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Senate

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

PRAYER

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

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

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

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

RECOGNITION OF THE ACTING MAJORITY LEADER

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

SCHEDULE

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

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

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

I yield the floor.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

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

The assistant legislative clerk read as follows:

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

The Senate resumed consideration of the bill.

Pending:

Jeffords amendment No. 1130, in the nature of a substitute.

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

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

Durbin amendment No. 1139 (to amendment No. 1130), to eliminate provisions relating to the discretion of the Secretary of Health and Human Services to track devices or to conduct postmarket surveillance of devices.

AMENDMENT NO. 1140

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

The Senator from Illinois.

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

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

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

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

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

Section 204 of the bill provides a full statutory directive to the agency adopt measures within 180 days of enactment to prevent conflicts of interest that may be involved with both an individual reviewer and with the reviewing organization. As with Senator DURBIN, this was a critical concern for members of the committee.

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

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

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

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

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

We all know people—family members and friends—whose health, and even lives, rely on important medication and devices. There are few jobs more significant than assuring the safety and efficacy of these items. In my mind, Mr. President, this is a role—protecting health and safety—that is best served by Government, rather than by the private sector. However, the bill before us takes a different view, and establishes a large-scale pilot project to allow private sector review of medical devices. If we are to take this step, it is absolutely critical that we subject those private sector reviewers to the same conflict-of-interest restrictions that Government reviewers are subject to.

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

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

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

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

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

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

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

The yeas and nays have been ordered.

The clerk will call the roll.

The assistant legislative clerk called the roll.

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

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

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

[Rollcall Vote No. 252 Leg.]

YEAS—40

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

NAYS—59

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

NOT VOTING—1

Helms

The amendment (No. 1140) was rejected.

AMENDMENT NO. 1139

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

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

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

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

Will the Senators to my left please cease audible conversation?

The Senator from Vermont.

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

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

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

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

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

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

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

Mr. JEFFORDS addressed the Chair.

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

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

Current law requires tracking for certain product types and gives the FDA discretion to require tracking for other products. It is simply not necessary for every current and future device in the mandatory category to be subject to the tracking requirement. This provision allows FDA affirmatively to indicate which products in the mandatory category should be subject to tracking. FDA may use its discretion to add new products to the list of products which must be tracked, or put a product back on the list for tracking if evidence indicates the need.

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

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

I urge defeat of the amendment.

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

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

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

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The yeas and nays were ordered.

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

The bill clerk called the roll.

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

[Rollcall Vote No. 253 Leg.]

YEAS—39

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

NAYS—61

Abraham	Brownback	Cochran
Allard	Bumpers	Collins
Ashcroft	Burns	Coverdell
Bennett	Campbell	Craig
Biden	Chafee	D'Amato
Bond	Coats	DeWine
Dodd	Jeffords	Roberts
Domenici	Kempthorne	Roth
Enzi	Kennedy	Santorum
Faircloth	Kyl	Sessions
Frist	Landrieu	Smith (NH)
Gorton	Lautenberg	Smith (OR)
Gramm	Lieberman	Snowe
Grams	Lott	Stevens
Grassley	Lugar	Thomas
Gregg	Mack	Thompson
Hagel	McCain	Thurmond
Hatch	McConnell	Warner
Helms	Moynihan	Wyden
Hutchinson	Murkowski	
Inhofe	Nickles	

The amendment (No. 1139) was rejected.

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

AMENDMENT NO. 1177

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

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

The PRESIDING OFFICER. The clerk will report.

The bill clerk read as follows:

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

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

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

The amendment is as follows:

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

The PRESIDING OFFICER. The Senator is recognized.

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

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

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

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

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

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

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

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

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

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

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

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

Essentially, what this says is if a manufacturer says, ''This is what we are going to do,'' on a label, this is all we can consider in our application process, even if the FDA considers the possibility of other uses or even, some would argue—even if the FDA felt that the label was misleading or, indeed, false.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Indeed, it is not as easy as it may appear for the FDA to step into the marketplace and get goods off or an item off the market that has already been approved. So I think the idea that this can be corrected after the fact is not sufficient weight to preclude us from taking effective steps before a device gets in the marketplace.

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

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

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

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

Mr. REED. I thank the Chair.

The PRESIDING OFFICER. Who seeks time?

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

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

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

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

The PRESIDING OFFICER. The Senator from Connecticut is recognized.

Mr. DODD. Thank you, Mr. President.

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

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

I want to just at the outset commend those who have been involved in it, explaining what the purpose of the intent here is. We have passed this bill out of our committee 14 to 4. There was some disagreement over a number of provisions, but I believe we produced a very fine product which is going to assist tremendously in making this even more secure in the quality of products we are getting but also the efficiency with which those products become available to patients and people in this country. I thank my colleague from Rhode Island for the explanation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have been given some examples over the past week of how the act would only test the intended use on the label. In fact, as I said, there are two tests under 510(k). In each of the examples that have been given, the FDA had the ability to stop the devices from going on the market because they failed the second test. No reference has been made to that. They failed the second test, not the intended purpose, but the technological differences.

