system. They will be buying home computers for children in the public school. And if the President's proposal is adopted sometime for uniforms, they will be buying uniforms in the public school system. They will be transporting students to afterschool programs or whatever in the public school system.

Now, Mr. President, it will also help private schools because those parents that have made that decision can also open up savings accounts, and all the things I have just said that would augment public education will augment private education.

Now, I guess this is the rub for the President. There will be some families who will use the savings account to change schools. They might leave a troubled school and go to another one, and he doesn't think they should have that right. He can say that. He can say it is good sound public policy for us to order families where they must go to school, but he may not assert that it undermines public schools, because it just isn't true. It is the reverse. It augments and brings vast new resources to all elementary education, public and private.

As I said when these remarks began, they are going to be the most intelligently spent dollars in all education because they are dollars being directed like a rifle shot to the exact problem the child has.

Vast public moneys, which do great good, cannot do that; parents do it. And we are giving them the tools to do it. That is a fact, Mr. President.

I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, as I understand the situation we are now under a time control of the minority leader?

The PRESIDING OFFICER (Mr. HAGEL). The Senator is correct.

Mr. KENNEDY. I thank the Chair. I yield myself such time as I might use.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

Mr. KENNEDY. Mr. President, the underlying piece of legislation that we have before the Senate is S. 830, which is the drug reform legislation. Earlier in the course of the debate and discussion, I pointed out one of the most serious proposals in that particular piece of legislation that puts the future health care of all at serious. I also pointed out the bewilderment the President of the United States and I share, which every consumer group shares: Why in the world are we providing the kind of change in protections for the American consumer that are included in this legislation?

I am reminded, Mr. President, that 30 years ago this Nation was faced with a thalidomide tragedy, and all the implications that that terrible situation had for hundreds of mothers and children. Twenty years ago, we had the Dalkon Shield tragedy, where 18 women died from perforated uteruses, 2,700 women had miscarrages, and millions of women were adversely affected with great illness and sickness and, in many instances, were unable to have children in the future. Why? Because we had a medical device that wasn't safe for American women.

Ten years ago, we had the Shiley heart valve. A certain part of that heart valve that was found to be unsafe here in the United States, but it was advertised and used overseas and resulted in hundreds of deaths.

We know that some medical devices can be dangerous. We have to ask ourselves, as we are coming into the final consideration of this legislation, why in the world we are retreating from protecting the American public in this area? That is what we are doing. We are putting the interests of the medical device industry ahead of the public health of the American people. For what reason? For the profits of those medical device industries.

The provisions of the legislation are clear and simple. S. 830 says:

> . . . prohibits FDA from reviewing the safety of a device for uses not listed by the manufacturer.

If the manufacturer labels a device as substantially the same as another device that has already been approved, the Food and Drug Administration cannot look at that medical device, beyond the use listed on the lablel, in terms of its safety and effectiveness in protecting the American consumer.

We are effectively handcuffing the Food and Drug Administration with this language. The amendment, which will be offered by Senator REED—on which I will join him, says:

> . . . prohibits FDA from reviewing the safety of a device for uses not listed by the manufacturer unless the label is false and misleading.

Who could defend a medical device manufacturer that knowingly submits false and misleading information? Anybody who is listening to this would say, we can't believe that, Senator. We can't believe that is really happening. Well they should believe it because that is what is happening.

The clearest illustration of this development is the use of a certain biopsy needle that has been manufacture by U.S. Surgical Co. A biopsy needle used to excise tumor tissue to see whether it is cancerous or not. The biopsy needle is maybe the size of the lead in a pencil. It is used to remove sufficient amount of material to be analyzed. Now, along comes U.S. Surgical Corp., which develops medical devices, with a new medical device that can take 50 times more material than the earlier biopsy needle. U.S. Surgical says: Look, this new device is the same purpose as the other medical device. It is substantially the same. It is for taking material that can be a biopsied. We have been approved previously in terms of safety and effectiveness. According to our label, this new device is a biopsy needle and, according to the law, under S. 830, FDA cannot look beyond that use and into the real purpose of this new device to determine whether or not the device is safe and effective for that new use.

