attend the kind of concerns that the medical device industry has put expressed, which we and the FDA and the administration were prepared to deal with, but the device industry is unprepared and unwilling to do so.

So if they are unwilling, we are unwilling at least to roll over. There are a variety of different procedures which we will have to resort to in order to make sure that this threat to the public health of the American people does not go forward over the objections of those who are in the best position and do represent the patients and the consumers.

By accepting this change in the protections available to the American public at this time, we are not saying that the health of the American people is going to be advanced. If this particular provision remains unchanged, a provision which effectively handcuffs the FDA, it is the bottom line of the medical device companies that will be enhanced. And ethical companies and the protection of the American people will suffer.

That makes absolutely no sense. It is basically and fundamentally wrong, and we will continue the battle ahead.

APPROPRIATIONS "TRIGGER"

Mr. COCHRAN. Madam President, as chairman of the Appropriations Subcommittee with funding jurisdiction for the Food and Drug Administration, I am compelled to state my opposition to the appropriations mandate in this bill. While this bill reauthorizes prescription drug user fees for the next 5 years, it also states that the FDA cannot assess those fees unless the appropriation for FDA salaries and expenses is at least equal to the appropriation for fiscal year 1997, adjusted for inflation.

The Appropriations Subcommittee will continue to balance the needs and requirements of all agencies and activi-

ties under its jurisdiction within the total amounts available for discretionary appropriations. Any member of the Senate who disagrees with the committee's recommendations is free to seek to change the allocation of resources proposed in the bill.

However, annual appropriations decisions should not be predetermined by the establishment of arbitrary appropriations "floors" and "ceilings" in authorization bills. In this particular case, the bill seeks to dictate that FDA's salaries and expenses appropriation be "held harmless" against inflation—that for each of the next five fiscal years, the appropriations be at least equal to the current appropriations level, adjusted for inflation. If not, FDA cannot assess prescription drug user fees.

Madam President, I am certain that each agency and program which receives appropriations would like to secure a similar protection against inflation. However, this is unrealistic in the current budget environment and inconsistent with the levels available for discretionary appropriations under the bipartisan budget agreement.

Industry paid fees are expected to supplement rather than supplant FDA spending for drug approvals. For this reason, I understand the industry's desire to make sure that FDA maintains its current level of effort relative to the drug approval process. However, as I indicated, it is unreasonable to attempt to guarantee FDA protection against inflation at the possible expense of other programs and activities. It would be difficult for me as chairman of the Appropriations Subcommittee of jurisdiction to predict what agency or program restructuring might occur over the next 5 fiscal years, what a program or agency's future resource requirements might be, or the fiscal constraints the subcommittee might face in each future year.

Mr. President, it could be that the minimum mandated appropriations level in this bill is met in each of those years. However, it is just as likely that it would not be. The Appropriations Committee will continue to do its work by considering the needs of every program and agency within its jurisdiction within the total resources available to it. It will not feel constrained to meet the proposed appropriations "trigger" for the collection of prescription drug user fees if it remains in this bill.

I do not think it is the intent of the Labor and Human Resources Committee or the Senate to set an arbitrary mandate that might result in a situation during the course of the next 5 years where these fees may not be collected. I believe this would undermine the existing drug approval process and run counter to the interests of the federal government, the industry, and the American public. The issues and concerns I raise are similar to those expressed by Senators GREGG and

McCONNELL in the additional views they incorporated in the committee's report accompanying S. 830.

Madam President, I am hopeful that the committee take this issue seriously and will work in conference to remove this appropriations mandate and possible impediment to the continued success of the Prescription Drug User Fee Act.

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

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

Mr. KENNEDY. Madam President, I am prepared to yield the remainder of our time this evening.

Mr. JEFFORDS. Madam President, we are not prepared to at this time, so I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

MILITARY AIR CRASHES

Mr. DASCHLE. Madam President, on Friday afternoon of last week, I was shocked and saddened to learn that a B-1B bomber had crashed near Alzada, MT, during a routine training mission over the Powder River military operations area. The bomber was assigned to Ellsworth Air Force Base in South Dakota, and all four crew members aboard the aircraft were killed.

I wish to extend my deepest sympathies to the families of those courageous individuals. They died in the service of their country, and I know my colleagues join me in honoring their memory and their sacrifice.

The B-1 accident was the sixth military air crash in 7 days. Although there is no apparent connection between the accidents, Secretary of Defense William Cohen rightly asked the Air Force and the other branches of the Armed Forces to implement a 24-hour safety stand down to allow those who fly and maintain U.S. military aircraft to focus on safety.

Despite the rash of accidents that occurred in recent days, the past year has been a relatively safe year for the Department of Defense.

Fifty-five military aviation accidents occurred this year compared to 67 last year, 69 in 1995, and 86 in 1994. Although this appears to be a good trend, the Pentagon must strive to improve its safety record even further, and they are doing that.

I commend Secretary Cohen for implementing a safety stand down and am confident it will yield positive results.

If it helps to prevent just one crash or the loss of just one life, the safety review will be well worth the effort.

As Secretary Cohen recently said, "The lives of our aircrews and passengers are very precious, and each loss is a great tragedy."

As the Air Combat Command, the Air Force and other branches of the Armed Forces study safety this week, I hope all of us will take a moment to reflect on those committed and dedicated individuals who lost their lives in military crashes in recent days. I would like to take a moment to review the exceptional lives of those four service members from Ellsworth Air Force Base who died in the tragic accident last week.

Col. Anthony Beat was born in Willard, OH, in 1951. He graduated from Ohio State University in 1973 and earned his commission through the Air Force Reserve Officer Training Corps the same year.

During his long tenure in the Air Force, Tony served in a number of capacities. He was a B-52 copilot, aircraft commander and instructor pilot. He was also assigned to the Bases and Units Division in the Strategic Air Command headquarters. Most recently, he served as the vice commander of the 28th Bomb Wing at Ellsworth Air Force Base.

My staff and I had worked closely with Colonel Beat on a number of issues during his tenure as vice commander. His expertise and many accomplishments had a profound impact on Ellsworth Air Force Base.

Colonel Beat was a member of the Ellsworth Black Hills Chapel and enjoyed jogging, hunting, and fishing. He is survived by his wife, Dolores Ann, and their son, James Allen.

Maj. Clay Culver grew up in Memphis, TN, and graduated from the Memphis State University in 1981. Since earning his commission in 1983, Major Culver was an Advanced Electronic Warfare Systems instructor in the 453d Flying Training Squadron, an assistant operations officer, and defensive systems officer instructor.

Most recently, he served as an assistant operations officer and weapons systems officer in the 37th Bomb Squadron at Ellsworth Air Force Base.

Major Culver is survived by his wife, Cynthia; a daughter, Ann; and son, Parker. Mrs. Culver said recently her husband "was doing the right thing, and it was a very honorable way to go."

Maj. Kirk Cakerice was born in 1954 in Eldora, IA. He graduated from the University of Northern Iowa in 1977 and married Myra Van Sickle the same year.

Kirk earned his commission in 1982 and served in a number of assignments including B-1B Aircraft Commander, instructor of B-1B Aircraft Commanders, and cadet squadron commander at the U.S. Air Force Academy in Colorado Springs. Most recently, he served as an assistant operations officer

in the 37th Bomb Squadron at Ellsworth Air Force Base.

A longtime friend of Major Cakerice said Kirk was the "prototypical Iowa boy." He "grew up in smalltown Iowa, tremendous sense of humor, very talented at sports, could learn something quickly and do it."

Major Cakerice was a member of the Canyon Lake United Methodist Church in Rapid City, SD. He is survived by his wife, Myra; son, Brett; and daughter, Kendra.

Capt. Gary Everett, who was engaged to be married, was the youngest of the four who died in the B-1B crash on Friday. He was born in Brooklyn, NY, in 1962 and grew up near Louisville, KY.

His parents, three brothers, and one sister still live in Kentucky.

Gary graduated from the University of Louisville with a degree in physics in 1986 and earned his commission through the Officers Training School 2 years later. He served as B-1B Defensive Systems Officer in the 34th Bomb Squadron and as a weapons systems officer in the 37th Bomb Squadron at Ellsworth Air Force Base.

Gary had many interests outside the Air Force, including an online service called RapidNet that he founded with two partners in Rapid City. Gary's sister-in-law, Karen Everett, said "Gary was a hero to all his younger cousins. He was a wonderful role model for all his achievements, in starting his own business, and for his emphasis on how important education is."

Captain Everett is survived by his parents, Joseph and Dorothy Everett, of Glasgow, KY; three brothers, James, Joe, and William; one sister, Carol Ann Johnson; and his fiancée, Karen Tallent of Rapid City, SD.

Mr. President, we suffered a tragic loss on Friday. Col. Tony Beat, Maj. Clay Culver, Maj. Kirk Cakerice, and Capt. Gary Everett served nobly, and they will be deeply missed. Their commitment and dedication to their families, the Air Force, and our country will not be forgotten.

Like many in South Dakota and throughout the country, my thoughts and prayers are with the families of those who lost their loved ones in this terrible tragedy. And we think of them now.

I yield the floor.

Several Senators addressed the Chair.

The PRESIDING OFFICER. The Senator from New Mexico.

Mr. DOMENICI. Senator LEAHY, how long will you go?

Mr. LEAHY. Madam President, I am sorry, I did not see the Senator from New Mexico. Under our normal practice in these kind of times we tend to go back and forth, so obviously the Senator from New Mexico would proceed.

Mr. DOMENICI. I have a few remarks regarding the IRS and the National Federation of Independent Businesses.

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

NFIB CAMPAIGN TO ABOLISH THE IRS CODE BY 2000

Mr. DOMENICI. Madam President, in 1990 Senator Nunn and I cochaired the Strengthening of America Commission which among its recommendations, called for abolishing the current income tax code, and replacing it with a progressive consumption-based income tax code that would encourage savings and investment.

The National Federation of Independent Business is in Independence, MO, today starting a nationwide petition drive that encourages all small business owners to sign a petition calling upon the President and Congress to abolish the IRS Code as of December 31, 2000 and to replace it with a simpler, fairer tax code which will reward work and savings.

I intend to sign this petition and encourage all of my colleagues to do likewise.

NFIB is launching the petition drive in Independence MO, home of President Harry Truman, who said, "The Buck stops here." NFIB is telling the American public that "the code stops here."

NFIB could have started their campaign in the town of Truth or Consequences, New Mexico. When dealing with the IRS, "tell the truth or pay the consequences" could be their motto.

But things have gone wrong. Compliance has become lax or nasty.

Despite a \$7 billion in annual budget and 106,000 employees the IRS failed to collect an estimated \$200 billion of taxes a year.

Tax collection is as nasty as it is lax.

In New Mexico, there is a sense of frustration among people trying to comply. Taxpayers receive computer generated letters. The letter is either a short, brutish demand for more money or an incomplete and unclear request for more documentation. The letters usually include no phone number, and no contact person. Now, that is actually from my staff working with constituents. The letters usually include no phone numbers and no contact person.

The letter strikes fear. The message is clear—TRUTH or PAY the consequences. But the letter usually fails to explain what truth, in the form of additional documentation, is needed to avoid the consequences.

In New Mexico, my home State, the IRS letter could originate in Phoenix, AZ, Ogden, UT, Albuquerque, NM, or Dallas, TX. When constituents fail to figure out the point-of-origin themselves they come to my office. It takes a professional case worker at least 2 days just to track down the IRS office handling the case of a New Mexico resident.

I know that the National Commission on Restructuring the IRS has issued its report and that Senators GRASSLEY and KERRY have turned the recommendations into legislation that takes a top-down approach giving the IRS commissioner a longer term and more flexibility.

But knowing what I know, I believe the legislation also needs to take a bottom-up, common sense approach. Simple things will make big differences.

For example, letters from the IRS should have a contact person and phone number that will be answered by that one-and-the-same person. I don't mean a 1-800 number that is totally automated. You have heard about it. It is the number that is always busy, but if you persist for about an hour you can get through. Then it puts you on hold for another hour, and finally provides the following helpful choices:

Press one for more instructions that you can't understand;

Press 2 for more information that will frighten you;

Press 3 for information that will confuse you further ;

Press 4 for information that contradicts what we told you when you pressed one, two or three;

Press 5 for information that contradicts what we told your accountant yesterday.

I wish I were kidding.

Part of the problem is the IRS. But part of the problem is the Congress, because we passed the tax laws that made the code too complicated. And for that we should all stand up, if we voted for those tax measures, and take our share of the blame.

The IRS simplest return, the EZ form 1040 has 33 pages of instructions. That is the easy form. The Form 1040 has 76 pages. The Earned Income Tax credit instructions are 23 pages and the worksheet is as ambiguous as it is long.

The National Federation of Independent Businesses estimates that America's businesses will spend 3.4 billion hours, and individuals will spend 1.7 billion hours, simply trying to comply with the tax code. That's equivalent to 3 million people working full time, year around, just on taxes.

Another problem with IRS compliance is that there are too many steps. I was recently contacted by constituents trying to get their Earned Income check. The IRS is 6 months behind in New Mexico in reviewing the tax forms filed for Earned Income credits. The IRS is looking into about 1,600 claims and requesting additional information from the taxpayers. I don't fault the IRS for making sure that the claims are legitimate, but I do find fault with their process.

The first letter from the IRS merely informs you that you are not going to get your EIC check until you contact IRS.

The next step is to contact them and wait. In 6 weeks they will get back to you with information on what information they want from you to verify your claim.

In northern New Mexico, many people speak Spanish. It is difficult for them to understand English and certainly difficult for them to understand the complexities that I have just described. It would be helpful if instructions were in Spanish as well as

English. The Grassley-Kerry bill calls for the creation of taxpayer assistance centers where people can go for face-to-face assistance. I would suggest that some of these places these people be bilingual for those who have difficulty speaking English and filling out complicated forms.

The current code is so complicated that unintended consequences are unavoidable.

We recently passed a middle class tax cut—but what the Congress intended, the alternative minimum tax takes away. New information from the Joint Committee on Taxation estimate that individuals paying the alternative minimum tax will increase from 605,000 in 1997 to 8.4 million families by 2007 unless something is changed. Part of this increase is caused by the new \$500 child credit and college tuition credits. The perversity of the alternative minimum tax is that the more credits a family is entitled to, the more likely it is that the family will have to pay the alternative minimum tax. But we just built these new credits into the code, taking much credit with middle-income Americans. Yet, the alternative minimum tax on individuals remains in effect. Put another way, the alternative minimum tax is hostile to families claiming the \$500 child credit and the college tuition tax credit. Middle class families will find that their middle class tax cut is partially taken away because of the alternative minimum tax.

The alternative minimum tax is complicated but it is also punitive. Families who thought they were in the 15 percent tax bracket find themselves in a 26 percent alternative minimum tax bracket. An 11 percent jump sounds bad but it is even worse when you remember that the alternative minimum tax base is broader than the regular income tax base. In other words, you apply the new rate, the higher rate, against a broader income than what you would have applied under the ordinary return.

As I wrote Secretary Rubin last Friday: "The alternative minimum tax is a trap for a growing number of American families. Most people don't know that it exists and those who do, view it as a tax on the rich, and not something to bother with. But that is not the case."

"The passage of the Taxpayer Relief Act is going to turn more and more middle class taxpayers into alternative minimum tax payers, and at the same time deny them a significant portion of the middle class tax cut[s] we have given them."

We have to fix this unintended consequence, and do it quickly.

Restructuring the IRS to be kinder and gentler will make taxpayers less frustrated, but an equally serious problem is the destructive impact that the current code has on the economy.

The current code adds about one-third to the cost of capital, makes us less competitive because it is not border adjustable, and it penalizes savings

and investment—two activities that are of tremendous value to our economy.

I have given dozens of speeches on the Senate floor about why this is so. I am not going to do that today.

My message today is first, to encourage every member of the Congress to sign the NFIB petition calling for a sunset to the IRS code, second, for Congress to work quickly to solve the alternative minimum tax problem which threatens to undermine the middle class tax cut that everyone worked so hard for, and, third, to move toward a new Tax Code that will foster economic growth.

Mr. President, I yield the floor.

Mr. LEAHY addressed the Chair.

The PRESIDING OFFICER [Mr. BROWNBACK]. The Senator from Vermont is recognized.

Mr. LEAHY. I thank the Chair.

FCC REGULATIONS AFFECTING RURAL TELEPHONE RATES

Mr. LEAHY. Mr. President, I would like to express my dismay, actually my increasing dismay, at the direction the Federal Communications Commission is taking, the misguided deregulation of local telephone markets.

When the Telecommunications Act was debated, and then when it was signed into law, many supporters hailed the legislation first and foremost as a boon to consumers.

We were told that because of the magical hand of competition, telephone rates for consumers would decrease; the free market system would take over.

Now, competition, if it is correctly injected into the telephone market, can lead to lower prices for consumers. But the FCC's ham-handed attempts to implement poor legislation—and it was poor legislation, which is why I voted against it—has made the problem even worse.

During the debate of the telecommunications bill, I took the Senate floor and expressed real strong concerns that skyrocketing telephone rates for rural areas, like my own State of Vermont, seemed likely. I wish I had been wrong, but unfortunately my concerns seem justified.

Even a bad telecommunications bill—and this was—could have been partially mitigated by careful and proper implementation. But the FCC seems bent on wanting to take what was a poorly done bill and make it worse. They want to exacerbate the conditions I expressed concern about during debate on the bill.

Here is what has happened.

Instead of increasing telephone service competition, there are three alarming FCC decisions that will in fact reduce telephone competition in rural areas and will likely result in much larger monthly telephone bills in States such as Vermont.

The result may be that many rural customers will not be able to afford a

telephone at home. The dream of linking America together on the information superhighway, a dream of linking all parts of America, urban and rural, together will remain just that, a dream, not a reality, because rural America will be cut off.

The Telecommunications Act directed the FCC to ensure that rates for phone service in rural areas remain reasonably comparable to rates in urban areas. Now, I understand there are details being worked out, but many of the decisions already rendered by the FCC do not bode well for rural States like Vermont.

For instance, the FCC decided the Federal universal service support would be raised only from the interstate revenues of interstate carriers. So what does that do? The FCC places off limits more than half of the retail revenue available from the telephone industry.

Second, the FCC has ruled they would support only 25 percent of the need even in a high-cost rural State like Vermont. This leaves 75 percent of the need to be raised by the States themselves, presumably from the intrastate revenues generated in those States, in other words, to raise the largest amount from the small rural States.

And third, they seem to repeal the high-cost support as we know it.

Let me show you on this chart, Mr. President. This shows a likely result of the FCC's three decisions.

This assumes the States are going to have to make up the support that the FCC now says it will not provide. Let us see what this means. The blue vertical bars show the anticipated State surcharges on intrastate revenues; that is, if they want to make up the difference. The red bars show an alternative approach, which the FCC did not adopt, where all needed support would come from a uniform Federal surcharge on all telephone revenues.

Let me tell you what this means. If they had done what they should have done, almost all States would have paid about a 2-percent surcharge to make up the difference. That is the red line on the chart. Whether you are in the District of Columbia or North Dakota, whether you are in New Jersey or Wyoming, you will be paying roughly the same.

However, instead of doing that, what the FCC has said, to heck with rural States. Instead of keeping a surcharge about the same for everybody, they tell North Dakota they will have to come up with about 33 percent, South Dakota about the same, Wyoming, just under 30 percent, Montana similar to that, New Mexico and Kansas up over about 12 percent. If you are a small rural State, what they are saying is forget about being part of the telecommunication revolution. If you are a small rural State, forget about being told the U.S. Congress has given you a good deal in the Telecommunications Act. You have just got a disconnect

signal. In fact, you probably have to pay for that.

Of the top 15 States, almost all rural States, they can buy with only a rate surcharge of 9 percent. That is money out of pocket. The act requires States to have reasonably comparable rates. Boy, this sounds great. You are from a rural State or from an urban State, roughly comparable rates. Who could disagree? Except what happens, if you are paying a 1- or 2-percent surcharge in one State and in another State a 30- or 35-percent surcharge, you are not roughly comparable, and there is no way these States can compete.

Would it not have made more sense to say every State pays about 2.6, 2.5 percent surcharge? Then everybody would be on an even playing field, whether you are a company in North Dakota or in Vermont, or you are a company in Michigan or Pennsylvania, at least basic costs would remain the same. If you were a homeowner, if you were a renter, if you were in those States, your costs would be roughly comparable.

Under the FCC's proposal, which make no sense at all, many experts predict an increase in the 100 percent to 200 percent range for phone rates in these very rural States. Now, I am one Vermonter who would not stand for that, and I cannot imagine any other Vermonter standing for that.

I think the time will prove these unfortunate predictions correct, as rural phone companies go out of business, the bigger competitors cherry pick the best customers, and the rural areas, you might as well go back to smoke signals, Pony Express, or shouting across the valleys because you will not be able to do it by picking up the phone.

I think the FCC is letting a golden opportunity slip by. I think, Mr. President, we may have given them the opportunity by casting rural areas over the side in that Telecommunications Act. Even tossing them over side, you would have thought the FCC would have put out a net or a helping hand. Instead, it looks like they tied the anchor around their neck as they went by and dropped them into the ocean.

LANDMINE BAN TREATY

Mr. LEAHY. Mr. President, last week, President Clinton announced that the United States would not join nearly 100 nations, including most of our NATO allies, in a treaty to ban antipersonnel landmines.

I want to take a few minutes to respond to the President's decision. First, let me say that President Clinton and I have spoken many times about the landmine issue. I am convinced he wants to see these weapons banned from the face of the Earth. He and I have discussed the horrendous toll of innocent lives that landmines cause, and in speeches at the United Nations he has twice called for a worldwide ban.

President Clinton said, "The United States will lead a global effort to eliminate these terrible weapons and stop the enormous loss of human life." Those were inspiring words. However, as convinced as I am of the President's desire for a ban, I am as convinced that a tremendous opportunity was lost last week. An opportunity that rarely comes in history.

As a USA Today editorial put it, "having blown the best chance ever to negotiate an acceptable international ban on landmines, the Clinton administration now finds itself churning in the wake of world affairs. The United States has joined a few nations, including rogue states like Iran and Iraq, on the outside of a remarkable process."

There are many losers in the administration's last-minute failed attempt to negotiate in Oslo. Unfortunately, the most notable losers were the innocent victims of landmines who the treaty aims to protect. Mr. President, the victims of landmines are almost invariably children and innocent civilians.

Because while the treaty is immensely important for establishing a new norm of conduct, until the United States signs it, there will never be a worldwide ban. There is simply no substitute for the credibility and influence of the United States to bring reluctant nations on board and make sure that violators of the treaty are caught and punished. There is no way to fully stigmatize these weapons and curtail the use, as has been done with poison gas, without U.S. leadership far stronger than we have seen today.

And the tragedy of our country's decision is that it was avoidable. Although the President said his administration had gone the extra mile to find an acceptable compromise in Oslo, I must respectfully and honestly disagree.

Two weeks ago I went to Oslo where I met with representatives of governments, including the United States, and nongovernmental organizations that were participating in the treaty negotiations.

The treaty they adopted was nothing short of a miracle. In less than a year, nations as diverse as our closest European allies who have been major producers of landmines, to Mozambique whose people have been killed and maimed by landmines, joined together in finalizing a treaty that does nothing less than ban the use, production, stockpiling, and transfer of a category of weapons that Civil War General William Tecumseh Sherman called "a violation of civilized warfare" over a century ago.

I call the Ottawa Treaty a miracle because it was only 11 months ago that Canadian Foreign Minister Lloyd Axworthy launched what is now called the "Ottawa process." At the time, no one knew how many nations would take part or where it would lead, not even Minister Axworthy. It was a bold and courageous leap of faith, and the

same kind of leadership I and so many others hoped to see from the White House last week.

The Ottawa Treaty culminates two decades of failed attempts to deal effectively with the landmine problem. Two decades ago many of the same nations that gathered in Oslo met in Geneva to draft a treaty to address the growing concerns of the effects of landmines on civilian populations. Landmines had been widely used in Southeast Asia, and they were being sown like seed in Afghanistan and Central America and many African countries. Vast areas were being laid to waste with the innocents paying the horrifying price. I have seen victims, all over the world, of these indiscriminate weapons.

My wife is a registered nurse and has visited the hospitals where the amputations take place, where broken bodies are put back together as best can be done in countries where medical care is often rudimentary.

That treaty, however—the Conventional Weapons Convention—utterly failed to achieve its goal. It was doomed to fail because of the fact that landmines are inherently incapable of distinguishing between civilians and combatants, and that fact was never even acknowledged in Geneva, much less addressed. Instead, in diplomatic niceties, by people who would never have to face landmines themselves, they adopted vague limits of how mines could be used. Those limits were then routinely ignored. In the years since then, the devastation inflicted by landmines on innocent people, often the poorest people in the world, has increased dramatically. In fact, Mr. President, it was the widespread recognition of the failure of that treaty which led to the Conventional Weapons Review Conference 2 years ago. Finally, it seemed there could no longer be any excuse for doing whatever was necessary to stop the carnage wrought by landmines.

That was the hope. Unfortunately, the reality was a lot different. Rather than devise a roadmap for ridding the world of these weapons, governments, including our own, fought for the right to use them. The idea of a ban was barely mentioned. The amended protocol, while preferable to the original, did far more to reaffirm the legitimacy of landmines than to stop their use. Once again, governments had failed to act with anything like the decisiveness that was called for.

So it is important to remember that the Ottawa process evolved only after years of failed attempts by governments to solve this problem in the traditional way. There was no shortage of impassioned speeches about the harm landmines were causing the innocent. But the expressions of outrage were qualified with the assertion that the problem wasn't the mines themselves, but other people, always other people, who used them irresponsibly. You would think it was a tea party rather than arms control. And the carnage, of course, continued.

But we hear those same arguments today. The same failed arguments of a decade ago. Today when a Pentagon official was asked about the tens of thousands of American landmine casualties in Vietnam, he said that was no longer relevant because "smart" mines had "solved their problem."

Of course, they have not solved it. Almost no one besides the United States uses those mines. In Bosnia, more than 250 U.N. and NATO soldiers and thousands of civilians have been injured or killed today by the same types of mines used in Vietnam a generation ago.

As I have said so many times, an effective international agreement based on stigmatizing a weapon cannot have different standards for different nations. The importance of this principle cannot be overstated. It is what underlies any international agreement.

When the Princess of Wales spoke about the insidious toll of landmines, she said, "Before I went to Angola, I knew the facts, but the reality was a shock." Unfortunately, the reality that Princess Diana saw was a reality which far too few government officials have experienced, including many people at the Pentagon. When people have gone with me and seen the carnage caused by landmines, they have a new understanding.

A year ago, after the President urged all nations to complete a ban treaty "as soon as possible," it became clear that the administration was not willing to show the kind of leadership that was necessary to turn those words into reality.

Instead, other countries, led by Canada and hundreds of nongovernmental organizations, stepped into the void. In a matter of months we saw the number of nations participating in the Ottawa process exceed 100, including many nations that were producers and exporters and users of antipersonnel mines.

Those nations came together determined to overcome past failures because they knew about those failures. Many had suffered the effects of landmines because of those failures. They came together to do the only thing that could solve the landmine problem—ban the types of landmines that are triggered by an innocent footstep, ban them without exception, ban them without reservation. And they wanted the United States to be part of it. When I was in Oslo I found a genuine desire to try to accommodate the United States, if it could be done without weakening the treaty.

But the administration seriously underestimated the worldwide commitment for a ban. For months, the White House belittled the Ottawa process. Since it wasn't their idea, they refused to take it seriously. And rather than throw the weight of the United States behind Canada to help achieve something unprecedented in history, something that would have taken both courage and imagination, the administration tried to talk other governments out of taking part.

They wasted valuable time by pursuing negotiations in the U.N. Conference on Disarmament even when it was clear that avenue was blocked. They said the United States would only give up its mines if all nations did, knowing that, like the chemical weapons treaty, there is no chance of that happening for decades. And when they finally decided at the 11th hour to go to Oslo, they went with demands that had no chance of being accepted, and little flexibility to negotiate.

Any of the nations in Oslo that have pledged to sign the Ottawa treaty could make a stronger case to continue using these weapons than the world's only superpower. Basically, the United States went to Oslo and said: we are the most powerful Nation on earth, but we can't give up our anti-personnel mines because we have better technology, but you less powerful nations, you should give up your mines.

Well, Mr. President, the Pentagon is, understandably, deeply reluctant to give up a weapon that has some utility—and it does—even if doing so would pressure others to end the suffering of innocent people. Like any government department, the Pentagon's job is to protect its options. It has always resisted giving up weapons, from countermanding General Pershing in the 1920's at the first Geneva convention when he wanted to ban poison gas, to nuclear testing in the 1990's. If a Pentagon official is asked what he or she needs, the answer is always "more." More firepower might mean fewer casualties, so the Pentagon has resisted the pressure to give up antipersonnel landmines.

The President is constantly faced with departments that do not want to cut their budget or eliminate programs. That is why he has the National Security bureaucracy, to make those hard decisions. In the case of weapons of mass destruction like nuclear and chemicals weapons, his advisers have found ways to work closely with the Pentagon to find creative solutions.