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

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

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

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

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

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

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

Mr. President, let me step back a second. There is not a single Member of this body that in any way wants to be associated with or part of an effort that is going to endanger anyone's life at all. In fact, quite the contrary. We want to do everything we can to see to it that people are getting safe products, efficient products, effective products that will serve their interests and protect their lives. That is our purpose and intent. We also want to see patients able to get products and have them reach the market. Certainly there are going to be those who will be fraudulent, bad actors. No one is suggesting they do not exist. Nothing we will do here will stop that, I suppose.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

By definition, the process of determining substantial equivalence, a label is neither true nor false. It is the same as the predicate. If it is not the same as the predicate, then it does not pass the first test. In effect, trying to squeeze false and misleading language into a place it doesn't fit means all devices would be undergoing the PMA process, a process that can take up to six times longer, six times longer. When there are patients out there and families out there that want to see this material get to them, we don't need to be complicating a process on low risk devices, delaying that event occurring, causing more pain and suffering. There are people who suffer as a result of a regulatory process that is so overburdened and so complicated that people cannot get these materials when they need them.

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

I yield the floor.

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

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

Mr. COATS. I thank the Senator for yielding.

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

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

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

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

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

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

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

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

The language that we are talking about here was proposed by Senator WELLSTONE—hardly someone who is viewed as being anticonsumer or someone viewed as trying to open a loophole so that the health and safety of Americans is jeopardized. In the negotiations and discussions, postcommittee markup, this wasn't on the list. I have in my hand the memo from the Labor Committee, from David Nexon, suggesting items that need to be covered and need to be discussed. This isn't even on the list. We went over these amendments. All of a sudden, when at one point, the only thing left, to our knowledge, was a resolution of the cosmetic portion of the bill, which was resolved, all of a sudden this then pops up. So you have to question what is going on here.

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

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

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

So that's what is at issue here. It is an issue that doesn't have to be here. It is an issue that we don't need to be talking about. No one raised it in committee. No one raised it in negotiations postcommittee. No one indicated that this was a bill stopper. The last indication of a bill stopper was the cosmetic concern, which was negotiated and an acceptable compromise was reached. Then, all of a sudden, this provision, 404(b), the language offered by the Senator from Minnesota, Senator WELLSTONE, and accepted by the committee as part of the bill, without objection, all of a sudden this now becomes the bill stopper, the killer language, the language that is going to destroy the FDA and place 260 million Americans in jeopardy of their life and their health.

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

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

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

At this point, I yield the floor.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Finally, the FDA has a host of criminal and civil penalties to prevent the marketing of mislabeled products including administrative detention and seizure, criminal and civil penalties, injunction, mandatory consumer and physician mandatory notifications, mandatory recall, and adverse agency publicity.

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

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

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

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

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

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

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

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

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

Go down the list of the organizations that are out there protecting the people that will benefit most from progress in these areas, and they say, ''Don't do this. Support the Reed amendment.'' Do they make the judgment that this is not important just because it deals only with class II devices—the relatively low risk devices. There has been the suggestion here on the floor of the Senate that these are virtually low-risk devices.

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

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

You have the fetal cardiac monitors that monitor infants.

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

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

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

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

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

Dear Senator KENNEDY:

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

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

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

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

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

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

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

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

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

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

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

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

How can anyone be opposed to that?

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

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

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

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

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

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

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

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

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

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

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

That is the issue.

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

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

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

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

We have just seen in the period of the last 5 days, the example of the terrible events concerning the off-label use of the drug fen/phen—and the health hazards and challenges faced by the people who have used it.

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

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

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

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

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

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

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

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

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

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

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

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

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

Mr. KENNEDY. I yield, sure.

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

Mr. KENNEDY. Has the Senator seen this video?

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

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

Mr. DODD. Will my colleague yield?

Mr. KENNEDY. I will yield in a second. We have just seen what the medical companies were doing with fen/phen. They weren't promoting it. All they were doing was paying the doctors thousands and thousands of dollars to go out and promote it. When we look at this promotion, it has ''U.S. Surgical'' on it, and it is a U.S. Surgical medical device—and we have the doctors' letters on this that say, ''The indications for the use of devices. . . it should be determined by appropriate—

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

Company representative—

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

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

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

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

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

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

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

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

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

Mr. COATS. Will the Senator yield?

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

Mr. COATS. If the Senator will yield——

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

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

This is the quote:

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

Not biopsy, surgery.

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

That sounds like an operation to me.

