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House of Representatives

The House was not in session today. Its next meeting will be held on Monday, September 22, 1997, at 12 noon.

Senate

FRIDAY, SEPTEMBER 19, 1997

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 God, it is startling to realize that there are over 6,000 people who work together to keep this Senate moving forward effectively. We thank You for the chiefs of staff, the schedulers, the legislative assistants, the secretaries, the media liaisons, the State staffs, and the interns who work in the Senators' offices. We thank You for the officers of the Senate, the Senate committee staffs, the security force, the custodians, and waiters and waitresses. Wherever we turn there are people employed to assist 100 men and women do their work of leading our Nation with excellence. Help us to take no one for granted. May this be a day in which we say, ''I appreciate you; thanks for what you do!'' to the people who work for us and those with whom we work. We are grateful for the gift of each person. In the name of our Lord and Saviour. Amen.

RECOGNITION OF THE ACTING MAJORITY LEADER

The PRESIDENT pro tempore. The able acting majority leader.

SCHEDULE

Mr. JEFFORDS. Mr. President, I announce on behalf of the majority leader that today the Senate will resume consideration of S. 830, the FDA reform bill, with Senator KENNEDY being recognized until the hour of 10:30 a.m. for debate only. Under the previous consent, at 10:30 a.m. Senator DURBIN will be recognized to debate his two amendments. Further, at 12 noon the Senate will proceed to a period of morning business, with Senator COVERDELL or his designee being recognized for 90 minutes from 12 noon until 1:30 p.m., and Senator DASCHLE, or his designee being recognized for 90 minutes, from 1:30 p.m. to 3 p.m.

As previously announced, there will be no rollcall votes during today's session of the Senate. Also as announced, the next rollcall votes will occur on Tuesday, September 23, at 9:30 a.m., on Senator DURBIN's amendments to S. 830, the FDA reform bill.

I thank my colleagues for their attention.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The PRESIDING OFFICER (Mr. SESSIONS). The clerk will report S. 830.

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 the consideration of the bill.

Pending:

Modified committee amendment in the nature of a substitute. (The modification incorporated the language of 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.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized for up to 1 hour.

Mr. KENNEDY. Mr. President, I yield myself 50 minutes.

Mr. President, this morning we continue the discussion of one of the most important and one of the most controversial and I believe one of the most dangerous provisions of S. 830. We are hopeful that we will be able to garner the attention of the Members of the Senate to support an amendment that will be offered and voted on Tuesday next that will address this dangerous provision that puts the American consumer at risk.

At the outset, I want to mention that those of us who are concerned about this particular provision are many. The Department of Health and Human Services, which is the principal agency of our National Government responsible for the health and safety of the American people, is strongly opposed to section 404, and supports the position that I have taken here today.

Other groups opposed to section 404. Those groups that are opposed to the provision also include the Patients' Coalition, which represents patients from all over this country, a real grassroots organization that understands, at the grassroots level, or the Main Street level, the dangers that this particular provision will mean unless we address

it; the Consumer Federation of America; the National Women's Health Network; the National Organization for Rare Disorders; the American Public Health Association, which is charged with protecting the public health of Americans; the Consumers Union, another grassroots organization that looks after the interests of the consumer for a range of different issues and has targeted this particular provision; the Center for Women's Policy Studies; the National Parent Network on Disabilities; the National Association of Social Workers; the Policy Center for Children, Youth and Families; the American Council on Consumer Awareness; and the TMJ Association, they are the victims of the artificial jaw joint group. All of these organizations, and there are many more, are reflecting the anxiety and very deep concern and legitimate concern that consumers have about a particular provision that is included in this legislation, which will effectively handcuff the FDA from looking beyond just the manufacturer's label to get to the bottom line, whether a particular device which has a manufacturer's label is really going to be both marketed and utilized in such a way as to pose a serious and grievous health hazard to the American consumer.

I think the National Women's Health Network states the situation very well. I will just take a moment, before getting into the principal reasons for hoping that we will be able to alter and change this provision on Tuesday next, to read it, because it really summarizes the concerns of, in this case, the National Women's Health Network representing the millions of women across this country.

> On behalf of the 13,000 individual and 300 organized members of the National Women's Health Network, I am writing to express our continued opposition to S. 830 because of the serious implications this legislation has for our Nation's women. The network is extremely concerned that section 404 prevents the FDA from requiring medical device companies to perform complete reviews of the safety and effectiveness of a medical device. This provision must be amended to give the FDA the authority to verify that the label used is not false or misleading.

That is what we are talking about this morning, labeling, by the manufacturing company, of a medical device, that is false and misleading. The amendment which we will offer next Tuesday will say that when FDA finds that the medical device company is filing a false and misleading label, that the FDA will be able to look at the safety considerations of that device in order to protect the American consumer.

The Food and Drug Administration has a staff of scientists and researchers, individuals who have expert knowledge of different medical devices, whose only purpose is to protect the public. It is that group of individuals that we entrust—we recognize that they are human and are capable of making mistakes, nonetheless, they are the principal agent to trust to protect the American public's health and safety. When we have false and misleading labels by medical device industries, we need to make sure that the FDA scientists and researchers, who are charged with protecting the American public, are going to be able to make a thorough determination as to the safety and the efficacy of the devices. This is the issue. That is what the National Women's Health Network illustrates. The letter continues:

> Women need the FDA to act as a safety sieve, screening out drugs and devices which are hazardous or ineffective. If section 404 were enacted, a device manufacturer could label its product for a very simple use and the FDA would be limited to asking for proof in safety and effectiveness about that use only. Even if it were clear from the device's technical characteristics that it might be used for other, riskier purposes, the FDA would be prevented from looking beyond the conditions of use on the label.

If we are concerned about protecting the American consumer, this makes no sense. We should not be tying the hands of the FDA when we should be protecting the health of the American consumer. Look at recent history and the medical device disasters that this country has faced. This bill opens the potential for those diasters to be replicated. We all hope they will not be. But one of the principal safeguards for preventing this is the FDA being able to examine the safety of devices. The letter goes on:

> Section 404 is a serious danger to women's health.

I repeat, this particular section, section 404—

> is a serious danger to women's health, which must be fixed before S. 830 is acted upon by the Senate. In light of today's front page coverage of the fen/phen catastrophe, in which women were the victims of off-label drug use, we find it inconceivable that the Senate would pass a bill with this provision.

There it is. They have it right. We just had the fen/phen disaster, in which scores of individuals have suffered—have perhaps lost their lives—as a result of off-label use. And here we have on the U.S. Senate floor a particular provision that will invite unscrupulous medical device companies not to clearly and accurately state what their medical device is going to be used for. This is the issue. We have scores of other letters, similar to the one I just read, expressing concern about section 404.

The issues are clear. Will the Senate vote in favor of approving a medical device based on false and 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?

Mr. President, let me point out, that if U.S. Surgical Corp. is able to have their way—if they are allowed to misleadingly label their medical device as being substantially equivalent—they will be virtually guaranteed approval under the language of this bill. Because this bill says that if the medical device is substantially equivalent to one that has been approved and meets those safety requirements, it must be approved. Despite the fact that this corporation, U.S. Surgical Corp., has a device that is being advertised and will be used for an entirely different purpose. A purpose for which it has not been tested for safety. What happens to the ethical companies? What happens to the other medical device companies that are trying to provide safe medical devices?

They are going to be at a competitive disadvantage because they will come up and say to the FDA, ''Look, our device is for this purpose and we have conducted these expensive safety tests.'' That is going to cost that company, and it means that their medical device is going to be more expensive. What happens to these other companies when a company like the U.S. Surgical Corp. is able to get in the door without providing safety information, without doing that kind of testing? This is also an issue.

It is not the most important argument. The most important one is health and safety. If this language is not altered or changed, it will be an invitation for medical device companies all over America to jump through this loophole in order to get their products on line. Will the Senate put a higher value on the profits of the powerful than the health of the American people?

Section 404 of the bill requires FDA to approve a medical device based on the use claimed on the label submitted by the manufacturer—even if that label is false and misleading.

Think of it. The FDA will be required to give approval even though the label is false and misleading. Whose interests are we protecting? Are we protecting the American consumers' interests, or are we protecting the profits of the medical device company? The way this law is currently constructed, it will help protect the profits of companies like U.S. Surgical Corp. It prevents the FDA from requiring manufacturers to demonstrate that their product is safe and effective for the purposes for which it will 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. For 20 years, since 1974, we have tried, through the FDA, to make sure that medical devices are safe and efficacious. This is the first time in over 20 years that we are taking a step backward. We take modest steps forward on the basis of experience, at both the FDA and across the country, to provide additional protections for the American consumer. Now we are faced with the first significant and major step backward.

Mr. President, to illustrate that, the U.S. Surgical Corp., a large and successful manufacturer of medical devices, submitted a new machine to the FDA for approval. This machine was called the Advanced Breast Biopsy Instrumentation System. The company claimed that the machine was to be used only for taking biopsies of breast tumors suspected of being cancerous. Cancer is a word that any family in America hates to hear. Many Members of this body, many Members of the House of Representatives and so many American families have been touched by cancer. There are few people listening today whose family has not been touched by cancer in some way. With the increasing number of breast cancers, this particular medical device is the most offensive, because the principal disaster is not only contracting cancer, but it is in the failure of being able to diagnose it and treat it effectively.

What has the U.S. Surgical Corp. done? The company claimed that the machine was to be used only for taking biopsies of breast tumors suspected of being cancerous, but the machine was designed to excise a piece of tissue 50 times as large as other biopsy devices already on the market. It was obvious from the machine's design that it was intended to remove breast cancer tumors, not simply take samples for biopsy.

