

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

U.N. ARREARAGES

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

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

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

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

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

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

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

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

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

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

I yield the time.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The Senate continued with the consideration of the bill.

AMENDMENT NO. 1177

The PRESIDING OFFICER. Who yields time?

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

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

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

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

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

I urge all of my colleagues to support this amendment.

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

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

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

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

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

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

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

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

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

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

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