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Senate

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:

Almighty God, our motto says, ''In God we trust.'' This morning our prayer is to put that motto into practice. Each of us comes to this time of prayer with his or her own set of personal needs. You know these, Lord. We place in Your strong hands whatever holds us captive to anxiety or worry. There are people in our lives for whom we are deeply concerned. We trust You with their care.

We pray for the peace of Jerusalem. We pray for the families of the 7 people who were killed in the bombing and ask for Your special care for the 200 that are now convalescing because of injuries in the bombing. O Lord, bless that city with peace.

Thank You for freeing our minds so we can work for Your glory today—with inner calm and serenity.

Lord, You know the agenda before the Senate is filled with crucial issues. We commit them to You and ask for Your guidance.

We pray that the trust we have in You may give us greater trust in one another. Make us trustworthy as we seek Your best for our Nation. Free us of defensiveness and suspicion of those who may not share our party loyalties or our particular persuasions. Bind us together in the oneness of a shared commitment to You, a passionate patriotism, and the loyal dedication to find Your solutions for the concerns that confront and often divide us.

Bless the women and men of this Senate as they place their ultimate trust in You and are faithful to the trust placed in them by the people. Through our Lord and Saviour. Amen.

RECOGNITION OF THE ACTING MAJORITY LEADER

The PRESIDENT pro tempore. The able acting majority leader is recognized.

SCHEDULE

Mr. JEFFORDS. Mr. President, for the information of all Members, this morning, the Senate will immediately begin debate on the motion to proceed to S. 830, the FDA reform bill, with the time until 9:50 a.m. equally divided in the usual form. As previously ordered, a cloture vote on the motion to proceed to the FDA bill will occur at 9:50 a.m. Also by previous consent, if cloture is invoked, the Senate will immediately begin 8 hours of debate equally divided between Senators JEFFORDS and KENNEDY on the motion to proceed. In addition, there will be an additional 4 hours of debate on the motion to proceed remaining on Monday. As a reminder to all Members, there will be a cloture vote on the motion to proceed to the FDA reform bill at 9:50 a.m. today. I thank my colleagues for their attention.

Mr. President, how much time do we have?

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997—MOTION TO PROCEED

The PRESIDING OFFICER (Mr. COATS). Under the previous order, there will be debate until 9:50 a.m., equally divided, on S. 830. It will be a little bit less than 12 minutes.

Mr. JEFFORDS. Mr. President, I yield myself 2 minutes.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. JEFFORDS. Mr. President, I salute the majority leader for moving the debate on the FDA modernization forward. We should no longer needlessly delay consideration of S. 830, the Food and Drug Administration Modernization and Accountability Act of 1997.

S. 830 represents months of bipartisan effort to address serious shortcomings in the FDA's regulatory procedures. Two hearings were held. The measure passed the committee with a strong bipartisan 14-to-4 vote, and months of negotiations have ensued with dozens of accommodations made for Senator KENNEDY and the administration.

For almost 20 years, Congress, the General Accounting Office, and numerous advisory commissions have examined, reviewed, and made recommendations to modernize the FDA.

During 1978 and 1979, Senator KENNEDY championed legislation that would have required FDA to do some of the very same things we are requiring of it in S. 830.

In 1982, the Commission on the Federal Drug Approval Process, convened at the request of Representatives ALBERT GORE and James Scheuer, recommended simpler investigational new drug requirements. The Commission recognized that drug effectiveness could be demonstrated by one study in appropriate cases, and it urged greater use of outside expert advice and improved interactions with industry.

In 1989, the advisory committee on the FDA, on which Dr. David Kessler served, made a key recommendation. It said:

> . . . the agency should be guided by the principle that expeditious approval of useful and safe new products enhances the health of the American people. Approving such products can be as important as preventing the marketing of harmful or ineffective products.

In 1991, Vice President Quayle's Council on Competitiveness recommended that the FDA expand the use of outside reviews and advisory committees, interpret efficacy with a more appropriate standard, and enhance internal agency management.

More recently, Vice President GORE has used the President's ''reinventing Government'' initiative to improve the FDA product approval system and to eliminate outmoded FDA regulations for a variety of drugs, medical devices, and food products.

● This ''bullet'' symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor.

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Last year, the committee on Labor and Human Resources held four hearings on reforming the FDA. The witnesses testified about the same problems that have been described for 20 years, and they recommended many of the same solutions that have been recommended for 20 years.

This year, the Labor Committee continued its effort to modernize the FDA. The committee held two hearings in early 1997. The first hearing was dedicated to the FDA, and the second hearing included representatives from patient and consumer coalitions and from the food, drug, and medical devices sector regulated by the FDA. It is no easy task that we ask FDA to perform. Americans want the FDA to hold the gate tightly shut against unsafe or ineffective products while opening it wide for the next generation of innovation. Clear statutory guidance is needed to assist the agency to find this delicate balance and to bring our food and drug laws and regulatory systems into the next century. S. 830 contributes significantly to reaching that balance. The measure embodies the bipartisan conclusions and recommendations reached for the past 20 years for accomplishing this difficult task of balancing risk and promise.

Mr. President, a few have charged that this Congress is moving too fast. They ask, ''What's the rush?'' But they have asked the wrong question. For the past 20 years, every administration has sought to make FDA better—to make better, safe and more effective products more readily available. After almost 20 years, we must ask ourselves, why delay further? Why continue to delay reforms that have been studied, reviewed, recommended, restudied, and endorsed again and again for over 20 years? Clearly, the FDA should be modernized now.

The PRESIDING OFFICER. The Chair informs the Senator from Vermont, on his time, there are 4 minutes 24 seconds remaining.

Mr. JEFFORDS. Thank you. I yield the floor.

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I have how much time?

The PRESIDING OFFICER. Eight minutes.

Mr. KENNEDY. I yield myself 6 minutes.

The PRESIDING OFFICER. The Senator is recognized for 6 minutes.

PRIVILEGE OF THE FLOOR

Mr. KENNEDY. Mr. President, I ask unanimous consent that Diane Robertson be given the privilege of the floor during the consideration of this legislation.

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

Mr. KENNEDY. Mr. President, first of all, I congratulate my friend and colleague, Senator JEFFORDS, for the attention he has given to trying to bring the FDA into the modern world and to trying to consider a wide variety of different recommendations and suggestions and for working with the members of our committee, both the Republicans and Democrats.

This has been a trying process, but I commend him—and I speak for all of those on our side—for the diligence with which he has approached this and the knowledge he has demonstrated on this particular range of issues.

We all understand, the American people understand, that the principal responsibility of the FDA is to preserve and protect the public health. This is different from other agencies. Therefore, any alteration or change in the authority of the FDA and in consideration that various aspects of the law have to be balanced against what is in the short-term, medium-term and long-term interest of the public health of the American people. The FDA is the singular agency throughout the world that has demonstrated that it understands that particular commitment and has done an extraordinary job.

Many of us have frustrations about the FDA on particular products in our State and about general kinds of process and procedure. But no one can review the history of the FDA and not understand that today the FDA is the principal instrument for approving new drugs and new medical devices. This legislation today is to try to extend what we call the PDUFA, which is a proposal that was enacted under the leadership of Senator HATCH and myself a number of years ago, which provides user fees by the major drug companies to make sure that we will have the expertise to consider various drug products more rapidly. There is an important need for the extension of that particular proposal, and all of us want to see it extended. I am a strong supporter of extending it. There are many, many features of this legislation which I support.

But having said that, Mr. President, we have to look at the remaining items that need attention and, in particular, one which is completely unacceptable and enough to warrant and justify the attention of the Members of the Senate about whether we are prepared to move ahead and consider this legislation, with that particular provision in in, that is now before the U.S. Senate. It is a provision that was not a part of either the initial proposal that was advanced last year by Senator Kassebaum or advanced this year by Senator JEFFORDS. It concerns the whole question of the preemption of the States with regard to cosmetics and over-the-counter medicines, but primarily on the issue of cosmetics.

There are other important protection items dealing with unsafe or ineffective medical devices, including provisions that could undercut FDA's ability to regulate cigarettes, and there is a back-door assault on one of the most important environmental protections. We will have a chance to get into those later in the course of the morning.

I want to point out what this legislation is going to do with regard to cosmetics, to all of the Members as we are coming over here to consider a cloture vote. We have to recognize and we will have a chance later on in the morning to point out the limitation of the Food and Drug Administration in regulating cosmetics. It has virtually no regulatory authority in this area.