Maybe it works. Maybe it is a major breakthrough. Maybe it can do all the things that the U.S. Surgical Corp. says can be done. Wouldn't that be wonderful? But we don't know. Maybe it doesn't. Maybe it doesn't work. Maybe when the doctor says we have excised the tumor, it doesn't do it completely. We don't know. Maybe when that woman walks out of the doctor's office or leaves the hospital, she is still in danger. She believes she has been treated effectively, but maybe this device isn't effective at removing tumors. Then there is the possiblity that in 4 weeks, 5 weeks, 6 months, 1 year, 1½ years, the cancer is still present and life and health are still at risk.

Why are we taking a chance, Mr. President? Because the medical device companies want this provision.

It was obvious from the machine's design that it was intended to remove breast cancer tumors. In fact, we have obtained a videotape, made in Canada, that demonstrates that the company knew it would be used for that purpose, despite their false claims to the FDA.

Here you have the U.S. Surgical Corp. saying to the FDA that we have a small biopsy needle the size of the lead in a pencil, that will be used to check a tumor, returning to the FDA for approval of what they label as a substantially equivalent medical device. Under this legislation—even though the company is out advertising that medical device for an entirely different purpose, for which they have not provided any health or safety information to the FDA and under this legislation—FDA would have to approve it. Despite the fact the FDA knows the device will be used for another purpose. Under this bill, the FDA could not say, ''Provide the information to show that this is safe and effective.''

This is the example, Mr. President. We are talking about cancer—breast cancer. We are talking about 1 out of 7 women who are going to be affected at some time in their lives. We know the enormous legitimate concerns that women have, that mothers have, that daughters have. And we are going to say we are prepared to allow them to have less than the best protections we can offer?

Mr. President, under this section of the FDA bill, the FDA would be forced to approve the new device without any evidence on the safety and effectiveness for new uses. American women do not want to die from breast cancer because the companies are allowed to sell devices whose safety and effectiveness have not been demonstrated.

No Senator would want their wife or mother or daughter to be subjected to such an untested device solely because a greedy company wants higher profits. The issue goes far beyond the products to excise breast cancer. It applies to lasers to treat prostate disease, stems to be placed in carotid arteries, imaging systems to detect breast cancer, and a host of other treatments for dreaded diseases.

Public health professionals will tell you as we continue to develop new technological advances this problem will only grow along with the threats to public health and safety. We will be rolling the dice. How many people are willing to roll the dice for a member of their family and use a medical device that has not been adequately tested? The companies are out there, Mr. President, and they won't mind if we roll the dice. Are we going to permit that?

This provision will give unscrupulous companies incentives to lie to the FDA. It will penalize ethical companies who are truthful and doing the necessary testing to demonstrate that their products are safe and effective. Most of all, it will put the health of the American people at risk so that a greedy few can increase profits. Companies that hope to benefit by weakening the FDA are already powerful and profitable. They believe they have the votes to push this disgraceful provision through the Senate—and this morning they probably would have. It is absolutely untenable and outrageous and unnecessary that we would, except to provide additional profits for a company that will use this loophole to get their devices on market earlier.

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 on Tuesday, 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 labels. Let me make it very clear that the Tuesday vote will not be the end of the story. We will continue to fight to keep this provision from becoming law, and I believe we will succeed in the end. The FDA bill has many constructive elements, but this disgraceful provision should be eliminated. The false or misleading label should have no place in the approval of medical devices. Unscrupulous manufacturers do not deserve a free ride at the expense of the public.

Mr. President, what we are talking about is S. 830, and section 404, which prohibits the FDA from reviewing the safety of a device for uses not listed by the manufacturer.

This provision handicaps the principal agency of Government that is charged with safety, and we are writing into the law language that will prohibit FDA—which is the agency charged with protecting the American people from unsafe pharmaceutical drugs and medical devices—from doing its job. The FDA would be prohibited from reviewing the safety of a device for uses not listed by the manufacturer.

What our amendment says is, OK, we'll prohibit the FDA from reviewing the safety of a device for uses not listed by the manufacturer—unless the label is false or misleading. How can Members of this body say that they will refuse to stand with those of us who support the Reed amendment that says ''unless the label is false and misleading''?

We have the example of U.S. Surgical Corp.'s biopsy needle. A needle designed to extract a small amount of cancerous tissue, maybe the size of a pen or the lead of a pencil. Now what has the company done? It has developed a much larger device that may be able to take a biopsy, but which, in fact, is primarily designed for tumor removal. But all they will have to be able to do is show that they are substantially equivalent.

Under this proposal, the FDA will not be able to look at what the real purpose of this medical device is. We know what the U.S. Surgical Corp.'s real purpose for this medical device is. We know because we have seen the advertisement they have already prepared. This device which can take out 50 times more material than its predecessor—50 times more material—is not intended to be used for a biopsy, but is designed to excise the tumor. Maybe it can do it well, Mr. President. Maybe it is an important and major step forward. But any woman who has a procedure done with this device, will not be able to judge from the safety information that is provided to the FDA because there has been none provided. They won't know the results of testing conducted on this device because there have been no tests submitted to the FDA. They won't know whether this is a successful device because there is no information to indicate its success.

We are talking about women and breast cancer. We are talking about a medical device that is put forward with virtually no intention for use for biopsies. Where an earlier smaller, less intrusive device already exists for biopsies. A device that is going to be used to remove tumors, and is advertised to doctors as such.

What are the American doctors supposed to believe? They say, ''Well, we have FDA approval.''

''Well, isn't that fine. Then it must be all right, it must be safe.''

But no doctor is able to give that kind of assurance to a woman who is going to have this particular medical device utilized to excise a tumor, because it has not been done. How would our amendment change that? Our amendment would say that if the advertising is false or misleading, that anyone would be able to see that this particular device is going to be used to excise a tumor—U.S. Surgical, show us your studies, show us your information that would indicate that this is safe for American women. Show us where you have tested it to show that it does the job. Show us that it will do what you are advertising will be done. Let us examine that. And if that is the case, we approve it for that particular purpose.

This provision is unconscionable, Mr. President, when you look at the tragedies that have resulted from device disasters. We are not talking about Band-Aids and tongue depressors. We have seen medical device disasters which have cost the lives of hundreds and thousands of American consumers.

I was here and chaired the hearings on the Dalkon shield IUDs, which injured tens of thousands of women. Their injuries included pelvic inflammatory disease, sterility and perforated uteruses. That is because, Mr. President, with the Dalkon shield we found out that bacteria crept through the string of the device and caused infections in American women.

As a result of this disaster in the mid-1970's we set up protections for the American consumer with regard to medical devices to ensure that they would be safe and efficacious. Prior to the mid-1970's we did not test for safety and efficacy. We want to be able to make sure that the FDA is going to be able to test for safety and efficacy on a product that is going to be the predominant use of a particular medical device.

In another example of a human and public health tragedy involving a medical device, the firm Telectronics marketed a pacemaker wire for use in the heart. Twenty-five thousand of these pacemakers were marketed, beginning in 1994, before it was discovered that the wire could break, cause damage to the wall of the heart, or even destroy the aorta.

Why are we being asked in the U.S. Senate to deny the FDA adequate authority to protect the American people? Safe and effective medical devices is what the American public deserve and it is what Senator REED's amendment to section 404 would ensure.

Mr. President, another example is patients with defective Shiley heart valves who died, underwent painful and dangerous surgeries to remove the valves.

The company increased the degree of a particular vent from 60 degrees to 70 degrees. But because FDA had the power to examine whether this presented any additional health hazards to the American people, the modified valve was not marketed in the U.S. The company sold them in Europe. And the modified valve had six times the amount of disasters in the hearts as a result of that 10-percent increase. Hundreds of deaths resulted in Europe and thousands and thousands of people put at risk.

Then we have the angioplasty catheters that failed causing dozens to suffer emergency coronary bypass surgery, cardiac damage and death.

Mr. President, this is what we are talking about. We are talking about S. 830 which allows false and misleading labels for medical devices. S. 830 could result in the surgical needles that do not safely remove the breast cancer tumors.

FDA has been asked to clear surgical lasers for marketing despite the lack of safety data submitted to support the clear intent of the manufacturer—to cut prostate tissue. What we have are laser manufacturers that say, ''Well, all right, we want to use lasers in the operations on the prostate. And a certain amount of cutting is going to be necessary.'' They effectively say, ''Our laser is substantially equivalent to lasers that are already approved for general cutting,'' when the intention of the company is to use the newer designed laser not just in the ordinary cutting of tissues but for use in a prostate operation. Therefore, through this loophole, a device may be used for a purpose for which it was clearly designed but not adequately tested.

We have also, Mr. President, the example of contact lenses that may cause blindness. FDA can tell by the materials and design of a contact lens that it will be used for extended wear. But a company could submit data only on a labeled use of daily wear and FDA would be prohibited from asking for additional information on extended wear. Extended wear lenses that are not adequately tested may cause ulcers on the cornea and can be sight-threatening.

Mr. President, we may see in the future digital mammography screening machines that may misdiagnose breast cancer. We have seen enormous progress being made in terms of mammography with all the benefits of early detection of breast cancer which permits early treatment and saves lives.

These advanced technologies, Mr. President, may be able to perform diagnostic mammography but not mammography screening. There is an important difference. The screening is used to find out whether there are tumors as compared to examining a tumor for diagnostic purposes to make a determination of the appropriate kinds of medical treatment. A mammography instrument labeled for use as a diagnostic machine could have features specific to mammography screening and the safety data should be submitted to support that use.