But when issue of landmines reached the surface a year and a half ago, nobody in the administration was willing to aggressively challenge and prod the Pentagon into finding a workable solution. Without that prodding, the Joint Chiefs put far more effort into blocking the U.S. from joining the ban than into planning how to live with it—even though there were those in the Pentagon who at least were honest enough to privately point out the fallacies in the assumptions underlying the Pentagon's own arguments.

As recently as a few weeks ago—and the Pentagon did not serve the White House well in this—White House officials were not even aware of the weaknesses in the Pentagon's doomsday predictions about the consequences of removing antipersonnel mines from Korea, or even aware of the fact that the Pentagon was, at least internally, divided over some of the same arguments they had made at the White House.

They did not even have a thorough grasp of the treaty's provisions. Right up until the end, there were those in the administration who were unaware that the treaty effectively grants a twelve-year grace period for removing existing minefields, such as in Korea. Last week, the Secretary of Defense wrote in the Washington Post that "millions" of lives could be lost if the U.S. signed the treaty because North Korea might interpret our signing as a loss of resolve and start a war because of it. Good Lord, Mr. President. This is as bad as "the Russians are coming, the Russians are coming" scenario we heard, even as the Russian army was collapsing internally. Not only is that about that as far-fetched as any dire Pentagon prediction I have heard yet—and that includes its assessment of the Red Army that was fit to conquer the world—it could not even conquer Chechnya—it ignores the conclusion of every serious Pentagon analyst that a North Korean invasion would be destroyed, with or without antipersonnel landmines, before it could traverse 50 miles down narrow, pre-targeted mountain passes to Seoul. If antipersonnel landmines are going to determine the fate of South Korea, South Korea ought to surrender. But the fact is, South Korea has a far better trained, better equipped army, is better motivated than North Korea, and is backed by the might of the most powerful Nation on earth. A North Korean invasion would be suicidal, and they know it and everyone knows it. A former commander of our forces in Korea says scattering landmines there would impede the mobility of our own forces, and inflict casualties on our own troops.

But it does not even matter, because the other countries in Oslo were prepared to try to accommodate U.S. concerns on Korea. Had the White House not waited until the last minute to get involved, a solution could have been found. In fact, many of us told them that months ago.

Over 60 Members of the U.S. Senate, Republicans and Democrats, including every veteran of combat in the Vietnam war, have signed onto legislation to ban antipersonnel landmines. In fact, Mr. President, the Leahy-Hagel bill would do no more than what Great Britain, Germany, South Africa, France, and a lot of other nations have already pledged to do, over the objections of some of their own armed forces. In fact, it does not go as far because it gives the President broad flexibility on Korea, which the Pentagon has called a unique situation—"the Cold War's last frontier." The Pentagon said they need time to take care of Korea. Our legislation gives them more time than they need.

I was encouraged by the President's statement last week that he wants to work with Congress. I welcome that, and I thank him for the kind words he spoke about my efforts. I really do believe that he wants to see a worldwide

ban on landmines. I have always supported efforts to negotiate an international export ban in the U.N. Conference on Disarmament.

But, Mr. President, the clock is ticking, and there should be no mistake. The Ottawa treaty is the only hope for achieving a comprehensive worldwide ban on these weapons. There is no other treaty. If the United States does not sign in December, we have to find a way to sign at the earliest possible time.

That is not going to happen as long as the Pentagon pretends that a weapon it called an antipersonnel landmine a few months ago, and which the President pledged to ban a year ago, has suddenly, miraculously, overnight become no longer an antipersonnel mine if it's placed near an antitank mine. They tried that in Oslo; they tried to change the definition. It would have invited any nation in the world to use antipersonnel mines—dumb, smart, just average, or any type—indeinitely, as long as they were in the vicinity of an antitank mine. It was a terrible idea and literally a loophole big enough to fly a 747 through.

If the use of antipersonnel mines near antitank mines is what prevents the United States from signing the treaty, then solve it. We run a little Rover around on Mars. If we can do that, we can solve this problem. If the Pentagon had spent the past three years since the President first called for a worldwide ban really trying to solve that problem rather than to keep from having to solve it, the United States might have been able to show the leadership on this issue that the world needs and, frankly, the world wants.

This is not a public relations problem to be managed. This is not about trying to find some way to convince a focus group. It is not a question of valuing the lives of American soldiers more or less than the lives and limbs of innocent civilians. Both soldiers and civilians will benefit from a landmine ban. It is about the one nation on this planet, whose power and influence and moral authority are unmatched, the nation that I am proud to serve in the U.S. Senate. It is about this nation seizing the best opportunity there is ever going to be to deal with a problem that is needlessly plaguing so many countries.

Staying outside this treaty is not an option. We have to be part of it, if not now, then we need to do what needs to be done to become part of it.

I might note, Mr. President, that Japan, which like the U.S. also expressed concerns about the treaty in Oslo, is apparently reconsidering its position and may sign in Ottawa after all. I wrote to their foreign minister saying I hope they do this. It would be extremely significant, as many Asian nations look to Japan for leadership.

President Clinton also spoke of efforts the United States is making to help other nations get rid of landmines,

and to aid the victims. I join him in that. But I remind the President and the Pentagon that each of these efforts was started by the Congress. They are vitally important, and I welcome the President's announcement that he wants to expand them. But even expanding something like the Leahy War Victims Fund is no substitute for putting an end to the use of these weapons.

I want the United States to show the kind of leadership that is expected of the world's leading democracy, the greatest democracy history has ever known. The United States was a founder of the League of Nations and the United Nations. We have been a leading force in every significant humanitarian law treaty and arms control treaty in history. Leadership by definition means taking risks. It means having the faith and courage to seize an opportunity that comes rarely in history and rejecting the conventional wisdom, and taking a dramatic step.

The chemical weapons treaty would not exist had it not been for the United States taking such a step. The nuclear test ban treaty would not exist without our leadership.

The United States showed its capacity for greatness with the Marshall Plan. We didn't say we would rebuild Europe "except for this country or that country." We said all should benefit, including our former enemies. I am proud of what my country did then, and I want to see the same kind of leadership now.

The Ottawa treaty will be signed in December. There is still time for the White House to reconsider. Fourteen Nobel laureates sent a letter to President Clinton last week urging him to reconsider. There is still time to aggressively engage the Pentagon on the technical issues that have prevented the President from agreeing to sign. If we do not have a plan for solving them by December, then get busy and solve them. At least commit to signing it at a future date. That is what the world needs to hear. It is the least we can do.

Mr. President, the Ottawa treaty will set a moral standard for the next century that even those nations who do not sign will ignore at the risk of being condemned as international outlaws. It will be a tribute to those nations who recognize the urgency that this humanitarian crisis demands. The treaty ends the 20th century, the bloodiest in history, in a way in which the world can be justly proud. It is our gift to the next century. The United States should be part of it.

I said in Oslo that my wife and I look forward, with great pleasure, to the birth of our first grandchild at the beginning of next year and, God willing, that child will live most of his or her life in the next century. My prayer is that it will be a century where armies of humanity dig up and destroy landmines and no one puts new ones down.

I ask unanimous consent that the Nobel laureates' letter to the President be printed in the RECORD.

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

SEPTEMBER 18, 1997.

DEAR PRESIDENT CLINTON: We are writing to demonstrate our support of the many other individuals and organizations urging the United States government to sign a treaty for a comprehensive ban on anti-personnel landmines along with 100 other nations scheduled to meet in Ottawa this December.

Mr. President, we ask you to reflect on repercussions of your final decision on this matter. We are aware that you plan to condition your approval of the ban on the inclusion of certain exceptions considered vital to U.S. security interests and in the best interest of military personnel. Consider for a moment the dangerous precedent that would be set if the United States asks for concessions. Indecision by a world superpower is sure to undermine the long effort to reach this ban, only leading to further delays.

It is clear that every additional week of delay will leave hundreds of innocent men, women, and children dead or maimed due to these devices whose military value is highly questionable. The recently publicized 1972 US Army report vividly describes the terrible toll US anti-personnel landmines have taken on its own soldiers during the Korean and Vietnam conflicts.

We, Nobel Peace Laureates, are joining the Albert Schweitzer Institute for the Humanities, named after the renowned humanist and Nobel Peace laureate Dr. Albert Schweitzer, and the Connecticut Coalition to Abolish Landmines in the international call to ban landmines. We add our collective voice to that of many other individuals, organizations and governments who strongly support this ban.

As the leader of a major world power, it is in your hands to demonstrate courageous leadership and endorse the comprehensive ban on landmines.

Donald S. Gann, on behalf of American Friends Service Committee, 1947; Dr. Norman E. Borlaug, 1970; Mairead Maguire, 1976; Betty Williams, 1976; Mother Theresa, 1979 (verbal agreement given three days before her death); Adolfo Perez Esquivel, 1980; Lech Walesa, 1983; The Most Rev. Desmond Tutu, 1984; Dr. Gurwarj Mutalik, on behalf of International Physicians for the Prevention of Nuclear War, 1985; Elie Wiesel, 1986; Oscar Arias Sanchez, 1987; Mikhail S. Gorbachev, 1990; Joseph Rotblat, on behalf of Pugwash Conferences on Science and World Affairs, 1995; Bishop Carlos Felipe Belo, 1996; Jose Ramos Horta, 1996.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNT- ABILITY ACT OF 1997

The Senate continued with the consideration of the bill.

Mr. LEAHY. Mr. President, after consultation with my distinguished colleague, my dear friend from Vermont, Senator JEFFORDS, I have been authorized to yield back all remaining time for today on S. 830.

The PRESIDING OFFICER. The time is yielded back.

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

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. LEAHY. Mr. President, I thank the Chair for his consideration and listening to this long speech. While I have spoken maybe 50 times on this issue on the floor, I thought it was important to put in the RECORD exactly what has happened and why the United States is not on the treaty, but to also implore the President, who I feel does want to see it ban landmines, to take the steps necessary so the United States can be part of this treaty.

I yield the floor.

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

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

MORNING BUSINESS

Mr. ENZI. Mr. President, I ask unanimous consent that there now be a period of morning business with Senators permitted to speak for up to 5 minutes each.

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

LABOR, HEALTH AND HUMAN SERVICES, EDUCATION APPROPRIATIONS ACT—AMENDMENT NO. 1122

Mr. GORTON. Mr. President, I am here to outline certain changes to my amendment that was accepted as part of the Labor, Health and Human Services, Education Appropriations Act as passed by the Senate. These changes will be submitted to the House-Senate conference committee. My amendment, No. 1122, would block grant funds from several K-12 education programs in the Department of Education and send those funds directly to school districts. These changes have been incorporated into a new draft of the amendment.

The genesis of the changes is a series of discussions with my colleagues in the Senate and other interested parties. While these changes correct minor drafting errors, they do so without changing the overall philosophy of the amendment. The most significant of the changes exclude from the block grant entirely any funds from the Adult Education, Vocational Education, and Rehabilitation Services programs, programs not primarily directed at K-12 education. Other programs excluded from the block grant are: Indian Education, the Inexpensive Book Distribution Program, Arts In Education, Star Schools Program, and Technology Innovation Challenge grants.

Finally, the distribution of bilingual education funds is changed. These funds will be sent to school districts in the same proportion as the funds were distributed in fiscal year 1997, much like title I funds are distributed in the amendment. For example, if a school district were eligible for .25 percent of all bilingual education funds in fiscal year 1997, it will be eligible for the same share in fiscal year 1998.

Mr. President, these changes correct minor drafting errors and incorporate the suggestions of several supporters for minor improvements. These changes, however, do not affect the amendment's overall philosophy, which is to restore the decisionmaking authority for the education of our children to where it belongs; the hands of parents, teachers, principals, superintendents, and school board members. I look forward to discussing this issue further with my colleagues during conference committee meetings.

THE VERY BAD DEBT BOXSCORE

Mr. HELMS. Mr. President, at the close of business yesterday, Monday, September 22, 1997, the Federal debt stood at \$5,378,803,586,241.44. (Five trillion, three hundred seventy-eight billion, eight hundred three million, five hundred eighty-six thousand, two hundred forty-one dollars and forty-four cents)

Five years ago, September 22, 1992, the Federal debt stood at \$4,040,323,000,000. (Four trillion, forty billion, three hundred twenty-three million)

Ten years ago, September 22, 1987, the Federal debt stood at \$2,353,878,000,000. (Two trillion, three hundred fifty-three billion, eight hundred seventy-eight million)

Fifteen years ago, September 22, 1982, the Federal debt stood at \$1,107,571,000,000. (One trillion, one hundred seven billion, five hundred seventy-one million)

Twenty-five years ago, September 22, 1972, the Federal debt stood at \$437,448,000,000 (Four hundred thirty-seven billion, four hundred forty-eight million) which reflects a debt increase of nearly \$5 trillion—\$4,941,355,586,241.44 (Four trillion, nine hundred forty-one billion, three hundred fifty-five million, five hundred eighty-six thousand, two hundred forty-one dollars and forty-four cents) during the past 25 years.

CONGRATULATIONS TO CHARLEY L. BYRD CELEBRATING HIS 100TH BIRTHDAY

Mr. ASHCROFT. Mr. President, I rise today to encourage my colleagues to join me in congratulating Charley L. Byrd of Lentner, MO, who will celebrate his 100th birthday on October 23, 1997. Charley is a truly remarkable individual. He has witnessed many of the events that have shaped our Nation into the greatest the world has ever known. The longevity of Charley's life has meant much more, however, to the many relatives and friends whose lives he has touched over the last 100 years.

Charley's celebration of 100 years of life is a testament to me and all Missourians. His achievements are significant and deserve to be recognized. I would like to join Charley's many friends and relatives in wishing him health and happiness in the future.

HONORING THE JOHNSONS ON THEIR 50TH WEDDING ANNIVERSARY

Mr. ASHCROFT. Mr. President, families are the cornerstone of America. The data are undeniable: Individuals from strong families contribute to the society. In an era when nearly half of all couples married today will see their union dissolve into divorce, I believe it is both instructive and important to honor those who have taken the commitment of "till death us do part" seriously, demonstrating successfully the timeless principles of love, honor, and fidelity. These characteristics make our country strong.

For these important reasons, I rise today to honor Lois and Delmer Johnson of St. Joseph, MO, who on October 12, 1997, will celebrate their 50th wedding anniversary. My wife, Janet, and I look forward to the day we can celebrate a similar milestone. The Johnsons' commitment to the principles and values of their marriage deserves to be saluted and recognized.

BUREAU OF LABOR STATISTICS TOXICOLOGY ANALYSIS

Mr. ENZI. Mr. President, the lack of information pertaining to alcohol and substance abuse fatalities in the workplace is alarming. If we are serious about the safety of American workers, we must carefully examine all contributing factors that pose a potential threat while on the job.

I had intended to offer an amendment to the Labor, HHS and Education Appropriations bill that would instruct the BLS to incorporate in their annual report an analysis of toxicology reports in the Census of Fatal Occupational Injuries. After meeting with the BLS Commissioner, Katharine Abraham, we agreed that the BLS will again perform this important analysis during the calendar year 1998 and issue a report no later than 6 months after the data collection is completed. This agreement dismisses the need for a congressional mandate. I appreciate BLS's cooperation in properly addressing this matter.

In 1992, the Department of Labor initiated a program to compile data on how alcohol and drugs contributed to fatal work injuries. The BLS's Census of Fatal Occupational Injuries Program collected 1,355 toxicology reports from 43 States and the District of Columbia—roughly one report for every four of the 1992 fatalities. About one-sixth of the cases for which toxicology reports were available, fatally injured workers tested positive for toxic substances. The most frequent cases showed alcohol use followed by cocaine and marijuana.

Unfortunately, the BLS stopped collecting this data in 1995. Although this data was only reported over a 3-year span, it clearly shows that alcohol and substance abuse is a major contributor to fatal workplace injuries. In an effort

to understand the safety of American workers, we must have data available to us. The inclusion of this analysis in the annual report sends a message that we do care about the safety of American workers.

Prior to being elected to the U.S. Senate, I was an accountant for Dunbar Well Service in Wyoming—a large, independent oil well servicing company. Aside from my accounting responsibilities, I also traveled the State collecting urine and saliva samples from our employees. Not only have I given alcohol and substance abuse tests, but I've been tested. I understand a thing or two about validity and dignity. This analysis doesn't hinder either of those traits. Safety in the workplace should be everyone's concern. However, if we don't understand how our workers are killed on the job, then we only deceive ourselves. This analysis will provide a better understanding of why and how frequently alcohol and drugs play a contributory role in fatal work injuries.

Mr. President, I ask unanimous consent that the letter sent to me from BLS Commissioner, Katharine Abraham, be printed in the RECORD.

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

U.S. DEPARTMENT OF LABOR,
Washington, DC, September 4, 1997.

Hon. MICHAEL B. ENZI,
U.S. Senate, Hart Senate Office Building,
Washington, DC.

DEAR SENATOR ENZI: I am writing regarding the proposal to require the Bureau of Labor Statistics (BLS) to gather and analyze toxicology reports on workers who have been fatally injured on the job.

Since 1991, the Bureau has conducted the Census of Fatal Occupational Injuries (CFOI), which compiles a complete roster of workers who are fatally injured at work each year, along with details about the fatal events. In 1991 and 1992, the Bureau conducted research studies in which toxicology reports were collected as part of the fatality census. The reports were analyzed with the help of Dr. William M. Marine, Professor of Preventive Medicine and Biometrics at the University of Colorado Health Sciences Center.

Toxicology reports were obtained from a variety of sources, including medical examiner or coroner reports, police reports of motor vehicle accidents, and autopsy reports. In some jurisdictions, toxicology reports are not available to BLS because of State confidentiality requirements. It also should be noted that toxicology tests are not completed for all deaths. Often tests are performed only when there is a suspicion of drugs present, though the practice regarding conduct of toxicology tests varies by State. In 1991, for example, the share of work-related fatalities for which toxicology reports were available varied from more than 50 percent (in 8 of 23 States for which reports were provided) to less than 10 percent (in 10 of the 23 States).

For 1991, 23 of 31 States that participated in the fatality census provided toxicology reports. Toxicology reports were available for 28% (829) of the 2,968 work-related fatalities in the 23 States. For 1992, 43 States and the District of Columbia submitted toxicology reports. Reports were received for 1,355 deaths representing 25% of the total work-related fatalities in these States.

Positive toxicology results were found for 125 of 829 cases for which reports were available for 1991. Alcohol was present in 49% of the 125 cases; amphetamines were present in 12%; marijuana in 12%; and cocaine in 10%. For 1992, positive toxicology results were found for 214 deaths out of 1,355 for which reports were received. Alcohol was present in 52% of the 214 cases; cocaine in 17%; marijuana in 13%; and antidepressants, amphetamines, barbiturates, morphine, codeine, methadone or other substances in 17%. These figures exclude cases in which there were toxicological findings that could have been due to the life-saving efforts of hospitals or others. A positive toxicological finding nonetheless does not establish the extent to which alcohol or drugs contributed to the fatality.

I would be happy to meet with you or your staff to discuss the toxicological studies the Bureau has conducted and their findings. If you feel, based on that discussion, that it would be valuable to repeat this type of study, the Bureau will gather and analyze toxicology reports on workers who have been fatally injured on the job during calendar year 1998, and will issue a report no later than six months after the data collection is completed.

I hope you find this information useful. Please let me know if we can be of further assistance.

Sincerely yours,
KATHARINE G. ABRAHAM,
Commissioner.

REGARDING PRODUCT LIABILITY REFORM

Mr. ENZI. President, I rise to briefly discuss S. 648, a bill to establish standards and procedures for products liability legislation. I am proud to be a cosponsor of that bill and I feel that it should be a legislative priority for consideration during this session of the 105th Congress.

In the 104th Congress, both the House and Senate passed meaningful product liability reform legislation only to have it vetoed by President Clinton. The President now indicates that he wants to sign a products liability reform bill. Legal reform has the broad support of the American people and strong bipartisan support in Congress.

With each passing day, we are losing an opportunity to do the people's business by not enacting common sense legal reform. S. 648 is designed to inject some common sense into runaway punitive damage awards in view of the need for some semblance of uniformity in our National interstate commerce system.

Last May, the United States Supreme Court held in *BMW in North America v. Gore*, that punitive damages can be considered so excessive as to violate a defendant's constitutional due process rights. It seems that many courts have not heeded this lesson. Just a few weeks ago, another case received national attention for the enormity of its punitive damage award. A jury in a Louisiana State court levied a \$2.5 billion punitive damage award against CSX Transportation corporation and \$1 billion against the other defendants in the case for their involvement in a 1987 tank car fire. The court

awarded this enormous punitive judgment despite findings by the National Transportation Safety Board (NTSB) that CSXT did not cause the accident and that no serious injuries resulted from the accident.

In light of these egregious examples, it is time for Congress to pass legislation to reign in these exploding legal costs which have hurt American businesses, stifled ingenuity, and punished consumers through higher prices and decreased competition. S. 648 would mark an important first step in reforming a tort system which all too often better resembles a lottery than a forum of justice. I urge our leadership to make S. 648 a priority in the first session of the 105th Congress.

MESSAGES FROM THE PRESIDENT RECEIVED DURING ADJOURNMENT

Under the authority of the order of the Senate of January 7, 1997, the Secretary of the Senate on September 22, 1997, received a message from the President of the United States submitting a nomination which was referred to the Committee on Foreign Relations.

The nomination received on September 22, 1997, is shown in today's RECORD at the end of the Senate proceedings.

EXECUTIVE AND OTHER COMMUNICATIONS

The following communications were laid before the Senate, together with accompanying papers, reports, and documents, which were referred as indicated:

EC-2996. A communication from the Council of the District of Columbia, transmitting, pursuant to law, copies of D.C. Act 12-117 adopted by the Council on July 1, 1997; to the Committee on Governmental Affairs.

EC-2997. A communication from the Council of the District of Columbia, transmitting, pursuant to law, copies of D.C. Act 12-119 adopted by the Council on July 1, 1997; to the Committee on Governmental Affairs.

EC-2998. A communication from the Council of the District of Columbia, transmitting, pursuant to law, copies of D.C. Act 12-125 adopted by the Council on July 1, 1997; to the Committee on Governmental Affairs.

EC-2999. A communication from the Council of the District of Columbia, transmitting, pursuant to law, copies of D.C. Act 12-128 adopted by the Council on July 1, 1997; to the Committee on Governmental Affairs.

EC-3000. A communication from the Council of the District of Columbia, transmitting, pursuant to law, copies of D.C. Act 12-129 adopted by the Council on July 1, 1997; to the Committee on Governmental Affairs.

EC-3001. A communication from the Council of the District of Columbia, transmitting, pursuant to law, copies of D.C. Act 12-130 adopted by the Council on July 1, 1997; to the Committee on Governmental Affairs.

EC-3002. A communication from the Council of the District of Columbia, transmitting, pursuant to law, copies of D.C. Act 12-131 adopted by the Council on July 1, 1997; to the Committee on Governmental Affairs.

EC-3003. A communication from the Council of the District of Columbia, transmitting, pursuant to law, copies of D.C. Act 12-132 adopted by the Council on July 1, 1997; to the Committee on Governmental Affairs.

EC-3004. A communication from the Council of the District of Columbia, transmitting, pursuant to law, copies of D.C. Act 12-139 adopted by the Council on July 1, 1997; to the Committee on Governmental Affairs.

EC-3005. A communication from the Council of the District of Columbia, transmitting, pursuant to law, copies of D.C. Act 12-140 adopted by the Council on July 1, 1997; to the Committee on Governmental Affairs.

EC-3006. A communication from the Council of the District of Columbia, transmitting, pursuant to law, copies of D.C. Act 12-143 adopted by the Council on July 1, 1997; to the Committee on Governmental Affairs.

EC-3007. A communication from the Council of the District of Columbia, transmitting, pursuant to law, copies of D.C. Act 12-144 adopted by the Council on July 1, 1997; to the Committee on Governmental Affairs.

EC-3008. A communication from the Council of the District of Columbia, transmitting, pursuant to law, copies of D.C. Act 12-126 adopted by the Council on July 1, 1997; to the Committee on Governmental Affairs.

EC-3009. A communication from the Acting Comptroller General of the United States, transmitting, pursuant to law, the reports and testimony for July 1997; to the Committee on Governmental Affairs.

EC-3010. A communication from the Acting Comptroller General of the United States, transmitting, pursuant to law, the report of a financial audit relative to the Internal Revenue Service; to the Committee on Governmental Affairs.

EC-3011. A communication from the Acting Comptroller General of the United States, transmitting, pursuant to law, a report relative to General Accounting Office employees; to the Committee on Governmental Affairs.

EC-3012. A communication from the Deputy Director of the U.S. Office of Government Ethics, transmitting, pursuant to law, a rule entitled "Removal of Superseded References to the Former Honorarium Ban" (RIN3209-AA00, AA04) received on September 11, 1997; to the Committee on Governmental Affairs.

EC-3013. A communication from the Director of the Office of the Secretary of Defense (Administration and Management), transmitting, pursuant to law, a rule entitled "The Privacy Program" received on September 8, 1997; to the Committee on Governmental Affairs.

EC-3014. A communication from the Executive Director, Committee for Purchase From People Who are Blind or Severely Disabled, transmitting, pursuant to law, a rule relative to additions to the procurement list, received on September 5, 1997; to the Committee on Governmental Affairs.

EC-3015. A communication from the Director of the U.S. Office of Personnel Management, transmitting, pursuant to law, a rule entitled "Federal Employees Health Benefits Program Acquisition Regulation" (RIN3206-AH45) received on September 8, 1997; to the Committee on Governmental Affairs.

EC-3016. A communication from the Acting Director of the U.S. Office of Personnel Management, transmitting, pursuant to law, a rule entitled "Pay Administration (General)" (RIN3206-AF89) received on September 18, 1997; to the Committee on Governmental Affairs.

EC-3017. A communication from the Acting Director of the U.S. Office of Personnel Management, transmitting, pursuant to law, a rule entitled "Federal Employees Health Benefits Program Acquisition Regulation" (RIN3206-AF32, AG79, AG68); to the Committee on Governmental Affairs.

EC-3018. A communication from the Director of the U.S. Office of Personnel Management, transmitting, a draft of proposed legislation to amend title 5, U.S.C., to extend the

Federal physicians comparability allowance authority, and for other purposes; to the Committee on Governmental Affairs.

EC-3019. A communication from the Chief Financial Officer of the Department of the Interior, transmitting, pursuant to law, the report on accountability for fiscal year 1996; to the Committee on Governmental Affairs.

EC-3020. A communication from the Director of the National Archives and Records Administration, Information Security Oversight Office, transmitting, pursuant to law, the report for calendar year 1996; to the Committee on Governmental Affairs.

EC-3021. A communication from the Chairman of the U.S. Merit Systems Protection Board, transmitting, pursuant to law, the report of cases decided during fiscal year 1996; to the Committee on Governmental Affairs.

EC-3022. A communication from the Chairman of the U.S. Merit Systems Protection Board, transmitting, pursuant to law, a report entitled "Achieving a Representative Federal Workforce: Addressing the Barriers to Hispanic Participation"; to the Committee on Governmental Affairs.

EC-3023. A communication from the Deputy Associate Administrator for Acquisition Policy, Office of Governmentwide Policy, U.S. General Services Administration, transmitting, pursuant to law, a rule entitled "Federal Acquisition Regulation" (RIN9000-AH21) received on September 23, 1997; to the Committee on Governmental Affairs.

EC-3024. A communication from the Director of the Office of Management and Budget, Executive Office of the President, transmitting, pursuant to law, a report relative to paperwork; to the Committee on Governmental Affairs.

EC-3025. A communication from the Acting Comptroller General of the United States, transmitting, pursuant to law, the report of the list of General Accounting Office reports and testimony for August 1997; to the Committee on Governmental Affairs.

EXECUTIVE REPORTS OF COMMITTEES

The following executive reports of committees were submitted:

By Mr. MCCAIN, from the Committee on Commerce, Science, and Transportation:

Robert L. Mallett, of Texas, to be Deputy Secretary of Commerce.

W. Scott Gould, of the District of Columbia, to be Chief Financial Officer, Department of Commerce.

W. Scott Gould, of the District of Columbia, to be an Assistant Secretary of Commerce, vice Thomas R. Bloom.

(The above nominations were reported with the recommendation that they be confirmed, subject to the nominees' commitment to respond to requests to appear and testify before any duly constituted committee of the Senate.)

Mr. President, for the Committee on Commerce, Science, and Transportation, I report favorably four nominations lists in the Coast Guard, which were printed in full in the CONGRESSIONAL RECORD on September 3, 15, and 18, 1997, and ask unanimous consent, to save the expense of reprinting on the Executive Calendar, that these nominations lie at the Secretary's desk for the information of Senators.