The American people should take no satisfaction in extent of the protections regarding the cosmetics they use every single day because the Food and Drug Administration does not have the jurisdiction to determine what is in those cosmetics, whether they are safe and whether they are effective. Absolutely none. There are only two members of the FDA who are out there supervising this issue—only two members of the FDA—in terms of looking out after the packaging and the labeling provisions—two members.

The enforcement, in terms of protection of the public health on the issues of cosmetics, are left to the States. That is where the real regulatory authority is today. And now, because of the greed—and it is greed—of the cosmetic industry and because of the success of a referendum in California, they want to preempt any kind of protections for the health and the safety enacted by the States with Federal legislation that will effectively eliminate for all time the possibility of the States providing protection on health and safety. That was put into this legislation as an amendment. That amendment has been objected to, not just by the Senator from Massachusetts, but by all of the Governors of the 50 States.

I will submit the correspondence from the National Governors' Association and from a principal Republican Attorney General Dan Lundgren of the State of California, a State that has done more in terms of protecting the American public as a result of the legislation passed in California than anyone else.

The last GAO study points out that in the cosmetics used primarily by women in this country every day, 125 ingredients are suspected of causing cancer, 20 ingredients are suspected of damaging the nervous system, 20 ingredients are suspected of causing birth defects. And the list goes on and on and on.

And to put that into this legislation without a single day of hearings—without a single day of hearings; the last hearings in the Senate of the United States were in 1978—will amount to a wholesale threat to the health of the American consumer. Primarily the women of this country do not deserve the kind of vote for cloture in moving ahead and effectively denying us the opportunity for a full debate and discussion of the issues that this provision deserves. That is why I hope that the vote on cloture is not successful.

The PRESIDING OFFICER. The time of the Senator has expired.

Mr. JEFFORDS. I yield 2 minutes to the Senator from Connecticut, Senator DODD, and the remaining time after that to Senator COATS.

Mr. DODD addressed the Chair.

The PRESIDING OFFICER. The Senator from Connecticut.

Mr. DODD. I thank my colleague from Vermont.

Mr. President, I urge our colleagues to vote to invoke cloture on this. But let me say at the outset here I want to commend our colleagues, and particularly my colleague from Massachusetts on this matter. He has labored for many, many years on FDA legislation. And he brings up an issue here regarding the cosmetics issue which will certainly be the subject of debate and has been the subject of debate in our committee over the last 2½ years. In the most recent round of markups—we have been through a couple markups—the bill has had pretty substantial bipartisan support coming out of the committee. I think our vote was something like 14 to 4 in the last markup.

This is an important piece of legislation. September 30 is coming. We have to reauthorize PDUFA. This is the first time we have been able to deal with FDA in a way that will not only guarantee that we will have a quicker response on these applications, but also a safe and efficient and effective response for the consumers, the patient groups of this country.

This is a very important piece of legislation. I commend my colleague from Vermont, the chairman of the committee, for his leadership on this. The committee has worked very, very hard on this, my colleague from Indiana and others. We have had some very difficult issues over the last 2½ years to try to reach compromise on and resolve them. And we have, by and large, with the exception of this one issue which is a great testament to the efforts of the members of the committee and the staffs that have worked on this.

But I think it is time now that we bring the bill to the floor and try to leave it up to the Members themselves to resolve any outstanding issues that we have or, hopefully, over the next coming days, to achieve a compromise so we can avoid a kind of battle here on the floor over one or two remaining issues.

Mr. President, I urge that we move forward on this. We have done a good job I think in the committee. It is not uncommon for there to be an outstanding issue. I urge the invoking of cloture.

The PRESIDING OFFICER (Mr. JEFFORDS). The Senator's time has expired.

The Senator from Indiana has 2 minutes 24 seconds.

Mr. COATS. I would like to yield some of that time to the Senator from Maryland, if she is interested in making some comments. I have a limited amount of time, but I would be happy to yield a portion of it.

Ms. MIKULSKI. Thank you very much.

I wish to say to my colleagues, we have worked very long and hard to move FDA reform ahead, to make sure that products, whether they be pharmaceuticals, biologics, or cosmetics, are available in a safe way to the American people. There are policy differences, but they should be decided on the basis of debates and votes. We should not hold up reform on the basis of process.

Let us vote for cloture. Let us move the bill forward. Let us resolve our differences in the usual and customary way. I ask my colleagues to join with me to vote for cloture, and then move forward in an adequate, robust and well-amplified debate on the issues.

I thank the Senator from Indiana.

Mr. COATS. Mr. President, I would like to add my support, in a bipartisan way, to the remarks as stated by the Senator from Connecticut and the Senator from Maryland and the efforts that have been undertaken by the chairman, Chairman JEFFORDS, and all of us on the committee over the past 2½ years to move this bill forward.

There has been extensive debate on this in committee, 2½ years' worth. There has been extensive hearings on this. There has been extensive negotiation, and there has been extensive compromise on the part of those of us who are advocating FDA reform.

We have made concession after concession after concession to Senator KENNEDY and the administration and to those who have opposed our efforts in an attempt just to get the bill to the floor. Every time we solved one issue, a new one pops up that we had discussed over and over and over and voted on in committee, but it does not mean that we should not move forward with the process.

All we are asking for today is to move this bill forward so that Senator KENNEDY and others who have concerns with it can raise their objections, can debate it once again, can negotiate some more. But to stop the bill from going forward, to keep the drugs from being approved, to keep funds from going into FDA, to deny people the benefits from FDA approval of drugs and devices, simply because a Senator has a problem with one portion of the bill, I think certainly does not serve this body well.

So I urge our colleagues to support the effort to invoke cloture so that we can move ahead with this.

Mrs. BOXER. Will the Senator yield?

Mr. COATS. I would be happy to.

The PRESIDING OFFICER. Time has expired.

Senator KENNEDY has 1 minute.

Mr. KENNEDY. Mr. President, it is not just one Senator. Let me read from ''The National Governors' Association, The National Conference of State Legislatures.''

When the Senate Labor and Human Resources Committee considered the Food and Drug Administration Reform legislation . . . the committee adopted an amendment proposed by Senator Gregg that preempts state regulations, disclosure requirements, labeling, and warning requirements as they apply to nonprescription drugs and cosmetics. The National Conference of State Legislatures and the National Governors' Association, vigorously oppose this provision and hope that it will not be part of the bill when it is reported by the Senate.

These are the Governors, the State legislatures. The Secretary of Health indicated that ''We and the administration all agree PDUFA is in the best interest. However, as maintained in its present form, with the outstanding issues not addressed, we will be forced to recommend to veto the legislation.''

We are talking about health and safety. And we will have a chance to develop that in the postvote of this. But this bill contains too many important provisions with PDUFA and the medical devices and the drug provisions to go forward. And I believe that it should go forward, but not with this provision.

The PRESIDING OFFICER (Mr. COATS). Time has expired.

CLOTURE MOTION

The PRESIDING OFFICER. By unanimous consent, pursuant to rule XXII, the Chair lays before the Senate the pending cloture motion, which the clerk will state.

The assistant legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, do hereby move to bring to a close debate on the motion to proceed to Calendar No. 105, S. 830, the FDA reform bill:

Trent Lott, Jim Jeffords, Pat Roberts, Kay Bailey Hutchison, Tim Hutchinson, Conrad Burns, Chuck Hagel, Jon Kyl, Rod Grams, Pete Domenici, Ted Stevens, Christopher S. Bond, Strom Thurmond, Judd Gregg, Don Nickles, Paul Coverdell.

The PRESIDING OFFICER. The question is, Is it the sense of the Senate that debate on the motion to proceed to the consideration of S. 830, the FDA Modernization and Accountability Act, shall be brought to a close?

The yeas and nays are required under the rule. The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. NICKLES. I announce that the Senator from Arizona [Mr. MCCAIN], the Senator from Alaska [Mr. MURKOWSKI], the Senator from Pennsylvania [Mr. SANTORUM], and the Senator from Wyoming [Mr. THOMAS] are necessarily absent.

Ms. MIKULSKI. I announce that the Senator from Kentucky [Mr. FORD] and the Senator from Ohio [Mr. GLENN] are necessarily absent.

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The yeas and nays resulted—yeas 89, nays 5, as follows:

[Rollcall Vote No. 220 Leg.]

