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 arrearages.

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 mentioned 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	McCain	

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 nonpatentable 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, INOUYE, 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 nongermane 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, Harvard Medical School.*

BRIAN M. BERMAN, M.D., *Complementary Medicine Program, University of Maryland.*

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

FREDI KRONENBERG, PH.D., *Center for Complementary and Alternative Medicine Research in Women's Health, Columbia University.*

M. ERIC GERSHWIN, M.D., *Division of Rheumatology, Allergy, and Clinical Immunology, University of California, Davis.*

GUY S. PARCEL, PH.D., *Center for Health Promotion 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 Therapies, University of Virginia School of Nursing.*

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

THOMAS J. KIRESUK, PH.D., *Center for Addiction and Alternative Medicine Research, University of Minnesota 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 reintroduced 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 insufficient 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 pubic 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 depends 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 legislation 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 prohibits 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 advertisment, 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 nonprescription 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,