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

(The nominations ordered to lie on the Secretary's desk were printed in

the RECORDS of September 3, 15, and 18, 1997, at the end of the Senate proceedings)

The following cadets of the U.S. Coast Guard Academy for appointment to the grade indicated in the U.S. Coast Guard under title 14, United States Code, section 211:

To be ensign

Steven C. Acosta, 0000
 Sterling V. Adlakha, 0000
 Marcie L. Albright, 0000
 Katie R. Alexander, 0000
 Jeremy J. Anderson, 0000
 William L. Arritt, 0000
 Leanne M. Bacon, 0000
 Matthew J. Baer, 0000
 Abraham C. Banks, 0000
 Gregory R. Barbiaux, 0000
 Jonathan Bates, 0000
 Paul R. Beavis, 0000
 Sean C. Bennett, 0000
 Chandler Benson, 0000
 Cheryl A. Berezny, 0000
 Brent R. Bergan, 0000
 Alex W. Bergman, 0000
 James B. Bernstein, 0000
 Jason M. Biggar, 0000
 Bryan R. Blackmore, 0000
 Anne M. Blandford, 0000
 Robert R. Borowczak, 0000
 John B. Brady, 0000
 Marc Brandt, 0000
 Thomas K. Brasted, 0000
 Mark A. Braxton, 0000
 Veronica A. Brecht, 0000
 Jason A. Brennell, 0000
 Joseph D. Brown, 0000
 Randall E. Brown, 0000
 David L. Burger, 0000
 Katrina D. Burritt, 0000
 Erin E. Calvert, 0000
 Gregg W. Casad, 0000
 George W. Cathey, 0000
 Kimberly B. Chapman, 0000
 Scott A. Clementz, 0000
 Jennifer J. Cook, 0000
 Thomas D. Crane, 0000
 Charles C. Culotta, 0000
 Kenneth C. Cutler, 0000
 Thomas C. D'Arcy, 0000
 Thomas W. Denucci, 0000
 Frederick D. Detar, 0000
 Alexander D. Dodd, 0000
 Roger S. Doyle, 0000
 John M. Dunlap, 0000
 Reginald C. Eisenhauer, 0000
 Meredith M. Engelke, 0000
 Brian C. Erickson, 0000
 Anthony S. Erickson, 0000
 Joshua W. Fant, 0000
 Louis B. Faulkner, 0000
 Gregory J. Ferry, 0000
 Benjamin E. Fleming, 0000
 Aurora I. Fleming, 0000
 Anthony T. Fratianna, 0000
 Matthew J. Funderburk, 0000
 Lawrence D. Gaillard, 0000
 Brent Garriepy, 0000
 Benjamin A. Gates, 0000
 Edward P. Geraghty, 0000
 Jennifer L. Girton, 0000
 Benjamin M. Golightly, 0000
 Jason M. Goodman, 0000
 Jennifer A. Green, 0000
 Robert M. Green, 0000
 Patrick A. Groves, 0000
 Andrew L. Guedry, 0000
 Thomas J. Hall, 0000
 Matthew W. Hammond, 0000
 Sean P. Hannigan, 0000
 Alan D. Hansen, 0000
 Justin H. Harper, 0000
 Rebecca J. Heatherington, 0000
 Casey J. Hehr, 0000
 Eric A. Helgen, 0000
 Brian J. Henry, 0000

Edward J. Hernaez, 0000
 Wesley H. Hester, 0000
 Curtis G. Huntington, 0000
 Kristin A. Jagmin, 0000
 Cassie Q. Janssen, 0000
 Graig T. Jeanquart, 0000
 Raymond M. Jebsen, 0000
 Andrew S. Joca, 0000
 Scott B. Jones, 0000
 Michael A. Keane, 0000
 Corinna M. Kellicut, 0000
 Paul W. Kemp, 0000
 Ibrahim M. Khalil, 0000
 Michael E. Kicklighter, 0000
 Justin A. Kimura, 0000
 Elizabeth A. Kirner, 0000
 Michael K. Klinge, 0000
 Lisa E. Knopf, 0000
 Dirk L. Krause, 0000
 Brian C. Krautler, 0000
 Jon M. Kreischer, 0000
 Jeffrey W. Kuck, 0000
 Matthew F. Lammer, 0000
 John J. Larkin, 0000
 Jeremy P. Law, 0000
 Nina C. Leonard, 0000
 Marcus A. Lines, 0000
 Monica B. Lomascolo, 0000
 Natalie J. Magnino, 0000
 Dana C. Mancinelli, 0000
 Heather R. Mattern, 0000
 Benjamin J. Maule, 0000
 Bryan L. May, 0000
 Benjamin E. Maynard, 0000
 James E. McCollum, 0000
 Iain L. McConnell, 0000
 Matthew V. McGuan, 0000
 Joseph E. Mause, 0000
 Joshua P. Miller, 0000
 John Miller, 0000
 Dean J. Milne, 0000
 Chris S. Moland, 0000
 Robert W. Moore, 0000
 Matthew P. Moore, 0000
 Stephanie A. Morrison, 0000
 Christian A. Munoz, 0000
 Sean D. Murphy, 0000
 David R. Ojeda, 0000
 Jeffrey P. Pace, 0000
 Timothy D. Payton, 0000
 Eric D. Peace, 0000
 Kristian B. Pickrell, 0000
 Jeffrey J. Pile, 0000
 Christopher M. Pisares, 0000
 Michael J. Plumley, 0000
 Jessica L. Plummer, 0000
 Eric C. Popiel, 0000
 Jody T. Popp, 0000
 Juan M. Posada, 0000
 Gabrielle E. Potter, 0000
 Clinton J. Prindle, 0000
 David A. Quattro, 0000
 Christopher G. Raia, 0000
 Arthur L. Ray, 0000
 Katie B. Richardson, 0000
 Roger G. Robitaille, 0000
 Brust B. Roethler, 0000
 Pedro J. Rubio, 0000
 Paul F. Rudick, 0000
 Shaun R. Ruffell, 0000
 Robert G. Salembier, 0000
 Stanton C. Sanchez, 0000
 Deanna L. Sand, 0000
 Michael R. Sarnowski, 0000
 Jamie L. Scholzen, 0000
 Richard M. Scott, 0000
 Kelly C. Seals, 0000
 James T. Sears, 0000
 Stephanie M. Sheridan, 0000
 Kenneth E. Shovlin, 0000
 Michael R. Sinclair, 0000
 Kelly K. Skiles, 0000
 Jason M. Stamper, 0000
 Joshua T. Steffen, 0000
 Erich V. Stein, 0000
 Blake D. Stockwell, 0000
 Jill A. Swaynos, 0000
 Scott G. Syring, 0000

Evelyn L. Taylor, 0000
 Shad A. Thomas, 0000
 Patrick M. Thompson, 0000
 Allen L. Thompson, 0000
 Gregory M. Tozzi, 0000
 Jason P. Travis, 0000
 Neil P. Travis, 0000
 Melissa M. Tulio, 0000
 Michael E. Vance, 0000
 Dianna L. Vanvalkenburg, 0000
 Joseph J. Vealencis, 0000
 Kristi L. Walker, 0000
 Daniel R. Warren, 0000
 Zachary A. Weiss, 0000
 Timothy P. Wieland, 0000
 Jerred C. Williams, 0000
 Darlene D. Wilson, 0000
 Amy E. Wirts, 0000
 Christopher G. Wolfe, 0000
 Marc A. Zlomek, 0000

The following-named officers for appointment to the grade indicated in the U.S. Coast Guard under title 14, United States Code, section 271:

To be commander

Frank M. Paskewich, 0000
 Anthony S. Reynolds, 0000
 Theodore A. Bull, 0000
 Timothy F. Mann, 0000
 Gary M. Alexander, 0000
 Gregory R. Haack, 0000
 Mark P. O'Mally, 0000
 Robert M. Palatka, 0000
 John J. Cook, 0000
 Mark A. Rose, 0000
 John F. Kaplan, 0000
 Timothy M. Close, 0000
 Pamela A. Russell, 0000
 William T. Devereaux, 0000
 Matthew J. Glomb, 0000
 David C. Eky, 0000
 Stephan A. Billian, 0000
 Mark E. Butt, 0000
 Peter S. Simons, 0000
 Thaddeus G. Sliwinski, 0000
 Steven R. Corporon, 0000
 James Y. Poyer, 0000
 Vince S. Sedwick, 0000
 Eugene F. Cunningham, 0000
 Joseph E. Mihelic, 0000
 Steven E. Carlson, 0000
 Michael C. Cosenza, 0000
 Raymond J. Petow, 0000
 Daniel J. McClellan, 0000
 Arthur C. Walsh, 0000
 Michael R. Kelley, 0000
 John A. Watson, 0000
 David A. Durham, 0000
 Leonard R. Radziwanowicz, 0000
 Michael N. Parks, 0000
 Craig A. Bennett, 0000
 Douglas G. Russell, 0000
 Thomas R. Hale, 0000
 George P. Hannifin, 0000
 James L. McDonald, 0000
 Kevin M. O'Day, 0000
 William J. Diehl, 0000
 Terry A. Bickham, 0000
 Morris B. Stewart, 0000
 Brian D. Kelley, 0000
 Thomas F. Atkin, 0000
 Joseph A. Servidio, 0000
 Joseph P. Seebald, 0000
 Edward W. Greiner, 0000
 Jeffrey S. Hammond, 0000
 John M. Weber, 0000
 Charley L. Diaz, 0000
 Fred M. Midgett, 0000
 Mark J. Dandrea, 0000
 Jeffrey S. Griffin, 0000
 William M. Randall, 0000
 Charles A. Mathieu, 0000
 Evan Q. Kahler, 0000
 Sandra L. Stosz, 0000
 George P. Cummings, 0000
 Fred T. White, 0000
 Andrew J. Berghorn, 0000

Stephen P. Metruck, 0000
 Vincent B. Atkins, 0000
 Thomas S. Morrison, 0000
 Thomas A. Abbate, 0000
 Roger E. Dubuc, 0000
 Michael E. Lehocky, 0000
 Edward Sinclair, 0000
 Mark A. Torres, 0000
 David R. Callahan, 0000
 Michael E. Sullivan, 0000
 Lance O. Benton, 0000
 Robert G. Mueller, 0000
 Hal R. Savage, 0000
 Rudy T. Holm, 0000
 David D. Simms, 0000
 Ronald E. Kaetzel, 0000
 Steven R. Baum, 0000
 Lyle A. Rice, 0000
 Joseph M. Hanson, 0000
 James B. McPherson, 0000
 Stephen M. Wheeler, 0000
 Richard G. Brunke, 0000
 Leonard L. Ritter, 0000
 Mark M. Campbell, 0000
 Fred R. Call, 0000
 Christopher W. Doane, 0000
 Michael A. Hamel, 0000
 Peyton A. Coleman, 0000
 Steven C. Taylor, 0000
 Michael D. Dawe, 0000
 Frank M. Reed, 0000
 Thomas M. Heitstuman, 0000
 Thomas E. Atwood, 0000
 Michael E. Kendall, 0000
 Robert L. Desh, 0000
 Daniel B. Abel, 0000
 Richard T. Gromlich, 0000
 Lincoln D. Stroh, 0000
 Keith A. Taylor, 0000
 Mark R. Higgins, 0000
 Frederick W. Tucher, 0000
 Kristy L. Plourde, 0000
 Richard D. Belisle, 0000
 Maura S. Albano, 0000
 David H. Gardner, 0000
 Paul E. Wiedenhoef, 0000
 John C. Odell, 0000
 Karl L. Schultz, 0000
 Bruce L. Toney, 0000
 Terry A. Boyd, 0000
 Edwin B. Thiedeman, 0000
 Kenneth K. Moore, 0000
 Mathew D. Bliven, 0000
 Todd Gentile, 0000
 Richard K. Murphy, 0000
 Eugene Gray, 0000
 John J. Jennings, 0000
 Robert M. Pyle, 0000

The following-named officers of the U.S. Coast Guard Permanent Commissioned Teaching Staff at the Coast Academy for appointment to the grade indicated in the U.S. Coast Guard under title 14, United States Code, Section 189:

To be commander

Stephen E. Flynn, 0000
 Jonathan C. Russell, 0000
 Michael A. Alfultis, 0000
 Vincent Wilczynski, 0000

The following-named officers for appointment to the grade indicated in the U.S. Coast Guard under title 14, United States Code, section 271:

To be captain

Michael F. Holmes, 0000
 Herbert H. Sharpe, 0000
 Erik N. Funk, 0000
 Marvin J. Pontiff, 0000
 John J. Davin, 0000
 Richard R. Houck, 0000
 David M. Mogan, 0000
 Richard R. Kowalewski, 0000
 James D. Spitzer, 0000
 Sally Brice-Ohara, 0000
 Kenneth W. Keane, 0000
 Peter A. Richardson, 0000

Christopher J. Snyder, 0000
 Paul D. Luppert, 0000
 Lawrence T. Yarborough, 0000
 Ronald J. Morris, 0000
 Randolph Meade, 0000
 Ronald L. Rutledge, 0000
 Eric N. Fagerholm, 0000
 George R. Matthews, 0000
 Geoffrey D. Powers, 0000
 Alan H. Moore, 0000
 Theodore C. Lefeuvre, 0000
 Richard R. Kelly, 0000
 Lawrence J. Bowling, 0000
 Glenn W. Anderson, 0000
 Loren P. Tschohl, 0000
 John A. Gentile, 0000
 Surran D. Dilks, 0000
 Terrence C. Julich, 0000
 John M. Krupa, 0000
 John C. Miller, 0000
 Geoffrey L. Abbott, 0000
 James S. Thomas, 0000
 Joseph A. Halsch, 0000
 Wayne R. Buchanan, 0000
 Glenn A. Wiltshire, 0000
 Mark S. Kern, 0000
 James E. Evans, 0000
 Stephen J. Krupa, 0000
 Richard D. Poore, 0000
 James W. Decker, 0000
 Glenn R. Gunn, 0000
 William W. Peterson, 0000
 Scott E. Davis, 0000
 Mark H. Johnson, 0000
 Glenn E. Gately, 0000
 James F. Murray, 0000
 Ivan T. Luke, 0000
 Arthur H. Hanson, 0000
 Michael K. Grimes, 0000
 James R. Mongold, 0000
 David J. Visneski, 0000
 Gregory J. Macgarva, 0000
 Arn M. Heggors, 0000
 James W. Stark, 0000
 John Astley, 0000
 Gilbert J. Kanazawa, 0000
 Scott J. Glover, 0000
 Kevin L. Marshall, 0000
 Paul A. Langlois, 0000
 Daniel B. Lloyd, 0000
 John P. Currier, 0000
 Wayne E. Justice, 0000
 William R. Webster, 0000
 Eric A. Nicolaus, 0000
 Charles J. Dickens, 0000
 Howard P. Rhoades, 0000
 Robert D. Allen, 0000
 Jody A. Breckenridge, 0000
 Russell N. Terrell, 0000
 Gregory F. Adams, 0000
 William L. Ross, 0000
 Beverly G. Kelley, 0000

(The above nominations were reported with the recommendation that they be confirmed.)

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 Mr. FRIST:

S. 1201. A bill to improve teacher preparation at institutions of higher education; to the Committee on Labor and Human Resources.

By Mrs. FEINSTEIN:

S. 1202. A bill providing relief for Sergio Lozano, Fauricio Lozano, and Ana Lozano; to the Committee on the Judiciary.

By Mr. D'AMATO (for himself, Mr. BENNETT, Mr. DODD, and Mr. BRYAN):
 S. 1203. A bill to amend the Electronic Fund Transfer Act to limit consumer liability

for the unauthorized use of a debit card, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

By Mr. COVERDELL (for himself, Ms. LANDRIEU, Mrs. HUTCHISON, Mr. CRAIG, Mr. MACK, Mr. BROWNBACK, Mr. KYL, Mr. BURNS, Mr. HATCH, Mr. ENZI, Mr. GRAMM, Mr. THURMOND, Mr. DORGAN, and Mr. REID):

S. 1204. A bill to simplify and expedite access to the Federal courts for injured parties whose rights and privileges, secured by the United States Constitution, have been deprived by final actions of Federal agencies, or other government officials or entities acting under color of State law; to prevent Federal courts from abstaining from exercising Federal jurisdiction in actions where no State law claim is alleged; to permit certification of unsettled State law questions that are essential to resolving Federal claims arising under the Constitution; and to clarify when government action is sufficiently final to ripen certain Federal claims arising under the Constitution; to the Committee on Judiciary.

By Mrs. MURRAY:

S. 1205. A bill to amend the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 to clarify that records of arrival or departure are not required to be collected for purposes of the automated entry-exit control system developed under section 110 of such Act, for Canadians who are not otherwise required to possess a visa, passport, or border crossing identification card; to the Committee on Judiciary.

By Mrs. SNOWE (for himself, Mr. JEFFORDS, Ms. MIKULSKI, Mr. ALLARD, Mr. HARKIN, and Mr. GRASSLEY):

S. 1206. A bill to provide for an enumeration of family caregivers as part of the 2000 decennial census of population; to the Committee on Governmental Affairs.

By Mrs. BOXER (for herself, Mr. BINGAMAN, Mrs. FEINSTEIN, Mr. DASCHLE, Mr. DORGAN, Mr. HARKIN, Mr. WELLSTONE, Mr. CONRAD, Ms. LANDRIEU, Mr. REED, and Mrs. MURRAY):

S. 1207. A bill to authorize the President to award a congressional gold medal to the family of the late Raul Julia, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

By Mrs. BOXER (for herself and Mrs. MURRAY):

S. 1208. A bill to protect women's reproductive health and constitutional right to choice, and for other purposes; to the Committee on Labor and Human Resources.

By Mr. KENNEDY (for himself, Mr. DODD, and Mr. KERRY):

S. 1209. A bill improving teacher preparation and recruitment; to the Committee on Labor and Human Resources.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mrs. FEINSTEIN:

S. 1202. A bill providing relief for Sergio Lozano, Fauricio Lozano, and Ana Lozano; to the Committee on the Judiciary.

PRIVATE RELIEF LEGISLATION

Mrs. FEINSTEIN. Mr. President, I rise today to offer legislation that provides permanent resident status to three children, Sergio, 17 years old; Fauricio 15 years old; and Ana Lozano, 14 years old; who were granted immigrant visas to come to the United States with their mother earlier this year. Now they have lost their mother

and could be deported because they were recently orphaned.

The children have lived with their mother, Ana Ruth Lozano, until her death in February of this year due to complications from typhoid fever. Since their mother's death, the children have been living with their closest relative, their U.S.-citizen grandmother who lives in Los Angeles.

Without their mother, the children do not have the legal right to remain in the United States. The Lozano children can be deported because the immigration law prohibits permanent legal residency to minor children without their parents.

Without their mother, these children can be deported by the INS despite the fact the children have no family who will take care of them in El Salvador except their estranged father who, INS reports show, was abusive to the mother and the children.

Without this bill, the children will most likely be sent to an orphanage in El Salvador. Here in the United States, the children have their U.S.-citizen grandmother and uncles who will give them a loving home.

I have previously sought administrative relief for the Lozano children by asking the INS district office in Los Angeles and Commissioner Meissner if any humanitarian exemptions could be made in their case. INS has told my staff that there is nothing further they can do administratively and a private relief bill may be the only way to protect the children from deportation.

I hope you will support this bill so that we can help the Lozano children begin to rebuild their lives in the United States.

Mr. President, I ask for unanimous consent that the attached news article and the bill be entered into the RECORD.

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

S. 1202

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

SECTION 1. PERMANENT RESIDENCE.

Notwithstanding any other provision of law, for purposes of the Immigration and Nationality Act (8 U.S.C. 1101 et seq.), Sergio Lozano, Fauricio Lozano and Ana Lozano, shall be held and considered to have been lawfully admitted to the United States for permanent residence as of the date of the enactment of this Act upon payment of the required visa fees.

[From the Los Angeles Times, May 29, 1997]

YOUTH'S VISAS IN DOUBT AFTER MOTHER'S DEATH

(By Patrick J. McDonnell)

Three El Salvadoran teenagers who were granted U.S. government permission to move to Los Angeles with their mother earlier this year now face deportation because their mother's death has left them without a legal right to be in the United States.

Ana Ruth Lozano a single mother who worked in a garment factory in El Salvador, had long dreamed that she and her children would be able to join relatives in Los Ange-

les, a glittering place with promise beyond the postwar tumult of Central America.

She died in El Salvador in February at the age of 33, apparently of complications from typhoid fever, three weeks after her family received visas to emigrate to the United States following an eight-year wait.

Ironically, relatives say; Lozano took ill on the day she was informed by officials in the U.S. Embassy in San Salvador that authorities were approving the family's long-delayed application.

"My mother always said we'd go to the United States and have a real chance to succeed," said Sergio Lozano, 17, who finally arrived here last month with his siblings, Fauricio, 15, and Ana, 14.

With the shock of her unexpected death still raw, the family is facing another blow: The Immigration and Naturalization Service says that Lozano's death means that her children must go back to El Salvador. Because she was the primary visa beneficiary, the INS says, the law calls for the papers of her children—the "derivative beneficiaries"—to be revoked upon her death.

The incredulous Lozano family has fallen into one of the many cracks in U.S. immigration law. Their case stands out even amid the often dramatic consequences in a legal arena replete with tales of separated families.

"It's just not fair to send these children back now," Zoila Esperanza Lozano, 54, the children's maternal grandmother, said as she fought back tears during an interview at her Los Angeles apartment, where a photograph of her late daughter and a Mother's Day poem from her are displayed prominently.

Rosemary Melville, INS deputy district director in Los Angeles, declined to discuss the Lozano case specifically, citing privacy laws. But she confirmed that visas for family members are considered "null and void" if the principal beneficiary dies before the visa is used. In "compelling" cases, Melville added, the agency has discretion to grant residency or block deportation based on humanitarian concerns.

In another era, legal observers say, authorities may have been inclined to stretch the letter of the law or issue a waiver allowing the Lozano children to stay. But such exceptions are more problematic amid today's national climate generally hostile to immigration.

"The unfortunate track record of immigration law is if you make one exception you find it spinning out of control," said Ira Mehlman of the Federation for American Immigration Reform, a group that seeks to reduce immigration levels and assails "loopholes" in the law.

Relatives of the Lozano children say they were assured by officials at the U.S. Embassy in San Salvador that the children's visas were still good, despite the mother's death. They learned otherwise upon the youths' arrival at Los Angeles International Airport last month, when, according to the family, the three youngsters were held and questioned for six hours and faced being sent back to El Salvador on the spot—an expedited "removal" procedure that has been in the INS arsenal since April 1, when a tough new immigration law went into effect.

Finally, inspectors agreed to allow the three into the country conditionally, pending the outcome of an agency review. The three teenagers have another date with the INS in Los Angeles on June 25.

The Lozano family has mobilized to do whatever necessary to keep the children in Los Angeles. The three, now enrolled at Belmont High School, are staying in their grandmother's one-bedroom Westlake apartment.

"For me, the children are a blessing from my beautiful daughter, and I'll do whatever I can for them," their grandmother said.

Tough of modest means, relatives here say they are willing to sign legally binding accords to care for the three and ensure that they do not become public charges.

Francisco Lozano, Ana Ruth's younger brother, is spearheading a letter-writing campaign to officials in Congress and elsewhere. "If I have to go and see President Clinton, I will," said Lozano, a hotel pastry chef.

In El Salvador, the family says, the three children have nothing to go back to: no home, no close kin, no means of support. Ana Ruth Lozano had been estranged from the children's father for years, relatives say. Most close relatives on their mother's side of the family are in the United States and Canada, as are many other Salvadorans, who left their homeland during the civil war that engulfed it in the 1980s.

The children's grandmother has supported them in El Salvador for years, sending back monthly checks of up to \$300, almost half her pay as a live-in housekeeper.

Seated in their grandmother's home on a recent afternoon, all three Lozano youths spoke of their desire to remain in the United States, study, and embark upon careers: Sergio wants to be a graphic artist, Fauricio would like to be an airline pilot, and Ana hopes to become a lawyer.

"I don't think I'd have any chance to even dream about such a thing back home," said Fauricio.

"Here one has the chance to better oneself," said the slender, reserved Ana. "This place is what our mother always wanted for us."

By Mr. D'AMATO (for himself, Mr. BENNETT, Mr. DODD and Mr. BRYAN):

S. 1203. A bill to amend the Electronic Fund Transfer Act to limit consumer liability for the unauthorized use of a debit card, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

THE DEBIT CARD CONSUMER PROTECTION ACT OF 1997

Mr. D'AMATO. Mr. President, today I introduce legislation that will protect tens of millions of consumers who carry bank debit cards, as well as millions more who are being targeted by banks to use this relatively new and unfamiliar payment card. This bill extends to the users of debit cards the protections that now already apply to users of credit cards. And I would like to thank my colleagues, Senators BENNETT, DODD, and BRYAN, for cosponsoring this important legislation.

In the past few years, millions of Americans have opened envelopes from their banks to find these new payment cards. These cards look like credit cards. They have "VISA" or "MasterCard" logos on the front of them—I am holding one up now—but they are actually debit cards, or, in the language of the industry, they are "off-line" debit cards. They are called "off-line" cards because they can be used with just a signature, and no PIN No., in order to access the consumer's bank account directly.

These off-line cards combine the convenience of a credit card with the simplicity of an ATM card. In order to make a purchase, the consumer simply presents the debit card to a merchant and signs a sales slip. The money for the payment is then automatically

withdrawn from the consumer's bank account and transferred to the merchant.

But if an off-line card is lost or stolen, it poses a little known and potentially unlimited danger to the consumer. Because it needs only a signature to authorize a purchase, a criminal who finds the card or who steals the card can easily use it to make purchases. He can go on a wild shopping spree and buy thousands of dollars worth of goods on that stolen card.

But unlike a stolen credit card, these fraudulent charges are immediately deducted from the victim's bank account. And unlike a stolen credit card, the law provides virtually no limit to the victim's liability.

And what happens to the consumer whose bank account is cleaned out by fraud? Soon her checks begin bouncing, bills go unpaid, late charges and overdraft fees pile up, suddenly the victim is facing financial disaster. Unraveling this mess can mean weeks of letters and phone calls, and nobody will compensate the victim for the lasting damage to his or her name or reputation.

Furthermore, the victim will be literally penniless until the bank investigates the theft and, hopefully, restores the account.

Under current law, the bank could take up to 20 days to complete this investigation. Imagine losing one's entire bank balance and then being unable to write a check for rent, car payment or groceries for 20 days.

Mr. President, I am concerned that consumers do not understand the off-line debit card. They may think it is just like an ordinary ATM card. But without the protection of a secret PIN number, the card is not secure. In reality, it is a direct line of access to the consumer's bank account. That line of access is open to anyone who possesses the card, including a thief. Just the number on the face of the card is all the thief needs to totally drain the consumer's bank account.

Financial institutions have sent out tens of millions of these cards unsolicited in the last few years. By 1994, there were 25 million off-line cards in circulation. By 1996, the number had jumped to more than 60 million. Millions more will be mailed out this year, because although banks cannot legally mail out an unsolicited credit card, a loophole in the law allows them to mail out these unsolicited off-line debit cards as replacements for consumer's ATM cards.

Mr. President, this is a ticking time bomb for millions of unwary consumers. Does the consumer understand how this new card differs from an ordinary ATM card? Does the consumer understand the risk that comes from carrying the new off-line card? Too often the answer is no. A recent survey by Mastercard found that 59 percent of the consumers who carry debit cards do not realize just how important it is to report a lost or stolen card immediately. At a minimum, consumers

need to be warned before they start carrying these off-line cards, and they need protection in the event that anything goes wrong.

Mr. President, we need reform and we need it soon. The bill we have introduced today, the Debit Card Consumer Protection Act of 1997, provides a level of protection that is clearly needed.

First, it prohibits the banks from mailing out unsolicited debit cards. Only people who want these cards should be getting them in the mail.

Second, it requires a clear disclosure to the consumer that the card provides a direct line of access to the consumer's bank account.

Third, it prohibits the bank from sending out live debit cards. Cards must not be valid for use until the recipient identifies himself or herself as the rightful owner.

Fourth, it limits the consumer's liability to \$50 in the event the card is lost or stolen.

Fifth, it expedites the restoration of funds to the consumer's account within 5 business days. Current law can make the consumer wait 20 business days.

Mr. President, this bill would bring the consumer protection laws up to date and into line with what the consumer is entitled to and expects. That is why consumer groups strongly support this bill, including the Consumer Federation of America, the Consumers Union, and the U.S. Public Interest Research Group. These organizations have all gone on record to say that this legislation provides essential protection for users of debit cards.

Now, Mr. President, some of the provisions of this bill were recently put forth in another bill, S. 1154, by my colleague, Senator REED of Rhode Island, who I see is on the floor. And some of these measures are now being implemented voluntarily by the industry. I want to commend Senator REED for his work in this area. I think that a consensus exists that consumer protections are needed to improve a situation that presents a very real risk for millions of consumers.

In fact, MasterCard and VISA recently announced that they will voluntarily cap the consumer's liability at \$50 in the event of an unauthorized use. One bank, Bank of America, has announced it will not hold consumers liable for any unauthorized charges. I commend the industry for responding to these concerns. Because of this responsiveness, I am hopeful the industry will vigorously support legislation to make these essential consumer protection laws permanent and universal.

Finally, I thank Senators BENNETT, DODD, and BRYAN for cosponsoring this bill. Senator BENNETT, as chairman of the Banking Subcommittee on Financial Services and Technology, is very aware of the enormous impact financial fraud is having on the industry and consumers. This legislation will help to protect both the industry and consumers from having to pay these high costs.

Mr. President, I ask unanimous consent 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. 1203

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 "Debit Card Consumer Protection Act of 1997".

SEC. 2. CONSUMER LIABILITY FOR UNAUTHORIZED DEBIT CARD TRANSACTIONS.