YEAS—89

Abraham	Baucus	Bingaman
Allard	Bennett	Bond
Ashcroft	Biden	Boxer

Breaux	Gramm	Mack
Brownback	Grams	McConnell
Bryan	Grassley	Mikulski
Bumpers	Gregg	Moseley-Braun
Burns	Hagel	Moynihan
Byrd	Harkin	Murray
Campbell	Hatch	Nickles
Chafee	Helms	Reid
Coats	Hollings	Robb
Cochran	Hutchinson	Roberts
Collins	Hutchison	Rockefeller
Conrad	Inhofe	Roth
Coverdell	Inouye	Sarbanes
Craig	Jeffords	Sessions
D'Amato	Johnson	Shelby
Daschle	Kempthorne	Smith (NH)
DeWine	Kerrey	Smith (OR)
Dodd	Kerry	Snowe
Domenici	Kohl	Specter
Dorgan	Kyl	Stevens
Enzi	Landrieu	Thompson
Faircloth	Lautenberg	Thurmond
Feingold	Leahy	Torricelli
Feinstein	Levin	Warner
Frist	Lieberman	Wellstone
Gorton	Lott	Wyden
Graham	Lugar	

NAYS—5

Akaka	Durbin	Reed
Cleland	Kennedy	

NOT VOTING—6

Ford	McCain	Santorum
Glenn	Murkowski	Thomas

The PRESIDING OFFICER. On this vote, the yeas are 89, the nays are 5.

Three-fifths of the Senators duly chosen and sworn having voted in the affirmative, the motion is agreed to.

Mr. JEFFORDS. Mr. President, I want to most sincerely thank my colleagues for the tremendous vote to move forward on FDA reform. This is most rewarding. All of the proponents and supporters are pleased to know that we can go forward at this time.

This is a tribute to a lot of hard work and compromise from a lot of Members on both sides of the aisle and both sides of the issue. The vote represents the best of bipartisanship from Senators who support it, and even from opponents and the administration. Today is just the first step, but it could hardly be a better one. We will need to debate this bill, consider amendments to it and, no doubt, improve it. I believe that there are still changes that can be made to accommodate the concerns that have been expressed here by the opponents. I know we can find solutions to those.

We will need to debate this bill, consider amendments and, as I say, no doubt, improve it. But I hope by this time next week, the Senate will have given its resounding support to this bill. It is too important to the American people to let it languish. It is too important for us not to move it out as quickly as possible.

Mr. President, I yield the floor.

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I understand we have a time agreement, am I correct? Would the Chair be kind enough to state it?

The PRESIDING OFFICER. The agreement is: Under a previous order, there will be 8 hours of debate, equally divided between the Senator from Vermont [Mr. JEFFORDS] and the Senator from Massachusetts [Mr. KENNEDY].

Mr. KENNEDY. I thank the Chair. The legislation we are debating today includes many positive elements. It reauthorizes the important prescription drug user fee program, one of the most effective regulatory reforms ever enacted. It includes a number of other provisions that will significantly improve and streamline the regulation of prescription drugs, biologic products, and medical devices. And I am pleased that through a long process of negotiation, both prior to and subsequent to the markup of the legislation, many provisions that seriously threaten public health and safety were dropped or compromised. But a bill that includes the damaging provisions that remain in this bill, should not become law.

I have received a letter this morning from the Administration announcing their opposition to these provisions and their judgment that the bill should be vetoed if they are not eliminated. It would be the height of folly for the Senate to doom this important legislation to failure by taking it up before the provisions that merit a veto are removed or changed.

The provisions that make this bill unworthy of passage by the Senate include: The preemption of State regulation of cosmetics and over-the-counter medicines; the elimination of two important protections against unsafe or ineffective medical devices, including a provision that could undercut FDA's ability to regulate cigarettes, and a backdoor assault on one of the most important environmental protections. The most egregious and unjustified provision in this bill would effectively preempt the State regulation of over-the-counter drugs and cosmetics. These provisions were not included in the chairman's original mark. They were not the subject of significant hearings. They have no place in a bill whose primary purpose is to reauthorize the Prescription Drug User Act.

If this bill were serious about dealing with issues of over-the-counter drug and cosmetic regulation, it would undertake a serious reform of the whole regulatory structure to assure that consumers are adequately protected and not include a single provision designed to protect the profits of wealthy companies at the expense of the health of consumers. Preemption of cosmetic regulation is fundamentally outrageous and shows a callous disregard for the health of American women, especially those who are pregnant. It shows a callous disregard for the likelihood of birth defects in newborn babies. Cosmetics are used far more broadly than most prescription drugs, medical devices, and biologic products.

Whether the issue is hair spray, or shampoo, or lipstick, or baby powder, or suntan lotion, or soap, or toothpaste, Americans assume that the products they use are safe. But this confidence is too often unjustified because Federal oversight of this $20 billion industry today is extremely limited. The basic law regulating cosmetics has not been updated since 1938. The FDA has less than 30 employees overseeing this huge industry. Only two deal with packaging and labeling.

The legislation, Mr. President, the food and drug and related law, has 126 pages dealing with drugs and devices. It has 55 pages for foods. It has 1½ pages of Federal law dealing with cosmetics. It basically does not deal with regulating the cosmetics of this Nation.

The FDA has no authority to require manufacturers of cosmetics to register their plans or products. The FDA has no authority to require manufacturers to register their plans or products. It cannot require manufacturers to file data on the ingredients of their products. So there is no information with regard to the ingredients of their products. That is completely different, obviously, from the complex and vigorous review schedules which are places for pharmaceuticals and for medical devices. The FDA cannot require the manufacturers of cosmetics to file data on the ingredients in their products. It cannot compel manufacturers to file reports on cosmetics-related injuries. It cannot require their products be tested for safety, nor can it require that the results of safety testing be made available to the agency. It has no power, as it does with prescription drugs and medical devices, to require that the tests be done or that they gather information as a result of tests. It has no oversight authority in terms of making sure there are safe manufactured products. None of that currently exists with regard to cosmetics. The FDA does not have the right of access to manufacturers' records, and it cannot require recall of a product. The FDA is virtually outside the loop with regard to giving assurances to the American people about the health and safety of their products. This is unlike prescription drugs, it is unlike over-the-counter drugs, it is unlike medical devices. The FDA is outside the loop.

A study by the respected, nonpartisan General Accounting Office reported that more than 125 ingredients available for use in cosmetics are suspected of causing cancer. Twenty cosmetic ingredients may cause adverse effects on the nervous system, including headaches, drowsiness, and convulsions. Twenty cosmetic ingredients are suspected of causing birth defects. The GAO concluded that cosmetics are being marketed in the United States that may pose a serious hazard to the public. That is the GAO. They concluded that cosmetics are being marketed in the United States that may pose a serious hazard to the public.

The legislation that is before us is saying that the States should not be able to do anything about it. This is the primary issue in terms of the health the American people—may we have order, Mr. President?

The PRESIDING OFFICER. The Senate will come to order. Senators will cease audible conversation. Would the

Senators to the Chair's left cease conversation.

The Senator from Massachusetts.

Mr. KENNEDY. The cosmetic industry wants the public to believe that no effective regulation is necessary at either the State or Federal level. They are the masters of the slick ad and expensive public relations campaign. But all the glamorous pictures of the world cannot obscure the basic facts. This is an industry that is underregulated and, too often, hazardous.

A mother of a beautiful 6-year-old girl in Oakland, CA, found this out when she used a hair product on her child that resulted in second-degree burns on her ears and neck. A 59-year-old California woman almost died from an allergic reaction to hair dye. A 47-year-old woman had her cornea destroyed by a mascara wand. In another tragic case, a woman's hair caught fire as a result of an inflammable hair treatment gel. She lost her hair and was severely scarred. Beauty parlor employees are particularly vulnerable to asthma and other diseases that result from exposure to chemicals in the products that they use.

In fact, for every 1 million cosmetic products purchased, there are more than 200 visits to the doctor to treat cosmetic-caused illnesses. In 1987, a study for the Consumer Product Safety Commission found that, in 1 year alone, cosmetic products resulted in 47,000 emergency room visits. These severe reactions are only the tip of the iceberg. As the GAO study points out, available estimates of cosmetic-related injuries do not accurately reflect the extent to which consumers are exposed to toxic cosmetic products and ingredients. Because symptoms of chronic toxic effects may not occur until months or years after exposure. The injury estimates generally account for only the acute toxic effects—the effects that are seen right away. It is a fact that many of the ingredients, according to the GAO, included in many products are toxic in nature, maybe carcinogens, that take time to work their way through the body system and only later reflect themselves in incidence of cancer, or assaults on the nervous system, or birth defects long after they are used.