Why do we have to take a chance on it? What is the compelling need to take a chance on women's health? Why shouldn't we say to FDA that if they have reason to believe that the primary purpose of this new machine is going to be for screening and the label is false and misleading that they can ask for safety data for the intended use.

Why should we hamstring the FDA when we know that the purpose for these new kinds of medical devices are not consistent with what is being labeled by the manufacturing company?

(Ms. COLLINS assumed the chair.)

Mr. KENNEDY. Under this legislation, the FDA, even though they know this might provide an important safety question for the American people, are handcuffed from doing anything about it. Why are we doing this to the American people? For what purpose? Are we that far behind in terms of online medical devices? We are not.

I can put in the RECORD the various publications of the medical device industry that show they have been making important progress over the past several years, and the profits have gone up, and a different atmosphere is out there to bring the various products on the market. A GAO report has shown that medical device review times are down.

So if that is the case, why, now, are we going to rush these devices on through when their purposes are clearly different from the labeled use and for which we do not have adequate safety data? This is a major step back, and puts the public at risk.

Madam President, we can go through what some of the dangers are when we find various devices are used for one purpose and then changed and altered for another purpose. In this diagram we have the long bone screws that are used effectively to mend bones. I have a member of my family that has had those implanted and they have been enormously effective. A member of the family had a broken shoulder, and I went back to see her 5 days later and she was able to move her arm, move her shoulder. It was unbelievable when you think of what most of us understood would be a recovery time of several months.

We have seen how, when used properly, how they can help mend a bone, give stability to bone, and be effective in helping and assisting those people with that kind of a break to long bones. Then what happened? We found out the screws were being sold to back surgeons for another purpose. They were marketed for use in the spinal column to give stability to the spine.

What happened? Madam President, the screws broke, and they were disasters for many Americans who had the operation. Those screws were not adequately tested for use in the back and should not have been used in that manner.

These examples are what is happening every day. We have the biopsy needle, the contact lenses, we have the long bone screws, and the list goes on. We ought to be very careful about denying the Food and Drug Administration needed information in terms of their safety and effectiveness.

Now, Madam President, we cannot prohibit off-label use of medical devices. We are not doing that in the proposed amendment. What we are saying is that when you have on the face of it a clear intention that the new proposal that is being submitted to the FDA is going to be used clearly as a dominant use for another purpose, such as the breast biopsy instrumentation, that the FDA ought to be able to look at the safety and efficacy of the device.

Why are we going through this, Madam President? Why are we tying the hands of the agency that has the skill and the knowledgeable people to try to protect the public?

All we are saying is when there is a clear record on the use of a device, make sure the American public's interest is going to be protected and not denied. All our amendment says is when the label is false and misleading, the FDA is going to be able to look behind it. That does not seem to me to be a very dramatic or radical kind of resolution to this particular issue.

We have indicated four or five different types of compromises to this particular measure to try to protect the public's interest. We are ready to look at different language to protect the public's interest. But the guiding light is, when we know a medical device is being submitted with false or misleading information and that the device is clearly designed for another purpose, the FDA should be able to look at the safety and the efficacy of the device.

We have seen in recent years the dangers of simple changes like the absorbency of tampon material. It looked like it was just a very modest kind of alteration or change. But women were injured, and subject to infections that caused toxic shock syndrome sometimes leading to death.

Why are we doing less for the protection of our consumers? Why are we restricting the protections of the American consumers? We are going to have a difficult enough time trying to make sure that when medical devices go through vigorous requirements for safety and effectiveness that they are indeed safe and efficacious. Some mistakes may very well be made. At least we will know we have given it our best shot. At least we will know we have given to the American people the best we have, in terms of scientists and researchers, to try to make sure those products are safe.

On this particular provision, for the first time in 23 years, we will be effectively rolling back public health protections at FDA. We will be effectively handcuffing the FDA on a major matter that affects the health and the safety of the American people. It is unwise. It is unjust. There is absolutely no rationale or justification for this provision other than the profits of the medical device industry.

Madam President, I cannot help but believe as the American people understand this issue, understand the health implications, understand on the one hand we are risking the public health of the American people in favor of the profits of the medical device industry, that they will be heard on this issue. This provision puts at serious risk the health of the American people—that is what the HHS says, that is what the Women's Health Network says, that is what the principal consumers groups that are out there to protect the American people say.

What is the benefit on the other side? The profits of unscrupulous medical device manufacturers. It is not only going to be the profit of those individual companies like U.S. Surgical, but it will be an invitation to other medical device companies to go through a loophole, because otherwise they will be put at a competitive disadvantage. It makes absolutely no sense.

I hope very much, that when the Senate addresses this issue in the next week, we can have the support of our colleagues and we will have the support of the House of Representatives and we can move forward with an otherwise reasonable bill.

I see my friend and colleague, Senator DURBIN, here on the floor. I yield the floor.

The PRESIDING OFFICER. The Senator from Illinois is recognized.

Mr. DURBIN. It is my understanding under the unanimous consent I am allotted 30 minutes, 15 minutes on each side, on two separate amendments, amendments 1139 and 1140. Is that correct?

The PRESIDING OFFICER. The Senator has the right under the agreement to call up either amendment 1139 or 1140. When he does so, he will have 30 minutes on each amendment, equally divided.

Mr. DURBIN. I thank you, Madam President.

AMENDMENT NO. 1140

(Purpose: To require that entities and individuals accredited to conduct reviews of device notifications be subject to the conflict of interest standards that apply to employees of the Food and Drug Administration)

Mr. DURBIN. I call up amendment 1140.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Illinois [Mr. DURBIN], for himself, Mr. FEINGOLD, and Mr. JOHNSON, proposes an amendment numbered 1140.

Mr. DURBIN. Madam President, I ask unanimous consent reading of the amendment be dispensed with.

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

The amendment is as follows:

In section 523 of the Federal Food, Drug, and Cosmetic Act, as added by section 204, strike subsection (b) and insert the following:

''(b) ACCREDITATION.—

''(1) IN GENERAL.—Within 180 days after the date of enactment of this section, the Secretary shall adopt methods of accreditation that ensure that entities or individuals who conduct reviews and make recommendations under this section are qualified, property trained, knowledgeable about handling confidential documents and information, and free of conflicts of interest.

''(2) STANDARDS.—In adopting the methods of accreditation, the Secretary shall ensure that the entities and individuals—

''(A) are subject to—

''(i) the conflict of interest standards applicable to employees of the Food and Drug Administration under subpart E, H, and I of part 73 of title 45, Code of Federal Regulations (as in effect on January 1, 1996); or

''(ii) if the standards described in clause (i) would be inappropriate for the entities and individuals, conflict of interest standards developed by the Secretary that are—

''(I) based on the standards described in clause (i); and

''(II) modified, as appropriate, to apply to the entities and individuals; and

''(B) are not subject to the conflict of interest standards under subpart J of such part.

''(3) PUBLICATION.—The Secretary shall publish the methods of accreditation in the Federal Register on the adoption of the methods.''.

Mr. DURBIN. Before proceeding, I ask unanimous consent Senators FEINGOLD and JOHNSON be added as cosponsors of amendment 1140.

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

Mr. DURBIN. Madam President, the bill before the Senate is one of the most important we will consider during the course of this Congress. I don't believe that is an overstatement. This bill addresses the future of the Food and Drug Administration, an agency which we literally entrust with the safety and efficacy of thousands of drugs and prescriptions which we keep in our home and give to members of our family.

This agency has to be above reproach, it has to be efficient and responsible. This amendment No. 1140 that I am offering is an attempt to make certain that the integrity of the Food and Drug Administration is not compromised by this bill. I think overall this is a good bill. There are some areas Senator KENNEDY and I and others feel need to be addressed. But the one part of this bill that I address with this amendment is one of great concern.

We are now going to say that we will take outside of this Federal agency, outside of the Food and Drug Administration, the review of medical devices. We will say to third parties, which are hired for the purpose of making these reviews, that they will decide whether or not a medical device is safe for the American people and whether it's effective; and having made that decision,

that company will then have an opportunity to sell that device across America. We as consumers will believe, as we should, that we can trust that judgment.

The purpose of amendment No. 1140 is to address the question of whether or not the third-party reviewers are credible. This bill dramatically expands the ability of medical device companies to purchase their own third-party reviewers. Senators FEINGOLD and JOHNSON and I are offering this amendment so that it's clear that it's only reviews and not approvals themselves that can be bought under this system.

Up to 60 percent of medical devices going through the premarket notification process could utilize the outside reviewing system. A program of this magnitude will not permit the same level of close monitoring and oversight by the FDA as is currently undertaken. There are fewer than 10 firms that are credited for this purpose. That is why explicit anti-conflict-of-interest standards need to be laid out in the law. We should not cut corners when it comes to the question of conflict of interest. If we are going to give to these companies the authority to review and approve medical devices to be used across America, let us have no question that they are doing it in a professional way.

The Project on Government Oversight, a nonpartisan, nonprofit Government watchdog group, described the bill's provisions in this area as grossly inadequate, and the Government Accountability Project, which is another watchdog group, described the current FDA regulations for their pilot program as ''inadequate to guard against conflict of interest.'' Both groups, along with a long list of consumer and patient groups, urge the Senate to adopt this Durbin amendment.

Given the importance to the public of keeping the approval process untainted by monetary influence, we must ensure that there are strict anti-conflict-of-interest standards for product reviews.