Well, Mr. President, unfortunately for U.S. Surgical Corp., a number of us have seen their ads and promotions for this particular medical device. What is U.S. Surgical Corp. promoting? It is promoting this new device as a device that is going to remove the tumor, not just take the biopsy, but remove the tumor from a woman's breast. Now, it may be very good in removing that tumor. It may be able to get all the cancerous material. It may do the job better than any other medical device we have had before. But we don't know that. The patient won't know it. The doctor won't know it. The family of the patient won't know it. Why? Because U.S. Surgical Corp. would not have to provide one paragraph of information demonstrating that this medical device is safe and effective for removing tumors. The doctors will see it and say, well, this has been approved by the FDA, it must be safe. I think I will use it, especially after reading about, hearing, or watching the promotion film used in Canada to promote this device.

The FDA would be prohibited from looking behind the labeling of the device to determine whether it is safe and effective. The FDA can say, look, we know the manufacturer is out there day in and day out promoting this device for tumor removal. They can hardly wait to get approval to go out and sell that medical device for the purposes of removing the tumor. According to the proposal under S. 830, if the label says that it is substantially equivalent to the biopsy needle, the Food and Drug Administration cannot require U.S. Surgical Corp. to provide information demonstrating that the device is safe and effective for its marketed purpose. That is wrong.

We are taking an important step backward in protecting the American people. And it is not just this particular medical device. The real concern is all the other medical devices that are out there now being considered. It is the mammography screening machines that are being used for breast cancer screening. The mammography screening machines may be very good in terms of the diagnostic evaluation of tumors, once the tumor is detected. They may be even better as screening tools to look for such a tumor. But we don't know because the FDA wouldn't be able to ask for safety and effectiveness data for its use in breast cancer screening. So we have examples of mammography machines coming into the FDA that will be approved because they are effective in terms of evaluating and diagnosing tumors, but have not been studied in terms of their effectiveness in screening. Yet we find the machine is being used for screening purposes. American women will say that they have been screened with

mammography machines, and they have been found to be free of any kind of cancer. They will be very happy about that. Since we have no data on how effective this device is for screening, they may find later, maybe too late, that they have some kind of a tumor. They may find out that this machine didn't do what it was represented to do because it had not been tested in terms of effectiveness. That should not be the case.

That is true with regard to the surgical lasers that haven't been tested for safety and effectiveness in cutting cancerous prostate tissue. It has been demonstrated that the lasers are safe and effective in cutting general tissue. But, the manufacturer changes the design and puts another laser in that also cuts tissue. But the purpose of that new laser is to cut through tissue in the prostate area, whether it is a cancerous tissue or noncancerous tissue. The laser has not been approved for that purpose. We do not have safety information to know that it is effective in dealing with this particular kind of operation. The manufacturer doesn't have to provide it. All they have to do is say it is a laser that cuts tissue and they get approved. The FDA can be fully aware that they are going to promote it for prostate cutting, but they will not be able to ask the manufacturer to provide safety information for that use.

The same is true with contact lenses that get approved though this loophole channel—saying that the lenses are substantially equivalent to equipment that has already been approved. But those lens manufacturers are intend to promote these new lenses for long-term use rather than short-term use like the ones that have been approved. The FDA can know about the advertising—and can even tell from the change in materials used to make the new lenses that they are designed for long-term use. But they cannot evaluate the new lenses for safety and long-term use. We can see the dangers that could result—maybe even blindness.

Mr. President, we shouldn't be taking a risk with the health of the American people in this way. It is fundamentally wrong. The only reason to do so is to give a competitive advantage to unethical medical manufacturing companies. Those are the ones that will use this loophole. And when they do, they will gain a competitive advantage over the ethical manufacturers that take the time and spend the money to conduct the safety and effectiveness studies to show that thier devices are safe. They will be at a financial and competitive disadvantage because less ethical companies will use this loophole for approval.