In the face of limited Federal authority to protect the public against these hazards, and the even more limited resources devoted to preventing them, you would think that the Congress would want to encourage the States to fill the regulatory vacuum. Since the Federal Government is not doing it, you would think we would want the States to make sure that they are protecting their consumers.

That is logical. We are talking about a health and safety issue. We are not talking about the economic regulations. We are talking about health and safety issues. If we are not going to have a responsibility in doing it, you would think we would want the States to move ahead and at least ensure the protections. But not in this legislation. Effectively we are preempting the States—telling the States they can't do it. We are not doing it, and we are not going to permit the States to do it either, ever.

That is the effect of the provisions that have been included and added on to the bill in Committee—not in the initial proposal offered by Senator Kassebaum, not in the initial proposal offered by Senator JEFFORDS. It was one of the last of the amendments that were considered. There have been no hearings on this issue since 1978, 1988 in the House of Representatives. Still we have moved ahead, basically at the whim of the cosmetic industry, a $20 billion industry. This bill entirely bars the States from regulating packaging and labeling and places severe limits on the States' ability to establish other forms of regulation.

Mr. President, just listen to this language on the scope of the preemption provision on the packaging or labeling of a cosmetic: ''* * * shall be deemed to include any requirement relating to public information, or any other form of public communication relating to the safety or effectiveness of a drug or cosmetic.''

There it is, clear as can be; no more information for the people of California, no more information for the people in the Midwest or the East. This is what it says. ''This preemption shall be deemed to include any requirement relating to public information, or any other form of public communication relating to the safety or effectiveness of a drug or cosmetic.''

We don't do it at the Federal level, and we are denying the States the opportunity. What is the cosmetic industry so afraid of that they are precluding any public information or any other form of public communication relating to safety? What are they so frightened about? Is the almighty dollar worth that much when you are talking about carcinogens and toxic substances?

There it is, Mr. President, as clear as can be. The language, no warning labels, no information that a product contains carcinogens or can cause severe allergic reactions; no ''keep out of the reach of children'' labels; no notification that a product has been recalled because it is dangerous or adulterated; no expiration dates. Mexico requires expiration dates. The European Union has expiration dates. Sri Lanka has expiration dates. But no way—particularly in products such as mascara that can deteriorate and adulterate and cause serious threats to people's eyes—no expiration dates. The materials have been held in terms of the danger of mascara over a period of time without endanger rates or warnings to the public that use mascara; no preemption, right here in this legislation.

We are talking about health and safety. That is why we voted on this measure—health and safety issues.

We have already spent more time on this issue now this morning than we spent in the committee in its discussion. No ''keep out of the reach of children'' labels; no notification that a product has been recalled because it is dangerous or adulterated; no notification. The cosmetic industry seems to believe that for purchases of their products ignorance is bliss. In fact, what you don't know today can severely injury you, or even kill you.

Some States are already taking an active role in protecting consumers. Many more may do so in the future. But not if this bill becomes law. Minnesota has passed a hazardous product labeling bill requiring a warning on all products that are ignitable, corrosive, reactive, or toxic. You would think that all consumers should be entitled to that kind of information about products which they put on their faces or spray on their hair or wash their bodies with. But the cosmetic industry disagrees.

California requires notification if a product contains carcinogens or reproductive toxins that cause birth defects. You would think every consumer should be entitled to that information. Not after you pass this provision. When you take the time later in this debate to go through each of these and show the medical information, the study, the research which supports that finding, there are products that contain carcinogens and reproductive toxins. The studies have been done by some of the great research institutions in this country, but the data from their studies, warnings to expectant mothers, or to others who are going to use that product cannot be communicated to the American public by the States.

That authority will be gone. You can do all the research you want, find everything you want, but that authority will be gone. It is out. You would think that the consumer should be entitled to that information.

We had support for nutritional labeling around here for consumers to have information. It is one of our most important achievements, that people have some idea of the nutritional content of their diets, their fiber, and the various nutritional elements included in those. People want to know. That is enormously important in terms of the general health and dietary needs of the American people. But here we are talking about carcinogens. We are talking about toxic substances. We have the information that is being made available to the public on the one hand. But when it comes back to items that are going to endanger the health and safety, we are saying, no way—no at the Federal level and no at the State level.

Texas is investigating hormone creams that may affect the reproductive health of young women. You would think the States should be encouraged to take this kind of action. But this law prohibits it.

New York requires expiration dates on cosmetics because products can break down and be subject to bacterial contamination after a certain time period.

Most of you would think that this is basic information that every consumer should have. But not the cosmetics industry. If you want to try to say, OK; we had a preemption of various States' activities with regard to food and nutrition, yes. We did. We worked that process out. It was worked out with the various interests of the American consumer, and it is protected. If you want to go back and see where you want to have a national program in terms of preemption in terms of these dangers, you are going to talk about a completely different regulation. But that isn't recommended. That isn't suggested. That isn't talked about. That isn't being considered here. No. All it is saying is you are not doing it here at the Federal level. Legislation under the Food and Drug Act doesn't permit you to do it, right in that page and a half. It shows that they don't have the authority to do it. And we are not going to permit you to do it at the State level.

Mr. President, this provision of the bill is an example of what I consider to be the worst kind of sweetheart deal for special interests at the expense of the public interest. It is intolerable that it should be included in a bill that purports to be the Food and Drug Administration Modernization and Accountability Act. We are supposed to be out here modernizing the FDA, on the one hand, balancing the very important public health interests and also trying to consider the legitimate interest of the patient and the consumers using medical devices and new pharmacy products. That is a balance. It is a difficult and a complex one. You want to bring on line the new kinds of innovative products. But you don't want to do it if it poses a threat to public safety. That is a balance. And we have differences about the time, the process, and the procedure. Those are legitimate public health debates and discussions.

But not with regard to cosmetics.

So we have worked through the whole area with regard to pharmaceuticals and with regard to devices. There are two items which I think are of major importance that still need to be addressed. We have made very significant and important progress on the matters that are enormously important to the health and the safety of the American public.

And because that train is going down the track, here comes an old industry, the cosmetic industry, to hook this sweetheart deal right on it; hook right on it.

I hope we are not going to hear from other Members that we now need to have hearings now on various other issues after what we have seen on the cosmetics. I hope we are not going to have those issues. I heard the other day that we need more study in terms of the testing of children. We need more hearings on all of this. We have had extensive hearings over in the House and some hearings over here. But we need many more days of hearings before we jump into this at this direction—when you are talking about health and safety. And that has effectively never been done.

Another unacceptable part of this bill, Mr. President, contains the two provisions dealing with the safety of medical devices, which I will come to in just a few moments.

I see a friend and colleague, the Senator from Rhode Island, here on the floor. I would be glad to yield to him whatever time he might take.

The PRESIDING OFFICER. The Senator from Rhode Island is recognized.

Mr. REED. Thank you, Mr. President. I thank the Senator from Massachusetts for yielding.

Mr. President, over the past several months, we on the Labor Committee have been working diligently and effectively to try to create a Food and Drug Administration reform bill—a bill that truly balances the need for technological innovations and flexibility but that doesn't upset the fundamental obligations of the Food and Drug Administration to protect the public's health and safety. And we have made progress.

We have to recognize that the purpose of this bill fundamentally is the reauthorization of the Prescription Drug User Fee Act. That is the critical dimension that we are faced with. With the expiration of that authority at the end of this month or the beginning of the next fiscal year, we would lose a very valuable program, a program that has generally provided great success in speeding up approval, of ensuring that drugs are brought to the marketplace in a much more efficient and effective way. Linking the authorization of the Prescription Drug User Fee Act to the controversial FDA reform proposals may threaten many of the benefits of PDUFA—the acronym for the Prescription Drug User Fee Act. I hope that will not be the case. I hope we can work out some of these details and reach a suitable conclusion.

Much of the credit is due to the leadership of both Senator JEFFORDS and Senator KENNEDY. They have been working diligently to arrive at a legislative proposal that would balance the need for a rapid and effective regulatory response to the approval of medical drugs and devices but also fundamentally protect the public health. Frankly, I suggest that this is the motivation for our debate today.

The critical issue has to be, must be, and should be the protection of the public health and safety. That is why we have a Food and Drug Administration. That is why we maintain a strong, vigilant Food and Drug Administration.

We have agreement, I believe, that PDUFA is working, and that we can move forward with PDUFA. The industry is, indeed, thrilled by it. It works well. They pay fees dedicated to the examination and review of proposed drugs and devices. These resources have enabled the FDA to speed up the process.