Only the vaguest language possible on the issue of preventing conflicts of interest is currently contained within the bill. Let me tell you what it says on page 16:

> The Secretary shall adopt methods of accreditation that ensure that entities or individuals who conduct reviews and make recommendations under this section are qualified, properly trained, knowledgeable about handling confidential documents and information and free of conflicts of interest.

Nowhere does the bill mention what we mean by ''free of conflicts of interest.'' What are the standards that we will use? No reference point is given for a basic minimum that would satisfy and ensure unbiased review.

Senator HARKIN was successful in adding language that allows the FDA to look at contractual arrangements between an outside reviewing laboratory or entity and the company whose product is being reviewed. We would like to go a step further and add more protections against approval peddling.

FDA employees themselves are subject to a wide range of anti-conflict-of-interest regulations. This amendment seeks to establish basic requirements, and it is very simple. It merely asks that outside reviewers not be allowed to have a financial interest in the company they review.

Think about what I just said. The outside reviewer, which will decide whether a medical device should go on the market, should not have a financial interest in the company that he is reviewing. That seems rather simple to me. Nor should they be allowed to receive gifts from a company that has products being reviewed, and they should not be actively looking for a job with that company while they are in the process of making their review. No gifts, no job offers, no stocks. It seems simple.

It is amazing to me that we are arguing over this provision. I would have thought this would have been accepted long ago by the majority. But instead, there is a fight as to whether or not we are going to demand the highest level of integrity and honesty when it comes to these third-party reviewers.

Let me tell you why this is critically important. The approval by the FDA of a device can have a dramatic positive or negative economic impact on a company. If the FDA rejects a device and doesn't approve it, a stock can languish for months, if not years. If the FDA approval goes through, it is the seal of approval, and that company knows that there is money to be made.

Look at this chart indicating what happened in four different instances with medical device companies when there was an FDA approval. QLT Phototherapeutics, Inc. Look at how the stock shot right up with FDA approval. ATL Ultrasound. After FDA approval, it skyrockets. Thoratec Laboratories Corp., the same story; the stock is moving along slowly, and then, after FDA approval, it climbs dramatically, 50 or 60 percent in 1 day. It was the same thing with Integra LifeSciences Corp.

What we are trying to say is, the people making the decision on behalf of us, as consumers, should make that decision without any concern about the bottom line of that company. Would you think twice about giving to a reviewer the decision to approve a product if you knew that reviewer owned a thousand shares of the company that made the product? I think most of us would. What if that reviewer and his family had just come back from a Caribbean vacation, paid for by the company that submits the medical device for approval, or if that reviewer happens to have sent his resume to that company a week before, saying, ''I would like to have a job with you and, incidentally, I am working on your FDA approval,'' with a wink and a nod? That doesn't make me feel any better about what we are dealing with here.

The Durbin amendment basically says, let's get rid of the doubt as to whether or not people are going to use the highest professional standards. We should not cut corners here when it comes to conflicts of interest, when it comes to these outside laboratories. We have to demand the highest standards of professionalism.

Time and again, companies have been shown to make dramatic profits with FDA approval. Dr. Kessler, a former head of the FDA, said, ''Make no mistake, they talk a lot about approvals in Europe and in other countries. They can be lucrative, they can be profitable. But if you can get the approval of the Food and Drug Administration of the United States of America, it is a seal of approval recognized worldwide. The product you are trying to sell becomes a winner overnight.'' Shouldn't the people making the decision as to whether or not this product is safe and efficacious be doing it on the basis of science, rather than on the question of their own financial interest?

The medical device industry produces over $50 billion annually in sales. In fact, in a recent article in Medical Economics entitled ''Why Medical Stocks Belong in Your Portfolio,'' the medical device industry was described as ''a hot market that's only getting hotter.'' It doesn't take much imagination to see why we would not want to allow a reviewer to have stocks in the company they were reviewing. The connection between FDA approval and stock gain is just too clear. The money stakes are high for investors; however, the stakes are even higher for the patients who rely on these devices.

The approval of an unsafe drug or device can have a devastating impact. Doctors, hospitals, nurses, and families rely on these decisions. If a corner is cut, if this reviewer has a financial interest and decides, well, I am just going to tip it a little bit toward my own stock portfolio here, the losers ultimately are the innocent people. Reviews must be of the most stringent nature and must be carried out without any outside corrupting influence.

Surely, it is not too much to ask that a reviewer be prevented from accepting a gift or a loan from a company that he or she is reviewing. I can't imagine we are debating this. Should we allow the reviewer to take a gift from the company he is reviewing? That is an obvious conflict of interest and one that we can address explicitly. The language in the bill, unfortunately, is loaded with ''weasel'' words—weasel words about what a conflict of interest might be. We should make it crystal clear. It would give this bill more stature. It is an important bill and it should have that.

Furthermore, a reviewer or their spouse or minor child should not be allowed to have a financial interest in the company being reviewed. That means owning stock or a mutual fund that has more than 10 percent invested in the company. This is all laid out in subpart H of the regulations that we refer to in our amendment. A final restriction that we are asking for is that

the reviewer may not be actively soliciting future employment within the company they are reviewing.

Our amendment, which sets out guidelines to prevent tainted reviews, allows the Secretary to modify such guidelines where it would be appropriate for outside reviewers.

Therefore, if any provision included in these regulations would clearly not apply or not be appropriate, the Secretary can modify it. We have that flexibility built into our amendment.

I have heard some of my colleagues argue for more flexibility. I believe our amendment gives enough. It sets out specific standards. I challenge any of my colleagues to suggest that a gift ban or a financial interest ban would be unreasonable. It would be a sad day in America if reviewers expect a gift, or a job offer, or some other financial gain in order to review a medical device and, worse, that we were not willing to categorically repudiate a potential for such ''approval peddling.''

This industry and their products are too important to the American people. These are literally life-and-death products. We should take a firm stand and specifically enumerate these basic standards within this legislation to prevent even the potential for the corruption of this process.

Madam President, I yield the remainder of my time on this amendment.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. JEFFORDS. Madam President, first, let me very briefly review where we are. There has been considerable debate up to this point. I think it is important for me as the chairman of the committee to remind people as to where we are.

We have before us a 152-page bill, which is the first real overhaul of the Federal Food, Drug and Cosmetic Act in the last 30 years. We have taken little tweaks here and there, but it has not been thoroughly reviewed and brought into the modern world.

Out of that 152 pages, we are now spending most of the time debating on 2 or 3 pages. That is why the minority ranking member has praised the bill, but then picked on one—basically, we are here because of one provision, which is 404. On some standards, we cannot agree on the precise wording.

So everybody agrees on almost all of this bill. The amendment that is being offered by the Senator from Illinois does get into a very, very important area, and we do not disagree with that. We praise him for having given us the opportunity to review, to restudy, and determine as to whether or not the provision he is striking with his amendment and replacing is necessary or appropriate. We have concluded—I say ''we'' because I am sure that Senator KENNEDY joins me in this statement—that we adequately take care of the conflict of interest in this bill.

Let me go through what his amendment attempts to do and what the bill provides. First of all, the Senator's amendment, at best, duplicates the third-party provision that we have in the bill now and, at worst, it unnecessarily constrains the agency.

Section 204, conflict of interest protections, which is being stricken and replaced, provides a full statutory directive to the agency 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(b) reads:

> Within 180 days after the date of enactment of this section, the Secretary shall adopt methods of accreditation that ensure that entities or individuals who conduct reviews and make recommendations under this section are . . . free of conflicts of interest.

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.

We believe the FDA is the one that can best understand what will be effective in this regard. The agency has already developed extensive conflict of interest guidelines as a part of its existing third-party program. The notice of April 3rd, 1996, has almost a full page of Federal Register type laying out the standards, including restrictions if ''the third party, or any of its personnel, involved in 510(k) reviews has any ownership, or other financial interest, in medical device, device manufacturer, or distributor.''

That is a quote from the wording.

The agency has not identified any difficulties in the implementation of the conflict of interest guidelines, and it has expressed no concern about the conflict of interest provisions, as drafted. We have reviewed the FDA standards that appeared in the Federal Register on Wednesday, April 3, 1996, at page 14794, and believe that they adequately and appropriately address the problems which we are reviewing here. The agency's strict guidelines resulted in the elimination of 30 of the 37 applicants that originally sought accreditation. That means, obviously, that the FDA policy is effective, and it has outlined and again recognized—as the Senator from Illinois is aware—that there are problems that must be protected against. And we agree with him on that.

The Durbin amendment attempts to set standards but in fact may constrain the agency. In fact, the standards cited are reportedly outdated and do not reflect recent revision. This may explain why in the second part of the amendment Senator DURBIN effectively gives the agency discretion to craft appropriate guidelines. Section 204 provides a full statutory directive to the agency to prevent conflicts of interest that may be involved with both an individual reviewer and the reviewing organization. Therefore, it appears to us that the amendment, although well-intended, may even make it more complicated than necessary, and that we will end up perhaps with a less effective system than is already contained in the bill.

Madam President, I ask, if we yield back time, what happens to that time? May we be advised on that?

The PRESIDING OFFICER. The time would just lapse. I believe the Senator from Illinois has yielded his time on this amendment. If the Senator from Vermont yields the remainder of his time, then the Senator from Illinois could call up his second amendment.

Mr. JEFFORDS. If at the end of the time we, for instance, end up instead of using an hour on the Durbin amendment using half an hour, does that time fall into the same category as the last half-hour of this unanimous consent? So we have an hour in that last part of the unanimous-consent request.

The PRESIDING OFFICER. The Chair is not clear about the Senator's question. We would proceed to the next amendment, and there would be 30 minutes equally divided on that amendment. Then we would stay on the bill, if that is the wish of the managers.