Section 909 of the Electronic Fund Transfer Act (15 U.S.C. 1693g) is amended by striking subsection (a) and inserting the following:

“(a) LIMITATION ON LIABILITY.—

“(1) IN GENERAL.—A consumer shall be liable for an unauthorized electronic fund transfer only if—

“(A) the card or other means of access used to make the unauthorized electronic fund transfer was an accepted card or other means of access;

“(B) the liability, including any overdraft or other fee imposed by the financial institution in connection with or as a result of the unauthorized electronic fund transfer, is not in excess of the lesser of—

“(i) \$50; or

“(ii) the amount of money or value of property or services obtained in such unauthorized electronic fund transfer prior to the time at which the financial institution is notified of, or otherwise becomes aware of, circumstances which lead to the reasonable belief that an unauthorized electronic fund transfer involving the consumer's account has been or may be effected;

“(C) the financial institution that issued the card or other means of access gave adequate notice to the cardholder of the potential liability;

“(D) such financial institution provided the consumer with a description of a means by which the institution may be notified of loss or theft of the card or other means of access, which description may be provided on the face or reverse side of the statement required by section 906(c) or on a separate notice accompanying such statement;

“(E) the unauthorized electronic fund transfer occurred before the financial institution was notified of such unauthorized transfer, or that such unauthorized transfer may occur as the result of loss, theft, or otherwise; and

“(F) the financial institution has provided a method whereby the consumer to whom the card or other means of access was issued can be identified as the person authorized to use it.

“(2) SUFFICIENCY OF NOTICE.—For purposes of paragraph (1), the financial institution has been notified when such steps have been taken as may be reasonably required in the ordinary course of business to provide the financial institution with the pertinent information, whether or not any particular officer, employee, or agent of the financial institution does in fact receive such information.”.

SEC. 3. AMENDMENTS TO DEFINITIONS.

Section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a) is amended—

(1) in paragraph (1), by striking “and received” and all that follows through “services” and inserting “or renewed and received such card or other means of access (including a non-protected access card and a protected access card)”; and

(2) by redesignating paragraphs (9) through (11) as paragraphs (11) through (13), respectively; and

(3) by inserting after paragraph (8) the following new paragraphs:

"(9) the term 'protected access card' means an accepted card or other means of access that requires use of a personalized code or other unique identifier (other than a signature) to initiate access to the account of a consumer;

"(10) the term 'non-protected access card' means an accepted card or other means of access that does not require the use of a unique identifier to initiate access to the account of a consumer, except that for purposes of this paragraph, a signature shall not be considered to be a personalized code or other unique identifier;"

SEC. 4. TIMING OF ERROR RESOLUTION.

Section 908 of the Electronic Fund Transfer Act (15 U.S.C. 1693f) is amended—

(1) in subsection (a)—

(A) by redesignating paragraphs (1) through (3) as subparagraphs (A) through (C), respectively, and indenting accordingly;

(B) by striking "(a) If a financial" and inserting the following:

"(a) IN GENERAL.—

"(1) NOTICE TO INSTITUTION.—If a financial";

(C) in the first sentence, by striking "ten business" and inserting "5 business"; and

(D) in the second sentence, by striking "The financial" and inserting the following:

"(2) WRITTEN CONFIRMATION OF ORAL NOTIFICATION.—The financial"; and

(E) by striking "the previous sentence" each place it appears and inserting "this paragraph";

(2) in subsection (c), by striking "ten business" and inserting "5 business"; and

(3) in subsection (f)(1), by inserting before the semicolon "including such unauthorized transfer by use of a protected access card or a non-protected access card".

SEC. 5. ISSUANCE OF CARDS.

(a) LIMITATIONS ON ISSUANCE.—Section 911 of the Electronic Fund Transfer Act (15 U.S.C. 1693i) is amended—

(1) in subsection (a)—

(A) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and indenting accordingly;

(B) by striking "(a) No" and inserting the following:

"(a) LIMITATIONS ON ISSUANCE.—

"(1) IN GENERAL.—No"; and

(C) by adding at the end the following:

"(2) RENEWALS; SUBSTITUTIONS.—For purposes of paragraph (1), a non-protected access card may only be issued in response to a request or application for, or as a renewal of or substitution for, a non-protected access card.";

(2) in subsection (b)—

(A) by striking "(b) Notwithstanding" and all that follows through "basis" and inserting the following:

"(b) CRITERIA FOR ISSUANCE.—A person may only issue to a consumer";

(B) by striking "distribution" each place it appears and inserting "issuance"; and

(C) by striking "distribute" and inserting "issue".

(3) in subsection (c), by striking "(c) For" and inserting the following:

"(d) DEFINITION.—For"; and

(4) by inserting after subsection (b) the following new subsection:

"(c) DISCLOSURE OF NON-PROTECTED ACCESS CAPABILITY.—In any case in which a non-protected access card is issued to a consumer, such issuance shall be accompanied by a clear and conspicuous printed disclosure designated as a warning that—

"(1) the card does not require a personalized code or other unique identifier (other than a signature) to initiate access to the consumer's account; and

"(2) loss or theft of the card could result in unauthorized access to the consumer's account.";

(b) FORM OF DISCLOSURE.—Section 904(b) of the Electronic Fund Transfer Act (15 U.S.C. 1693b(b)) is amended by striking "section 905" and inserting "sections 905 and 911".

SEC. 6. NOTIFICATION TO CONSUMERS OF RESTITUTION POLICY.

Section 905 of the Electronic Fund Transfer Act (15 U.S.C. 1693c) is amended—

(1) in paragraph (2), by striking "than an" and inserting "that an";

(2) in paragraph (7), by striking ". The financial institution" and all that follows through "year" and inserting "which summary shall be transmitted to the consumer thereafter not less frequently than annually";

(3) by redesignating paragraphs (8) and (9) as paragraphs (9) and (10), respectively; and

(4) by inserting after paragraph (7) the following new paragraph:

"(8) the policy of the financial institution regarding restitution to the consumer of any fees imposed by a person other than the financial institution as a result of an unauthorized electronic fund transfer, including returned check fees, late charges, and other fees;"

Mr. DODD. Thank you, Mr. President. I am pleased to take the floor today in support of the Consumer Payment Card Security Act of 1997. This legislation, of which I am an original cosponsor, would address a serious gap in our consumer laws which govern the use of debit or check cards. I would particularly like to thank my friend and Chairman of the Banking Committee, Senator D'AMATO, for his leadership role in developing this legislation.

Many of my colleagues may be aware of these cards through the intensive ad campaign mounted by VISA and MasterCard with such famous celebrities as Michael Jordan, Bugs Bunny, and our former colleague, Bob Dole. But these commercials may not exactly explain how these check cards—or debit cards—work. Essentially, a debit card is a card that looks just like your ATM card that uses the National Credit Card Electronic Networks to access your checking account. In this way, you could go into any business that accepts VISA or MasterCard, and instead of charging your purchase, you could pay for it right out of your checking account. Thus, bank customers have access to their accounts in hundreds of thousands of locations across the globe, not just at the ATM machines that are part of their banks' network.

In general, I believe that the private sector should be commended for developing this new technology. Clearly, if used properly, these debit cards will provide bank customers with greater flexibility and convenience.

However, we would not be standing on the floor today introducing legislation if the introduction of this card had gone as smoothly as everyone may have hoped. As with all new technologies, there are growing pains, and in this particular case, legislation appears necessary to help ease those pains.

The goal of this legislation is refreshingly simple: It puts debit cards under the same umbrella of consumer protections that currently govern the use of both credit cards and ATM cards.

Let me briefly recount some of the debit card problems—some might go so far as to say abuses—confronted by consumers and how the legislation would address them.

First, since a debit card looks almost identical to an ATM card, many consumers don't know that their bank has made a switch. Until very recently, this could have posed a significant financial hardship for consumers since debit card liability—if it's lost or stolen—isn't capped at \$50 the way it is capped for both credit cards and ATM cards. Also, debit cards are known as "off-line" cards; in other words, no PIN—personal identification number—is required to use the card—a crook can simply swipe it through any electronic scanner, just like a credit card, and empty your bank account.

It should be noted that in the last few weeks, the industry—particularly VISA and MasterCard, responding to increasing public pressure, has voluntarily moved to change these practices. Nevertheless, these belated efforts, while laudable, do not provide the same certainty to consumers that the statutes do. This legislation would clearly limit consumer liability to \$50. It would also ensure that consumer disclosure is improved so that the bank customer is aware that these cards do not need a PIN to be used.

The legislation would also end the practice of replacing ATM cards with debit cards without a customer's consent. One of the ways in which these cards become subject to abuse is that consumers aren't aware that they've even received this debit card as a replacement for their old ATM card. The legislation would conform debit cards with credit cards by preventing the mailing of unsolicited cards to bank customers.

Last, the bill would address a potential problem by shortening the dispute resolution process from 20 to 5 days, again conforming it to the standards currently in use for credit cards. When there is credit card fraud, the cardholder is credited for the loss until the investigation is complete, and that investigation must be done within 5 days. Under current law, debit cardholders are not always credited pending investigation and those investigations can take as long as 20 days. That's a long time for someone whose checking account has been emptied by a criminal.

Again, Mr. President, I note that in most instances, the legislation codifies what has become the industry standard. But the fact remains that given the difficulties surrounding the introduction of debit cards, and the uncertainties that arise from some companies failing to follow the industry standard, it is incumbent upon the Congress to provide the same statutory safeguards for debit card users as we

have for both credit card and ATM card users.

I hope that I will soon be able to stand here and mark the passage of this important legislation.

By Mr. COVERDELL (for himself, Ms. LANDRIEU, Mrs. HUTCHISON, Mr. CRAIG, Mr. MACK, Mr. BROWBACK, Mr. KYL, Mr. BURNS, Mr. HATCH, Mr. ENZI, Mr. GRAMM, Mr. THURMOND, Mr. DORGAN, and Mr. REID):

S. 1204. A bill to simplify and expedite access to the Federal courts for injured parties whose rights and privileges, secured by the U.S. Constitution, have been deprived by final actions of Federal agencies, or other government officials or entities acting under color of State law; to prevent Federal courts from abstaining from exercising Federal jurisdiction in actions where no State law claim is alleged; to permit certification of unsettled State law questions that are essential to resolving Federal claims arising under the Constitution; and to clarify when government action is sufficiently final to ripen certain Federal claims arising under the Constitution; to the Committee on the Judiciary.

THE PROPERTY OWNERS ACCESS TO JUSTICE ACT OF 1997

Mr. COVERDELL. Mr. President, I am introducing today, with Senators LANDRIEU and DORGAN, the Property Owners Access to Justice Act of 1997, a bill to simplify access to the Federal courts for private property owners whose rights may have been injured by government action. The fifth amendment to the U.S. Constitution provides individuals with protection from having their property taken by the Government. The Constitution requires that when private property is taken for a public purpose, the property owner must be compensated.

However, property owners seeking protection of their rights are frequently frustrated by endless bureaucratic delay and countless procedural hurdles that prevent them from having their day in court. They are told they must resolve all of their State court remedies and all of their administrative remedies before their case is ripe for a hearing in Federal court.

Unfortunately, most property owners cannot afford the long and often fruitless process of resolving all possible remedies before their case is ripe. This process can mean years of court battles and tens of thousands of dollars in legal fees just to win the right to have the merits of the case heard in Federal court. The hurdles are so oppressive that one study concluded less than 6 percent of takings claims filed during the 1980's were ever deemed ripe for Federal court adjudication.

This unfair result happens because the requirement to exhaust all administrative remedies before getting their day in court subjects property owners to endless rounds of appeals with the relevant agency. However, property

owners should be able to know with some degree of certainty what rights they have in their own property. The Property Owners Access to Justice Act says that property owners must try to resolve their differences with the agency in question, but once the agency has denied their appeal or waiver attempt, the property owner has the right to go to court.

The property owner would still shoulder the burden of proof that he or she has been injured and deserves compensation, but at least the owner will be able to have the merits of the case heard. And there is an end to the process, instead of leaving the property owner in the regulatory limbo of appealing and appealing and appealing before getting the right to seek relief in court.

To deal with the problem of resolving all State court remedies, this bill essentially gives property owners a choice of how to assert their property rights under the Constitution. If the property owner wants to pursue action against a local or State agency that has infringed on his or her rights, the property owner can sue in State or local court, as he would now. Or, if the property owner wants to reject that route and instead pursue only a fifth amendment takings claim, the case can be heard in Federal court.

This will correct the current situation in which a property owner can be bounced between State and Federal courts for years, with the merits of their Federal claim never being heard.

The Property Owners Access to Justice Act of 1997 is strictly procedural in nature. It does not change substantive law. It does not define a taking or establish a trigger for when compensation is due. It does not give property owners any special access to the Federal courts. On the contrary, it allows property owners the same access to Federal courts that other claimants currently have. Citizens alleging violations of their first amendment rights or fourth amendment rights are not told to resolve their administrative and State court remedies first—they go to Federal court. Property owners deserve to be treated the same as everyone else.

Mr. President, this bipartisan bill is simply an effort to provide property owners with a less complicated way to have their day in court. It gives them the access to justice and the chance to present the merits of their case that all Americans expect as a matter of simple fairness.

I urge my colleagues on both sides of the aisle to support the Property Owners Access to Justice Act of 1997 and ask unanimous consent that the full text of the bill be entered in the RECORD.

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

S. 1204

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 "Property Owners Access to Justice Act of 1997".

SEC. 2. JURISDICTION IN CIVIL RIGHTS CASES.

Section 1343 of title 28, United States Code, is amended by adding at the end the following:

"(c) Whenever a district court exercises jurisdiction under subsection (a), it shall not abstain from exercising or relinquish its jurisdiction to a State court in an action where no claim of a violation of a State law, right, or privilege is alleged.

"(d) Where the district court has jurisdiction over an action under subsection (a) that cannot be decided without resolution of a significant but unsettled question of State law, the district court may certify the question of State law to the highest appellate court of that State. After the State appellate court resolves the question certified to it, the district court shall proceed with resolving the merits. The district court shall not certify a question of State law under this subsection unless the question of State law—

"(1) will significantly affect the merits of the injured party's Federal claim; and

"(2) is so unclear and obviously susceptible to a limiting construction as to render premature a decision on the merits of the constitutional or legal issue in the case.

"(e)(1) Any claim or action brought under section 1979 of the Revised Statutes of the United States (42 U.S.C. 1983) to redress the deprivation of a property right or privilege secured by the Constitution shall be ripe for adjudication by the district courts upon a final decision rendered by any person acting under color of any statute, ordinance, regulation, custom, or usage, of any State or territory of the United States, that causes actual and concrete injury to the party seeking redress.

"(2) For purposes of this subsection, a final decision exists if—

"(A) any person acting under color of any statute, ordinance, regulation, custom, or usage, of any State or territory of the United States, makes a definitive decision regarding the extent of permissible uses on the property that has been allegedly infringed or taken, without regard to any uses that may be permitted elsewhere; and

"(B) the applicable statute, ordinance, regulation, custom, or usage provides for a right of appeal or waiver from such decision, and the party seeking redress has applied for, but has been denied, one such appeal or waiver.

The party seeking redress shall not be required to apply for an appeal or waiver described in subparagraph (B) if the prospects of success are reasonably unlikely and intervention by the district court is warranted to decide the merits.

"(3) For purposes of this subsection, a final decision shall not require the party seeking redress to exhaust judicial remedies provided by any State or territory of the United States."

SEC. 3. UNITED STATES AS DEFENDANT.

Section 1346 of title 28, United States Code, is amended by adding at the end the following:

"(h)(1) Any claim brought under subsection (a) that is founded upon a property right or privilege secured by the Constitution, but was allegedly infringed or taken by the United States, shall be ripe for adjudication upon a final decision rendered by the United States, that causes actual and concrete injury to the party seeking redress.

"(2) For purposes of this subsection, a final decision exists if—

"(A) the United States makes a definitive decision regarding the extent of permissible uses on the property that has been allegedly infringed or taken, without regard to any uses that may be permitted elsewhere; and

"(B) an applicable law of the United States provides for a right of appeal or waiver from

such decision, and the party seeking redress has applied for, but has been denied, one such appeal or waiver.

The party seeking redress shall not be required to apply for an appeal or waiver described in subparagraph (B), if the prospects of success are reasonably unlikely and intervention by the district court or the United States Court of Federal Claims is warranted to decide the merits."

SEC. 4. JURISDICTION OF COURT OF FEDERAL CLAIMS.

Section 1491(a) of title 28, United States Code, is amended by adding at the end the following:

"(3) Any claim brought under this subsection founded upon a property right or privilege secured by the Constitution, but allegedly infringed or taken by the United States, shall be ripe for adjudication upon a final decision rendered by the United States, that causes actual and concrete injury to the party seeking redress. For purposes of this paragraph, a final decision exists if—

"(A) the United States makes a definitive decision regarding the extent of permissible uses on the property that has been allegedly infringed or taken, without regard to any uses that may be permitted elsewhere; and

"(B) an applicable law of the United States provides for a right of appeal or waiver from such final decision, and the party seeking redress has applied for, but has been denied, one such appeal or waiver.

The party seeking redress shall not be required to apply for an appeal or waiver described in subparagraph (B) if the prospects of success are reasonably unlikely and intervention by the United States Court of Federal Claims is warranted to decide the merits."

SEC. 5. EFFECTIVE DATE.

The amendments made by this Act shall apply to actions commenced on or after the date of the enactment of this Act.

Ms. LANDRIEU. Mr. President, I am proud to join my colleague from Georgia, Senator COVERDELL, in introducing the Property Owners Access to Justice Act of 1997.

Mr. President, in my view, this bill is particularly aptly named. Justice and fairness are what this bill is all about. Unlike other countries, when this Nation was created, we did so with a contract between the people and the Government. It is not very long, but the freedoms it guarantees are quite profound. Among its provisions is a simple promise from the Government to the people. Private property shall not be taken for public use without just compensation. These very few words included in our Constitution provide one of the strongest defenses we have against arbitrary government. The certainty that our property cannot be expropriated by government without our being compensated, provides the essential infrastructure for America's great economic strength. We could never be the world's largest market without such an assurance.

However, for often well-intentioned reasons, all levels of government have made claims on private property which conflict with the protections of the fifth amendment. Whether through zoning, environmental protections, or claims of eminent domain, people have found their property rights under increasing assault. Unfortunately, not

only are their rights under assault, but then they have inadequate protection in our legal system.

We should not be confused as to whom this bill helps. Large corporations and wealthy landowners and developers do not need our help in Congress. They can hire a legion of lawyers and lobbyists to take up their case at city hall, at the statehouse, or even here in Washington. Whether this bill passes or not, their interests will be protected. The people we help with this bill are the small landowners and family farmers who lack the means to expedite the administrative process. It will help first-time home buyers in my State, who are trying to build their first home but have to put their plans on hold because they run into administrative deadlocks.

Our bill will help these people and countless others in two ways. First, it will clarify when a person has exhausted their administrative remedies. Right now, property owners spend countless hours and great expense in fruitless litigation over this subject. Legislation to end this unproductive debate should be welcomed by all parties.

Second, the bill would allow property owners to choose between bringing their claim for relief before Federal or State courts. As it stands, we all possess a fifth amendment right which we have no practical way of enforcing. The Supreme Court has interpreted the fifth amendment as applying to the States under the due process clause of the fourteenth amendment. However, the Federal courts have left it to State courts to adjudicate fifth amendment claims in this area. Only if issues of State law are resolved in the case, may plaintiffs have their constitutional claim heard in Federal court. Working people simply cannot afford a process that would require them to go all the way through the State court system and then into the federal courts to enforce their constitutional rights.

Mr. President, it is my hope that our colleagues will join this bipartisan effort and take a concrete step to provide real relief to middle class people. We will all benefit by a judicial process that is more equitable and transparent.

By Mrs. MURRAY:

S. 1205. A bill to amend the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 to clarify that records of arrival or departure are not required to be collected for purposes of the automated entry-exit control system developed under section 110 of such act for Canadians who are not otherwise required to possess a visa, passport, or border crossing identification card; to the Committee on the Judiciary.

THE ILLEGAL IMMIGRATION ACT CANADIAN EXEMPTION ACT OF 1997

Mrs. MURRAY. Mr. President, today I am introducing legislation to amend a controversial provision in last year's illegal immigration legislation that

threatens to stifle legal travel and commerce between the United States and Canada.

Section 110 of the 1996 Immigration Reform Act requires the Immigration and Naturalization Service to develop an automated entry and exit system for the purpose of documenting the entry and departure of every alien entering and leaving the United States. The legislation I am introducing today, will amend the illegal immigration legislation to clarify that records of entry and departure are not required for Canadians. This is consistent with longstanding U.S. policy toward Canadian citizens traveling to the United States.

My constituents are extremely concerned about the onerous implications of section 110. As a frequent visitor to Bellingham and Whatcom County, I hear again and again from the local community about the importance of unimpeded travel between the United States and Canada. I've visited the border crossings at Blaine, WA. At certain times, travel between the United States and Canada is already subject to lengthy delays and traffic back-ups that sometimes exceed 1 mile in length. Section 110 will further complicate border crossings if it is ever instituted on our northern border.

I have been a long proponent of strengthening and promoting the partnership between Washington State and British Columbia, Canada. British Columbia is a billion dollar neighbor for my State, generating jobs and economic activity important to all of Washington. Canadian tourism and commerce is particularly important to Bellingham and northwest Washington where border trade thrives to the benefit of both Americans and Canadians.

This legislative initiative follows up on a late 1996 letter I sent to Attorney General Janet Reno inquiring about section 110. The letter expressed my strong opposition to a border fee or other interpretation of section 110 which would inhibit legal tourism and trade between the United States and Canada. I continue to vigorously oppose nuisance measures that will unduly delay legal border crossings. A border tax is the most obvious nuisance measure, however, section 110 if fully implemented will have a potentially disastrous impact on communities in my state.

I do not expect section 110 to ever be applied to Canadians. To do so, would be a phenomenal waste of limited resources. We can't neglect our northern Border, but we can certainly be a lot smarter. Exempting Canadians from section 110 is the smart thing, the right thing to do.

I encourage my colleagues to review this important legislation and to join me in supporting the passage of this legislative exemption at the earliest opportunity.

By Ms. SNOWE (for herself, Mr. JEFFORDS, Ms. MIKULSKI, Mr. ALLARD, Mr. HARKIN, and Mr. GRASSLEY):

S. 1206. A bill to provide for an enumeration of family caregivers as part of the 2000 decennial census of population; to the Committee on Governmental Affairs.

THE FAMILY CAREGIVERS ACT OF 1997

Ms. SNOWE. Mr. President, I rise today to introduce legislation to highlight the millions of family caregivers across this country, by calling on the Census Bureau to count family caregivers in the Census 2000. This bill is a companion to House legislation introduced by Representative CANADY. I would like to thank Senators JEFFORDS, MIKULSKI, ALLARD, HARKIN, and GRASSLEY for joining me in support of family caregivers by cosponsoring this bill.

As the population of this country ages, more and more Americans have and will assume the role of family caregivers—people who provide non-compensated care for an elderly or disabled family member in their own home. Today, nearly 80 percent of elderly people needing long-term care services are estimated to reside outside the nursing home setting, and many nonelderly people are cared for by a family member as well. In fact, family caregivers provide two-thirds of all home care services in this country.

The decision to care for a loved one who is ill or incapacitated on a full-time basis requires significant personal sacrifice on the caregiver's part. Yet the compassionate services provided by family caregivers to those who are unable to care for themselves is invaluable. Without the contributions of caregivers, immense pressure would be brought to bear on our nursing home and health care systems. Unfortunately, caregivers and their contributions to the Nation's public health system have historically gone unrecognized.

While the issue of family caregivers has obvious policy implications, adequate statistical and survey information is not available to help policymakers address issues concerning these individuals. That is why I am introducing legislation to request that family caregivers be counted by the Census Bureau in the Census 2000. By counting caregivers in the census, we will be able to collect more information about this rapidly-growing group and form policy solutions that will take into account their special needs.

In her book, "Helping Yourself Help Others," former First Lady Rosalynn Carter reminds us that there are only four kinds of people in the world: those who have been caregivers, those who are caregivers, those who will be caregivers, and those who will need caregivers. I urge my colleagues to support this important legislation and to draw attention to the needs of family caregivers.

By Mrs. BOXER (for herself, Mr. BINGAMAN, Mrs. FEINSTEIN, Mr. DASCHLE, Mr. DORGAN, Mr. HARKIN, Mr. WELLSTONE, Mr. CON-

RAD, Ms. LANDRIEU, Mr. REED, and Mrs. MURRAY):

S. 1207. A bill to authorize the President to award a Congressional Gold Medal to the family of the late Raul Julia, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

CONGRESSIONAL GOLD MEDAL LEGISLATION

Mrs. BOXER. Mr. President, I rise today to introduce legislation authorizing the President of the United States to award a Congressional Gold Medal in honor of the late Raul Julia, a remarkable person who touched the lives of millions.

Raul Julia is known to most people as a talented actor who performed in movies and on stage. He excelled in such films as "The Kiss of the Spider Woman," "Presumed Innocent," and "The Eyes of Laura Mars." In his greater love, the theater, he starred in several productions, including the New York Shakespeare Festival's "Macbeth," "Othello," and "The Taming of the Shrew." His brilliant career earned him four Tony Award nominations and a countless number of accolades.

However, Raul Julia was more than just a remarkable actor and entertainer—through his work, he was able to conquer stereotypes unfairly attached to Latin actors and performers. It is clear that the Latino community still suffers discrimination in the entertainment field. Too many times, we see Latinos cast as gang members, drug dealers, and other negative characters.

With his dignified presence and undeniable talent, Raul Julia was able to overcome these stereotypes. He became a role model for Latinos trying to break into the entertainment industry, and today is still an inspiration to Latino and non-Latino alike.

Raul Julia was also a dedicated activist and humanitarian. He was especially concerned with worldwide hunger, in part because of his upbringing in Puerto Rico. In honor of his lifetime of unselfish giving, this legislation will divide profits from the sale of duplicate medals equally between the Raul Julia Hunger Fund and the National Hispanic Foundation for the Arts.

A Congressional Gold Medal is a fitting tribute to the life and work of Raul Julia. I urge my colleagues to support this bill.

I ask unanimous consent that the full text of the bill be printed at this point in the RECORD.

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

S. 1207

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

SECTION 1. FINDINGS.

The Congress finds that—

(1) Raul Julia was an accomplished, talented performer, entertaining millions through his work in film and theater;

(2) Raul Julia was a leader in the entertainment industry, particularly as a tireless mentor and role model to emerging Latino actors;

(3) a dedicated activist and humanitarian, Raul Julia was a major supporter and spokesperson for the Hunger Fund, a non-profit organization committed to the eradication of world hunger; and

(4) Raul Julia received the Hispanic Heritage Award recognizing his many career achievements for the Latino community, including his involvement in "La Familia", a New York City outreach program for Latino families in need, the Puerto Rican traveling theater, the Museo del Barrio, and the New York Shakespeare Festival.

SEC. 2. CONGRESSIONAL GOLD MEDAL.

(a) PRESENTATION AUTHORIZED.—The President is authorized to present, on behalf of the Congress, to the family of the late Raul Julia a gold medal of appropriate design, in recognition of his dedication to ending world hunger and his great contributions to the Latino community and to the performing arts.

(b) DESIGN AND STRIKING.—For purposes of the presentation referred to in subsection (a), the Secretary of the Treasury (hereafter in this Act referred to as the "Secretary") shall strike a gold medal with suitable emblems, devices, and inscriptions to be determined by the Secretary.

(c) GIFTS AND DONATIONS.—

(1) IN GENERAL.—The Secretary may accept, use, and disburse gifts or donations of property or money to carry out this section.

(2) APPROPRIATION AUTHORIZED.—No amount is authorized to be appropriated to carry out this section.

SEC. 3. DUPLICATE MEDALS.

The Secretary may strike and sell duplicates in bronze of the gold medal struck pursuant to section 2 under such regulations as the Secretary may prescribe, at a price sufficient to cover the cost thereof, including labor, materials, dies, use of machinery, and overhead expenses, and the cost of the gold medal.

SEC. 4. STATUS OF MEDALS.

The medals struck pursuant to this Act are—

(1) national medals, for purposes of chapter 51 of title 31, United States Code; and

(2) numismatic items, for purposes of section 5134 of title 31, United States Code.

SEC. 5. TRANSFER OF ANY PROFIT TO LIBRARY OF CONGRESS.

The Secretary shall transfer in equal amounts from the Numismatic Public Enterprise Fund an amount equal to the amount by which the sum of any gifts and donations received by the Secretary in accordance with section 2(c)(1) and any proceeds from the sale of duplicate medals pursuant to section 3 exceeds the total amount of the costs incurred by the Secretary in carrying out this Act to—

(1) the Raul Julia Ending Hunger Fund; and

(2) the National Hispanic Foundation for the Arts.

By Mrs. BOXER (for herself and Mrs. MURRAY):

S. 1208. A bill to protect women's reproductive health and constitutional right to choice, and for other purposes; to the Committee on Labor and Human Resources.