In terms of the FDA process, PDUFA has done a great deal. The bill that we are considering on the floor today includes a reauthorization of PDUFA, and represents many improvements in the original bill that we started with, and, indeed, even the bill that emerged from the committee. But there are still critical issues that have to be addressed in terms of protection of the public health and safety. They are complicated issues. They are issues that require careful review and deliberation.

One of the disappointing aspects of this process is that the final version of this bill was just released publicly Wednesday, the same time the cloture motion was filed. Again, in the spirit of careful, thorough, thoughtful review, this does not provide the best opportunity to review all the nuances of this legislation.

So that is why I believe the effort today, led by Senator KENNEDY, is a very important one. It allows this body to more carefully, more intelligently and more thoroughly review provisions that will affect the lives of untold Americans. I daresay that the Food and Drug Administration reaches the lives of every American, probably more so than any regulatory agency in this country.

All the prescription drugs on the shelves, all of the medical devices that are used—all of them, the food additives, all of these things—are influenced by FDA action. We have to be very careful, very thoughtful and, I believe, methodical. So today's debate—and again I commend Senator KENNEDY for ensuring that we do have a thorough debate—is vitally important to that goal.

I mentioned that we have made progress on this bill, but I should say there are also areas that need improvement—desperately need improvement. There is one in particular I would like to speak to for a moment, and that is the issue of medical device labeling.

This bill contains a medical device provision which potentially opens up a serious public health loophole. Section 404 of this bill would prevent the Food and Drug Administration, before clearing a device for the market, from examining whether a device will be used for an unlabeled use before clearing it for use in the market. This provision could allow the gaming of the FDA process where companies could attempt to escape a requirement of providing essential safety and effectiveness data by adopting a very narrow use for the device.

For example, under this bill, a company could get approval for a biopsy needle from the FDA, even though it may be used in practice—and, indeed, this would be something that the company might have knowledge of—for an entirely different purpose, such as for tumor removal. Yet, the company could avoid submitting to the FDA any safety or effectiveness data on this device for tumor removal because FDA

would be prohibited by law from asking for that data. In other words, the FDA would be prohibited from looking behind the limited proposed use of the device.

Another example is a company which receives approval of a general surgical laser, even though the laser is clearly designed for prostate surgery. The public health of the American people is dependent upon a thorough and complete review of such devices, and yet, section 404 would essentially put blindfolds on the agency. They very well might know from general literature, the company might very well know from its sales force who, when they present this product, hear medical professionals saying, ''This is great, but I'll use it for something else,'' and yet the FDA would not be able to require data on this likely use. This provision would prevent the FDA from providing for the safety and effectiveness of medical devices.

The issue of allowing FDA to look beyond the conditions of use on the label and evaluating the use of a device is somewhat of a gray area. Certainly, advances in technology, new uses by the medical profession of devices should not be inhibited, but we also do not want to compromise the ability of the FDA to protect the public health. That is the great balance we must strike in this legislation: allowing for technological flexibility, regulatory efficiency, but not compromising the public health of the American people. It is a balance that we are edging close to.

We have made progress since the adoption of this bill at the committee level, but more progress can and should be made. We are committed to making such progress. We are committed, I think, to coming up with final legislation that will reflect both the need for technological efficiency and innovation, but also protecting the public health of the American people.

I hope we can do that. I know that we desperately want, all of us, to reauthorize PDUFA so that we can continue that outstanding record of regulatory efficiency and approvals that have been generated by PDUFA. But, I don't think any of us want to create a situation where months from now or years from now we are confronted with public health problems because we acted hastily or we acted without the thoughtful, careful review that is necessary to develop legislation that protects the public health and provides for all of the new innovations that are fast becoming part of our medical marketplace.

Again, I commend Senator KENNEDY for his unflinching efforts to ensure that these concerns are fully addressed. I also thank and commend the chairman of the committee who has worked diligently, sincerely and doggedly over these last several months to try to bring together opposing views on the committee. I believe we are close but not quite there yet. I believe in the days ahead, we can, in fact, reach a position of which we will all be very, very proud. At this time, I am prepared to yield back to the senior Senator from Massachusetts.

Mr. KENNEDY. I thank the Senator very much for identifying not only this issue on cosmetics, but also the issue of the medical devices proposal. That is an extremely important measure. Obviously, if there is advertisement and an intention for a certain kind of purpose and technologically it is suitable for that purpose, it meets the health and safety standards to be used for other kinds of purposes, that raises some very, very important questions.

The particular example that the Senator gave with regard to the biopsy needle is a current one. We understand it might be a suitable device in getting a biopsy in terms of cancer, but there are those actually using it to extract certain kinds of tumors. Whether it does that or not—and people assume it is going to be effective in doing that because it is used for other purposes—this is something that the device has not been tested for or intended. I think they there are very important health issues that are related and can be addressed. There are ways of trying to address those particular issues. We have tried to do this, and we still have important health and safety issues which I think are unresolved.

Mr. REED. If the Senator will yield for response, one of my fears is that not only would this situation result in perhaps not giving the FDA data on uses that the companies are aware of in the marketplace, but it might provide a subtle incentive in marketing these devices to encourage uses that are not authorized by the FDA and certainly not to be attentive to those types of uses and report back to regulatory authorities.

Again, when we think about this legislation, we have to think about also that there are a complex set of incentives and disincentives for the best possible behavior by pharmaceutical and device companies. I don't think any of us would like to unwittingly create a situation in which devices approved for one use are cavalierly marketed by companies for other uses and are merely winked at when they do not fall within the category of the approval. So that is another important issue.

There is another aspect of this which I would like to raise with Senator KENNEDY, and that is, I understand that Secretary Shalala has communicated concerns about this issue. I understand that she is concerned about this and her concern may be of such a level that it could suggest that she recommend to the President a veto of this legislation. A veto would be, I think, particularly unfortunate since we have worked so hard, we have made so much progress, and we have reached a point where we are very close to legislation which could virtually pass with unanimity in this body. It would be unfortunate that this type of provision of the bill would disrupt that process. I wonder if that is correct.

Mr. KENNEDY. The Senator is quite correct. In the Secretary's letter, she mentioned several items. I ask unanimous consent that the letter be printed in the RECORD.

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

THE SECRETARY OF HEALTH AND HUMAN SERVICES,
Washington, DC, September 5, 1997.

Hon. JAMES M. JEFFORDS,
Chairman, Committee on Labor and Human Resources, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: I am writing to reiterate the Administration's commitment to continue working with you to accomplish the timely reauthorization of the Prescription Drug User Fee Act (PDUFA) of 1992 and the passage of constructive bipartisan Food and Drug Administration (FDA) reforms. I very much appreciate your leadership and hard work on the important issues that are raised by the FDA legislation and the spirit of cooperation and accommodation that resulted in agreement on so many of the provisions in the Food and Drug Administration Accountability Act of 1997, S. 830. However, we are concerned that a timely reauthorization of PDUFA is in jeopardy.

Mr. Chairman, since S. 830 was reported out of Committee in June, we have come a long way and have reached agreement on what appeared to be the most difficult issues in the bill, including the dissemination of information by drug and device manufacturers, the effectiveness standard for drugs and biologics, the regulation of health economic claims, and the regulation of drugs made through pharmacy compounding. Unfortunately, we continue to have serious concerns about a number of issues that remain unresolved. We think that most of these issues can be worked out, but there are four issues that have the potential for jeopardizing our mutual goal of timely reauthorization of PDUFA and passage of constructive, bipartisan FDA reform.

The first of these issues is preemption of the state regulation of over-the-counter drugs and cosmetics. The Administration has serious concerns about far-reaching preemption—particularly in the absence of a strong federal program. The second issue relates to what FDA may consider in making substantial equivalence determinations for newly marketed devices. For example, the bill requires the Agency to review the intended use of a new device based on the manufacturer's proposed labeling—even if the device's technology clearly indicates that the device will be used for a use not included in the labeling. Third, the bill seriously undermines what was sought to be accomplished by the National Environmental Policy Act by virtually eliminating the requirement that FDA disclose the environmental impact of new products that it approves. The Administration recently took significant steps to decrease the burdens that were associated with conducting environmental assessments for FDA-approved products. We can think of no reason to jeopardize the environment by eliminating a review that is not costly to industry. Fourth, the PDUFA trigger as currently proposed in the bill would undercut the bipartisan budget agreement by denying FDA access to user fees at expenditure levels consistent with the Balanced Budget Agreement and would interfere with my ability to allocate resources appropriately throughout the Department. Finally, with respect to the pediatric labeling issue, we want to work with the Congress to assure that any provisions in the final bill complement the recent FDA actions and reach our mutual goal of effectively protecting our nation's children

and providing needed information to health professionals who treat them.