Mr. JEFFORDS. Madam President, I believe I understand the ruling of the Chair. I appreciate that.

The PRESIDING OFFICER. Regardless of the amount of time we use today, on Tuesday we will have 5 hours on the bill itself equally divided.

Mr. JEFFORDS. I appreciate that clarification because this does get a little bit complicated as we move forward. This is an important issue.

I think at this time I will just again restate that we believe that the bill as written adequately covers the problems of the conflict of interest situation.

We commend the Senator from Illinois for really focusing attention on this and bringing it to our attention again so that all of my colleagues hopefully will understand that the bill—this is agreed to I believe also by Senator KENNEDY—is effective in accomplishing the goals of the Senator from Illinois.

So, again I commend him for what he has done.

Madam President, I yield the remainder of my time.

The PRESIDING OFFICER. All time on the amendment has been yielded.

AMENDMENT NO. 1139 TO MODIFIED COMMITTEE SUBSTITUTE AMENDMENT NO. 1130

(Purpose: To eliminate provisions relating to the discretion of the Secretary of Health and Human Services to track devices or to conduct post-market surveillance of devices)

Mr. DURBIN. Madam President, under the unanimous-consent request, I would like to call up my amendment 1139.

The legislative clerk read as follows:

> The Senator from Illinois [Mr. DURBIN], for himself, Mr. HARKIN, and Mr. JOHNSON, proposes an amendment numbered 1139 to the modified committee substitute amendment numbered 1130.

The amendment is as follows:

On page 46, beginning on part 5, strike sections 605 and 606.

Mr. DURBIN. Madam President, I ask unanimous consent that Senator HARKIN be added as a cosponsor of amendment No. 1139.

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

Mr. DURBIN. Madam President, the conflict of interest provision which we have just discussed is a very important one, but the one which I am addressing with this amendment may be even more important.

Consider this possibility. On Monday of next week you go out to buy a Pontiac. On Tuesday when you go to the doctor, he says, ''You are going to have to go to the hospital, and you are going to need a pacemaker.'' In 1 week you have a Pontiac and a pacemaker. What is the difference? When you bought the Pontiac, General Motors took note of your name and address. If anything went wrong with the Pontiac, they would contact you in 6 months, 1 year, 2 years, or even later, and say, ''Bring it in. It needs to be fixed.'' It might not be safe, if you didn't. However, under this bill the pacemaker that you are going to have implanted by the surgeon perhaps a few days later doesn't have the same kind of following. Why? Because we let that exist.

Why would we let people have lifesaving devices implanted in their bodies and not keep track of that fact? That is what this amendment is all about, because this bill, as good as it is, takes away the mandatory requirement that we have surveillance and tracking of these high-risk devices that can be implanted in people.

I am glad to be joined by Senators HARKIN and Senator JOHNSON in offering this amendment which strikes the sections of the bill that undermine many of the patient protections for medical devices put in place by the Safe Medical Device Act of 1990.

This act of 1990 instituted a mandatory surveillance program to identify quickly any potential problems with approved high-risk devices. A mandatory tracking system to locate patients in the event a safety recall was also added.

Sections 605 and 606 in this act are nothing more than a backdoor attempt to eliminate these programs that industry considers burdensome. Yes, they are burdensome. To keep track of the name and address of each person who is given a pacemaker is a big burden on industry. But what kind of burden is it on the patient when the pacemaker fails and the patient can't be found? I would suggest that it is a much greater burden. That is what this amendment addresses.

Proponents of sections 605 and 606 say that the FDA has not been vigilant with respect to overseeing these vital programs. Does anyone imagine they are going to be more vigilant in enforcing these safety protections when they are relegated to an optional or discretionary status? Especially given CBO's high estimate of this bill's additional costs to the FDA without any corresponding increase in funding. Pressure can only increase on the agency to curtail its efforts in discretionary programs.

Opponents of this amendment will point to the fact that the administration went along with this change. This point is in fact even more worrisome when you look at what types of devices we are talking about, and the tragedies that may occur.

Many of us remember the tragedies that resulted from the Bjork-Shiley heart valve failures. Extensive congressional hearings were held in the late 1980's examining what had gone wrong and how we might prevent future repeats of these terrible tragedies.

Over 300 people died in the United States from these heart valve failures, and over 1,000 worldwide.

After it was concluded that these heart valves were defective—after they realized the product had failed—over 50 percent of the patients with these heart valves couldn't be located.

One widow testified—and this is a tragic story—about how her husband, who had a Bjork-Shiley heart valve implant, suffered chest pains but had no idea that the heart valve was the cause of the problem. She was in a position to choose from two hospitals. She quickly raced to one hospital, and made the wrong choice. She went to the hospital that didn't specialize in heart surgery when her husband needed to live. She didn't know. Why didn't she know? She wasn't on the list. Her husband's name and address were not on the list to be notified that the heart valve he carried in his body was failing him.

What does tracking actually involve? It involves a patient—this is I don't think a burden from that perspective—filling out a registration form with their address so they can be located if there is a recall of a pacemaker, or high-risk device. Most companies make this request already.

What kind of devices are we talking about? Just about anything? No. There are 17 specific types of devices that require mandatory tracking. We are talking about heart valves; pacemakers and pacemaker leads; vascular stents; jaw, shoulder, and hip joint replacements; windpipe prosthesis; breathing monitors and ventilators.

It is hard to imagine the tracking of these high-risk devices could ever been made optional, and yet that is exactly what this bill does.

FDA has already complained that they find it extremely difficult to enforce this provision, and yet, instead of making it stronger and helping them with enforcement, this bill weakens it. It weakens the FDA's ability to make this kind of adequate tracking and surveillance available.

Automobile manufacturers are required to have a tracking system to notify those who buy cars. It even happens with motorcycles. Look at this. What a coincidence. In the Phoenix Gazette of Friday, January 11, 1991, there are two articles next to one another. Harley-Davison recalls its motorcycles. We have a problem here. It turns out that their brake calipers are defective and could cause their front wheels to lock while driving.

Right next to it, on Consumer Watch, jaw implants. It is found that the implants of Vitek of Houston caused bone degeneration. If we cannot track the people who bought the jaw implants through their surgeon, we can certainly find the owners of the Harley-Davidsons. Does that make sense?

I would like to submit for the RECORD a letter that I received from Victims Against Lethal Valves, a support group out of Pittsburgh for those who have suffered from defective heart valves. They urge the Senate to adopt my amendment. If you read this letter from the families of those who were caught unaware that they had a defective heart valve, you might think twice. I hope my colleagues will.

I ask unanimous consent that this letter be printed in the RECORD.

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

VICTIMS AGAINST LETHAL VALVES,
Pittsburgh, PA, September 16, 1997.

U.S. Senate,
Washington, DC.

DEAR SENATOR: As a Bjork-Shiley heart valve survivor and founder of VALV, a support group for people with the Bjork-Shiley heart valve, I strongly urge you to support Senator Durbin's amendment to S. 830 to maintain mandatory tracking and postmarket surveillance of high risk medical devices like heart valves.

The Bjork-Shiley heart valve experience was a major impetus to enacting these two provisions in 1990. Almost 1,000 people (world-wide, the device was marketed longer in Europe than in the U.S.) have died as a result of the fracture of the Bjork-Shiley valve. S. 830 makes tracking and postmarket surveillance of these very high risk devices discretionary rather than mandatory.

The Bjork-Shiley disaster highlighted the need to implement a systematic method for tracking the device recipients. When the FDA finally ''caught up'' with the significant numbers of Bjork-Shiley heart valve fractures and ordered the company to notify recipients of the valve's potential failure, what symptoms to look for, and what to do if these symptoms appeared, the manufacturer claimed that they had no record of how to find as many as half of the recipients. Should a defect in a device be identified, it is critical that device recipients be notified so they can seek medical attention.

The manufacturer knew that the Bjork-Shiley heart valve had a tendency to fracture very soon after it went on the market. But the firm conducted no systematic surveillance, and did not accurately report the information about problems it received to the FDA. Section 522 was designed to remedy this gap in reliable, verifiable information—so that the manufacturer would know, and the FDA could check—on problems with new post-1991 devices.

Most Market surveillance and tracking are consumer safeguards that were won with the lives of people like me and the members of

VALV. We urge you to adopt Senator Durbin's amendment and keep these consumer protections in place.

Sincerely,

ELAINE LEVENSON,
Founder.

Mr. DURBIN. Madam President, another key aspect of the Safe Medical Device Act, which this bill undermines, is the mandatory surveillance program for high-risk medical devices.

These surveillance programs are extremely important for early detection.

In some cases, the initial breakage of a device may not cause instantaneous harm. For example, in the case of the Telectronics Heart Pacemaker ''J'' Leads which are found to be defective in 12 percent of the patients with them, breakage didn't result in any harm until the next bout of heart arythmia. Surveillance of these leads identified problems in some patients. And this led to the notification of patients with these leads of the need to have them checked.

Likewise, in the case of the Bjork-Shiley heart valves, 300 Americans died when this tiny heart valve no bigger than a pen turned out to have a structural defect.

This is a blowup of a photograph of a heart valve. And it shows a crack in one of these struts on this heart valve. This crack alone wouldn't be lethal. But when the strut next to it cracks, it is too late. You are going to die unless you have immediate surgical relief.

We believe that once you know that the heart valve is in danger, you should know the people who have received it so that you can notify them so that they can go to a doctor and have the necessary test to see if they are in danger.

Early detection and correction could have prevented many of the 300 deaths that occurred when this Bjork-Shiley valve failed.