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

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

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

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

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

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

because I know there are others who wish to speak.

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

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

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

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

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

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

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

That is what we are talking about.

Mr. KENNEDY. Sure.

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

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

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

Mr. COATS. Will my colleague yield?

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

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

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

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

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

THERMO ELECTRON,
Waltham, MA, October 8, 1996.

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

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

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

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

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

Best regards,

GEORGE N. HARSOPOULOS,
Chairman of the Board.

(Mr. SESSIONS assumed the chair.)

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

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

THERMO ELECTRON,
Waltham, MA, October 8, 1996.

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

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

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

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

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

Best regards,

GEORGE N. HARSOPOULOS,
Chairman of the Board.

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

Mr. DODD. Will my colleague yield?

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

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

Mr. KENNEDY. On the needle? All right.

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

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

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

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

Mr. KENNEDY. If my colleague——

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

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

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

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

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

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

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

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

Maybe U.S. Surgical convinced the Senator from Connecticut. But the documents and their promotional materials indicate what they are about, and that is to provide for removal of tumors from American women, one out of seven, who have breast cancer. And doctors who see, ''Approved by the FDA,'' then tell their patient this has been approved by the FDA, that it must be safe, and so they undergo tumor removal with this device. These women are entitled to adequate protection, to know whether that device was safe in removing that tumor. They do not know that today.

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

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

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

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

Mr. DODD. Will my colleague yield?

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

We can use what U.S. Surgical did, where they denied—denied—that they were promoting it, and yet they had some other group that was putting promoting it with their logo, talking about using it for an entirely different purpose.

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

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

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

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

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

Section 404 of the FDA bill requires the FDA to approve a medical device based on the user claim on the label submitted by the manufacturer, even if that label is false or misleading. It prevents the FDA from requiring the manufacturers to show their product is safe and effective for the purposes for which it will really be used—as opposed to the purpose falsely claimed on the label. It stands 20 years of progress toward safer and more effective medical devices on its head.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If section 404 is passed in its current form, the FDA will be handcuffed in its efforts to protect the public against untested and potentially harmful—even fatal—devices. Under current law, the FDA is able to require that the company develop data to show that the new device was safe and effective for removing tumors—the real use intended by the company, not the false and misleading use submitted on their proposed label. When the FDA made a mistake and inappropriately cleared the device, it had the authority to go back to the company and warn that it would revoke their approval unless adequate warnings were placed on the label and necessary clinical testing was performed.

I hope our colleagues will listen to this.

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

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

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

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

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

Companies that hope to benefit by weakening the FDA are powerful and profitable. They believe they have the votes to push this disgraceful provision through the U.S. Senate. Later today, we will see if they are correct. But if the American people truly understand what is at stake, I do not believe they will permit this dangerous provision to become law. When the vote comes, we will see how many Senators are willing to stand with the American people—and how many are willing to vote in favor of false and misleading labeling. And let me make very clear that this vote will not be the end of the story, whichever way it ends up. We will continue to fight to keep this provision from becoming law, and I believe we will ultimately succeed.

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

The Reed-Kennedy amendment will protect Americans against dangerous

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

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

I yield the floor.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

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

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

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

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

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

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

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

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

So that evidence is with respect to two points: First, these are rare things and, second, there is the present ability to handle those situations.

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

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

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

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

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

I yield to the Senator from Connecticut.

Mr. DODD. I thank my colleague for yielding.

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

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

Mr. DODD. I thank my colleague for yielding.

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

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

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

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

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

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

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

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

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

ABBI biopsy device chronology

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

ABBI biopsy device chronology—Continued

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

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

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

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

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

All we are saying here is, the FDA ought to look at the intended purpose listed, and ought not try and go beyond that, particularly when they have full authority to apply the second test of reviewing technological differences. All we are trying to do here is to expedite the process a bit so we do not delay further the ability of very worthwhile devices to get approved by the FDA and get to the marketplace.

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

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

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

The PRESIDING OFFICER. The Senator from Indiana.

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

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

Mr. KENNEDY. Will the Senator yield?

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

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

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

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

Mr. KENNEDY. Will the Senator yield?

Mr. COATS. Happy to yield for a question.

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

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

Mr. COATS. Reclaiming my time.

Mr. KENNEDY. I had yielded——

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

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

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

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

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

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

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

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

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

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

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

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

UNANIMOUS-CONSENT AGREEMENT

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

The PRESIDING OFFICER. Is there objection?

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

Mr. JEFFORDS. After the vote.

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

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

RECESS

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

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

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

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

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

LANDMARK HEARINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

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

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

ORDER OF PROCEDURE

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

The PRESIDING OFFICER. The Senator from New Hampshire.

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

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

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

The PRESIDING OFFICER. Is there objection?

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

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

Mr. KENNEDY. I have no objection.

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