Mr. Chairman, we in the Administration all agree that reauthorization of PDUFA is in the best interest of the American public. We believe that we are close to reaching consensus on a bipartisan bill that includes this essential reauthorization. However, if the bill were maintained in its present form, and the outstanding issues were not addressed, I would be forced to recommend to the President that he veto this legislation.

The Office of Management and Budget advises that there is no objection to the presentation of this report, and that enactment of S. 830 would not be in accord with the President's program.

Sincerely,

DONNA E. SHALALA.

Mr. KENNEDY. Mr. President, the letter says:

The second issue relates to what FDA may consider in making substantial equivalence determinations for newly marketed devices. For example, the bill requires the agency to review the intended use of a new device based on the manufacturer's proposed labeling, even if the device's technology clearly indicates the device will be used for a use not included in the labeling.

So I think the point the Senator makes where they get approval for a particular purpose, it might be easier to get it for one purpose but with the clear intention of marketing for another purpose in which there has not been testing, and that can produce a hazard to the individual.

We have seen, for example, in some of the laser technologies that they have been approved for certain kinds of cutting procedures, and then they have been in certain instances adopted, for example, for prostate cancer, where they have not been tested and have not been effectively cleared and pose some very important health hazards.

So this is something that is very important, as we are moving through innovation, because we want to make sure we get those innovations. We want to make sure that the products are tested and have full information and disclosure.

I thought we worked out language to try and deal with that. It is an important health issue, and I appreciate the Senator's focus and attention on it. It is a matter of sufficient importance in terms of public health that we would have this identified by the Secretary as being one of the two or three items that the Secretary has identified would pose sufficient health hazard as to indicate a recommendation for a veto.

Mr. REED. If the Senator will yield again, I concur with his analysis, with the danger, and also with the fact this has risen to the level of the Secretary of Health and Human Services as a significant an obstacle to passage or acceptance by the President. Again, I don't think any of us are suggesting that pharmaceutical and device manufacturers are going to—some may, but I hope not—deliberately try to bait and switch. But the market is evolving so much and there is so much innovation that if the FDA can't, by reviewing the literature, make an estimate of what a device might be used for and ask for data on that likely use, then I think we are really constraining FDA—as I said before, putting blinders on the FDA.

That, I think, would be a mistake in policy. And I also feel, based upon my sense of the progress we have made to date, that this is not an unsolvable issue. This issue is one that there is compromise language, with which we can both provide for innovation, we can provide for marketing, we can avoid cumbersome demands by the FDA. But we can still give the FDA the authority to say, ''Listen, you are marketing this device for a very specific use, but we are aware that it would likely be used two or three others ways. How does this device work in those contexts?'' This is a very serious issue.

Once again, without the efforts of the Senator from Massachusetts to try to focus on these issues, it well could have been lost in the clamor of getting out of here and getting on with other business. It would be, in the long run, unfortunate for the public health of the American people.

Let me conclude by saying that it is vitally important in ensuring when the bill passes—and I believe we all hope it passes—it passes in a way we will all be proud of and will deal with all these issues that, leaving no unintended loophole or unintended consequences. I hope that we will have thought it through, worked it out and come up with legislation that will provide for the kind of technological innovation we all want, provide for the kind of efficient regulatory review that we all want and certainly protect the safety of the American public which not only we want but the American people demand. I yield the floor.

Mr. KENNEDY. Mr. President, I thank the Senator from Rhode Island for raising those issues, because that is a rather technical issue, it is a rather targeted question, but one that is of very significant importance.

I certainly agree with the Senator that we don't believe that the overwhelming majority of the medical device manufacturers don't intend to do such things. But what we have to try and do is make sure that those who may want to—and that is basically what happens in any regulatory procedure—you want to try and catch those particular items which are dangerous; that this is one that, with the tremendous expansion, in terms of certainly medical device technology, that we should address.

I appreciate the Senator saying that it can be addressed. We had language that we had considered, that I thought the device industry had been very supportive of and was acceptable. Then in the rush at the end, somehow individuals who had been involved in it felt they didn't want to have any further kind of adjustment or change in the language.

I think it is significant—and I am sure the Senator would agree and the chairman would agree—that we have had, in the fashioning of this bill great support and cooperation from the industry, from the pharmaceutical and also the device industry. We have perhaps some differences that have been moving along on particular kinds of items, but I must say—and I think the Senator would agree; I know he is proud of the industry in his own State, as I am in my State—we have had enormous cooperation and help. So many of these items are technologically difficult, complicated, and involved. We are basically generalists as Members of the Senate. We have some information and try to develop some expertise in particular areas of responsibility, but this gets to an involvement in detail which is enormously complex. When we have responsible industry involvement trying to help us. I did find that in other parts of the legislation it was very helpful. What we hope to do as this whole process moves ahead is come back and visit this provision and see if we cannot address it.

Mr. REED. If I may, if the Senator will yield, I, too, concur with the support, the assistance, the advice, and I think the general goodwill that the industry has brought to this debate. We are now, though, at the detail level, the fine detail, technical detail, and that is critically important. These are the types of details which later on come back to haunt us sometimes if they are not done well.

Mr. KENNEDY. Yes.

Mr. REED. The industry has been responsive and reasonable, and we want to incorporate their best advice but also recognize that our ultimate responsibility is to the health of the American people.

Something else, too, that the Senator alluded to was that this industry is becoming a very important part of our economy, not just nationally but locally. In Rhode Island we have several companies that are emerging as leaders in the industry. They offer not only extraordinary opportunities to help the American people, indeed, the people of the world, through medicine and devices, but also are becoming increasingly important economic powers within our communities—sources of jobs, employment and the types of activity that we certainly want to encourage.

Part of our motivation today is to ensure that we do this right. We need to give them the kind of direction and incentives that will make them stronger competitors in the international marketplace, stronger sources of strength in the communities of America, but also make them responsible and accountable to the American people through appropriate regulation. All of these things we can accomplish because I believe that the differences that separate us at the moment are not fundamental, ideological or in any other sense broad based. They are, rather, important details which will ensure or not ensure that this legislation can be used effectively to protect the public health.

So again I thank the Senator.

Mr. KENNEDY. I thank the Senator.

When we are talking about these technicalities, we have to remember that some of these items, particularly those medical devices that enter the body, have enormous health implications. I remember chairing, in 1974 or 1975, the Dalkon shield hearings where we found that 2,300 American women died from a perforated uterus from the Dalkon shield. That was before we had a Food and Drug Administration that really looked into medical devices.

We have the Shiley heart valve that passed through the FDA, and then eventually the FDA was able to uncover some of the difficulties with that and took steps. I think, if my memory serves me correctly, they were going to use a perfected Shiley heart valve over in Europe, and they altered some opening where the blood went through by just about 10 degrees, and that resulted in a rather significant increase in the failure of that medical device which was actually marketed abroad. The FDA was very much involved in seeing the termination of that.

So even very modest changes or alterations can have important kinds of health implications. We are not going to be able to solve all the problems and we are not interested in producing a bureaucracy that is going to halt innovative and creative ways of dealing with some of these issues. But it is important that we are talking about a Food and Drug Administration and public health.

As I mentioned briefly at the outset, this is the one agency that is intimately involved with public health. It has broad jurisdiction on a wide variety of items, and it has important responsibilities for the public health. This is where the buck stops. Some feel it ought to just be the agency to fast track various kinds of devices or fast track various pharmaceuticals without considering the health and efficaciousness of those products. That is why I think it is useful to pause here for a little while to give some focus to exactly this legislation and what its implications are going to be in terms of public health.

I thank the Senator.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. I would like to speak for a few moments just to try to allow those of my colleagues who are viewing us here as to why all this controversy. We just saw a vote of 89 to 5 in favor of moving forward with a bill that has come out and is ready to be placed before the body. Why is that occurring with all of these horrible problems which we have just been hearing about?

Take a look at this bill. This bill is 152 pages long—152 pages long. We are talking about four pages on cosmetics and two pages on medical devices. So we have to keep things in perspective. This bill has tremendous support because in almost every instance the issues that are of concern to people are taken care of.

But why all of this discussion about cosmetics? Because nobody is doing anything. That is why the controversy. The question is who should do something. Now, the question is whether or not you want some uniformity, and that is the Federal Government, the FDA, which we have tremendous confidence in, to take on the issue of warning about the problems of cosmetics and to have a uniform approach, uniform labels and those things so, if you go from one place to another, you don't get confused about what you should or should not be using or doing.