Let me tell you about another case, teflon jaw implants. People with the temporal mandibular problems—TMJ—have turned to these implants as a way of dealing with a maddening situation, and a very painful one.

In the case of the implants made by Vitek in the 1980's, early detection unfortunately wouldn't help. These implants splintered and caused massive corrosion of jaws and skull due to the triggering of inflammation and other immune responses. By the time the patients suffered pain, for many of them it was too late. Many of the patients required the removal of much of their jawbone structure because this implant had failed. Even some of their skulls were exposing their brain because of this subsequent surgery.

If a surveillance program had been in place prior to the Vitek jaw implant defect, many of the patients would have been able to have their implants removed prior to the full deterioration of their jaws. In fact, many individuals would have been saved altogether from ever having the implants inserted in the first place.

Vitek jaw implants were first marketed in 1983, but it wasn't until 1990 that FDA sent out a safety alert, and in 1991 issued a recall.

Think about that, 7 or 8 years later we finally realized that there was a problem with this implant.

At that stage, between 25,000 and 26,000 patients had received these implants. The rate of failure was nearly 100 percent.

Here on these charts you see some of the sad stories of the victims. These are troublesome to see, but think about these poor people and what they went through. Asking these companies to keep track of the people who received these implants is not unreasonable when you take this lovely young lady in this picture and look how she deteriorated after these implants started to fail. And the same thing, this lovely lady in this picture and what happened to her face as a result of the implant failure. On this one, look at this. After the implant failed, look what happened. It actually emerged from the skin.

Is this something that we want to think twice about? I would think that as a matter of just decency we should include in this bill tracking and surveillance to try to avoid this from happening to anybody in the future.

Some may try to argue we still have the medical device reporting system. That is no substitute for company surveillance. The medical device reporting system is basically a body count program. We hope that we could have a strong program to detect problems before death and injury. That is exactly what a surveillance program does. Many medical devices on the market are approved on the basis of data from trials of shorter than the lifespan of the device. Vascular stint, approved by the FDA this year, was approved on data after 6 months of use. FDA requires surveillance to check if the device will be safe for a longer period similar to the life expectancy of the device.

I would like to also bring to the attention of my colleagues a recent GAO report on the inadequacies of the medical device reporting system before anyone starts arguing that it is a substitute for surveillance programs. This report from the GAO states that between March 1994 and April 1995, a backlog of about 48,000 malfunction reports from manufacturers accumulated at the FDA. Many of the malfunction reports, according to GAO, were not entered into the adverse event reporting system until 1996—almost 2 years in some instances. In fact, the House device bill suggests eliminating even this report because of its inefficiencies.

In contrast to that system, the tracking and surveillance programs which I am pushing for are much more effective. This January a good example of this was seen in the case of a runaway pacing implantable cardioverter defibrillator manufactured by Ventritex. Due to their surveillance programs, Ventritex realized the clock in the defibrillator was running radically.

For those who are not familiar, it is a situation where a person has a heart problem where the heart beats irregularly. The defibrillator feeds a shock to the heart to stop the defibrillation and save the person's life. The company realized it was not working right. That kind of problem could be fatal for individuals with these defective devices implanted. On January 15, the company met with FDA and proposed a temporary fix that could set these devices straight. Within less than a month, over 97 percent of the 5,600 patients were found and their devices were reprogrammed. Thousands of lives may have been saved by this effective tracking and surveillance.

Shouldn't this be the case for every lifesaving device? Why does this bill water it down? Why does this bill take away the tracking and surveillance that would give us the necessary information to track this very sort of thing to save people's lives.

In the pretracking days, before we started doing this, I have a letter from a lady named Charlotte Evans. She only discovered this year that her teflon jaw implant might be defective even though the product has been off the market for over 7 years, but no tracking program had been in effect when she bought it. For 11 years since she had this device implanted, her jaw had been undergoing deterioration due to this defect, but she had no notice of any problems with the device.

I think the final chart says it all. Mandatory surveillance leads to early detection of problems, which results in fewer deaths and less serious injuries. Mandatory tracking gives us effective recall and saves lives. To rely only on the medical device reporting system is to treat American people as though they were lab rats while we wait for the body and injury count to mount.

Let me tell you who supports my amendment: Victims Against Lethal Valves, the TMJ Association, the National Breast Implant Task Force, NORD, AARP, Consumers Union, Consumer Federation of America, Bazelon Center for Mental Health Law, the American College of Nurse-Midwives, AMFAR, the AIDS Action Council, DES Action, Center for Medical Consumers, Committee for Children, Human Rights Campaign, National Women's Health Network, Public Citizen, and the Treatment Action Group.

I hope that it will also be supported by a majority of my colleagues. If any of us believed for a moment that someone we love, a member of our family, was about to undergo a surgery and have a device implanted in their body and then be lost so that if something is found wrong with that device later on and their lives are in danger, we would think twice about this provision in the bill.

Let us keep tracking and surveillance in the bill. The medical device manufacturers must accept the burden

of keeping track of the people who receive these devices. If something goes wrong, it is literally our only way to avoid injury and save lives.

Mr. President, at this point I yield back the remainder of my time.

The PRESIDING OFFICER (Mr. BURNS). The time of the Senator from Illinois has expired. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, I again commend the Senator from Illinois for focusing on some of the most critical problems that we have with respect to devices. However, I would only point out that the bill as is at this time is subject to a bipartisan agreement with full concurrence of FDA.

At this time I ask unanimous consent that Senator COLLINS be recognized for up to 10 minutes as if in morning business and that upon completion of her remarks the Senate return to the consideration of S. 830 and the Durbin amendment.

The PRESIDING OFFICER. Without objection, it is so ordered. The Senator from Maine is recognized for 10 minutes.

Ms. COLLINS. Mr. President, I thank the distinguished manager of the bill for yielding to me.

(The remarks of Ms. COLLINS pertaining to the introduction of S. 1199 are located in today's RECORD under ''Statements on Introduced Bills and Joint Resolutions.'')

The PRESIDING OFFICER. Who seeks recognition? The Senator from Vermont.

Mr. JEFFORDS. Mr. President, I now return to the Durbin amendment.

Section 605, is also the subject of bipartisan agreement, with FDA's concurrence. By way of brief explanation, device tracking is intended to facilitate a product recall.

Current law requires tracking for certain product types and also gives FDA discretion to require tracking for other products. It simply is not necessary for every device in the mandatory category to be subject to the tracking requirement. This provision allows FDA to affirmatively 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.

This provision is needed because today, FDA will often indicate to a manufacturer that a product need not be tracked, even if it is in the mandatory category. While this many be good policy in the specific case, it puts both the FDA and the manufacturer in an undesirable legal situation. This provision allows FDA to exercise proper discretion and removes any potential cloud of legal liability which exists today.

It is inconceivable that FDA would not require tracking in the tragic cases identified by the Senator. The provision in the bill is logical, safe, and necessary. Further, the GAO report cited by the Senator refers to areas of FDA control totally unrelated to device tracking and surveillance.

SECTION 606: POSTMARKET SURVEILLANCE

Some have asked why we have made the FDA's postmarket surveillance authority discretionary. I am pleased to address that question and I think my colleagues will understand the good reasons for doing so. First, let me clearly state the FDA is in full concurrence with the appropriateness of this policy. I should add that FDA has actually required relatively few products to conduct postmarket surveillance. It is important to differentiate between this authority and the medical device reporting [MDR] and user reporting programs which are unaffected by this provision. The Medical Device Reporter Program is the keystone to the postapproval system for identifying hazardous or defective medical devices on the market place. The MDR Program, coupled with FDA's authority to force product recalls and the device tracking provisions are a strong web of protection for the consumer. User reports, submitted to FDA and manufacturers by hospitals and physicians, are an additional layer of information on the status of medical devices in the healthcare system.

Postmarket surveillance has a different purpose—to gather additional data to provide the extra assurance in the relatively rare situation where FDA has approved a product, yet still believes that the product should be subject to a limited period of postmarket evaluation. This is because for certain types of devices, problems may arise years after approval—problems which may not be detected in even the most elaborate clinical trial but could be dangerous to the individual, or even life threatening.

It is instructive to consider the history of this authority. The Safe Medical Devices Act of 1990 included a provision requiring a manufacturer to conduct postmarket surveillance for any device first marketed after January 1, 1991, that is a permanent implant the failure of which may cause serious adverse health consequences or death, is intended for use in supporting or sustaining human life, or potentially presents a serious risk to human health.

In other words, if you have something which can prevent death or serious injury, you certainly want to try it and use it, but you want to keep track of it to make sure if it proves to be the reverse in certain situations, that you at least know that and then can take appropriate action.

In addition to this mandatory surveillance, FDA was authorized to require postmarket surveillance for any device when the agency determined that surveillance is necessary to protect the public health or to provide safety or effectiveness data. All manufacturers subject to mandatory postmarket surveillance were required to submit protocols for FDA approval within 30 days of first marketing the device. The FDA was required to determine the adequacy of the principal investigator and the protocol and to approve the protocol after review by an appropriately qualified advisory committee.