THE FAMILY PLANNING AND CHOICE PROTECTION ACT OF 1997

Mrs. BOXER. Mr. President, I come today to the Senate floor to introduce the Family Planning and Choice Protection Act of 1997, a comprehensive pro-choice, pro-family planning, and pro-women's health bill. The bill is cosponsored in the Senate by Senator

MURRAY, and the companion bill was introduced by Representative NITA LOWEY.

This bill has three purposes: to improve family planning programs and services; to strengthen women's right to choose; and to increase research on women's health.

In the past months and years, Congress has curbed women's reproductive rights again and again. We've seen it in the appropriations process, as women in the military and military dependents are prevented from using their own funds to obtain an abortion at military facilities. Similarly, the District of Columbia has been prevented from using local funds to provide abortion services. These are just two examples. Bit by bit, anti-choice legislators are chipping away at women's fundamental right to choose.

Even family planning programs and services have been under attack. In June, the House of Representatives voted to cut off funding for family planning to overseas organizations unless they comply with certain restrictions. These restrictions amount to a global gag rule, prohibiting these organizations from using even non-Federal funds to provide abortion services or advocate to change abortion laws or policies abroad.

The Family Planning and Choice Protection Act of 1997 addresses these attacks. It is a positive statement of what freedom of choice really means. The bill has three parts—family planning, choice protection, and health.

The family planning part does four things. First, it authorizes additional funds for family planning services. Second, it bans gag rules, which have restricted the information health providers can give and women can receive about reproductive health services. Third, it requires all health plans to cover contraceptive services and drugs if they cover other prescription drugs. Fourth, it promotes understanding of emergency contraceptives, which can be used after intercourse to prevent pregnancy.

The part on choice protection has four elements. First and foremost, it takes the basic principles of Roe versus Wade and makes them Federal law. Second, it repeals the many restrictions that Congress has placed on funding of abortions, including services for poor women, women in the military, women in the District of Columbia, and Federal employees. Third, it calls for additional Federal resources to ensure that women and health care providers have safe access to reproductive health clinics, and protection against violence at these clinics. Fourth, it directs the Department of Health and Human Services to ensure that the approval of RU-486 is based on health considerations only—not political decisions.

The third part of the bill focuses on women's health. First, it supports funding for preventive health measures in all 50 States, such as screening for breast and cervical cancer and

chlamydia. Second, it calls for funding for more research on contraception and infertility.

The American people overwhelmingly support a woman's right to choose, family planning, and women's health research. Yet there are those in this Congress who are determined to turn the clock back. This bill works to ensure that no American woman will ever have to go back to the days of ignorance, isolation, and injustice. The women of America cannot afford to go back. The Family Planning and Choice Protection Act of 1997 calls on Congress to strengthen women's right to choose and to hold firm against further attacks on this fundamental right.

I am proud to sponsor this important initiative in the Senate, and proud to join Representative LOWEY and groups such as the National Abortion Rights Action League to make this positive statement for women's rights and health.

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

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

S. 1208

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 "Family Planning and Choice Protection Act of 1997".

SEC. 2. FINDINGS.

Congress finds that—

(1) reproductive rights are central to the ability of women to exercise full enjoyment of rights secured to women by Federal and State law;

(2) abortion has been a legal and constitutionally protected medical procedure throughout the United States since 1973 and has become part of mainstream medical practice as is evidenced by the positions of medical institutions including the American Medical Association, the American College of Obstetricians and Gynecologists, the American Medical Women's Association, the American Nurses Association, and the American Public Health Association;

(3) the availability of abortion services is diminishing throughout the United States, as evidenced by—

(A) the fact that 84 percent of counties in the United States have no abortion provider; and

(B) the fact that, between 1982 and 1992, the number of abortion providers decreased in 45 States; and

(4)(A) the Department of Health and Human Services and the Institute of Medicine of the National Academy of Sciences have contributed to the development of a report entitled "Healthy People 2000", which urges that the rate of unintended pregnancy in the United States be reduced by nearly 50 percent by the year 2000;

(B) nearly 60 percent, or approximately 3,100,000, of all pregnancies in the United States each year are unintended, resulting in 1,500,000 abortions in the United States each year; and

(C) the provision of family planning services, including emergency contraception, is a cost-effective way of reducing the number of unintended pregnancies and abortions in the United States; and

(5) at a minimum, Congress must enact legislation establishing or retaining the fol-

lowing policies to preserve the choice and reproductive health of women:

(A) Authorization of family planning programs.

(B) The prohibition of any gag rule on information pertaining to reproductive medical services.

(C) The promotion of equitable treatment and coverage of prescription contraception drugs and devices in the provision of health insurance.

(D) The provision of funding for emergency contraceptive education.

(E) The establishment of breast cancer, cervical cancer, and chlamydia screening programs in all 50 States.

(F) Full implementation of contraceptive and infertility research programs.

(G) Funding through the medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) for abortion services.

(H) Protection of women from clinic violence.

(I) Final approval of the drug called Mifepristone or RU-486.

(J) The maintenance of a fundamental right to choose, as stated in the Supreme Court decision in Roe v. Wade, 410 U.S. 113 (1973).

(K) The establishment of the right of the District of Columbia to access locally raised revenue to provide abortion services to low-income women.

(L) The promotion of fairness in insurance.

(M) The establishment of the ability of military personnel overseas to obtain abortion services.

TITLE I—PREVENTION

Subtitle A—Family Planning

SEC. 101. FAMILY PLANNING AMENDMENTS.

Section 1001(d) of the Public Health Service Act (42 U.S.C. 300(d)) is amended to read as follows:

"(d) For the purpose of making grants and entering into contracts under this section, there are authorized to be appropriated \$275,000,000 for fiscal year 1999 and such sums as may be necessary for each of fiscal years 2000 through 2003."

SEC. 102. FREEDOM OF FULL DISCLOSURE.

Title XI of the Civil Rights Act of 1964 (42 U.S.C. 2000h et seq.) is amended by adding at the end the following:

"SEC. 1107. INFORMATION ABOUT AVAILABILITY OF REPRODUCTIVE HEALTH CARE SERVICES.

"(a) DEFINITION.—As used in this section, the term 'governmental authority' means any authority of the United States.

"(b) GENERAL AUTHORITY.—Notwithstanding any other provision of law, no governmental authority shall, in or through any program or activity that is administered or assisted by such authority and that provides health care services or information, limit the right of any person to provide, or the right of any person to receive, nonfraudulent information about the availability of reproductive health care services, including family planning, prenatal care, adoption, and abortion services."

Subtitle B—Prescription Equity and Contraceptive Coverage

SEC. 111. FINDINGS.

Congress finds that—

(1) each year, approximately 3,100,000 pregnancies, or nearly 60 percent of all pregnancies, in this country are unintended;

(2) contraceptive services are part of basic health care, allowing families to both adequately space desired pregnancies and avoid unintended pregnancy;

(3) studies show that contraceptives are cost-effective: for every \$1 of public funds invested in family planning, \$4 to \$14 of public funds is saved in pregnancy and health care-related costs;

(4) by reducing rates of unintended pregnancy, contraceptives help reduce the need for abortion;

(5) unintended pregnancies lead to higher rates of infant mortality, low-birth weight, and maternal morbidity, and threaten the economic viability of families;

(6) the National Commission to Prevent Infant Mortality determined that "infant mortality could be reduced by 10 percent if all women not desiring pregnancy used contraception";

(7) most women in the United States, including two-thirds of women of childbearing age, rely on some form of private employment-related insurance (through either their own employer or a family member's employer) to defray their medical expenses;

(8) the vast majority of private insurers cover prescription drugs, but many exclude coverage for prescription contraceptives;

(9) private insurance provides extremely limited coverage of contraceptives: half of traditional indemnity plans and preferred provider organizations, 20 percent of point-of-service networks, and 7 percent of health maintenance organizations cover no contraceptive methods other than sterilization;

(10) women of reproductive age spend 68 percent more than men on out-of-pocket health care costs, with contraceptives and reproductive health care services accounting for much of the difference;

(11) the lack of contraceptive coverage in health insurance places many effective forms of contraceptives beyond the financial reach of many women, leading to unintended pregnancies; and

(12) the Institute of Medicine Committee on Unintended Pregnancy recently recommended that "financial barriers to contraception be reduced by increasing the proportion of all health insurance policies that cover contraceptive services and supplies".

SEC. 112. AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (as added by section 603(a) of the Newborns' and Mothers' Health Protection Act of 1996 and amended by section 702(a) of the Mental Health Parity Act of 1996) is further amended by adding at the end the following new section:

"SEC. 713. STANDARDS RELATING TO BENEFITS FOR CONTRACEPTIVES.

"(a) REQUIREMENTS FOR COVERAGE.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, may not—

"(1) exclude or restrict benefits for prescription contraceptive drugs or devices approved by the Food and Drug Administration, or generic equivalents approved as substitutable by the Food and Drug Administration, if such plan provides benefits for other outpatient prescription drugs or devices; or

"(2) exclude or restrict benefits for outpatient contraceptive services if such plan provides benefits for other outpatient services provided by a health care professional (referred to in this section as 'outpatient health care services').

"(b) PROHIBITIONS.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, may not—

"(1) deny to an individual eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan because of the individual's or enrollee's use or potential use of items or services that are covered in accordance with the requirements of this section;

"(2) provide monetary payments or rebates to a covered individual to encourage such individual to accept less than the minimum protections available under this section;

"(3) penalize or otherwise reduce or limit the reimbursement of a health care professional because such professional prescribed contraceptive drugs or devices, or provided contraceptive services, described in subsection (a), in accordance with this section; or

"(4) provide incentives (monetary or otherwise) to a health care professional to induce such professional to withhold from a covered individual contraceptive drugs or devices, or contraceptive services, described in subsection (a).

"(c) RULES OF CONSTRUCTION.—

"(1) IN GENERAL.—Nothing in this section shall be construed—

"(A) as preventing a group health plan and a health insurance issuer providing health insurance coverage in connection with a group health plan from imposing deductibles, coinsurance, or other cost-sharing or limitations in relation to—

"(i) benefits for contraceptive drugs under the plan, except that such a deductible, coinsurance, or other cost-sharing or limitation for any such drug may not be greater than such a deductible, coinsurance, or cost-sharing or limitation for any outpatient prescription drug otherwise covered under the plan;

"(ii) benefits for contraceptive devices under the plan, except that such a deductible, coinsurance, or other cost-sharing or limitation for any such device may not be greater than such a deductible, coinsurance, or cost-sharing or limitation for any outpatient prescription device otherwise covered under the plan; and

"(iii) benefits for outpatient contraceptive services under the plan, except that such a deductible, coinsurance, or other cost-sharing or limitation for any such service may not be greater than such a deductible, coinsurance, or cost-sharing or limitation for any outpatient health care service otherwise covered under the plan; and

"(B) as requiring a group health plan and a health insurance issuer providing health insurance coverage in connection with a group health plan to cover experimental or investigational contraceptive drugs or devices, or experimental or investigational contraceptive services, described in subsection (a), except to the extent that the plan or issuer provides coverage for other experimental or investigational outpatient prescription drugs or devices, or experimental or investigational outpatient health care services.

"(2) LIMITATIONS.—As used in paragraph (1), the term 'limitation' includes—

"(A) in the case of a contraceptive drug or device, restricting the type of health care professionals that may prescribe such drugs or devices, utilization review provisions, and limits on the volume of prescription drugs or devices that may be obtained on the basis of a single consultation with a professional; or

"(B) in the case of an outpatient contraceptive service, restricting the type of health care professionals that may provide such services, utilization review provisions, requirements relating to second opinions prior to the coverage of such services, and requirements relating to preauthorizations prior to the coverage of such services.

"(d) NOTICE UNDER GROUP HEALTH PLAN.—The imposition of the requirements of this section shall be treated as a material modification in the terms of the plan described in section 102(a)(1), for purposes of assuring notice of such requirements under the plan, except that the summary description required to be provided under the last sentence of section 104(b)(1) with respect to such modification shall be provided by not later than 60

days after the first day of the first plan year in which such requirements apply.

"(e) PREEMPTION.—Nothing in this section shall be construed to preempt any provision of State law to the extent that such State law establishes, implements, or continues in effect any standard or requirement that provides protections for enrollees that are greater than the protections provided under this section.

"(f) DEFINITION.—In this section, the term 'outpatient contraceptive services' means consultations, examinations, procedures, and medical services, provided on an outpatient basis and related to the use of contraceptive methods (including natural family planning) to prevent an unintended pregnancy."

(b) CLERICAL AMENDMENT.—The table of contents in section 1 of such Act, as amended by section 603 of the Newborns' and Mothers' Health Protection Act of 1996 and section 702 of the Mental Health Parity Act of 1996, is amended by inserting after the item relating to section 712 the following new item:

"Sec. 713. Standards relating to benefits for contraceptives."

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after January 1, 1998.

SEC. 113. AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT RELATING TO THE GROUP MARKET.

(a) IN GENERAL.—Subpart 2 of part A of title XXVII of the Public Health Service Act (as added by section 604(a) of the Newborns' and Mothers' Health Protection Act of 1996 and amended by section 703(a) of the Mental Health Parity Act of 1996) is further amended by adding at the end the following new section:

"SEC. 2706. STANDARDS RELATING TO BENEFITS FOR CONTRACEPTIVES.

"(a) REQUIREMENTS FOR COVERAGE.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, may not—

"(1) exclude or restrict benefits for prescription contraceptive drugs or devices approved by the Food and Drug Administration, or generic equivalents approved as substitutable by the Food and Drug Administration, if such plan provides benefits for other outpatient prescription drugs or devices; or

"(2) exclude or restrict benefits for outpatient contraceptive services if such plan provides benefits for other outpatient services provided by a health care professional (referred to in this section as 'outpatient health care services').

"(b) PROHIBITIONS.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, may not—

"(1) deny to an individual eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan because of the individual's or enrollee's use or potential use of items or services that are covered in accordance with the requirements of this section;

"(2) provide monetary payments or rebates to a covered individual to encourage such individual to accept less than the minimum protections available under this section;

"(3) penalize or otherwise reduce or limit the reimbursement of a health care professional because such professional prescribed contraceptive drugs or devices, or provided contraceptive services, described in subsection (a), in accordance with this section; or

"(4) provide incentives (monetary or otherwise) to a health care professional to induce such professional to withhold from a covered individual contraceptive drugs or devices, or

contraceptive services, described in subsection (a).

“(c) RULES OF CONSTRUCTION.—

“(1) IN GENERAL.—Nothing in this section shall be construed—

“(A) as preventing a group health plan and a health insurance issuer providing health insurance coverage in connection with a group health plan from imposing deductibles, coinsurance, or other cost-sharing or limitations in relation to—

“(i) benefits for contraceptive drugs under the plan, except that such a deductible, coinsurance, or other cost-sharing or limitation for any such drug may not be greater than such a deductible, coinsurance, or cost-sharing or limitation for any outpatient prescription drug otherwise covered under the plan;

“(ii) benefits for contraceptive devices under the plan, except that such a deductible, coinsurance, or other cost-sharing or limitation for any such device may not be greater than such a deductible, coinsurance, or cost-sharing or limitation for any outpatient prescription device otherwise covered under the plan; and

“(iii) benefits for outpatient contraceptive services under the plan, except that such a deductible, coinsurance, or other cost-sharing or limitation for any such service may not be greater than such a deductible, coinsurance, or cost-sharing or limitation for any outpatient health care service otherwise covered under the plan; and

“(B) as requiring a group health plan and a health insurance issuer providing health insurance coverage in connection with a group health plan to cover experimental or investigational contraceptive drugs or devices, or experimental or investigational contraceptive services, described in subsection (a), except to the extent that the plan or issuer provides coverage for other experimental or investigational outpatient prescription drugs or devices, or experimental or investigational outpatient health care services.

“(2) LIMITATIONS.—As used in paragraph (1), the term ‘limitation’ includes—

“(A) in the case of a contraceptive drug or device, restricting the type of health care professionals that may prescribe such drugs or devices, utilization review provisions, and limits on the volume of prescription drugs or devices that may be obtained on the basis of a single consultation with a professional; or

“(B) in the case of an outpatient contraceptive service, restricting the type of health care professionals that may provide such services, utilization review provisions, requirements relating to second opinions prior to the coverage of such services, and requirements relating to preauthorizations prior to the coverage of such services.

“(d) NOTICE.—A group health plan under this part shall comply with the notice requirement under section 713(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of this section as if such section applied to such plan.

“(e) PREEMPTION.—Nothing in this section shall be construed to preempt any provision of State law to the extent that such State law establishes, implements, or continues in effect any standard or requirement that provides protections for enrollees that are greater than the protections provided under this section.

“(f) DEFINITION.—In this section, the term ‘outpatient contraceptive services’ means consultations, examinations, procedures, and medical services, provided on an outpatient basis and related to the use of contraceptive methods (including natural family planning) to prevent an unintended pregnancy.”.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to group health plans for plan years beginning on or after January 1, 1998.

SEC. 114. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT RELATING TO THE INDIVIDUAL MARKET.

(a) IN GENERAL.—Subpart 3 of part B of title XXVII of the Public Health Service Act (as added by section 605(a) of the Newborn's and Mother's Health Protection Act of 1996) is amended by adding at the end the following new section:

“SEC. 2752. STANDARDS RELATING TO BENEFITS FOR CONTRACEPTIVES.

“The provisions of section 2706 shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.”.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 1998.

Subtitle C—Emergency Contraceptives

SEC. 121. EMERGENCY CONTRACEPTIVE EDUCATION.

(a) DEFINITION.—In this section:

(1) EMERGENCY CONTRACEPTIVE.—The term “emergency contraceptive” means a drug or device (as the terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that is designed—

(A) to be used after sexual relations; and

(B) to prevent pregnancy, by preventing ovulation, fertilization of an egg, or implantation of an egg in a uterus.

(2) HEALTH CARE PROVIDER.—The term “health care provider” means anyone licensed or certified under State law to provide health care services who is operating within the scope of such license.

(3) INSTITUTION OF HIGHER EDUCATION.—The term “institution of higher education” has the meaning given the term in section 1201(a) of the Higher Education Act of 1965 (20 U.S.C. 1141(a)).

(b) EMERGENCY CONTRACEPTIVE PUBLIC EDUCATION PROGRAM.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, shall develop and disseminate to the public information on emergency contraceptives.

(2) DEVELOPMENT AND DISSEMINATION.—The Secretary may develop and disseminate the information directly or through arrangements with nonprofit organizations, consumer groups, institutions of higher education, Federal, State, or local agencies, and clinics.

(3) INFORMATION.—The information shall include, at a minimum, information describing emergency contraceptives, and explaining the use, effects, efficacy, and availability of the contraceptives.

(c) EMERGENCY CONTRACEPTIVE INFORMATION PROGRAM FOR HEALTH CARE PROVIDERS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration, shall develop and disseminate to health care providers information on emergency contraceptives.

(2) INFORMATION.—The information shall include, at a minimum—

(A) information describing the use, effects, and efficacy and availability of the contraceptives;

(B) a recommendation from the Secretary regarding the use of the contraceptives in appropriate cases; and

(C) information explaining how to obtain copies of the information developed under subsection (b), for distribution to the patients of the providers.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section \$5,000,000 for the period consisting of fiscal years 1999 through 2001.

TITLE II—RESEARCH

SEC. 201. PREVENTIVE HEALTH MEASURES REGARDING BREAST AND CERVICAL CANCER AND CHLAMYDIA.

It is the sense of Congress that the programs of grants under section 318 and title XV of the Public Health Service Act (42 U.S.C. 247c and 300k et seq.) should receive a level of funding that is adequate for all States, or entities in all States, as appropriate, to receive grants under such section and title.

SEC. 202. PROGRAMS REGARDING CONTRACEPTION AND INFERTILITY.

(a) RESEARCH CENTERS.—It is the sense of Congress that the program assisting research centers under section 452A of the Public Health Service Act (42 U.S.C. 285g-5) should receive a level of funding that is adequate for a reasonable number of research centers to be operated under the program.

(b) LOAN REPAYMENT PROGRAM REGARDING CONDUCT OF RESEARCH.—It is the sense of Congress that the program of loan-repayment contracts under section 487B of the Public Health Service Act (42 U.S.C. 288-2) should receive a level of funding that is adequate for a reasonable number of individuals to conduct research under the program.

TITLE III—CHOICE PROTECTION

SEC. 301. FUNDING FOR ABORTION SERVICES.

It is the sense of Congress that Federal and State governments should provide funding for abortion services to women eligible for assistance through the medicaid program carried out under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), as such services are essential to the health and well-being of women.

SEC. 302. CLINIC VIOLENCE.

It is the sense of Congress that—

(1) Federal resources are necessary to ensure that women have safe access to reproductive health facilities and that health professionals can deliver services in a secure environment free from violence and threats of force; and

(2) it is necessary and appropriate to use Federal resources to combat the nationwide campaign of violence and harassment against reproductive health centers.

SEC. 303. APPROVAL OF RU-486.

The Secretary of Health and Human Services shall—

(1) ensure that a decision by the Food and Drug Administration to approve the drug called Mifepristone or RU-486 shall be made only on the basis provided in law; and

(2) assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of the drug or other antiprogestins.

SEC. 304. FREEDOM OF CHOICE.

(a) FINDINGS.—Congress finds the following:

(1) The 1973 Supreme Court decision in *Roe v. Wade*, 410 U.S. 113 (1973) established constitutionally based limits on the power of States to restrict the right of a woman to choose to terminate a pregnancy. Under the strict scrutiny standard enunciated in the *Roe v. Wade* decision, States were required to demonstrate that laws restricting the right of a woman to choose to terminate a pregnancy were the least restrictive means available to achieve a compelling State interest. Since 1989, the Supreme Court has no longer applied the strict scrutiny standard in reviewing challenges to the constitutionality of State laws restricting such rights.

(2) As a result of the recent modification by the Supreme Court of the strict scrutiny

standard enunciated in the *Roe v. Wade* decision, certain States have restricted the right of women to choose to terminate a pregnancy or to utilize some forms of contraception, and the restrictions operate cumulatively to—

(A)(i) increase the number of illegal or medically less safe abortions, often resulting in physical impairment, loss of reproductive capacity, or death to the women involved;

(ii) burden interstate and international commerce by forcing women to travel from States in which legal barriers render contraception or abortion unavailable or unsafe to other States or foreign nations;

(iii) interfere with freedom of travel between and among the various States;

(iv) burden the medical and economic resources of States that continue to provide women with access to safe and legal abortion; and

(v) interfere with the ability of medical professionals to provide health services;

(B) obstruct access to and use of contraceptive and other medical techniques that are part of interstate and international commerce;

(C) discriminate between women who are able to afford interstate and international travel and women who are not, a disproportionate number of whom belong to racial or ethnic minorities; and

(D) infringe on the ability of women to exercise full enjoyment of rights secured to the women by Federal and State law, both statutory and constitutional.

(3) Although Congress may not by legislation create constitutional rights, Congress may, where authorized by a constitutional provision enumerating the powers of Congress and not prohibited by a constitutional provision, enact legislation to create and secure statutory rights in areas of legitimate national concern.

(4) Congress has the affirmative power under section 8 of article I of the Constitution and under section 5 of the 14th amendment to the Constitution to enact legislation to prohibit State interference with interstate commerce, liberty, or equal protection of the laws.

(b) **PURPOSE.**—The purpose of this section is to establish, as a statutory matter, limitations on the power of a State to restrict the freedom of a woman to terminate a pregnancy in order to achieve the same limitations as were provided, as a constitutional matter, under the strict scrutiny standard of review enunciated in the *Roe v. Wade* decision and applied in subsequent cases from 1973 through 1988.

(c) **DEFINITION.**—As used in this section, the term "State" includes the District of Columbia, the Commonwealth of Puerto Rico, and each other territory or possession of the United States.

(d) **GENERAL AUTHORITY.**—A State—

(1) may not restrict the freedom of a woman to choose whether or not to terminate a pregnancy before fetal viability;

(2) may restrict the freedom of a woman to choose whether or not to terminate a pregnancy after fetal viability unless such a termination is necessary to preserve the life or health of the woman; and

(3) may impose requirements on the performance of abortion procedures if such requirements are medically necessary to protect the health of women undergoing such procedures.

(e) **RULES OF CONSTRUCTION.**—Nothing in this section shall be construed to—

(1) prevent a State from protecting unwilling individuals or private health care institutions from being required to participate in the performance of abortions to which the individuals or institutions are conscientiously opposed;

(2) prevent a State from declining to pay for the performance of abortions; or

(3) prevent a State from requiring a minor to involve a parent, guardian, or other responsible adult before terminating a pregnancy.

SEC. 305. FAIRNESS IN INSURANCE.

Notwithstanding any other provision of law, no Federal law shall be construed to prohibit a health plan from offering coverage for the full range of reproductive health care services, including abortion services.

SEC. 306. REPRODUCTIVE RIGHTS OF WOMEN IN THE MILITARY.

Section 1093 of title 10, United States Code, is amended—

(1) in subsection (a), by inserting before the period the following: "or in a case in which the pregnancy involved is the result of an act of rape or incest or the abortion involved is medically necessary or appropriate";

(2) by striking subsection (b) (as added by section 738 of the National Defense Authorization Act for Fiscal Year 1996 (Public Law 104-106; 110 Stat. 383)); and

(3) by adding at the end the following:

"(b) **ABORTIONS IN FACILITIES OVERSEAS.**—Subsection (a) does not limit the performing of an abortion in a facility of the uniformed services located outside the 48 contiguous States of the United States if—

"(1) the cost of performing the abortion is fully paid from a source or sources other than funds available to the Department of Defense;

"(2) abortions are not prohibited by the laws of the jurisdiction where the facility is located; and

"(3) the abortion would otherwise be permitted under the laws applicable to the provision of health care to members and former members of the uniformed services and their dependents in such facility."

By Mr. KENNEDY (for himself, Mr. DODD, and Mr. KERRY):

S. 1209. A bill improving teacher preparation and recruitment; to the Committee on Labor and Human Resources.

THE HIGHER EDUCATION ACT TITLE V REAUTHORIZATION ACT OF 1997

Mr. KENNEDY. Mr. President, I am honored to introduce President Clinton's proposal for the reauthorization of title V of the Higher Education Act. The goal of this important legislation is to improve the quality of teacher preparation programs and to bring more qualified teachers into America's classrooms, particularly in the areas of highest need.

Investing in teachers is an investment in the Nation's children and its future. The Nation is clearly committed to the highest quality training for our doctors, engineers, and attorneys, both in their initial training and in subsequent professional development opportunities. President Clinton is right to ask us to make that same commitment to the training of teachers who are charged with educating the Nation's most precious resource—our children. Not since the Teacher Corps initiatives of the 1970's has the Federal Government given such high priority to teaching and teachers. Through inaction, the Nation has tacitly condoned low standards in too many schools, particularly in urban and rural areas. Through inaction, we have left

too many of these schools understaffed and unsupported. We must recognize the urgency of this situation and act now.

In other initiatives, we are already asking teachers to ensure that children meet high standards, but we are not asking whether teachers are ready to meet this challenge. Because of the shortage of teachers, many educators are forced to teach subjects outside their certification area. This shortage is especially serious in communities with high concentrations of students from low-income families. Annually, more than 50,000 underprepared teachers enter the classroom. One in four new teachers do not fully meet State certification requirements, and 12 percent of new hires have had not teacher training at all. Students in inner-city schools have only a 50-percent chance of being taught by a qualified science or math teacher. In Massachusetts, 30 percent of teachers in high-poverty schools do not even have a minor degree in their field.

This gap is unacceptable. Teachers must have a strong knowledge base in their subject area, so that they can motivate young learners and teach strong basic skills. Teachers must be comfortable with topics, so that they encourage extended thinking and questioning on issues. Teachers must also have opportunities to improve their own skills, learn how to integrate technology, and employ strategies that encourage all students to achieve.

Clearly, we must invest in better teacher preparation, do all we can to ensure that all of our schools are fully staffed with qualified teachers. We must attract the best and the brightest new teachers to adequately prepare students to compete in the global marketplace. During the next decade, because of rising student enrollment and massive teacher retirement, the Nation will need over 2 million new teachers. But teacher preparation programs are currently producing between 100,000 and 150,000 new teachers a year, leaving the system with an annual deficit of at least 50,000 teachers, particularly in underserved, high-poverty schools.

The Federal Government, through the Eisenhower Professional Development Program, already invests in upgrading the skills of current teachers, but the investment is far from sufficient. In addition, we must invest in the front end of teacher training, to ensure that the Nation's children are taught by highly qualified, well informed teachers. The President's proposal will help improve teacher preparation and bring well-qualified teachers into more classrooms.

The legislation addresses these issues by encouraging strong partnerships among institutions of higher education with exemplary teacher preparation programs, other institutions that want to improve their programs, and the school districts that they serve. The program would be authorized at \$67

million for fiscal year 1999. A Lighthouse Partnership Program will identify lead institutions from the variety of successful teacher preparation programs that now exist. These programs provide aspiring teachers with the newest information about the best classroom practices, and give them the concrete clinical experiences they need to develop the skills to help students achieve high standards.

State and local education agencies, community colleges, and other professional groups will participate as partner institutions. The lead institutions will demonstrate their strength in cutting-edge, clinically based teacher preparation and course content. They must also demonstrate that they are committed to strong ongoing cooperation with school districts that serve needy families in rural and urban America.