That is the question here. It revolves down to this. Right now, the States say, oh, my God, you can't tell us what we can do. Well, they haven't been doing anything, with the exception of California. It is not something we are moving into and pushing aside all existing regulations; there are none. The question is who ought to do it. Well, to California we said, OK, you have that so we will carve you out. Go forward. You have yours out there. That is fine. The Federal Government will not intervene, will not do away with that. So the bill presently says, California, what you have done is fine. The question is everyone else.

Now, since nobody has moved into this, it is not like you have a whole bunch of States out there panicked because their existing rules and regulations are going to be superseded. It is natural for Governors and State legislatures to scream and say, oh, my gosh, you can't take our power away to do something.

So where did we get down to before we came here? We got down to this close—this close. This is how close we are. We said, OK, if the FDA has not done something and has not established that this cosmetic is a dangerous one, then the States can move in. And if they feel differently, that it is and therefore we should do it, they have the power to do that.

That is the way it is right now. But we say that if the FDA has acted, then we want uniformity and so we should try to make sure that people across the country will have uniformity.

Then the issue was raised, well, suppose the FDA says that it is dangerous because it may cause problems on your face. Suppose the State believes it may have something to do with your blood system. Does that mean they cannot warn people that this cosmetic may be dangerous if it gets into your bloodstream?

Well, that is the issue. That is how far apart we are. On the two pages that deal with devices, the issue is about as narrow as that. It comes down to the question of, if a manufacturer says this device is for this purpose, and the FDA says, well, maybe we want to make sure that we know all the other purposes it might be used for, so they should alert us to those. We are down that far on those two pages, and we are down to within a few lines on the other four pages, but the other 146 pages there isn't really much disagreement with.

So I want to make sure we have things in perspective here. That is why the support, that is why we had the 89-to-5 vote on moving forward on this. But these are important issues. It is important for us to make sure that people know that with respect to cosmetics they are going to be protected and who is going to do it and what kind of awareness are we going to be able to have and what are the States rights versus the Federal Government.

So that is where we are. I will go at length later, but right at this point I want to make sure we understand where we are and what the issue is. In cosmetics, nobody is doing anything now with the exception of the State of California. We think the FDA ought to get in there. They ought to make sure that the cosmetics that are advertised are safe, that we know what problems could be caused and that we have uniformity in the country, so that when you go one place to another, you will have the ability to be able to rely upon uniformity as to what the various products may or may not do to you.

On the other hand, if the FDA does not take any action and a State thinks that this particular cosmetic or whatever is harmful, then they have the power to act.

So that is where we are. I want to reassure people that this bill does not ignore the problem of cosmetics. For the first time it really emphasizes that the FDA and the States should do something. What should they do? That is not going to be taken care of in the legislation because we would not know. But we do know that there is a need out there and that the FDA should have the authority to act and that they should have the authority to provide uniformity. But, on the other hand, the States should not be stripped of their rights to protect their people in the event the FDA has not acted.

Mr. President, I just wanted at this time to pause to try to make sure that everybody understands where we are and why we got the 89-to-5 vote to move forward.

I yield the floor.

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. The fact is that the FDA does not have the authority today—just does not have it. It has the authority to deal with pharmaceuticals and with medical devices but not with the issues which involve health and safety.

I will spend a moment or two just going through the Food and Drug Administration Act, the actual law. It is a page and a half. And there cannot be a fair reading of this, of these provisions, section 601 to 603. To believe that there is any adequate protection for American consumers in this page and a

half is folly. I mentioned earlier the FDA has no authority to require manufacturers to register their plants or products. It cannot require manufacturers to file the data on the ingredients in their products. It cannot compel manufacturers to file reports on the cosmetic-related injuries. It cannot require that products be tested for safety or that the results of safety testing be made available to the agency. It does not have the right to have access to manufacturers' records. It cannot recall a product.

Now, those are powers the FDA has with regard to pharmaceuticals and medical devices, but not with regard to cosmetics that may also be carcinogenic, and may also include toxins. We are not talking about an unimportant matter. We are talking about questions of health and safety. I find it difficult, with all respect, to say, ''Well, look, in California, we've carved that out. All of our Members will probably understand that means. ''We have carved out California.'' California considered this and took action. But if Minnesota—and they have been interested in taking some action on some products—wants to take action down the road in the future to protect its consumers, it cannot do it. In my State of Massachusetts, that has very similar legislation to that of California pending now, and they hope to be able to pass it in the next legislative session—they are out. They are finished.

We have taken care of one State, California. I am glad we did not wipe out California because I am interested in the protection of the citizens of California. They are going to get some protection, but not full protection, because you are going to preempt other health and safety statutes in California. This did not provide all the protections in California. Nonetheless, I am glad that the consumers in California are going to get some protection. But I cannot understand why we are denying other States from making a judgment that they want some protection. That is what this legislation does.

An additional point others will make is, ''Well, we're just dealing with packaging and labeling.'' But that is where the States act, with packaging and labeling. We do not see the withdrawal of products. They are able to do that and have been effective at it, in California. And I will get into how effective they have been, because they have been very effective in protecting consumers, not only in California, but the rest of the country, because when California, as a result of an extensive kind of medical research, has discovered that various products may contain carcinogens or dangerous and toxic substances, and required those products to be labeled, what happened? The manufacturer changed the product. And I will get into the examples.

This is the power that regulations on labeling and packaging can have. This is where they have been effective. These are the key elements, the possibility of developing warning labels. They have not had to develop the warning labels in California because the companies and the manufacturers have changed the products. One of the outstanding examples is Preparation H. Where there were products that were dangerous to consumers, the California regulations were effective in improving product safety. The manufacturer reformulated the product itself and says now it is better than it even was before. That was as a result of research that was done to uncover potentially dangerous substances that had been included in the product.

So, Mr. President, we have an agency that cannot practically deal with and has been restricted from packaging and labeling. We have seen a carveout, a carveout in the FDA authority in section 601 that talks about various products. It says they will not be able to deal with either poisonous or adulterated cosmetics, and cannot apply to coal-tar hair. Coal-tar hair dye. There is the cosmetic industry able to write right into the law ''coal-tar hair dye,'' even though the research has shown what that has done in terms of making hair dyes more dangerous than they need to be. The cosmetics industry has been effective enough to get written into this legislatively that, even though it is dangerous, there cannot be any kind of oversight of it. That is the power. That is real legislative power.

Mr. President, just on this question of the FDA and its ability to deal with this, let us go back to what the GAO said should be done if we were to have an FDA that would be able to provide adequate protection for the public health. This is a public health issue and a safety issue. That is what we are dealing with with regard to cosmetics.

The other items that we mentioned earlier deal with health and safety and are of importance. But on cosmetics, we are effectively talking about health and safety issues. When the GAO last looked at the FDA, and were charged with making recommendations, these are the recommendations that they made. They said:

> We recommend that the Congress amend the Food, Drug and Cosmetic Act to give FDA adequate authority for regulating cosmetic products. Specifically, we recommend that the Congress authorize FDA to require:
>
> Registration of all cosmetic manufacturers.
>
> Registration of cosmetic products and filing of ingredient statements [so that they know what ingredients are in the various products].
>
> Manufacturers to submit to FDA data to support the safety of their products and the ingredients in them [to demonstrate the safety of their products prior to putting them on the market. Before marketing, to be able to give the assurance of safety and also to be able to get the ingredients of these products].
>
> Premarket approval by FDA of certain classes of cosmetics or ingredients when the agency deems such approval necessary to protect the public health.

Why? Because they take notice that some of these products contain possible carcinogens and some of them have toxic products. They are saying we ought to be able to demonstrate the safety of those products rather than put them out in the marketplace and endanger the public.

The GAO report further recommends that:

> Manufacturers to submit to FDA consumer complaints about adverse reactions to cosmetics.
>
> Manufacturers to perform specific testing FDA deems necessary to support the safety of a cosmetic or an ingredient.

So if the FDA were to make a judgment that they believe that items may cause birth defects, may cause an assault on the nervous system, may somehow threaten seriously the health and the well-being of the consumer, that they would be able to ensure there is going to be adequate testing. Those are very minimal standards. These recommendations are from the last review for the power and the authority for the FDA.

Now, do you think we have any of those today? No, we do not have any of those. And all we have to protect the consumer is what is happening at the State level. That is all we have. With this legislation, we are effectively preempting the States from providing those protections to the consumers in their States.