In practice, the provision for mandatory surveillance, like the one for mandatory tracking, is so broadly worded that it is causing a good deal of uncertainty about those devices which are subject to this requirement. In some cases, companies and the FDA are technically exposed to unfair liability when the FDA does not require surveillance for products where it is, in fact, not necessary. We simply give FDA the discretion to require postmarket surveillance on any product it deems appropriate. This provision in no way suggests that FDA should cease to require surveillance for the types of devices it is currently covering under the existing authority. Indeed, we expect that FDA will by and large continue to require surveillance for most if not all of the products currently covered in the mandatory category. The committee and FDA believe this will be an appropriate way to bring clarity and efficiency to this important agency function. Indeed, FDA Director of Surveillance, Larry Kessler, recently said that he hoped Congress would join FDA in moving toward doing more discretionary and less required postmarket surveillance. They want to ensure that they can use their time as is most appropriate and most effective and efficient for their work, and not be required to do things which their judgment has found not necessary to take their time.

So, for that reason I must oppose this, and as I pointed out, Senator KENNEDY, as well as the FDA, would concur in opposition to this amendment.

I think now I will take some of the time to go back and discuss the 404 situation here, why we are here. Senator KENNEDY has taken extensive time last night and today. Certainly this is an important issue. It is an extremely important issue.

The PRESIDING OFFICER. The Senator has 5 minutes.

SECTION 404: LABELING CLAIMS FOR MEDICAL DEVICES

Mr. JEFFORDS. Mr. President, with the medical device amendments of 1976, Congress intended that device classification and approval decisions be made based on the intended use of devices as described in labeling. In the 20th century, major strides in medical technology have revolutionized the practice of medicine. Thanks to achievements in such fields as fiber optics, imaging, biomaterials, electronics, and biotechnology, today's medical technology is faster, more efficient and more productive than ever. These achievements have provided benefits to individual patients and to society at large—benefits such as better health, more cost-effective medical treatments and the return of patients

to productive lives more quickly. Today more than ever, medical technology is advancing at an astounding rate. Around the world, medical providers and device innovators are working together to bring better, more cost effective therapies to patients.

That is what we are involved with here. So we want to keep in mind, and this is why we sometimes have an interesting dilemma, where you have something which the patients' groups are plotting and which the consumer groups sometimes take an opposite position on, based upon their fears that this process may lead to something getting on the market which might cause a problem and they do not have the confidence that is built into the oversight part. I urge people to understand, the devices we are talking about are important to health. If we delay, as has been the case here, delay after delay after delay, unnecessarily so, then those who need it, those who are trying to improve their health, are denied it because some are so concerned that the delays which are deemed, really, unnecessary, lead to people having devices denied them.

Over the years, FDA has made premarket regulatory decisions based on uses for devices that are unrelated to the intended uses set forth in labeling. S. 830 includes two provisions that express the committee's specific intention to limit FDA's review of premarket submissions to the proposed labeling before the agency. Considerations like cost-effectiveness, relative effectiveness, or whether the product effects some improvement in a patient's quality of life, are irrelevant to a premarket review unless such claims are included in proposed labeling. Simply put, the FDA should not exceed its jurisdictional responsibilities by incorporating into the review process claims not before the agency for review consideration.

For premarket notification submissions, the labeling proposed in the submission will be controlling of a device's intended use. If the intended use is the same or sufficiently similar to the intended use of a predicate device, then the device may be found to be substantially equivalent to the predicate. No considerations outside of the proposed labeling for the 510(k) device should bear on the question of whether or not the proposed labeling of the newer device is compatible with the labeling of the predicate device.

For premarket approval applications, the determination of whether or not there is a reasonable assurance of device safety and effectiveness must be based on claims in proposed labeling if such labeling is neither false nor misleading. The FDA may fairly consider all facts which are pertinent to proposed labeling in PMA's in determining whether or not the labeling is false or misleading. Facts which are pertinent to proposed labeling are those which directly relate to claims in such labeling. For example, proposed labeling which states that a device is for use in treating atherosclerosis cannot be false or misleading because another device is more effective for that purpose. Nor can the proposed labeling be false or misleading because another device provides the same treatment benefits but is less expensive to purchase and operate. However, the failure to state a material fact about the device itself will make labeling in a pending PMA false or misleading.

This provision, which has strong bipartisan support, provides a much needed element of due process to product reviews. We preserve all of FDA's enforcement authority and leave the agency wide discretion in making judgments about new products.

What is at stake here? The ability of FDA to hold up a manufacturer's product on the basis of how a product might be used in the future—even if the company does not seek authority to market a product for those future uses.

I think it will be helpful to delve a little deeper into the technical issues related to this amendment dealing with one part of section 404—it is worth a brief explanation of how FDA clears for marketing new products which are similar to older, legally marketed products, this is the 510(k) process. The agency considers whether the new product is substantially equivalent to the older one. In this process, FDA asks two questions. First, does the new product have the same intended use as the older product? Second, are there issues raised by technological differences in the new product compared to the older one?

On the first question, FDA must not be allowed to second guess or impute new intended uses that the manufacturer does not claim—essentially acting as judge and jury on that question. That is what our bill does. This is simply too subjective a question to allow FDA broad latitude. This bill would not allow that. If the product before FDA claims a legitimate intended use and the product can perform that intended use, this part of the test is met.

But what if the new product has technological features not present in the older product which give rise to different safety and efficacy concerns? Under the bill, and it would certainly be my intent, FDA should and can demand data on those concerns or else not clear the product for marketing. That is what they do today, and that is what they would do under the bill. Further, if FDA determines that a manufacturer is promoting a product for a use that is not approved, all of its enforcement authority is available to correct that situation.

Section 404 simply establishes a proper balance in the product review process and focuses FDA's authority on the more objective ground of technological considerations.

Mr. MACK. Mr. President, I want to add my strong support for S. 830, which will reauthorize the Prescription Drug User Fee Act as well as provide much-needed reforms to the FDA, and the approval process for prescription drugs and medical devices.

I want to specifically address one area of FDA reform which has become one of the most controversial, and most often misunderstood, provision of this legislation. I'm referring to the issue of off-label information dissemination.

This is an issue I've worked on for more than 2 years. Joining me in this effort have been Senators FRIST, DODD, WYDEN, and BOXER. We come from different political parties. We have different political philosophies. But, there is one principle upon which we strongly agree.

Physicians, and other health care professionals, should have the ability to receive credible scientific information from reputable medical journals and medical textbooks in order to make informed treatment decisions with their patients.

However, because of an FDA policy—not a law, not a regulation, but a policy—that is not happening today.

Let me explain.

When the FDA approves a prescription drug or medical device, it does so for specific uses. Frequently, scientists find the FDA-approved prescription drug or medical device is also effective for other uses. Doctors are legally able to prescribe drugs or use devices for these new uses, which are called off-label uses.

According to the American Medical Association, between 40 and 60 percent of all prescriptions written are for off-label uses. For cancer patients, up to 80 percent of prescriptions are for off-label uses. For example, the prescription drug Intron A has been approved by the FDA for the treatment of melanoma, hepatitis B, and other diseases. Additional studies, which were published in such prestigious publications as the New England Journal of Medicine and the Journal of Clinical Oncology, have shown the drug is also effective for such diseases as kidney cancer, myeloma—cancer of bone marrow—and bladder cancer.

However, since 1991, the FDA has maintained a policy which prohibits manufacturers from giving doctors and other health care professionals scientific data about new uses of FDA-approved drugs and medical devices.

That's simply bad public health policy—and the bipartisan agreement we have reached will correct this intolerable situation.

The agreement will permit the dissemination to health care professionals of balanced, peer-reviewed articles from reputable medical journals and medical textbooks about new uses of FDA-approved prescription drugs and medical devices.

It will also ensure that the important research on these important new uses of prescription drugs and medical devices moves forward.

We ensure that only the highest quality of information can be disseminated

by defining the specific criteria for medical journals and medical textbooks. It is important to note this legislation does not permit the dissemination of marketing materials, brochures, promotional materials, newspaper or magazine articles, or other industry-generated materials.

Our legislation ensures that a balance of material about the use must be disseminated. Sixty days prior to dissemination, manufacturers must submit the article it desires to disseminate to FDA along with a bibliography of other medical journal articles about that off-label use. The Secretary has the option of adding an objective statement which describes additional scientific findings about that off-label use of the prescription drug or medical device.

The intent is that the statement be limited to objective and scientific information, and not present an opportunity to editorialize about independently derived scientific information. That statement, along with the required bibliography, must accompany the article or textbook. In addition, companies must also submit and disseminate a detailed statement which discloses that the article being disseminated describes a scientific study about an off-label use; any potential conflict of interest of the authors of the article; the source of funding for both the study and the dissemination of the article; and a statement which discloses if other products or treatments have been approved by the FDA for the use described in the article.

In other words, in addition to the article the company wants to share, the doctor will also receive: the disclosure statement; a statement of additional scientific findings from the Secretary of HHS; any previous FDA notices about that off-label use; a bibliography of other articles about that off-label use; and a copy of the FDA-approved labeling for the drug or device described in the article.

In order to disseminate the medical journal articles and textbooks, manufacturers must agree to conduct the required clinical trials in order to apply for a supplemental new drug application.

Companies must either certify they will file an SNDA within 6 months, or they must submit a clinical trial protocol and time schedule for conducting the needed studies to apply for an SNDA within 3 years. The Secretary of HHS may grant a 2-year extension to comply with this requirement if the company is acting in due diligence to conduct the studies in a timely manner. Periodic progress reports are required to be filed with the Secretary. Companies may apply for an exemption under very limited circumstances.

The manufacturer is also required to share with the Secretary new information about that same off-label use of the drug or device. If the Secretary determines the new information demonstrates that the drug or device may not be effective or may pose a significant risk to public health, then the Secretary shall, in consultation with the manufacturer, take corrective action to ensure public health and safety.