A second major part of the President's proposal focuses on recruiting the best and the brightest teachers to serve in needy school districts. It supports partnerships between teacher preparation institutions and local education agencies that provide scholarships and other assistance to students who complete teacher preparation programs and agree to teach in targeted underserved areas for at least 3 years.

President Clinton's proposal is far-reaching, and it discusses broad bipartisan support. The United States is in urgent need of creating and maintaining a stronger supply of world-class teachers. These wise investments will provide high-quality opportunities today to the teachers who will be teaching the Nation's children tomorrow. I look forward to working with my colleagues on both sides of the aisle to enact this major teacher recruitment and training proposal.

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. 1209

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

TITLE V—EDUCATOR RECRUITMENT, PREPARATION, AND INDUCTION

Sec. 501. Findings.

Sec. 502. Purpose.

Sec. 503. Authorization of appropriations.

PART A—LIGHTHOUSE PARTNERSHIPS

Sec. 511. Definitions.

Sec. 512. Grants to Lighthouse Partnerships.

Sec. 513. Preapplications and applications.

Sec. 514. Uses of funds.

Sec. 515. Selection of applications.

Sec. 516. Evaluation.

Sec. 517. National activities.

PART B—RECRUITING NEW TEACHERS FOR UNDERSERVED AREAS

Sec. 521. Program authorized.

Sec. 522. Definitions.

Sec. 523. Grant conditions.

Sec. 524. Grant applications.

Sec. 525. Uses of funds.

Sec. 526. Selection of applicants.

Sec. 527. Duration and amount of assistance; relation to other assistance.

Sec. 528. Scholarship conditions.

Sec. 529. Service requirements.

Sec. 530. Evaluation.

Sec. 531. National activities.

“TITLE V—EDUCATOR RECRUITMENT, PREPARATION, AND INDUCTION

“FINDINGS

“SEC. 501. The Congress finds as follows:

“(1) What teachers know and can do has a critical impact on student achievement, yet too often prospective teachers are not receiving the initial preparation they need in order to teach children from diverse backgrounds to challenging standards.

“(2) A number of elementary and secondary schools throughout the United States are implementing educational reform strategies that are research-based, have records of demonstrated effectiveness in enabling students to achieve to high State or local standards, are replicable in diverse and challenging circumstances, and are supported by networks of researchers and experienced practitioners. Yet preparation to implement these strategies is not generally a central component of initial teacher preparation.

“(3) Institutions of higher education that provide teachers for urban and rural schools that enroll concentrations of children from low-income families often have the greatest need to restructure their teacher preparation programs because the teachers they graduate will face the greatest classroom challenges.

“(4) Improvement of teacher preparation in mathematics and reading represents a particular challenge for American education. For example, most future elementary and middle-school mathematics teachers take no more than one or two college-level mathematics courses, and these courses are not designed for prospective teachers and do not cover the mathematics content that elementary and middle-school teachers should teach to enable students to meet challenging mathematics standards. In reading, most teacher preparation programs have not incorporated the large body of research on effective reading instruction.

“(5) If current trends continue, American schools will need to hire more than two million teachers in the next decade to educate an increasing number of students and to replace current teachers who will retire or leave the profession. High-poverty urban and rural schools will experience the most severe teacher shortages. Of the more than two million teachers needed, approximately 15 percent, or 345,000, will be needed in central cities, in schools with large concentrations of low-income students. An additional 207,000 teachers will be needed in isolated, and often poor, rural areas. Recent trends in the number of people preparing to enter teaching indicate that the normal operation of the labor market, by itself, will not produce the number of qualified teachers schools will need.

“(6) Schools are already having trouble recruiting qualified teachers. Nearly three-quarters of physical science students and one-third of English students in high-poverty schools take classes with teachers who lack even a college minor in their field. The National Commission on Teaching and America's Future found that 50,000 uncertified individuals annually enter teaching because schools, frequently those in urban and rural areas with large concentrations of children from low-income families, cannot find all the certified teachers they need.

“(7) Teaching excellence and diversity are inextricably connected. By bringing distinctive life experiences and perspectives into the classroom, enriching the instructional curriculum and the school climate, and

strengthening connections to parents and communities, teachers from diverse racial and ethnic groups, and those with disabilities, enhance the quality of American education. Yet today, while one-third of American students are members of minority groups, members of racial and ethnic minority groups make up only 13 percent of the teaching force and nearly half the school districts in the Nation have no minority teachers. In addition, few individuals with disabilities are teaching in American classrooms.

“(8) The Federal Government, by itself, cannot ensure needed improvements in teacher preparation or solve the problem of teacher shortages. However, the Government can make limited, targeted investments that—

“(A) encourage more institutions of higher education that operate teacher preparation programs, working in partnership with local educational agencies and States, to adopt the practices and strategies of the best programs;

“(B) encourage a more diverse mix of Americans to enter teaching and complete high-quality preparation programs; and

“(C) encourage more Americans to serve as teachers in underserved communities.

“PURPOSE

“SEC. 502. The purpose of this title is to help meet the national need to recruit, prepare, and retain a high-quality and diverse supply of elementary and secondary education teachers, and to help meet the needs of schools in urban and rural areas with concentrations of children from low-income families, by—

“(1) authorizing support for partnerships among institutions of higher education that operate exemplary teacher preparation programs, other institutions of higher education seeking to improve their programs, public elementary and secondary schools, and States, in order to improve the quality of the initial preparation of teachers for high-poverty communities;

“(2) authorizing support for partnerships to increase the number and diversity of students who enter teacher education programs and complete high-quality preparation programs, and to increase the quality of teaching in underserved urban and rural communities; and

“(3) encouraging, through such partnerships, the creation of a more diverse teaching force, through the recruitment and preparation of minority individuals, including language minority individuals, and individuals with disabilities, to enter teaching.

“AUTHORIZATION OF APPROPRIATIONS

“SEC. 503. (a) AUTHORIZATION FOR PARTS A AND B.—There are authorized to be appropriated—

“(1) \$30,000,000 for fiscal year 1999 and such sums as may be necessary for each of the four succeeding fiscal years to carry out the program of Lighthouse Partnerships under part A; and

“(2) \$37,000,000 for fiscal year 1999 and such sums as may be necessary for each of the four succeeding fiscal years to carry out the program of Recruiting New Teachers for Underserved Areas under part B.

“(b) TRANSITION.—Notwithstanding any other provision of law, the Secretary may use funds appropriated under subsection (a) to make continuation awards for projects that were funded under subpart 2 of part E of title V of this Act, as in effect prior to enactment of [inset name of reauthorization Act].

“PART A—LIGHTHOUSE PARTNERSHIPS

“DEFINITIONS

“SEC. 511. As used in this part, the following terms have the following meanings:

“(1)(A) The term ‘lead institution’ means an institution of higher education that—

“(i) operates an exemplary teacher preparation program of significant size in one or more areas of teacher preparation, which may include the preparation of principals and other educational administrators;

“(ii) desires to assist other institutions of higher education in improving their programs and to serve as a national model for effective teacher preparation; and

“(iii) places a significant percentage of its teacher preparation graduates in teaching positions in urban and rural communities with concentrations of children from low-income families.

“(B) A lead institution may participate in a consortium with one or more two-year colleges with which it has articulation agreements relating to teacher preparation.

“(2) The term ‘lighthouse partnership’ means a partnership of a lead institution, partner institutions, and State and local educational agencies, that is dedicated to improving the quality of teacher preparation programs. Within each partnership, the lead institution shall act as the fiscal agent for the grant.

“(3) The term ‘local educational agency’ has the meaning given that term in section 14101(18) of the Elementary and Secondary Education Act of 1965.

“(4) The term ‘partner institution’ means an institution of higher education that—

“(A) prepares teachers for their initial entry into the teaching profession;

“(B) desires to improve its program with assistance from a lead institution; and

“(C) prepares teachers for teaching positions in urban and rural communities with concentrations of children from low-income families.

“(5) The term ‘teacher preparation program’ means a program operated by an institution of higher education that prepares students to obtain initial teacher licensure and to teach in elementary and second schools. Such a program may also prepare students to become preschool teachers if the institution serves a State or school districts in which preschool education is provided as free, public education.

“GRANTS TO LIGHTHOUSE PARTNERSHIPS

“SEC. 512. (a) GRANTS AUTHORIZED.—(1) From funds appropriated under section 503(a)(1) for this part for each fiscal year, the Secretary shall make competitive grants to lighthouse partnerships.

“(2) Each grant under paragraph (1) shall be for a period not to exceed five years.

“(3) The Secretary shall—

“(A) make continuation awards, for the second and succeeding years, only after determining that the partnership is making satisfactory progress in carrying out the grant; and

“(B) conduct an intensive review of the partnership’s progress, with the assistance of outside experts, before making the continuation award for the fourth year of the grant.

“(b) LIMITATION.—No partnership may receive more than two grants under this part.

“PREAPPLICATIONS AND APPLICATIONS

“SEC. 513. (a) PREAPPLICATIONS.—Each lead institution that wishes to participate in a lighthouse partnership that will apply for a grant under this part shall submit a preapplication to the Secretary at such time, in such manner, and containing such information as the Secretary may require, except that the lead institution need not identify the other members of the partnership until it submits an application under subsection (b). The Secretary shall use a peer review process to review these preapplications.

“(b) APPLICATIONS REQUIRED.—Any lighthouse partnership desiring to receive a grant under this part shall submit an application to the Secretary at such time, in such form,

and containing such information as the Secretary may require.

“(c) CONTENTS.—Each application shall include—

“(1) a description of the teacher preparation program operated by the lead institution, including information on the curriculum, the faculty, and the number and characteristics of students served;

“(2) evidence of the quality of the institution’s teacher preparation program, covering—

“(A) the extent to which the institution provides a coherent program that—

“(i) reflects the best of what is known, from research and practice;

“(ii) prepares teachers to implement research-based instructional programs of demonstrated effectiveness and to teach their students, particularly those in high-poverty schools, to high State and local content standards; and

“(iii) reflects high standards for teaching, such as the standards of the National Board for Professional Teaching Standards, and for teacher education;

“(B) the commitment of the institution to its program of teacher preparation;

“(C) the connections between the institution’s teacher preparation program and its departments or schools of arts and sciences, to ensure the integration of pedagogy and content in teacher preparation;

“(D) the extent to which the institution operates a clinically based teacher preparation program, particularly in high-poverty schools, through which prospective teachers participate in intensive, structured clinical experiences, with extensive faculty involvement, throughout their preservice education, and the extent to which those experiences are integrated into the curriculum;

“(E) the extent to which the institution’s program offers continuous assistance to its graduates during their initial years in the classroom;

“(F) the extent to which the institution’s program meets the needs of, and has strong connections with, elementary and secondary education (particularly with urban and rural schools and school systems that serve concentrations of students from low-income families and with the education reforms under way in the institution’s State), which may include the involvement of elementary and secondary educators in the continuing development, improvement, and implementation of the teacher preparation program;

“(G) the success of the institution in preparing teachers to teach individuals from diverse populations effectively;

“(H) the extent to which the institution is preparing teachers to use technology to teach children to high standards;

“(I) the record of the institution’s teacher preparation program in attracting and graduating a diverse student body (including the recruitment and enrollment of individuals with disabilities);

“(J) the procedures the institution uses to measure the quality of its teacher preparation program (including the extent to which graduates improve their subject matter knowledge and teaching ability as a result of their participation in the program) and to improve its program, using information generated through those procedures;

“(K) the success of the program in graduating students who are fully qualified to teach to high standards in the State or region served by the institution;

“(L) the quality of the program’s graduates, as documented through such evidence as the graduates’ record of obtaining (and retaining) teaching positions and the opinions of school district officials, in the State or region, of the quality of those graduates;

“(M) if applicable, the quality of the institution’s program for the preparation of

school principals and other school administrators, and of the success of that program; and

“(N) involvement and leadership of the institution in national, regional, and State efforts to improve teacher education and licensure;

“(3) evidence of the extent to which—

“(A) graduates have taken teaching positions in urban and rural schools in communities with concentrations of students from low-income families; and

“(B) the institution recruits and serves students (such as education paraprofessionals) from those communities;

“(4) evidence of the experience of the lead institution in creating or participating in networks with other institutions to improve the quality of teacher preparation programs;

“(5) a description of how the partnership will operate a program under this part, including—

“(A) a description of the governance structure that the partnership will establish (through a written partnership agreement) for the grant, which shall include the active involvement of high-level administrators of the lead institution and representatives of—

“(i) both the teacher preparation program and the school or department of arts and sciences in the lead institution;

“(ii) the partner institutions involved with the grant;

“(iii) local educational agencies (including teachers and other school-level officials) served by the lead institution and one or more of the partner institutions; and

“(iv) State officials with authority over teacher licensure and teacher preparation in the States in which the lead institution and one or more of the partner institutions are located;

“(B) a description of how the partnership will fully engage local educational agencies in the activities carried out under the grant, including how the partnership will use grant funds to address the teacher training needs of the local educational agencies that are members of the partnership, consistent with section 514;

“(C) a description of how the activities undertaken with the grant will support, and be integrated with, the educational reforms under way in the States of the lead and the partner institutions, including a description of plans for coordinating activities carried out under the grant with activities carried out under other Federal or State professional development programs or activities designed to improve pre-service and in-service teacher training; and

“(D) a description of—

“(i) the measurable goals the partnership expects to achieve through the grant, including—

“(I) goals for improvements in the teacher preparation programs of the partner institutions;

“(II) goals for improvements in the quality, and increases in the number, of the graduates of teacher preparation programs operated by members of the partnership who take teaching positions in high-poverty schools of the local educational agencies in the partnership;

“(III) goals for meeting the teacher preparation needs of the local educational agencies in the partnership, in order to improve student achievement; and

“(IV) such other goals, consistent with the purposes of this part, as the partnership may select;

“(ii) how the partnership will achieve the goal of increased diversity among its teacher preparation graduates; and

“(iii) how the partnership will determine whether it is meeting the goals described in clauses (i) and (ii); and

“(6) a description of the partnership’s plan for institutionalizing the activities it is carrying out under this part, so that those activities will continue once Federal funding ceases.

“USES OF FUNDS

“SEC. 514. (a) REQUIRED ACTIVITIES.—In order to increase the quality and number of teachers it is preparing for positions in urban and rural areas with concentrations of low-income families, and to increase the diversity of elementary and secondary teachers, each partnership selected to receive a grant under this part shall use the grant funds for each of the following purposes:

“(1) Further development, refinement, assessment of, and dissemination of information on, the teacher preparation programs operated by the lead institution, including activities that document, for other institutions nationally and for policymakers, effective practices in teacher preparation and that produce curricular and other materials for use by other institutions preparing teachers.

“(2) Technical assistance by the lead institution to the partner institutions in improving the partner institutions’ teacher preparation programs (and, if applicable, their principal and other administrator preparation programs), based on the experience of the lead institution and the particular needs of the partners.

“(3) Making subgrants to the partner institutions for implementation of program improvements at those institutions, through adoption or adaptation of the teacher preparation practices of the lead institution, to meet the needs of the high-poverty schools in the urban and rural communities they serve. Each partnership shall use at least 40 percent of its grant for this purpose.

“(4) Joint activities with the local educational agencies in the partnership, and with other local educational agencies, that increase the involvement of classroom teachers and school administrators in the design and implementation of teacher preparation programs operated by the lead and partner institutions (and thereby make those programs more responsive to the needs of teachers and administrators), and other activities to improve teaching and administration, and to support new teachers, in the high-poverty schools of those local educational agencies.

“(5) Cooperation and interaction with other lighthouse partnerships and with other institutions, organizations, and public agencies, on activities aimed at the improvement of teacher preparation nationally, including improvement of teacher licensure and relicensure requirements.

“(6) Assessment of the effectiveness of the activities carried out under the grant, including the extent to which the partnership is achieving its goals under section 513(c)(5)(D).

“(b) OPTIONAL ACTIVITIES.—Each partnership selected to receive a grant under this part may also use the grant funds for joint activities with States that promote the development and implementation of State policies to facilitate the improvement of teacher preparation programs (and, if applicable, principal and other administrator preparation programs) within the States, as a component of comprehensive education reforms.

“SELECTION OF APPLICATIONS

“SEC. 515. (a) PEER REVIEW.—The Secretary shall, using a peer review process, select applicants to receive grants under this part on the basis of—

“(1) the quality of the teacher preparation program operated by the lead institution in a proposed partnership;

“(2) the quality of the partnership’s plan for carrying out activities under the grant; and

“(3) the capacity of the lead institution and its partners to carry out the proposed activities successfully.

“(b) CRITERIA.—(1) In selecting grantees under this part, the Secretary shall seek to ensure that—

“(A) lighthouse partnerships represent a variety of approaches to teacher preparation;

“(B) lead institutions represent a variety of institutions of higher education; and

“(C) there is an equitable geographic distribution of awards.

“(2) In addition to complying with paragraph (1), the Secretary shall give special consideration to applications for—

“(A) projects that are likely to have the most significant impact on the quality of teaching in high-poverty urban and rural schools;

“(B) projects that are likely to result in improvement of teacher preparation in the areas of mathematics and reading; and

“(C) projects that are likely to prepare a significant number of minority individuals, including language minority individuals, and individuals with disabilities to be effective teachers.

“(c) SECOND FIVE-YEAR GRANTS.—In selecting grantees to receive second grants under this part, the Secretary shall give a preference to applicants whose projects have resulted in—

“(1) the placement and retention of a substantial number of high-quality graduates in teaching positions in underserved, high-poverty schools;

“(2) the adoption of effective teacher preparation programs, particularly those meeting the needs of high-poverty urban and rural areas, by the partner institutions; and

“(3) effective partnerships with elementary and secondary schools that are supporting improvements in student achievement.

“EVALUATION

“SEC. 516. The Secretary shall provide for an evaluation of the program carried out under this part, including an assessment of such issues as—

“(1) the extent to which the activities carried out through Lighthouse Partnership grants result in significant and positive changes in the teacher preparation programs operated by partner institutions, as well as improvements in the programs operated by lead institutions, that are likely to lead to improvements in teaching and learning;

“(2) the extent to which lighthouse Partnership grants enhance the effectiveness, including the technological proficiency, and the diversity, of students completing teacher preparation programs in the institutions of higher education participating in the grants; and

“(3) the involvement of elementary and secondary schools and school districts serving concentrations of children from low-income families in the activities carried out under this part, and the extent to which those activities result in benefits to those schools and districts, including information on the extent to which involvement in the grants improves the instructional programs and the educational outcomes for students in those schools and districts.

“NATIONAL ACTIVITIES

“SEC. 517. The Secretary may reserve up to 5 percent of the funds appropriated to carry out this part for any fiscal year for—

“(1) peer review of applications;

“(2) evaluation of the program under section 516, and measurement of its effectiveness in accordance with the Government Performance and Results Act of 1993;

“(3) conferences and networks of lighthouse partnerships, and other entities, in order to facilitate the exchange of information and ideas among the participating part-

nerships and other institutions, agencies, and individuals, including recipients of funds under part B of this title, who are interested in the improvement of teacher preparation and parallel improvements in principal and administrator preparation; and

“(4) technical assistance and other activities to enhance the success of the program carried out under this part or of teacher education more generally.

“PART B—RECRUITING NEW TEACHERS FOR UNDERSERVED AREAS

“PROGRAM AUTHORIZED

“SEC. 521. From funds appropriated to carry out this part under section 503(a)(2) for each fiscal year, the Secretary shall make competitive grants to eligible applicants for programs that—

“(1) provide scholarships and, as necessary, support services for students with high potential to become effective teachers, particularly minority students, including language minority students, and students with disabilities, seeking to complete teacher preparation programs;

“(2) increase the quality and number of new teachers nationally; and

“(3) increase the ability of schools in underserved areas to recruit a qualified teaching staff.

“DEFINITIONS

“SEC. 522. As used in this part, the following terms have the following meanings:

“(1)(A) The term ‘eligible applicant’ means a partnership of—

“(i) an institution of higher education that grants baccalaureate degrees and prepares teachers for their initial entry into the teaching profession; and

“(ii) one or more local educational agencies that are in underserved areas.

“(B) Such a partnership may also include—

“(i) two-year colleges that operate teacher preparation programs and maintain articulation agreements, with the baccalaureate-granting institution, for the transfer of credits in teacher preparation;

“(ii) State agencies that have responsibility for policies related to teacher preparation and licensure; and

“(iii) other public and private, nonprofit agencies and organizations that serve, or are located in, communities served by the local educational agencies in the partnership, and that have an interest in teacher recruitment, preparation, and induction.

“(2) The term ‘local educational agency’ has the meaning given that term in section 14101(18) of the Elementary and Secondary Education Act of 1965.

“(3) The term ‘support service’ includes—

“(A) academic advice and counseling;

“(B) tutorial services;

“(C) mentoring; and

“(D) child care and transportation, if funding for those services cannot be arranged from other sources; and

“(4) The term ‘underserved area’ means—

“(A) the three local educational agencies in the State that have the highest numbers of children, ages 5 through 17, from families below the poverty level (based on data satisfactory to the Secretary); and

“(B) any other local educational agency in which the percentage of such children is at least 20 percent, or the number of such children is at least 10,000.

“GRANT CONDITIONS

“SEC. 523. (a) GRANTS AUTHORIZED.—(1)(A) The Secretary shall carry out this part by making competitive grants to eligible applicants.

“(B) Each grant under subparagraph (A) shall be for a period not to exceed five years.

“(2) The Secretary shall—

“(A) make continuation awards, for the second and succeeding years, only after determining that the grantee is making satisfactory progress in carrying out the grant; and

“(B) conduct an intensive review of the grantee’s progress, with the assistance of outside experts, before making the award for the fourth year of the grant.

“(3) No partnership may receive more than two grants under this subsection.

“(b) MATCHING REQUIREMENT.—(1) The Federal share of the cost of activities carried out under a grant made under subsection (a) shall not exceed—

“(A) 90 percent of the cost in the first year of the grant;

“(B) 80 percent in the second year;

“(C) 70 percent in the third year;

“(D) 60 percent in the fourth year; and

“(E) 50 percent in the fifth year and any succeeding year (including each year of the second grant, if any).

“(2) The non-Federal share of activities carried out with a grant under subsection (a) may be provided in cash or in kind, fairly evaluated, and may be obtained from any non-Federal public or private source.

“(c) PLANNING GRANTS.—(1) The Secretary may make planning grants to eligible applicants that are not yet ready to implement programs under subsection (a).

“(2) Each planning grant shall be for a period of not more than one year, which shall be in addition to the period of any grant under subsection (a).

“(3) Any recipient of a planning grant under this subsection that wishes to receive a grant under subsection (a)(1) shall separately apply for a competitive grant under that subsection.

“GRANT APPLICATIONS

“SEC. 524. (a) APPLICATIONS REQUIRED.—Any eligible applicant desiring to receive a grant under this part shall submit an application at such time, in such form, and containing such information as the Secretary may require.

“(b) APPLICATION CONTENTS.—Each application for a grant under section 523(a) shall include—

“(1) a designation of the institution or agency, within the partnership, that will serve as the fiscal agent for the grant;

“(2) information on the quality of the institution’s teacher preparation program, which may include the types of information described in section 513(c)(2), and how the applicant will ensure, through improvements in its teacher preparation practices or other appropriate strategies, that scholarship recipients will receive high-quality preparation;

“(3) a description of the assessment the institution, the local educational agency partners, and other partners have undertaken—

“(A) to determine—

“(i) the most critical needs of the local educational agencies, particularly the needs of schools in high-poverty areas, for new teachers (which may include teachers in particular subject areas or at certain grade levels, including the prekindergarten level, minority teachers, and teachers who are disabled who will contribute to the diversity of the local educational agency’s teachers, or teachers who are fluent in languages spoken by students in the local educational agency); and

“(ii) how the project carried out under the grant will address those needs; and

“(B) that reflects the input of all significant entities in the community (including organizations representing teachers and parents) that have an interest in teacher recruitment, preparation, and induction;

“(4) a description of the project the applicant will carry out with the grant, including information on—

“(A) the recruitment and outreach efforts the applicant will undertake to publicize the availability of scholarships and other assistance under the program;

“(B)(i) the number and types of students that the applicant will serve under the program, which may include education paraprofessionals seeking to achieve full teacher certification; teachers whom the partner local educational agencies have hired under ‘emergency certification’ procedures; or former military personnel, mid-career professionals, or AmeriCorps or Peace Corps volunteers, who desire to enter teaching; and

“(ii) the criteria that the applicant will use in selecting those students, including criteria to determine whether individuals have the capacity to benefit from the program, complete teacher certification requirements, and become effective teachers;

“(C) the activities the applicant will carry out under the grant, including a description of, and justification for, any support services the institution will offer to participating students;

“(D) the number and funding range of the scholarships the institution will provide to students; and

“(E) the procedures the institution will establish for entering into, and enforcing, agreements with scholarship recipients regarding their fulfillment of the service commitment described in section 529;

“(5) a description of how the institution will use funds provided under the grant only to increase the number of students with high potential to be effective teachers, participating in its teacher preparation programs, or in the particular type or types of preparation programs that the grant would support, or to increase the number of their graduates with high potential to be effective teachers who are minority individuals, including language minority individuals, or individuals with disabilities;

“(7) a description of commitments, by the partner local educational agencies, to hire qualified scholarship recipients in their schools and in the subject areas or grade levels for which the recipients will be trained, and description of the actions the grantee institution, the local educational agencies, and the other partners will take to facilitate the successful transition of those recipients into teaching; and

“(8) a description of the applicant’s plan for institutionalizing the activities it is carrying out under this part, so that those activities will continue once Federal funding ceases.

“USES OF FUNDS

“SEC. 525. IN GENERAL.—Each grantee under section 523 (a) shall use the grant funds for the following:

“(1) Scholarships to help students pay the costs of tuition, room, board, and other expenses of completing a teacher preparation program.

“(2) Support services, if needed to enable scholarship recipients to complete postsecondary education programs.

“(3) Follow-up services provided to former scholarship recipients during their first three years of teaching.

“(4) Payments to partner local educational agencies, if needed to enable them to permit paraprofessional staff to participate in teacher preparation programs (such as the cost of ‘release time’ for those staff).

“(5) If appropriate, and if no other funds are available, paying the costs of additional courses taken by former scholarship recipients during their initial three years of teaching.

“(b) PLANNING GRANTS.—A recipient of a planning grant under section 523(c) shall use the grant funds for the costs of planning for

the implementation of a grant under section 523(a).

“SELECTION OF APPLICANTS

“SEC. 526. (a) PEER REVIEW.—The Secretary, using a peer review process, shall select applicants to receive funding under this part on the basis of—

“(1) the quality of the teacher preparation program offered by the institution;

“(2) the quality of the program that would be carried out under the application; and

“(3) the capacity of the partnership to carry out the grant successfully.

“(b) CRITERIA.—(1) making selections, the Secretary shall seek to ensure that—

“(A) in the aggregate, grantees carry out a variety of approaches to preparing new teachers; and

“(B) there is an equitable geographic distribution of awards.

“(2) In addition to complying with paragraph (1), the Secretary shall give special consideration to—

“(A) applications most likely to result in the preparation of increased numbers of individuals with high potential for effective teaching who are minority individuals, including language minority individuals, and individuals with disabilities; and

“(B) applications from historically black colleges and universities, Hispanic-serving institutions, and Tribal Colleges and Universities, as defined in title III of this Act.

“(c) SECOND FIVE-YEAR GRANTS.—In selecting grantees to receive second grants under this part, the Secretary shall give a preference to applicants whose projects have resulted in—

“(1) the placement and retention of a substantial number of high-quality graduates in teaching positions in undeserved, high-poverty schools;

“(2) the adoption of effective programs that meet the teacher preparation needs of high-poverty urban and rural areas; and

“(3) effective partnerships with elementary and secondary schools that are supporting improvements in student achievement.

“DURATION AND AMOUNT OF ASSISTANCE; RELATION TO OTHER ASSISTANCE

“SEC. 527. (a) DURATION OF ASSISTANCE.—No individual may receive scholarship assistance under this part—

“(1) for more than five years of postsecondary education; and

“(2) unless that individual satisfies the requirements of section 484(a)(5) of this Act.

“(b) AMOUNT OF ASSISTANCE.—No individual may receive an award under this program that exceeds the cost of attendance, as defined in section 472 of this Act, at the institution the individual is attending.

“(c) RELATION TO OTHER ASSISTANCE.—A scholarship awarded under this part—

“(1) shall not be reduced on the basis of the individual’s receipt of other forms of Federal student financial assistance; and

“(2) shall be regarded as other financial assistance available to the student, within the meaning of sections 471(3) and 480(j)(1) of this Act, in determining the student’s eligibility for grant, loan, or work assistance under title IV of this Act.

“SCHOLARSHIP CONDITIONS

“SEC. 528. (a) IN GENERAL.—A recipient of a scholarship under this part shall continue to receive the assistance only as long as he or she is—

“(1) enrolled as a full-time student and pursuing a course of study leading to teacher certification, unless he or she is working in a public school (as a paraprofessional, or as a teacher under emergency credentials) while participating in the program; and

“(2) maintaining satisfactory progress as determined by the institution.

"(b) SPECIAL RULE.—Each grantee shall modify the application of section 527(a)(1) and of subsection (a)(1) of this section to the extent necessary to accommodate the rights of students with disabilities under section 504 of the Rehabilitation Act of 1973.

