that there would be full and open debate on this issue without a time limit, that there would be an opportunity to amend. We can fix the bill with amendments. We can accommodate Members' concerns. We can improve the bill or we can even defeat the bill, as my colleague from Kentucky may choose to do. But that is different than last year when we were given only 2 days, no amendments, and a cloture vote.

The agreement that was just propounded was significantly better in that regard. The agreement would give the American people the opportunity with some certainty to know about when this issue was going to come up so that the people across the country could write their Representatives, call their Representatives, e-mail their Representatives, and say, ''We'd really like this bill passed'' or ''We'd like it killed'' or ''We'd like it changed.'' I think all of this is embodied in the proposal.

So I say, on behalf of myself and Senator MCCAIN, if I may do so, that, apart from this small issue of the exact timing, that this agreement, once agreed to, will do what we want it to. It is what we want. It is what we worked for for a long time, while all the pundits, especially in this town, have said that the issue will never come up. Most importantly, when we have this debate—and it will be in the near future—I am confident it will be done in an orderly manner. And it will give the American people what they deserve, an opportunity to have a real debate on this issue instead of just an endless stream of reports of abuses with regard to campaign financing throughout their Government.

So, Mr. President, I am very optimistic that this brief conversation here was merely a blip and that we will not be forced to use the tactic of having to try to attach this legislation to other bills and in fact S. 25, which of course is still the McCain-Feingold bill, will in fact come before this body in the relatively near future.

I want to thank the majority leader for his cooperation on this. I want to thank my leader for his efforts to try to resolve these differences at this point. I want to thank all 45 members of my caucus, all the Democrats for having signed on to the McCain-Feingold bill. Of course I want to thank the other cosponsors of the bill, Senator THOMPSON and Senator COLLINS on the other side of the aisle.

I want to thank the President. The President has been very steadfast in trying to move this legislation forward. His staff has worked closely with us on a day-to-day basis to try to see if we could resolve the very difficult differences between the parties so we could have this matter debated.

Mr. President, we will get there. We are getting there. I hope we can today begin to tell the American people they are finally going to be able to participate in, hear and understand the debate about whether big money is going to continue to control the Government of the people of the United States.

Mr. President, I yield the floor.

Mr. MCCONNELL addressed the Chair.

The PRESIDING OFFICER. The Chair recognizes the Senator from Kentucky.

Mr. MCCONNELL. Mr. President, I listened with interest to the comments of the Democratic leader and Senator FEINGOLD. I would just like to say briefly in response, there is no reluctance to debate this issue. Those of us who oppose McCain-Feingold look forward to the debate. We relish the debate.

My colleague in the chair remembers when we stayed up all night to debate this about 5 weeks before the 1994 election, which was the greatest victory for my party in congressional races in this century.

So let me just disabuse all of my colleagues of the notion that there is any reluctance on the part of those who oppose putting the Government in charge of political speech of individual groups, candidates, and parties in this country, any reluctance to debate the merits of that proposal. There is no reluctance whatsoever.

What the majority leader was trying to do here today was to structure that debate in such a way as to provide minimal inconvenience to Members of the Senate. The Democratic leader said we can get there the hard way or the easy way. We have no reluctance to get there the hard way, Mr. President, no reluctance whatsoever.

The majority leader was simply trying to accommodate all of the Senate by providing an orderly, structured way to have a debate that we relish, look forward to making. My experience with this issue over the years is the more colleagues and the American people and, yes, the press learns about the issue the better, the greater likelihood the first amendment will be protected.

So bring on the debate. We are ready for it. But, obviously, it will be a lot easier on everyone if we did it an orderly, structured way. That is what the majority leader was seeking to do. I commend him for that, and look forward to the debate that will be forthcoming. We will be happy to do it either the hard way or the easy way, whichever seems to suit the Senate the best.

Mr. President, I yield the floor.

The PRESIDING OFFICER (Mr. GORTON). The Senator from Georgia.

EDUCATION REFORM

Mr. COVERDELL. Mr. President, we have spent the better part of the morning talking about our initiatives to begin to get at the core problems in elementary education in America. We have talked about creating an education savings account that allows every family the opportunity to save and build resources to deal with whatever deficiencies are troubling their children.

We talked about the Presiding Officer's amendment which would move $11 billion or $12 billion to local school districts without the strings and encumbrances that Washington cannot ever seem to free itself of. Just put the resource at the local level.

We have talked about a proposal to create scholarships in the District of Columbia to try to allow these families in certifiably troubled schools a way out.

Three things, all of which are addressed where the real problem in American education is occurring: Elementary and high school.

Now, what has been the opposition? What is the opposition? It began when the savings account was put in the tax relief proposal. The President told the Speaker that if it was left in the proposal, the savings account for families to help kids in elementary school, he would veto all of it, all the tax relief would be vetoed.

So obviously it was removed. But we have not retreated. We have brought the proposals back. The Speaker introduced the education savings account on the House side, and myself and the majority leader on this side.

Now, what is the reason? Why would the President go to such lengths to clamp down on an education savings account? Well, he and the Secretary of Education say it would undermine public education—remove resources from public education.

Mr. President, I have to assume they are just misinformed by their own staffs. I can come to no other conclusion—that they just have become so accustomed to the status quo and to beating down any new idea that there is a knee-jerk reaction. They always try to infer that these ideas will somehow impair or undermine public education. Wrong, wrong, and wrong.

In fact, it is the reverse, the exact reverse. The savings account will infuse public education with new money. The vast majority of students are in public schools and the vast majority of students will stay in public schools. The savings accounts that the parents of those children create will come to the aid of—there is not a single dime, Mr. President, not 10 cents, that will be removed from public schools.

Conversely, billions—billions—of new dollars will come to the support of public schools. The child in a public school who needs a tutor, the child in public school—which, incidentally, will be a public schoolteacher. If I was a public schoolteacher I would be rushing in support of the education savings account because it will give them a vast, vast new opportunity to teach, which they love to do, and earn compensation, which will help them. Not one dime is removed.

Every family that opens this savings account will continue to pay their property tax for the public school—every one. They will set up the savings account. They will hire tutors from the public school system. They will be tutoring children in the public school

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