The provision provides the Secretary of HHS with strong oversight authority, including the ability to stop dissemination of articles and the ability to require manufacturers who violate the provisions of this legislation to either take corrective action or return to compliance. The Secretary can order a manufacturer to cease dissemination if the SNDA application is denied.

We also require that two future studies be performed. One study will examine the impact this legislation has had on FDA resources. The other study will assess the quality of the information disseminated and it will examine how useful the information has been to doctors and other health care providers.

It is important to note that this legislation will expire in 2006, unless Congress acts to continue it.

This legislation has earned the enthusiastic support of the American Medical Association. Let me quote from the AMA's Council on Scientific Affairs report:

> It is imperative that physicians have access to accurate and unbiased information about unlabeled uses of prescription drugs. Dissemination of independently derived scientific information about unlabeled uses by manufacturers to physicians can help physicians have access to the latest, scientifically credible information.

A Roper poll of oncologists released in July 1997 found that 70 percent of doctors believe FDA rules about off-label information stand in the way of doctors' efforts to get the most credible information about cancer treatments. The poll also found that 99 percent found peer-reviewed medical journal articles is a source they use when making prescription decisions.

In addition, numerous patient organizations also support the dissemination of scientific information regarding off-label uses of prescription drugs and medical devices. These organizations include the American Cancer Society, the Leukemia Society of America, the American Osteoporosis Foundation, the American Society of Clinical Oncology, the Cystic Fibrosis Foundation, the A–T Children's Project, the American Liver Foundation, and the National Alzheimer's Association.

Mr. President, for the past 2 years, this bipartisan group of Senators—myself and Senators FRIST, DODD, WYDEN, and BOXER—have worked together to craft legislation which will permit health care professionals to receive important scientific information while ensuring consumer safeguards.

This bipartisan effort is based upon the belief that health care professionals should be able to receive scientific data while ensuring patient protections.

Most importantly—and this is key—from a patient's point of view, this legislation will greatly increase one's odds of getting state-of-the-art treatment which could cure a disease, slow the progression of a disease, or, at minimum, improve one's quality of life.

It is simply wrong to continue this policy which denies the ability of a health care professional to receive an article from a medical journal or medical textbook.

Doctors, nurses, and other caregivers help patients make life or death decisions every day. They need access to credible scientific information to discuss with patients. We must take this commonsense step to make sure they are able to receive accurate, unbiased information, including information about off-label uses, which will help them make informed treatment decisions with their patients.

I am very pleased to report this agreement has received the support of our colleague, Senator TED KENNEDY, the ranking member of the Senate Committee on Labor and Human Resources. It also has the support of the Secretary of Health ad Human Services, Donna Shalala.

I would like to thank them, along with Richard Tarplin, Assistant Secretary of HHS, and Bill Schultz and Dianne Thompson of the FDA, for their cooperation in reaching this historic agreement on what has been a very contentious issue.

Finally, I want to thank my colleagues who worked with me on this agreement, Senators FRIST, DODD, WYDEN, and BOXER. It's been a pleasure to work with each of you, and I look forward to working with you on other public health issues in the future.

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. 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.

Mr. JEFFORDS. I understand the Senator from Georgia has time, and I ask if he would yield me 5 minutes.

Mr. COVERDELL. I yield up to 5 minutes to the distinguished Senator from Vermont.

The PRESIDING OFFICER (Mr. HAGEL). Without objection, it is so ordered.

Mr. JEFFORDS. I am sorry to have to report, we have been trying in this last 45 minutes to see if we could move some amendments that everybody has agreed to and to show that we are really trying to bring this bill before this body and to make progress so we can decrease the amount of time that will be needed at the end as we move through the cloture process.

Unfortunately, we have not been able to get that agreement. So such amendments as those of Senator MURRAY, Senator DEWINE, and others, that would have been approved by unanimous consent by will have to wait for

some future time in hopes that we can get agreement.

I want to point out there are a large number of amendments pending on this bill, many of which are agreed to, others that probably will fall by the wayside, it should not be that difficult to finish work on this bill. However, if we continue to have this delay, without any cooperation to move the process forward, then it is going to foul up our very crowded calendar. That is unfortunate, as we all want to get the legislation done, get the conference reports on appropriations bills passed, and other pending legislation which is essential, so that we do not have to shut the Government down. If we fail to get the cooperation of the minority in even agreeing to things that everybody agrees to, it is unfortunate.

Let me point out some of the Senators we would have helped today: Senator DEWINE, for instance, and Senator DODD; their amendments should have been agreed to. They have shown great leadership in advocating greater research into pediatric uses of new and existing drugs. Their amendment reflects Senator DEWINE's successful effort to marry the mandated approach in the administration's regulations with the incentive-based approach underlying Senator DEWINE and Senator DODD's provision. Senator MURRAY has worked diligently to protect the health and safety of children. Her amendment, which everybody agrees should be approved, modifies the national uniformity provision clarifying that the exemption requirement is applicable to the health and safety of children.

Other amendments by other Members that we could have adopted today will have to be done at some later time as long as the minority continues to block progress on the 152-page bill, of which 150 pages are agreed to. That does not make much sense. Why do we have this delay over a provision on which there is a disagreement, and general knowledge that the disagreement will have to be taken care of in the conference committee. The White House will insist that we come up with something different than is in the bill and the House has already taken a different position. Why should we delay the meeting of that conference committee?

I urge the minority to let us vote—they are holding up an extremely important piece of legislation. The only advantage in doing this is to raise more public attention to one issue—that the minority is willing to tie up the Senate over one sentence in this bill in full knowledge that further work will be done on the issue in conference.

So let's move this bill along, get it to conference. The House is moving expeditiously, so we can go to conference probably at the end of next week if we can get this bill done. I urge the minority to change the tactics of delaying any progress on this bill.

I yield the floor.

The PRESIDING OFFICER. The Senator from Georgia.

EDUCATION REFORM

Mr. COVERDELL. Mr. President, this Congress began its deliberations in a very interesting way. Our conference, our side of the aisle, met before the convening of the 105th Congress and concluded or defined 10 major issues they thought should be brought before the Nation.

The first issue, which resulted in the first piece of legislation for this Senate, for this Congress, was education. It was unanimous agreement in the conference that our first expression in this Congress on our side of the aisle would be about education and its importance. Not long after that the President of the United States announced that education would become a centerpiece of his activities during this Congress, and he actually visited Georgia, he visited various locales across the country, and he talked about, by and large, the requirement or need that people have some relief from the costs of higher education.

It is interesting, and in a sense in a bipartisan way, we had key leaders in both parties focusing on this issue. It is certainly exactly what ought to have happened. I believe the genesis of American glory is that we have been a free people. I have said more than once that an uneducated people cannot be free. An uneducated people cannot be free.

So as we, the custodians of this great democracy, prepare for a new century, we have to be asking ourselves the question over and over: Are we preparing the generation that will lead that century with the tools that they will need and require to be ready to do that job? Unfortunately, the news is not altogether comforting when you review the data.

Despite the intense interest in the last tax relief proposal on costs of higher education, that higher education is not where America is in trouble in its education. America is in trouble in its elementary and high school level.

I was reading just the other day a prominent survey of the condition in elementary schools. It is fairly alarming. It suggested that 4 out of 10 students in elementary school today are frightened by some aspect or fearful of violence in the school. Mr. President, the survey concluded that 3 out of 10 students in elementary school will have property stolen from them in the schools. It suggested that 1 out of 10 will be confronted with a deadly weapon while they are in school.

When you look at the condition of our reading proficiency, our basic skills—reading, writing, adding and subtracting—we are not comforted by the data which, of course, has led to this massive debate about skills that students have to achieve by the time they are in the fourth grade, have to achieve by the time they are in the eighth grade, and how are we going to certify that it has happened.

I have spent the better part of the last 2 years talking about the fact that we have a drug epidemic in the United States, particularly among our younger teenagers. We have seen statistics that show that drug use has doubled in the last 36 to 40 months. These are schoolchildren, Mr. President. If you go to these schools—and I invite anybody to do it—the students are very savvy, they know exactly what is happening, and they know that there are drugs and violence surrounding their environment in school.

So, 4 in 10 are fearful; 3 in 10 are going to be robbed; 1 in 10 is going to face a weapon; and all of them will tell you the nature of drugs and the availability of drugs.

Three out of ten who come to college this September will have to take remedial training in reading. In other words, 30 percent-plus of the students that have gone through our elementary school system and our high school system are not ready for college and can't read well. So I guess the story is beginning to frame itself: We have a problem in K through high school. An American family ought to at least expect that when their child graduates from an American high school, they can do the ABC's, they can read, they can write, and they can do their arithmetic, and they are not behind. Society spends millions upon millions of dollars retraining these students by the time they get to college.

Well, I think this data and these statistics, Mr. President, are the reason that when you poll Americans, the vast majority of them now put education as the No. 1 issue. It is because they are reading the same data that we are reading. And, of course, it is the reason that leadership in both parties have come forward of late and have suggested that we need to make the Federal Government be the appropriate partner—the appropriate partner; not the governor, not the manager, but a good partner—in helping our States and our local communities get a handle on what is going wrong in public education at the elementary and high school level.

So, as a result, the first bill was introduced, S. 1, which contained three major initiatives. First, there was tax relief making employer-provided educational assistance tax free to help make up this shortfall, help these employers bring new educational opportunity to their employees. That is now law.

S. 1 allows State prepaid tuition plans to pay for both college tuition and room and board. That is now law.

S. 1, our first piece of legislation, made interest on student loans tax deductible. That is now law.

S. 1 provided education savings accounts for college. That is now law. That was a compromise and a coming together of the President's proposals and of our conference proposals.