"SERVICE REQUIREMENTS

"SEC. 529. (a) REQUIREMENT.—Each partnership receiving a grant under this part shall enter into an agreement, with each student to whom it awards a scholarship under this part, providing that a scholarship recipient who completes a teacher preparation program under this part shall, within five years of completing that program, teach full-time for at least three years in a high-poverty school in an underserved geographic area or repay the amount of the scholarship, under the terms and conditions established by the Secretary.

"(b) REGULATIONS.—The Secretary shall prescribe regulations relating to the requirements of subsection (a), including any provisions for waiver of those requirements.

"EVALUATION

"SEC. 530. The Secretary shall provide for an evaluation of the program carried out under this part, which shall assess such issues as—

"(1) whether institutions taking part in the partnerships are successful in preparing scholarship recipients to teach to high State and local standards;

"(2) whether scholarship recipients are successful in completing teacher preparation programs, becoming fully certified teachers, and obtaining teaching positions in underserved areas, and whether they continue teaching in those areas over a period of years;

"(3) the national impact of the program in assisting local educational agencies in underserved areas to recruit, prepare, and retain diverse, high-quality teachers in the areas in which they have the greatest needs;

"(4) the long-term impact of the grants on teacher preparation programs conducted by grantees and on grantees' relationships with their partner local educational agencies and other partners; and

"(5) the relative effectiveness of different approaches for preparing new teachers to teach in underserved areas, including their effectiveness in preparing new teachers to teach to high content and performance standards.

"NATIONAL ACTIVITIES

"SEC. 531. The Secretary may retain up to five percent of the funds appropriated for this part for any fiscal year for—

"(1) peer review of applications;

"(2) conducting the evaluation required under section 530; and

"(3) technical assistance and other activities to facilitate the exchange of information and ideas among participating partnerships, and other activities to enhance the success of the program carried out under this part."

ADDITIONAL COSPONSORS

S. 61

At the request of Mr. LOTT, the names of the Senator from Kansas [Mr. BROWNBACK] and the Senator from Iowa [Mr. GRASSLEY] were added as cosponsors of S. 61, a bill to amend title 46, United States Code, to extend eligibility for veterans' burial benefits, funeral benefits, and related benefits for veterans of certain service in the United States merchant marine during World War II.

S. 219

At the request of Mr. DASCHLE, the names of the Senator from Montana

[Mr. BAUCUS], the Senator from Illinois [Mr. DURBIN], and the Senator from Montana [Mr. BURNS] were added as cosponsors of S. 219, a bill to amend the Trade Act of 1974 to establish procedures for identifying countries that deny market access for value-added agricultural products of the United States.

S. 449

At the request of Mr. KYL, the name of the Senator from South Dakota [Mr. JOHNSON] was added as a cosponsor of S. 449, a bill to prohibit the restriction of certain types of medical communications between a health care provider and a patient.

S. 512

At the request of Mr. FAIRCLOTH, his name was added as a cosponsor of S. 512, a bill to amend chapter 47 of title 18, United States Code, relating to identity fraud, and for other purposes.

S. 755

At the request of Mr. CAMPBELL, the names of the Senator from Iowa [Mr. GRASSLEY], the Senator from Kansas [Mr. BROWNBACK], the Senator from Arkansas [Mr. HUTCHINSON], the Senator from Iowa [Mr. HARKIN], the Senator from Montana [Mr. BURNS], and the Senator from North Dakota [Mr. CONRAD] were added as cosponsors of S. 755, a bill to amend title 10, United States Code, to restore the provisions of chapter 76 of that title (relating to missing persons) as in effect before the amendments made by the National Defense Authorization Act for fiscal year 1997 and to make other improvements to that chapter.

S. 778

At the request of Mr. LUGAR, the names of the Senator from Mississippi [Mr. COCHRAN] and the Senator from Connecticut [Mr. LIEBERMAN] were added as cosponsors of S. 778, a bill to authorize a new trade and investment policy for sub-Saharan Africa.

S. 887

At the request of Ms. MOSELEY-BRAUN, the name of the Senator from New York [Mr. D'AMATO] was added as a cosponsor of S. 887, a bill to establish in the National Service the National Underground Railroad Network to Freedom Program, and for other purposes.

S. 1135

At the request of Mr. MCCONNELL, the name of the Senator from North Carolina [Mr. HELMS] was added as a cosponsor of S. 1135, a bill to provide certain immunities from civil liability for trade and professional associations, and for other purposes.

S. 1154

At the request of Mr. REED, the name of the Senator from Connecticut [Mr. DODD] was added as a cosponsor of S. 1154, a bill to amend the Electronic Fund Transfer Act to clarify consumer liability for unauthorized transactions involving debit cards that can be used like credit cards, and for other purposes.

S. 1169

At the request of Mr. REED, the name of the Senator from New York [Mr. MOYNIHAN] was added as a cosponsor of S. 1169, a bill to establish professional development partnerships to improve the quality of America's teachers and the academic achievement of students in the classroom, and for other purposes.

S. 1182

At the request of Ms. SNOWE, the name of the Senator from Washington [Mr. GORTON] was added as a cosponsor of S. 1182, a bill to amend the Congressional Budget and Impoundment Control Act of 1974 to limit consideration of nonemergency matters in emergency legislation and permit matter that is extraneous to emergencies to be stricken as provided in the Byrd rule.

S. 1192

At the request of Ms. SNOWE, the names of the Senator from Rhode Island [Mr. CHAFEE], and the Senator from Maine [Ms. COLLINS] were added as cosponsors of S. 1192, a bill to limit the size of vessels permitted to fish for Atlantic mackerel or herring, to the size permitted under the appropriate fishery management plan.

S. 1194

At the request of Mr. KYL, the names of the Senator from Alaska [Mr. MURKOWSKI], the Senator from South Carolina [Mr. HOLLINGS], the Senator from Indiana [Mr. COATS], the Senator from North Carolina [Mr. FAIRCLOTH], and the Senator from Florida [Mr. MACK] were added as cosponsors of S. 1194, a bill to amend title XVIII of the Social Security Act to clarify the right of medicare beneficiaries to enter into private contracts with physicians and other health care professionals for the provision of health services for which no payment is sought under the medicare program.

SENATE CONCURRENT RESOLUTION 51

At the request of Mr. HELMS, the names of the Senator from Oregon [Mr. SMITH], the Senator from Minnesota [Mr. WELLSTONE], and the Senator from Virginia [Mr. ROBB] were added as cosponsors of Senate Concurrent Resolution 51, a concurrent resolution expressing the sense of Congress regarding elections for the legislature of the Hong Kong Special Administrative Region.

SENATE RESOLUTION 119

At the request of Mr. FEINGOLD, the names of the Senator from South Dakota [Mr. DASCHLE], and the Senator from Maine [Ms. COLLINS] were added as cosponsors of Senate Resolution 119, a resolution to express the sense of the Senate that the Secretary of Agriculture should establish a temporary emergency minimum milk price that is equitable to all producers nationwide and that provides price relief to economically distressed milk producers.

AMENDMENT NO. 1177

At the request of Mr. REED the names of the Senator from Massachusetts [Mr. KENNEDY], and the Senator from

New Mexico [Mr. BINGAMAN] were added as cosponsors of amendment No. 1177 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.

At the request of Mr. DURBIN his name was added as a cosponsor of Amendment No. 1177 proposed to S. 830, supra.

AMENDMENT NO. 1182

At the request of Mr. HATCH the name of the Senator from Oregon [Mr. WYDEN] was added as a cosponsor of amendment No. 1182 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.

NOTICE OF HEARINGS

COMMITTEE ON LABOR AND HUMAN RESOURCES

Mr. JEFFORDS. Mr. President, I would like to announce for information of the Senate and the public that a Executive Session of the Senate Committee on Labor and Human Resources will be held on Wednesday, September 24, 1997, 9:30 a.m., in SD-430 of the Senate Dirksen Building. The following are on the agenda to be considered: S.1186, Workforce Investment Partnership Act of 1997; and nominations, Public Health Service Corps, 128 candidates. For further information, please call the committee, 202/224-5375.

COMMITTEE ON LABOR AND HUMAN RESOURCES

Mr. JEFFORDS. Mr. President, I would like to announce for information of the Senate and the public that a hearing of the Senate Committee on Labor and Human Resources will be held on Thursday, September 25, 1997, 10 a.m., in SD-430 of the Senate Dirksen Building. The subject of the hearing is Tobacco Settlement, part II. For further information, please call the committee, 202/224-5375.

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. MURKOWSKI. Mr. President, for the information of the Senate and the public I am announcing that the Committee on Energy and Natural Resources will hold an oversight hearing to receive testimony on the impacts of a new climate treaty on U.S. labor, electricity supply, manufacturing, and the general economy.

The hearing will be held on Tuesday, September 30, 1997, at 9:30 a.m., in room SD-366 of the Dirksen Senate Office Building.

Those interested in testifying or submitting material for the hearing record should write to the Committee on Energy and Natural Resources, U.S. Senate, Washington, DC 20510 attn: David Garman at (202) 224-8115.

ADDITIONAL STATEMENTS

TRIBUTE TO THE UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES UPON ITS 25TH ANNIVERSARY

• Ms. MIKULSKI. Mr. President, it is with great pride that I rise today to recognize the 25th Anniversary of the Uniformed Services University of the Health Sciences [USUHS]. Over the past 25 years, USUHS has provided an invaluable service to our Armed Forces and to our Nation.

The founders of USUHS wanted to create a medical school to produce physicians who would remain on active duty for a full career, ensuring the continuity of lessons learned in the practice of uniformed medicine. This concept has made USUHS a unique institution which enables doctors to target their skills to meet the changing demands of the modern battlefield.

USUHS is essential to our military mission because it ensures readiness. Readiness doesn't just mean supplying our troops with the best equipment and training. It also means that we are ready to provide the best possible medical care in the worst possible situations. If we send our military to battle without skilled and experienced medical professionals—we are sending them out unarmed.

This concept for medical training was a success during recent conflicts. During Operation Desert Storm, USUHS physicians were immediately deployable to combat areas and utilized their training in military combat, unconventional warfare, and preventive medicine. This saved countless lives during the gulf war and will keep our troops safe in any future military conflict.

I am proud of USUHS's accomplishments. I hope they will continue serving our armed services by keeping them safe and healthy well into the 21st century. •

AVIATION INSURANCE REAUTHORIZATION ACT OF 1997

• Mr. GORTON. Mr. President, I am pleased to join with my distinguished colleagues, Senator MCCAIN, Senator HOLLINGS, and Senator FORD, to introduce the aviation insurance reauthorization Act of 1997. The bill would reauthorize the aviation insurance program for five years. The program is set to expire at the end of this fiscal year.

The aviation insurance program, commonly known as war-risk insurance, has been in place since 1951. It insures air carriers against losses resulting from war, terrorism, or other hostile acts, when commercial insurance is canceled, or is unavailable at reasonable rates. For an air carrier to qualify for the program, the President must determine that a flight is essential to the foreign policy interests of the United States.

The FAA can issue both premium and nonpremium insurance under the pro-

gram. Premium insurance is issued to air carriers flying commercial operations in foreign air commerce, or between two or more points outside the United States. Nonpremium insurance is issued to air carriers flying missions for Federal agencies, such as the Departments of Defense and State, that have indemnification agreements with the Department of Transportation. Nonpremium insurance accounts for 99 percent of the aviation insurance program.

Both the premium and nonpremium insurance provides hull coverage for the loss of, or damage to aircraft. The insurance also provides liability coverage for death or bodily injury, and damage to property, baggage and personal effects. Program coverage is limited to the amount of insurance that an air carrier's commercial policy would have provided. The program is self-financed through the aviation insurance revolving fund.

Reauthorization of the aviation insurance program is noncontroversial. The program enjoys the support of all of its participants. I want to note, however, that my bill adds a new element to the program. It authorizes the Federal Aviation Administration [FAA] to borrow money from the Federal treasury to pay a claim, in the event that the revolving fund is not sufficient to cover a large claim, or simultaneous claims. I believe that this provision is necessary to ensure that timely payments for hull losses can be made to air carriers. These same carriers typically lease aircraft under agreements that stipulate that the carriers must repair or replace damaged aircraft within 30 days of the incident.

Although the Congressional Budget Office claims that this provision does not have a significant budget impact, I understand that the Office of Management and Budget [OMB] may disagree. The FAA and the OMB are working with the aviation leadership on the Commerce Committee to resolve this issue. I pledge my full cooperation, and I hope and expect that we can resolve this issue before the Commerce Committee reports out the legislation.

The Commerce Committee plans to report out the bill as early as next week. The House plans to approve companion legislation next week, as well. I urge my colleagues to work with me to reauthorize the aviation insurance program before it expires at the end of the fiscal year. •

IN RECOGNITION OF 10TH ANNUAL HEAT'S ON DAY

• Mr. LEVIN. Mr. President, I rise today to bring to my colleagues' attention to the HEAT'S ON partnership of Grand Rapids, MI, which serves people who need special assistance in preparation for the harsh winter months that lie ahead.

On Saturday, September 27, 1997, plumbers and steamfitters of UA Local

70 and the Mechanical Contractors Association of Grand Rapids will join together with Community Action to participate in the 10th annual HEAT'S ON Day. The HEAT'S ON—Handicapped and Elderly Assistance to Serve Our Neighbors—Program began in 1987 in Minneapolis and St. Paul, MN. HEAT'S ON Day has become an annual event in the Grand Rapids area, as members of plumbers and steamfitters local 70 and the Mechanical Contractors Association of Grand Rapids donate their time and talents to ensure that the homes of elderly and disabled people in Grand Rapids and the nearby cities of Grandville, Kentwood, Walker, and Wyoming are safe for the winter.

Participating servicepeople check homes approved for the program and repair and replace broken parts in furnaces and heating units. They also install easy-to-read thermostats and smoke alarms for people who need them. In the past 9 years, HEAT'S ON participants have discovered more serious—and potentially life-threatening—problems, such as plugged chimneys, defective furnaces, and homes exposed to carbon monoxide poisoning. These discoveries have enabled homeowners to have the problems repaired before suffering dangerous accidents.

HEAT'S ON is a community effort, as evidenced by local businesses who contribute time, money, and products to help defray the costs. Consumers Power, Meijer, and Dominos are just a few of the local businesses who participate in this vital program.

HEAT'S ON Day brings together many people to help ensure that nobody who requires assistance needlessly suffers through a cold winter. In Grand Rapids, union workers and business owners combine their resources and abilities to serve those in need. They are an inspiration, and they deserve our recognition. I know my colleagues will join me in extending our congratulations and thanks to the HEAT'S ON partnership of Grand Rapids, MI for 10 years of service to their community.●

CHARACTER COUNTS IN NEW MEXICO

● Mr. DOMENICI. Mr. President, as we approach National Character Counts Week, October 19–25, I want to relate another example of how character education programs are expanding across the State of New Mexico.

In New Mexico, over 30 communities and cities have adopted partnerships with their school systems to promote the Six Pillars of Character: trustworthiness, respect, responsibility, fairness, caring, and citizenship. There are literally thousands of young people involved in character-related programs in their youth organizations and public or private schools. Some communities have expanded their local efforts to include Character in the Workplace programs.

Character Counts is not just a slogan. It represents, instead, exciting and well-developed programs by citizens

who believe there are important and positive benefits to be derived from good character. Because families, churches, community groups, civic leaders, and school administrators and teachers want to place more emphasis on the value of ethical behavior, Character Counts has become one of the fastest growing and localized movements in the State's history.

As an example, in Farmington, NM, the Navajo Preparatory School is initiating an all-encompassing character education program for its students. The Navajo Preparatory School is chartered by the Navajo Nation to operate as a college preparatory school program for Navajo and other native American youth. Its mission is to educate highly motivated and talented students who have the potential and desire to achieve a college education and become leaders of their respective communities. It has 195 boarding and day students from the Navajo Nation, Jicarilla Apache, and various Pueblo Tribes. It has an excellent academic record, with 85 percent of its graduating students enrolled in college.

Some weeks ago I was invited to visit the school to hear about its Character Counts Program. Attending were teachers, students, school administration officials, and members of the board of trustees. The briefing included an innovative audio-visual program designed to transfer the concepts of the Six Pillars of Character into traditional Navajo teachings, as well as a review of the schools's translation of the Six Pillars into the Navajo language. In addition to its Character Counts curriculum, Navajo Prep also supports the development of student activities that will maximize the messages of the Six Pillars. It wants to ensure that its students have a comprehensive and cohesive program that surrounds both their academic and social conduct.

The board of trustees presented their resolution for "Endorsing and Implementing the Character Counts Program at the Navajo Preparatory School." I would like to quote from this resolution so Members of Congress will know how thoroughly the school's officials have developed this character education program.

The Navajo Preparatory School Board supports and endorses Character Counts which are based on six core ethical values: trustworthiness, respect, responsibility, fairness, caring, and citizenship.

The Navajo Preparatory School Board requests its staff to examine the curriculum and integrate Navajo-specific character development teachings, strategies, methods and partnership initiatives into the overall school program as an ongoing part of school instruction.

The Navajo Preparatory School Board empowers the school staff to join forces with the State of New Mexico Navajo Nation and other local organizations and become a leader for community action through teaching, enforcing, advocating and modeling the six pillars of character.

The Navajo Preparatory School staff shall pursue available funding to develop Navajo curriculum materials which promote the development of good character.

As evidenced by Navajo Prep's creative character education program and

as explained well in its resolution, " * * * no single entity can instill ethical behavior in youth and adults if it is acting without the support of the other institutions and groups." Character-building activities are for all. They can be embraced by the young and old and the public and private sectors in a way the transcends political, cultural, religious, and socioeconomic differences.

In New Mexico, Character Counts is a statewide and communitywide effort. It is a program with unbelievable energy because everyone who hears about it believes in it and wants it to work. It works because people, like those associated with the Navajo Preparatory School, are wholeheartedly committed to making it a reality.

I applaud the fine work of the Navajo Preparatory School, and welcome it as a new member of the ever-growing family of Character Counts enthusiasts.●

AMERICAN HERITAGE RIVERS INITIATIVE

● Mr. SARBANES. Mr. President, I rise in strong opposition to the proposed amendment by my colleague from Arkansas.

First, I think it is important to point out that the American heritage rivers initiative does not force designation upon any river or river community. It is a voluntary program.

American heritage rivers enables communities who wish to protect, restore, and revitalize their waterways, who want to protect their vital natural, historical, cultural, and recreational resources, to voluntarily develop and submit a locally driven nomination and to seek designation.

As proposed by the administration, any nominated river must demonstrate broad community support for the nomination. It must demonstrate that members of the river community have had ample opportunities to comment on the nomination and plan of action. The administration has also made it very clear that if a Member of Congress opposes a river designation in his or her district, the designation will not occur in that district.

Second, American heritage rivers establishes no new regulations, and was specifically designed to streamline Federal assistance to community-led riparian restoration efforts. By requiring written approval from all property owners along a river, and subjecting designation to a lengthy congressional selection process, this amendment in effect creates crippling delays and places unnecessary regulatory burdens on the nomination preparation and selection processes.

Third, this amendment unnecessarily restricts the broad objectives of American heritage rivers by focusing only on the water pollution aspects of river revitalization. American heritage rivers is designed to celebrate and address

not only natural resource and environmental protection, but to also promote economic development and the protection of our historical, cultural, and recreational resources.

In my own State of Maryland, and throughout the entire Potomac watershed, a broad coalition of local governments, private citizens, businesses, and others, known as the Friends of the Potomac, has mounted a concerted effort to nominate the Potomac. This coalition is striving to make "Our Nation's River" one of the first 10 designated American heritage rivers, and I fully support and encourage their efforts.

Mr. President, the American heritage rivers initiative is simply an effort to better coordinate and leverage existing Federal resources. The Council on Environmental Quality, participating agencies and departments already have congressionally provided authority and responsibility to carry out this program. I urge my colleagues to join me in opposing this amendment.●

THE 50-YEAR ANNIVERSARY OF THE KSEN RADIO STATION IN SHELBY, MT

● Mr. BURNS. Mr. President, I rise today to salute the KSEN radio station in Shelby, MT, for 50 years of service to the Golden Triangle area in north central Montana.

As a former broadcaster, I applaud KSEN for the valuable service they provide to the Shelby area, especially to the agricultural community. KSEN works hard to provide the area with farm and market reports, weather, local news, and sports broadcasting as well as national programs. KSEN radio is a very important tool for the area's farmers and ranchers.

KSEN radio has won more broadcasting awards than any other station in Montana and is the smallest market in the United States to receive the Crystal Award from the National Association of Broadcasters for its outstanding public service.

Congratulations to Mr. Jerry Black and the staff at KSEN radio in Shelby, MT, for a fabulous 50 years of service to our great State.●

THE 50TH ANNIVERSARY OF THE WISCONSIN LEGISLATIVE COUNCIL

● Mr. FEINGOLD. Mr. President, today, I want to pay tribute to an important institution in the Wisconsin State Legislature on its 50th anniversary: the Wisconsin Legislative Council.

The legislative council was created as a joint committee of the State legislature in 1947, charged with convening special committees each biennium to study the more complex, controversial or sometimes tedious but necessary legislative issues, and to develop legislative solutions. The unique aspect of the council's directive has been to identify and appoint knowledgeable Wisconsin citizens to work alongside

legislators to craft bills, often recodifying whole chapters of the statutes at a time.

The Wisconsin Legislative Council is derived from the same Wisconsin Idea, fostered by the Progressives in the early part of this century, that created the Congressional Research Service. Senator "Fighting Bob" LaFollette saw the importance of having non-partisan, professional staff provide research, analysis and bill-drafting to legislative bodies. The Wisconsin version, which has been the model for many other State legislatures, further improves on the concept by setting up a mechanism for open discussion and citizen participation directly in the development of legislative solutions in subjects selected by a bicameral body every 2 years.

Since its inception, the joint legislative council has overseen 426 individual studies, conducted by not only State legislators but also including over 6,000 Wisconsin citizens as full voting members of committees. These committees are staffed by the legislative council staff under the direction of the joint legislative council. These nonpartisan professional staff members further support the work of the legislature by staffing committees, providing research and analysis to individual legislators and their staff, and performing a technical review of all proposed State regulations.

Many of the members of the Wisconsin congressional delegation have had the experience of serving on legislative council committees—I served on three, once as chairman of a study committee reviewing laws on interstate sales and use taxes.

On its 50th anniversary, I am pleased to pay tribute to Wisconsin's Joint Legislative Council and the dedication of the legislative council staff. May they continue their service to the state for many years to come.●

DAVID SCHMELTZER

● Mr. D'AMATO. Mr. President, today I rise to honor a truly outstanding, dedicated public servant—David Schmeltzer. Dave is retiring from the Federal Government after 35 years of service, including 25 years at the U.S. Consumer Product Safety Commission, where he is the Director of the Office of Compliance. Over the years I have been fortunate to have gotten to know Dave personally. A native New Yorker, he received a bachelor of arts degree from Long Island University in 1957. He attended Brooklyn Law School with my dear friend Larry Elovich, and became a member of the New York Bar after graduating in 1960. I want to wish Dave, his wife Louise, and their son Daniel and his family the best of luck on this happy occasion.

David Schmeltzer has had a truly remarkable career in Federal service. I am unaware of anyone with Dave's experience and knowledge when it comes to product safety regulation and en-

forcement. At the U.S. Consumer Product Safety Commission, in addition to his current position as Director of the Office of Compliance, Dave has served as both Deputy General Counsel and Acting General Counsel. Before joining the Commission in 1973—at its inception, I should note—Dave served as the Assistant Chief Counsel for Enforcement and Administrative Law with the National Highway Traffic Safety Administration. He has also served as the Vice Chairman for the International Consumer Health and Safety Organization Symposium [ICPHSO] and is presently on ICPHSO's executive committee.

While the list of Government positions Dave has held is quite impressive, it does not begin to measure his contributions in improving product safety for all Americans of all ages, from infants to our seniors. Dave has never been someone who has ducked the tough calls, and he has been willing to take the heat for doing so when many others would have run away. He has always been fair and balanced in exercising his judgment, a real straight shooter. The results speak for themselves. On behalf of those consumers who have been spared the pain of a loss or devastating injury to a child or other loved one, I want to thank Dave Schmeltzer for his years of service and wish him well in his future endeavors.●

COMMEMORATING THE INDEPENDENCE OF ARMENIA

● Mr. LEVIN. Mr. President, I rise today to honor the sixth anniversary of Armenian Independence.

With the fall of the Soviet Union, Armenians were quickly faced with the possibility of realizing a vision which they had long sought—independence. On September 21, 1991, Armenia held a referendum to decide its future. More than 94 percent of Armenia's eligible voters turned out to support independence. Two days later, on September 23, the Armenian Parliament made the people's desire official when it declared Armenia's independence from the Soviet Union.

The historic vote for independence on September 21, 1991, has far greater significance when examined in light of Armenia's modern history. Throughout the last century, the Armenian people have experienced incredible hardship and tragedy in their efforts to rule themselves. Armenia began the 20th century under the control of the Ottoman Turks. Ottoman Turk rule turned savage at the beginning of World War I when it waged a government-organized genocide on the Armenians. During the Armenian Genocide of 1915–23, 1.5 million people perished as the Ottoman Turks tried to permanently silence Armenian calls for independence.

Following the defeat of the Ottoman Turks in World War I, Armenians were able to briefly fulfill their wishes of independence. On May 28, 1918, the Republic of Armenia was established.

However, this independence was short-lived as the Republic of Armenia soon collapsed because of renewed Turkish and Soviet pressure. On November 29, 1920, Armenia was declared a Soviet republic and spent the next 71 years under Soviet rule. With the fall of the Soviet Union in 1991, Armenia was finally able to fulfill its goal of self-determination.

Today, September 23, Armenia celebrates the sixth anniversary of its independence. I know that the many Armenian-Americans in Michigan and the United States join in this celebration. The support Armenian-Americans have given to their homeland has been indispensable as Armenia emerges from many years of Soviet domination. I applaud their efforts and the efforts of the Armenian people to build an independent and democratic Armenia.●

FURTHER EVIDENCE OF NEED FOR LEGAL REFORM NOW

● Mr. GORTON. A jury in New Orleans the other week issued a clarion call for legal reform. A monstrous judgment against CSX Transportation and four other companies illustrates once again the arbitrary and perverse nature of our current tort system.

Mr. President, I rise today to bring to my colleagues' attention a \$2.5 billion punitive damage award against CSX Transportation stemming from a 1987 chemical-car fire in the New Orleans neighborhood of Gentilly. Even in the context of our current broken legal system, this one is shocking. The jury awarded \$2.5 billion, out of a total punitive damage award of \$3.4 billion, against CSXT, Mr. President, despite the fact that Federal experts had determined that CSX was not at fault; despite the fact that the jury did not allocate any significant portion of the compensatory damages to CSXT; despite the fact that actual compensatory damages awarded to date in the case are only \$2 million; and despite the fact that the accident resulted in no deaths, no serious injuries, and no significant property damage.

Comparisons made in a New Orleans Times Picayune article put the total punitive damage award into perspective, warped as it is. Consider that the punitive damage award in this case is seven times the amount Union Carbide paid to settle a claim relating to a chemical leak in Bhopal, India, that killed 4,000 people and injured 300,000. Despite only minor property damage, this award is two-thirds of the punitive damage award against Exxon for the environmentally devastating spill that occurred in Alaska in 1989.

Let me set out the facts of the case as I understand them from the press accounts. On September 9, 1987, a railroad tank car containing butadiene, a volatile compound used in making synthetic rubber, was located in a rail yard in New Orleans on tracks that belonged to CSXT. Due to a faulty gasket, the contents of the car leaked and

the car caught fire. Local officials determined that the best approach was to let the fire burn itself out. To avoid harm to nearby residents, authorities ordered the evacuation of those living near the yard. Many people were inconvenienced, but although there are 8,000 people in the plaintiff class, only 2,300 people claim to have been located within the evacuation zone, and contemporary estimates of how many people were actually evacuated put the number at about 1,000.

One year after the accident, the National Transportation Safety Board, the Federal agency that investigates transportation accidents, determined that a misaligned gasket and other factors, not involving CSXT, had caused the accident. In fact, other than providing the track on which the train car was placed, CSXT had no connection to the car. CSXT did not own or repair the tank car, and it did not transport the car.

Significantly, even though the NTSB determined that CSTX had not caused the accident, the jury held CSXT 15 percent responsible for the \$2 million on compensatory damages that have been awarded to 20 plaintiffs at this time. The remaining plaintiffs will have to prove their damages in separate proceedings. Though it seems unfair that CSXT would be responsible for any compensatory damages if it was not at fault, it is unspeakably outrageous that CSXT would be assessed over 75 percent of the punitive damages, and only 15 percent of the compensatory damages.

How can it be that a Federal agency determines that a company has no responsibility for causing an accident and yet this huge verdict is awarded? The answer, unfortunately, is that our tort system is broken. The case in New Orleans is the latest, though perhaps most egregious, example of why we have to reform our civil justice system, to place some reasonable limit on punitive damage awards, to modify the laws regarding joint and several liability, and to provide disincentives for lawyers to go after the "deep pockets," simply because they're there.