That is why each and every one of these consumer groups are opposed to this provision—why we have recommended five different alternatives to address this issue over the past weeks. The medical device industry has turned those down because they say they have the votes. They can roll over the public health concerns of the American people. That has happened in the past. But I hope it will not happen next Tuesday. This issue is too important. It is important for our wives, our daughters, our sons, our fathers, our grandparents—to be sure that when they have to use medical devices, those devices are going to be safe and effective. We have the ability to ensure safety in so many new ways—ways that were unimaginable years ago.

But with this provision, we are effectively tying the hands of the FDA. If there is an appropriate title for the provision, it is the false-claims provision of the medical device and pharmacy legislation, S. 830. And it is the wrong way to go.

We look forward to debating this issue next week. I am hopeful that we can address it in a way that will provide the real protection the American people deserve.

Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

BANNING ANTIPERSONNEL LANDMINES

Mr. LEAHY. Mr. President, earlier this week, the President of the United States announced that the United States would not sign the landmine treaty that was just negotiated in Oslo. This treaty is the culmination of a process begun a year ago in Ottawa, Canada, by the Foreign Minister of Canada, Lloyd Axworthy, who invited nations around the world to sign a treaty that would be a comprehensive ban on the use and the export and the manufacture and stockpiling of antipersonnel landmines.

Antipersonnel landmines are these weapons that destroy the lives—either by maiming or killing—of 26,000 people a year. There are approximately 100 million landmines in the ground of the 65 nations—or more—around the world. And more are being put down every day. As one person from one of the nations most severely impacted by landmines told me once, they clear the landmines in their country ''an arm and a leg at a time.''

Thanks to the leadership of Canada, and Minister Axworthy, this effort gained support around the world. Close to 100 nations joined together in Oslo to put the final pieces together on a comprehensive landmine treaty that would be signed in Ottawa in December.

The United States had basically boycotted this process, preferring a much slower and less effective one in Geneva following a very traditional route, the one that showed absolutely no movement. To the administration's credit, they finally did join the process, although at the 11th hour. Unfortunately, when they went to Oslo, they went to Oslo saying that the United States would need some major changes in the treaty to accept it, that they would have to have the treaty rewritten to accommodate the United States, and that these positions were not negotiable.

I applauded the United States for going to Oslo, but I was disappointed in the steps they took once they were there. I went to Oslo for a few days and met with many of the delegates, including the chairman of the conference. Then it became clear to me—I also spoke to the American delegation—that the United States had come with basically a take-it-or-leave-it attitude and that other countries were not going to agree.

The President said that we had obligations in Korea that were unique to the United States. We do have special obligations in Korea. But that was not an insurmountable issue. In fact, those who went there had said almost a year before, if the United States made an effort, they would help accommodate our security interests in Korea, but the United States ignored the entire process.

Finally, hours, literally hours before the conference was to end, the United States became engaged and said, well, we need some changes. If you will give them to us, we can sign. The first change is to have a treaty that would not take effect for 9 years, plus the 10 years as provided for in the treaty to remove existing minefields. That is 19 years from this December. We would actually be in the year 2017 before the mines would be removed. The United States asked for a 19-year period even though countries far less powerful than us were willing to act much quicker. The United States was saying that even though we are the most powerful nation on Earth, we want the ability to be able to use our antipersonnel landmines all over the world for another 9 years, and the antipersonnel mines we use near antitank mines, forever. And, lastly, of course, accommodate us on Korea. It became a bridge too far for the other nations. They said we were asking too much. They were, after all, the nations being hurt by landmines and they would go forward with the treaty with or without the United States, and that is where we now stand.

After that, the President of the United States announced a number of steps that he is willing to take unilaterally, and I commend him for these steps because he has said that he also wants to see, as we all do, this scourge of landmines to end.

Interestingly enough, many of the steps that he talks about are in legislation pending before the Senate—legislation sponsored by both the distinguished occupant of the chair right