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 President, I ask unanimous consent that the order for the quorum call be rescinded.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

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

U.N. ARREARAGES

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

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

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

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

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

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

The new Secretary General of the United Nations has given a significant number of talks on this topic. He has pushed forward an agenda for reform. But his agenda for reform doesn't go as far as the agreed to package, which passed out of this Senate with an overwhelming vote.

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

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

I yield the time.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The Senate continued with the consideration of the bill.

AMENDMENT NO. 1177

The PRESIDING OFFICER. Who yields time?

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

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

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

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

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

I urge all of my colleagues to support this amendment.

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

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

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

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

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

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

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

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

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

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