CSXT is a big corporation, but that should not be reason to impose huge penalties on it, penalties that could affect its thousands of employees, thousands of middle-class stockholders who own shares in the company through their pension plans, and everyone who uses its vital transportation facilities. Until we undertake meaningful legal reform, we will continue to disadvantage businesses and consumers, stunt career opportunities, breed contempt for the law, and do injustice.●

THE 200TH ANNIVERSARY OF TRUMBULL, CT

● Mr. DODD. Mr. President, located in the hilly country of southwestern Connecticut in the watershed of the Pequonnock River is the quaint residential community of Trumbull. De-

spite its proximity to many highly industrialized cities, Trumbull has been able to preserve its small-town New England character and charm, and this year the town of Trumbull will celebrate its 200th anniversary.

The Trumbull area was permanently settled in 1690, and in the following years families began migrating to this secluded wilderness region, building mills, churches, and schools. In 1725, the settlement officially became the village of Unity, and this village was eventually absorbed by the larger community of North Stratford. Nearly a century after it was settled, the residents began the petition process for independence from North Stratford, and in 1797, the general assembly granted this request, established town bounds, and declared that this area shall forever be a distinct town known by the name of "Trumbull."

The town was named after one of the most respected families in Connecticut history, the Trumbulls of Lebanon, CT. The family's patriarch, Jonathan Trumbull, Sr., was the first of four "Governor Trumbulls" in Connecticut. He was a close ally of George Washington, and he was the only colonial Governor to support the Revolution. In recognition of his contributions to his State and his country, a statue of Jonathan Trumbull, Sr., currently stands in the Statuary Hall of the U.S. Capitol.

His son, Jonathan Trumbull, Jr., also had an illustrious career as an early American statesman. He was a member of the U.S. House of Representatives where he served as Speaker of the House. He also represented the State as a U.S. Senator and was elected Connecticut's governor in 1797, shortly after the town of Trumbull was incorporated.

In addition, Jonathan Trumbull, Sr.'s youngest child, John, was one of the most noteworthy American artists known for painting important historical events. Today, four of his paintings hang in the U.S. Capitol rotunda, his most famous being "The Surrender of Cornwallis."

While the namesakes for this town were truly heroic individuals, the many generations of Trumbull residents who have settled this town and shepherded its evolution over the years are equally heroic in their own right. They met the crises of their times. They worked hard to ensure a promising future for their children. They lent a helping hand to their neighbors when they were in need. They did all of the things that are necessary to sustain a community and help it develop into a wonderful place to live.

Today, Trumbull is a vibrant residential community which is dedicated to the preservation of its family-oriented atmosphere. Its schools are among the best in the State and the Parent-Teachers Association is very active. There are places of worship for more than a dozen different religions, strengthening the fabric of the community and adding to its diversity. More

than 1,000 acres of town-owned open space are set aside for recreational use, and Trumbull is renowned for its numerous public parks. Trumbull has also invested in its children by establishing an excellent youth sports program. In fact, one of the town's and the State of Connecticut's proudest moments came when a resilient group of 11- and 12-year-olds from Trumbull pulled off one of the greatest upsets in baseball history and won the Little League World Series in 1988.

Trumbull's motto is "Pride in our past. Faith in our future." I would like to personally say that the people of Trumbull should be very proud of their town's history and heritage. But more important, I have complete faith that the future for the people of Trumbull will be even brighter than the past. I congratulate the town of Trumbull on this historic milestone and offer my best wishes for future centuries of success and prosperity.

INTERIOR APPROPRIATIONS—NATIONAL PARK AND ENVIRONMENTAL IMPROVEMENT FUND

• Mr. McCAIN. Mr. President, as part of the Interior appropriations bill (H.R. 2107) the Senate adopted an amendment I offered with Senator STEVENS to create a National Park and Environmental Improvement Fund. The fund is financed with \$800 million in disputed oil revenue awarded to the Federal Government by the Supreme Court. Under the amendment, the annual interest from the fund would be available, subject to appropriation, for top priority capital improvements within the National Park System; to assist States with their own park planning and development; and to finance ocean research.

As I stated, disbursements of the interest revenue would be subject to appropriation. I want to be clear that it is not our intent to create this fund in vain, by appropriating the interest and reducing other vital park or environmental accounts in order to remain below the applicable budget caps. Our goal and intent is to ensure these funds will supplement the appropriations parks and environmental accounts would otherwise receive. The distinguished chairmen of the Budget Committee and the Appropriations Committee have agreed to work to ensure that end and I thank them for their courtesy and leadership.

Mr. DOMENICI. Mr. President, the Senator is correct. I look forward to working with him next year to address this issue during the budget process to ensure this fund provides additional resources to meet park and relevant environmental needs so that it will not require offsets from other park or vital environmental accounts.

Mr. STEVENS. Mr. President, I concur with my colleagues, and I will work as chairman of the Appropriations Committee to make sure that these funds are additional, not replacement,

revenues to meet park and environmental purposes.●

ELIMINATION OF SECRET SENATE "HOLDS"

• Mr. WYDEN. Mr. President, I am submitting for the RECORD a notification of a proposal I intend to offer.

I ask that the proposal be printed in the RECORD.

The proposal follows:

(Purpose: To eliminate secret Senate "holds")

At the appropriate place, insert:

SEC. . ELIMINATING SECRET SENATE "HOLDS."

(a) STANDING ORDER.—It is a standing order of the Senate that a Senator who provides notice to leadership of his or her intention to object to proceeding to a motion or matter shall disclose the objection (hold) in the Congressional Record not later than 2 session days after the date of said notice.

(b) RULEMAKING.—This section is adopted—
(1) as an exercise of the rulemaking power of the Senate and as such it is deemed a part of the Rules of the Senate and it supersedes other rules only to the extent that it is inconsistent with such rules; and

(2) with full recognition of the constitutional right of the Senate to change its rules at any time, in the same manner, and to the same extent as in the case of any other rule of the Senate.●

RETIREMENT TRIBUTE TO JIM WENGERT

• Mr. HARKIN. Mr. President, I rise to pay tribute to the work of Jim Wengert—a good friend and great fighter for working people across the state of Iowa and around the country.

For well over a generation, Jim Wengert has been a leader at the Iowa Federation of Labor. From 1966 to 1979, he was Secretary-Treasurer of the statewide organization. And from 1979 until his retirement this year, Jim has been at the helm of the Iowa Federation of Labor serving as its President.

Prior to his years at the Iowa Fed, Jim worked at Swift and Company in Sioux City. In 1952, he joined Local 71 of the United Packinghouse Workers of America and he wasted no time rising up the ranks. He served as Vice President and Steward of his local—and Recording Secretary and President of the Woodbury County Labor Council.

In addition, Jim has been a legislator in the Iowa General Assembly, and a member of the United States Commission on Civil Rights, the University of Iowa Labor Advisory Committee, and the Iowa Workers' Compensation Advisory Committee.

Mr. President, Jim Wengert has had a long and distinguished career but there is a common thread that weaves all his work together. For almost half a century, Jim Wengert has been on the frontlines of the battle for dignity and economic and social justice for the working people of this country.

That fight has not been easy—far too often, the deck has been stacked against working people. But Jim never picked his battles because the odds

were on his side. He did it because America's best values were on his side. Values like dignity, justice and fair play. Time and again, Jim Wengert put it on the line for workers on the line.

To Jim, it's simple. Fighting for working people is a labor of love. That's why he has used his position and his platform to speak out for good jobs, a living wage, secure pensions, and a better future for our children and grandchildren.

And if one looks across the landscape of Iowa and at all that's happened that's been good for working people, I guarantee you'll find the fingerprints of Jim Wengert. Because whether it's passing legislation, electing progressive candidates, or changing attitudes, Jim helped make it happen.

Mr. President, Jim Wengert is an optimist, a doer and a believer. He believes with his head and his heart that tomorrow can be better than today. And the power to make that happen isn't in the hands of "them"—the powerful and privileged. The power to make the future brighter rests with us—by organizing and working together.

That is what a union is all about. And that's what Jim Wengert is all about.

I know the Senate joins me in wishing Jim many more years of health and happiness. And even though his retirement is a loss for the working people of Iowa, it is truly a gain for the Wengert family—for Jim's wife Joanne, his children and, of course, his grandchildren.

Once again, Mr. president I want to thank Jim Wengert for his commitment and service. We owe him an enormous debt for a lifetime of building our communities and advancing the cause of justice and dignity for the working people of Iowa and our Nation.●

AUSTRIAN-AMERICAN DAY

Mr. ENZI. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 168, S. Res. 122.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

A resolution (S. Res. 122) declaring September 26, 1997 as "Austrian-American Day."

There being no objection, the Senate proceeded to consider the resolution.

Mr. ENZI. Mr. President, I ask unanimous consent that the resolution be agreed to, the motion to reconsider be laid upon the table, and that any statements relating to the resolution appear at this point in the RECORD.

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

The resolution (S. Res. 122) was considered and agreed to.

The preamble was agreed to.

The resolution, with its preamble, is as follows:

S. RES. 122

Whereas 1997 marks the 50th anniversary of General George C. Marshall's plan for assisting the free countries of Europe in their post-World War II rebuilding process;

Whereas on September 26, 1945, upon the insistence of the United States, a conference was held in Vienna by the Allies and the 9 Austrian Federal State Governors, that laid the foundation for the first post-war Austrian Government recognized by the United States and the other Allied Forces;

Whereas this treaty saved Austria from being divided into an East and West, as in Germany;

Whereas Austrians are thankful for the generosity demonstrated by the citizens and the Government of the United States after World War II;

Whereas Austrian-Americans have made important contributions to the American way of life as well as in industry, education, culture, and the arts and sciences; and

Whereas Austrian born Americans, or Americans of Austrian descent, have brought prestige and recognition to the United States as Nobel laureates in medicine, economics, and the sciences: Now, therefore, be it

Resolved, That the Senate—

(1) declares September 26, 1997, as "Austrian-American Day"; and

(2) authorizes and requests the President to commend this observance to the citizens of the United States in honor of this momentous occasion.

CONVEYANCE OF A PARCEL OF LAND TO THE DOS PALOS AG BOOSTERS

Mr. ENZI. Mr. President, I ask unanimous consent the Agriculture Committee be discharged from further consideration of H.R. 111, and further the Senate proceed to its immediate consideration.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

A bill (H.R. 111) to provide for the conveyance of a parcel of unused agricultural land in Dos Palos, California to the Dos Palos Ag Boosters for use as a farm school.

Mr. ENZI. I ask unanimous consent the bill be considered read a third time and passed, the motion to reconsider be laid upon the table, and that any statements relating to the bill appear at this point in the RECORD.

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

The bill (H.R. 111) was considered read the third time, and passed.

EXECUTIVE SESSION

EXECUTIVE CALENDAR

Mr. ENZI. Mr. President, I ask unanimous consent that the Senate immediately proceed to executive session to consider the following nominations on the Executive Calendar, Calendar No. 259 and Calendar No. 260.

I further ask unanimous consents the nominations be confirmed, the motions to reconsider be laid upon the table, and any statements relating to the nominations be printed at this point in the RECORD, the President be immediately notified of the Senate's action, and the Senate then return to legislative session.

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

The nominations considered and confirmed are as follows:

NAVY

The following named officer for appointment in the United States Navy to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be admiral

Adm. Harold W. Gehman, Jr., 0000.

MARINE CORPS

The following named officer for appointment in the United States Marine Corps to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be general

Lt. Gen. Charles E. Wilhelm, 0000.

LEGISLATIVE SESSION

The PRESIDING OFFICER. Under the previous order, the Senate will resume legislative session.

REMOVAL OF INJUNCTION OF SECRECY—TREATY DOCUMENTS NOS. 105-28, 105-29, AND 105-30

Mr. ENZI. As in executive session, I ask unanimous consent that the injunction of secrecy be removed from the following treaties transmitted to the Senate on September 23, 1997, by the President of the United States:

Comprehensive Test-Ban Treaty (Treaty Document No. 105-28);

Protocol Amending Tax Convention With Canada (Treaty Document No. 105-29);

Extradition Treaty With India (Treaty Document No. 105-30).

I further ask that the treaties be considered as having been read the first time; that they be referred, with accompanying papers, to the Committee on Foreign Relations and ordered to be printed; and that the President's messages be printed in the RECORD.

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

The President's messages are as follows:

To the Senate of the United States:

I transmit herewith, for the advice and consent of the Senate to ratification, the Comprehensive Nuclear Test-Ban Treaty (the "Treaty" or "CTBT"), opened for signature and signed by the United States at New York on September 24, 1996. The Treaty includes two Annexes, a Protocol, and two Annexes to the Protocol, all of which form integral parts of the Treaty. I transmit also, for the information of the Senate, the report of the Department of State on the Treaty, including an Article-by-Article analysis of the Treaty.

Also included in the Department of State's report is a document relevant to but not part of the Treaty: The Treaty on the Establishment of a Preparatory Commission for the Comprehensive Nuclear Test-Ban Treaty Organization, adopted by the Signatory States to the Treaty on November 19, 1996. The Text provides the basis for the work of the Preparatory Commission for the Comprehensive Nuclear Test-Ban Treaty Organization is pre-

paring detailed procedures for implementing the Treaty and making arrangements for the first session of the Conference of the States Parties to the Treaty. In particular, by the terms of the Treaty, the Preparatory Commission will be responsible for ensuring that the verification regime established by the Treaty will be effectively in operation at such time as the Treaty enters into force. My Administration has completed and will submit separately to the Senate an analysis of the verifiability of the Treaty, consistent with section 37 of the Arms Control and Disarmament Act, as amended. Such legislation as may be necessary to implement the Treaty also will be submitted separately to the Senate for appropriate action.

The conclusion of the Comprehensive Nuclear Test-Ban Treaty is a signal event in the history of arms control. The subject of the Treaty is one that has been under consideration by the international community for nearly 40 years, and the significance of the conclusion of negotiations and the signature to date of more than 140 states cannot be overestimated. The Treaty creates an absolute prohibition against the conduct of nuclear weapon test explosions or any other nuclear explosion anywhere. Specifically, each State Party undertakes not to carry out any nuclear weapon test explosion or any other nuclear explosion; to prohibit and prevent any nuclear explosions at any place under its jurisdiction or control; and to refrain from causing, encouraging, or in any way participating in the carrying out of any nuclear weapon test explosion or any other nuclear explosion.

The Treaty establishes a far reaching verification regime, based on the provision of seismic, hydroacoustic, radio-nuclide, and infrasound data by a global network (the "International Monitoring System") consisting of the facilities listed in Annex 1 to the Protocol. Data provided by the International Monitoring System will be stored, analyzed, and disseminated, in accordance with Treaty-mandated operational manuals, by an International Data Center that will be part of the Technical Secretariat of the Comprehensive Nuclear Test-Ban Treaty Organization. The verification regime includes rules for the conduct of on-site inspections, provisions for consultation and clarification, and voluntary confidence-building measures designed to contribute to the timely resolution of any compliance concerns arising from possible misinterpretation of monitoring data related to chemical explosions that a State Party intends to or has carried out. Equally important to the U.S. ability to verify the Treaty, the text specifically provides for the rights of States Parties to use information obtained by national technical means in a manner consistent with generally

recognized principles of international law for purposes of verification generally, and in particular, as the basis for an on-site inspection request. The verification regime provides each State Party the right to protect sensitive installations, activities, or locations not related to the Treaty. Determinations of compliance with the Treaty rest with each individual State Party to the Treaty.

Negotiations for a nuclear test-ban treaty date back to the Eisenhower Administration. During the period 1978–1980, negotiations among the United States, the United Kingdom, and the USSR (the Depositary Governments of the Treaty on the Non-Proliferation of Nuclear Weapons (NPT)) made progress, but ended without agreement. Thereafter, as the nonnuclear weapon states called for test-ban negotiations, the United States urged the Conference on Disarmament (the “CD”) to devote its attention to the difficult aspects of monitoring compliance with such a ban and developing elements of an international monitoring regime. After the United States, joined by other key states, declared its support for comprehensive test-ban negotiations with a view toward prompt conclusion of a treaty, negotiations on a comprehensive test-ban were initiated in the CD, in January 1994. Increased impetus for the conclusion of a comprehensive nuclear test-ban treaty by the end of 1996 resulted from the adoption, by the Parties to the NPT in conjunction with the indefinite and unconditional extension of that Treaty, of “Principles and Objectives for Nuclear Non-Proliferation and Disarmament” that listed the conclusion of a CTBT as the highest measure of its program of action.

On August 11, 1995, when I announced U.S. support for a “zero yield” CTBT, I stated that:

“... as part of our national security strategy, the United States must and will retain strategic nuclear forces sufficient to deter any future hostile foreign leadership with access to strategic nuclear forces from acting against our vital interests and to convince it that seeking a nuclear advantage would be futile. In this regard, I consider the maintenance of a safe and reliable nuclear stockpile to be a supreme national interest of the United States.

“I am assured by the Secretary of Energy and the Directors of our nuclear weapons labs that we can meet the challenge of maintaining our nuclear deterrent under a CTBT through a Science Based Stockpile Stewardship program without nuclear testing. I directed the implementation of such a program almost 2 years ago, and it is being developed with the support of the Secretary of Defense and the Chairman of the Joint Chiefs of Staff. This program will now be tied to a new certification procedure. In order for this program to

succeed, both the Administration and the Congress must provide sustained bipartisan support for the stockpile stewardship program over the next decade and beyond. I am committed to working with the Congress to ensure this support.

“While I am optimistic that the stockpile stewardship program will be successful, as President I cannot dismiss the possibility, however unlikely, that the program will fall short of its objectives. Therefore, in addition to the new annual certification procedure for our nuclear weapons stockpile, I am also establishing concrete, specific safeguards that define the conditions under which the United States can enter into a CTBT. . . .”

The safeguards that were established are as follows:

- The conduct of a Science Based Stockpile Stewardship program to ensure a high level of confidence in the safety and reliability of nuclear weapons in the active stockpile, including the conduct of a broad range of effective and continuing experimental programs.
- The maintenance of modern nuclear laboratory facilities and programs in theoretical and exploratory nuclear technology that will attract, retain, and ensure the continued application of our human scientific resources to those programs on which continued progress in nuclear technology depends.
- The maintenance of the basic capability to resume nuclear test activities prohibited by the CTBT should the United States cease to be bound to adhere to this Treaty.
- The continuation of a comprehensive research and development program to improve our treaty monitoring capabilities and operations.
- The continuing development of a broad range of intelligence gathering and analytical capabilities and operations to ensure accurate and comprehensive information on worldwide nuclear arsenals, nuclear weapons development programs, and related nuclear programs.
- The understanding that if the President of the United States is informed by the Secretary of Defense and the Secretary of Energy (DOE)—advised by the Nuclear Weapons Council, the Directors of DOE’s nuclear weapons laboratories, and the Commander of the U.S. Strategic Command—that a high level of confidence in the safety or reliability of a nuclear weapon type that the two Secretaries consider to be critical to our nuclear deterrent could no longer be certified, the President, in consultation with the Congress, would be prepared to withdraw from the CTBT under the standard “supreme national interests” clause in order to conduct whatever testing might be required.

With regard to the last safeguard:

- The U.S. regards continued high confidence in the safety and reliability of its nuclear weapons stockpile as a matter affecting the supreme interests of the country and will regard any events calling that confidence into question as “extraordinary events related to the subject matter of the treaty.” It will exercise its rights under the “supreme national interests” clause if it judges that the safety or reliability of its nuclear weapons stockpile cannot be assured with the necessary high degree of confidence without nuclear testing.
- To implement that commitment, the Secretaries of Defense and Energy—advised by the Nuclear Weapons Council or “NWC” (comprising representatives of DOD, JCS, and DOE), the Directors of DOE’s nuclear weapons laboratories and the Commander of the U.S. Strategic Command—will report to the President annually, whether they can certify that the Nation’s nuclear weapons stockpile and all critical elements thereof are, to a high degree of confidence, safe and reliable, and, if they cannot do so, whether, in their opinion and that of the NWC, testing is necessary to assure, with a high degree of confidence, the adequacy of corrective measures to assure the safety and reliability of the stockpile, or elements thereof. The Secretaries will state the reasons for their conclusions, and the views of the NWC, reporting any minority views.
- After receiving the Secretaries’ certification and accompanying report, including NWC and minority views, the President will provide them to the appropriate committees of the Congress, together with a report on the actions he has taken in light of them.
- If the President is advised, by the above procedure, that a high level of confidence in the safety or reliability of a nuclear weapon type critical to the Nation’s nuclear deterrent could no longer be certified without nuclear testing, or that nuclear testing is necessary to assure the adequacy of corrective measures, the President will be prepared to exercise our “supreme national interests” rights under the Treaty, in order to conduct such testing.
- The procedure for such annual certification by the Secretaries, and for advice to them by the NWC, U.S. Strategic Command, and the DOE nuclear weapons laboratories will be embodied in domestic law.

As negotiations on a text drew to a close it became apparent that one member of the CD, India, would not join in a consensus decision to forward the text to the United Nations for its adoption. After consultations among countries supporting the text, Australia requested the President of the

U.N. General Assembly to convene a resumed session of the 50th General Assembly to consider and take action on the text. The General Assembly was so convened, and by a vote of 158 to 3 the Treaty was adopted. On September 24, 1996, the Treaty was opened for signature and I had the privilege, on behalf of the United States, of being the first to sign the Treaty.

The Treaty assigns responsibility for overseeing its implementation to the Comprehensive Nuclear Test-Ban Treaty Organization (the "Organization"), to be established in Vienna. The Organization, of which each State Party will be a member, will have three organs: the Conference of the States Parties, a 51-member Executive Council, and the Technical Secretariat. The Technical Secretariat will supervise the operation of and provide technical support for the International Monitoring System, operate the International Data Center, and prepare for and support the conduct of on-site inspections. The Treaty also requires each State Party to establish a National Authority that will serve as the focal point within the State Party for liaison with the Organization and with other States Parties.

The Treaty will enter into force 180 days after the deposit of instruments of ratification by all of the 44 states listed in Annex 2 to the Treaty, but in no case earlier than 2 years after its being opened for signature. If, 3 years from the opening of the Treaty for signature, the Treaty has not entered into force, the Secretary-General of the United Nations, in his capacity as Depositary of the Treaty, will convene a conference of the states that have deposited their instruments of ratification if a majority of those states so requests. At this conference the participants will consider what measures consistent with international law might be undertaken to accelerate the ratification process in order to facilitate the early entry into force of the Treaty. Their decision on such measures must be taken by consensus.

Reservations to the Treaty Articles and the Annexes to the Treaty are not permitted. Reservations may be taken to the Protocol and its Annexes so long as they are not incompatible with the object and purpose of the Treaty. Amendment of the Treaty requires the positive vote of a majority of the States Parties to the Treaty, voting in a duly convened Amendment Conference at which no State Party casts a negative vote. Such amendments would enter into force 30 days after ratification by all States Parties that cast a positive vote at the Amendment Conference.

The Treaty is of unlimited duration, but contains a "supreme interests" clause entitling any State Party that determines that its supreme interests have been jeopardized by extraordinary events related to the subject matter of the Treaty to withdraw from the Treaty upon 6-months' notice.

Unless a majority of the Parties decides otherwise, a Review Conference will be held 10 years following the Treaty's entry into force and may be held at 10-year intervals thereafter if the Conference of the States Parties so decides by a majority vote (or more frequently if the Conference of the States Parties so decides by a two-thirds vote).

The Comprehensive Nuclear Test-Ban Treaty is of singular significance to the continuing efforts to stem nuclear proliferation and strengthen regional and global stability. Its conclusion marks the achievement of the highest priority item on the international arms control and nonproliferation agenda. Its effective implementation will provide a foundation on which further efforts to control and limit nuclear weapons can be soundly based. By responding to the call for a CTBT by the end of 1996, the Signatory States, and most importantly the nuclear weapon states, have demonstrated the bona fides of their commitment to meaningful arms control measures.

The monitoring challenges presented by the wide scope of the CTBT exceed those imposed by any previous nuclear test-related treaty. Our current capability to monitor nuclear explosions will undergo significant improvement over the next several years to meet these challenges. Even with these enhancements, though, several conceivable CTBT evasion scenarios have been identified. Nonetheless, our National Intelligence Means (NIM), together with the Treaty's verification regime and our diplomatic efforts, provide the United States with the means to make the CTBT effectively verifiable. By this, I mean that the United States:

- will have a wide range of resources (NIM, the totality of information available in public and private channels, and the mechanisms established by the Treaty) for addressing compliance concerns and imposing sanctions in cases of non-compliance; and
- will thereby have the means to: (a) assess whether the Treaty is deterring the conduct of nuclear explosions (in terms of yields and number of tests) that could damage U.S. security interests and constraining the proliferation of nuclear weapons, and (b) take prompt and effective counteraction.

My judgment that the CTBT is effectively verifiable also reflects the belief that U.S. nuclear deterrence would not be undermined by possible nuclear testing that the United States might fail to detect under the Treaty, bearing in mind that the United States will derive substantial confidence from other factors—the CTBT's "supreme national interests" clause, the annual certification procedure for the U.S. nuclear stockpile, and the U.S. Safeguards program.

I believe that the Comprehensive Nuclear Test-Ban Treaty is in the best interests of the United States. Its provisions

will significantly further our nuclear nonproliferation and arms control objectives and strengthen international security. Therefore, I urge the Senate to give early and favorable consideration to the Treaty and its advice and consent to ratification as soon as possible.

WILLIAM J. CLINTON.

THE WHITE HOUSE, September 22, 1997.

To the Senate of the United States:

I transmit herewith for Senate advice and consent to ratification the Protocol Amending the Convention Between the United States of America and Canada with Respect to Taxes on Income and on Capital Signed at Washington on September 26, 1980 as Amended by the Protocols Signed on June 14, 1983, March 28, 1984 and March 17, 1995, signed at Ottawa on July 29, 1997. This Protocol modified the taxation of social security benefits and the taxation of gains from the sale of shares of foreign real-property holding companies.

I recommend that the Senate give early and favorable consideration to this Protocol and give its advice and consent to ratification.

WILLIAM J. CLINTON.

THE WHITE HOUSE, September 23, 1997.

To the Senate of the United States:

With a view to receiving the advice and consent of the Senate to ratification, I transmit herewith the Extradition Treaty Between the Government of the United States of America and the Government of the Republic of India, signed at Washington on June 25, 1997.

In addition, I transmit, for the information of the Senate, a related exchange of letters signed the same date and the report of the Department of State with respect to the Treaty. As the report states, the Treaty will not require implementing legislation.

The provisions in this Treaty follow generally the form and content of extradition treaties recently concluded by the United States.

Upon entry into force, this Treaty would enhance cooperation between the law enforcement authorities of both countries, and thereby make a significant contribution to international law enforcement efforts. With respect to the United States and India, the Treaty would supersede the Treaty for the Mutual Extradition of Criminals between the United States of America and Great Britain, signed at London December 22, 1931, which was made applicable to India on March 9, 1942, and is currently applied by the United States and India.

I recommend that the Senate give early and favorable consideration to the Treaty and give its advice and consent to ratification.

WILLIAM J. CLINTON.

THE WHITE HOUSE, September 23, 1997.

ORDERS FOR WEDNESDAY,
SEPTEMBER 24, 1997

Mr. ENZI. Mr. President, I ask unanimous consent that when the Senate

completes its business today it stand in adjournment until the hour of 12 noon on Wednesday, September 24. I further ask that on Wednesday, immediately following the prayer, the routine requests through the morning hour be granted and the Senate immediately resume consideration of S. 830, the FDA reform bill.

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

PROGRAM

Mr. ENZI. Mr. President, tomorrow the Senate will resume consideration of S. 830, the FDA reform bill. Under the previous order, at noon the Senate will conclude the remaining 4 hours of debate on that measure. Therefore, Members can anticipate a vote on final passage of S. 830, between 3:45 and 4 o'clock tomorrow afternoon.

Following disposition of S. 830, it is hoped the Senate will begin consideration of the District of Columbia ap-

propriations bill. Members can expect additional votes during Wednesday's session of the Senate, following the final passage vote of S. 830. In addition, the Senate may consider any other legislative or executive business that can be cleared for action.

I thank all Senators for their attention.

ADJOURNMENT

Mr. ENZI. Mr. President, I now ask unanimous consent that the Senate stand in adjournment under the previous order.

There being no objection, the Senate, at 7:04 p.m., adjourned until Wednesday, September 24, 1997, at 12 noon.

NOMINATIONS

Executive nominations received by the Secretary of the Senate September 22, 1997, under authority of the order of the Senate of January 7, 1997:

DEPARTMENT OF STATE

RICHARD FRANK CELESTE, OF OHIO, TO BE AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO INDIA.

CONFIRMATIONS

Executive nominations confirmed by the Senate September 23, 1997;

NAVY

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE U.S. NAVY TO THE GRADE INDICATED WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, UNITED STATES CODE, SECTION 601:

To be admiral

ADM. HAROLD W. GEHMAN, JR., 0000.

IN THE MARINE CORPS

THE FOLLOWING-NAMED OFFICER FOR APPOINTMENT IN THE U.S. MARINE CORPS TO THE GRADE INDICATED WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, UNITED STATES CODE, SECTION 601:

To be general

LT. GEN. CHARLES E. WILHELM, 0000.