I find it extraordinary how quickly we are to be willing to accept that particular provision without hearings. We understand the power of the cosmetic industry. We understand why this has come up. This has come up, Mr. President, because of the action that has been taken by California. Because California has acted in various cases in order to ensure that the cosmetics that are being used by Californians are safe and effective. They do not want to have to keep dealing with this. Nonetheless, manufacturers have changed their products. They have made them, in so many different instances, safer. That is the way it should be.

If we are not going to do it at the Federal level, why do we take away the power of the various States? It is effectively like preempting the States from having State police. All the States have various State police in order to look after safety and security in their States. We are saying, we are not going to provide any kind of help and assistance, but, in addition, we are taking away your safety, a means of protecting your people as well. And that, I believe, is wrong.

Mr. President, I want to just mention some of the various items since we have talked in generalities here about some of them. Some of these items that we have addressed here have posed a threat to the health and safety.

First of all, we have hair dye, the coal tar in the hair dye. That is a potential carcinogen. It is a danger in terms of the American public and the consumer. One State, California, has a State law. Ohio has tried to deal with this, but they have been basically unable to do so. The industry has been so

powerful it has been able to get written into the law, into the bill itself, that we cannot tamper with something we know is directly a public health hazard. In public health we know that, and still it is written into the law.

We have the old Grecian Formula. It does not have to go through the FDA. It had lead in it—lead. People thought, well, we can use it because it is just a hairspray. We know what happens when lead is ingested. We know it causes mental retardation, for example, in children.

One of the principal problems in inner cities is old paint chips that have the lead content. We know the incidence of mental retardation, and if you go into any urban area in this country and go to the great county hospitals, they have a lead paint poisoning program. You see the incidents of mental retardation that are a direct cause of lead in the paint. The children are either eating the chips or they are playing outdoors and the chips are ingested. They get on the cats and dogs, and children pet them and then scratch themselves or put their hands in their mouths.

It just goes on. We understand that. That has been well understood and documented for 30 years now. But we now know there was lead in Grecian Formula. This came out as a result of the various analyses in California. There was a certain amount of concern about it, but then there was action by the company, and they said, look, maybe there is lead in it, but it is on your hair, and you are not ingesting it, so, therefore, it is not a problem. Then other studies showed that people were washing their hair and were also embracing their children and touching their children and working with their animals or their pets, and this was picking up the flakes and, if the dye was being used over a considerable period of time, the lead posed a significant and important threat to children.

So what happened? Grecian Formula changed their ingredients as a result of this to make a safer product. They did not miss a beat in terms of being able to market it and being able to be successful. But it was changed, and that is because of local activity—not the FDA, but because of local activity.

Mr. President, I will give further illustration, but I will just at this point remind Senators, as we are going through some of these examples, there may be those who say, ''Well, OK, you've got a half dozen out there, but is that really enough to try to resist this provision to preempt State activities?'' Well, the last serious study that was done by a congressional committee was actually done by our colleague, Congressman WYDEN, who held landmark hearings in 1988.

The industry gave his subcommittee a list of 2,983 chemicals used in cosmetics. The National Institute of Occupational Safety and Health at NIH analyzed the 2,983 chemicals and found 884 cosmetic ingredients had been reported to the Government as toxic substances. Let me just repeat that: The industry, the cosmetic industry, provided to the Congress a list of 2,983 chemicals that are being used in cosmetics.

The National Institute of Occupational Safety and Health, what we call NIOSH, which is the center for expertise in being able to analyze various toxic substances, and NIH analyzed these chemicals and found that 884 cosmetic ingredients have been reported to the Government as toxic substances.

We have known for 10 years that a third of cosmetic chemicals are toxic, but we have done nothing to strengthen the consumer protections. Instead, we would rather weaken the consumer protections. Instead of trying to make some progress to protect the consumer we are taking steps to put them at greater risk. Does that make any sense?

We had debate and discussion about the Delaney amendment with regard to carcinogens and processed food and we debated those issues and said is it not time to alter, change, and modify that? We passed very good legislation dealing with pesticides, insecticides, and fungicides just 2 or 3 years ago because we were looking at the fact that the best estimate is that there are probably 2,600 to 3,000 Americans that were dying because of pesticides and insecticides that were being put on products and were being ingested. We have run into problems. We had extensive hearings about the dangers of insecticides on children, because children eat more bananas and certain types of food and products have more insecticides, and therefore it has more of an impact in terms of their bodily functions.

We spent hours and hours and days and days on hearings because we wanted to provide protection against carcinogens in our food supply. Here we have now, according to NIOSH, and according to the NIH, 884 cosmetic ingredients that have toxic substances. Rather than trying to do something about those in terms of examining those in relationship to what is being done in the House and in terms of the well-being of the consumer, we have not only had no enforcement or regulatory protection at the Federal level but we are eliminating what actions could be taken at the State level.

It makes no sense, Mr. President, makes no sense at all. That is what the effect of the preemption does. I read the language on the preemption and that is effectively what that language does.

Now, Mr. President, we have a situation, for example, that has come up in fairly recent time, a hair spray that might be inflammable, and we find out that the State of Minnesota was looking at trying to make some effort to try and identify the dangers that result from this.

Mr. President, there is a Senator here that would like to address the Senate and I am happy to accommodate him.

Mr. JEFFORDS. Mr. President, I yield such time as he may consume to the Senator from Indiana.

The PRESIDING OFFICER. The Senator from Indiana.

Mr. COATS. Mr. President, I thank the chairman and I thank the ranking members who are ahead of me for allowing me this time. I have a schedule conflict and I appreciate the opportunity to say a few words.

I will have more to say as we move forward with this legislation. I wanted to make some opening remarks. I am very pleased that we are actually here at this time with the legislation on the floor. It has been a long and arduous road that we have traveled over this past 2½ years to address the need for FDA reform. We have, as the chairman and Senator KENNEDY said, had numerous hearings. We have listened to the Commissioner of the FDA and his representatives and employees and colleagues. We have listened to outside experts. We have heard from the various industry groups. But the real reason that we are here is not just the fact that a few Senators got an idea that perhaps we ought to address some issues at FDA. The real reason we are here is that all of us have been besieged by consumers, by patients, by, yes, manufacturers of drugs and devices and others who have outlined to us the nightmare that exists at FDA in terms of approving products for beneficial use by patients.

What I will primarily do this morning is briefly state the ''why'' of the need for FDA reform and save my remarks on what we have done—which I am sure will be outlined by many others—save my remarks on what we have done for debate on Monday, Tuesday, or following that, depending on how long this discussion goes on.

First of all, let me state that the precipitating reason for moving forward was the need to reauthorize PDUFA. That is the user fee that is paid for by the drug prescription industry to allow FDA to hire additional personnel and to employ additional technology to speed up the approval of drugs. I am not sure who bears the responsibility for lack of personnel or lack of updating technology.

I have worked with Senator MIKULSKI on a more comprehensive modernization of FDA, consolidating their campus, giving them the new technology that they need, and giving them the personnel that they need. Because SBA was in such desperate shape in terms of its ability to use drugs we enacted sometime ago a user fee whereby the industry itself would be taxed with the money designated specifically to hire the personnel and improve the process and procedures for approval of prescription drugs. That is what finally moved us from debate and delay to the NIOSH action.

I am particularly pleased that Senator JEFFORDS, the chairman, responded to my concerns that if we move only with a limited PDUFA reauthorization we will have addressed only

a small part of the problem that exists at FDA, that what we needed was a comprehensive bill, broad in scope, that would allow us to address a number of problems that exist at FDA, including substantive reform for medical devices and other products regulated by the agency. I commend the chairman for agreeing to do that. We held extensive hearings and broadened the scope of the bill. The bill we have put forward is one that does address a number of issues and that is why it receives such widespread support from the Congress.

Clearly, the vote in committee, a strong bipartisan vote for moving this process forward in support of the comprehensive bill and the vote that was just taken this morning—overwhelming, almost historic in proportion—vote on cloture I think indicates the depth and the breadth not only of the bill but of the support for the bill with Democrats, Republicans, liberals, conservatives, moderates, everybody in between. Only a handful, literally a handful of Senators voted against cloture. So I think that shows the need for moving forward on this bill.

FDA bureaucracy and delay, inconsistent rules, lack of willingness to use outside expertise—all of this has jeopardized the health of American patients. FDA opponents of reform like to state, ''Oh, we cannot jeopardize the health and safety of Americans,'' and yet in their insistence on maintaining virtually status quo in total FDA control on their assistance on that, they have denied Americans lifesaving and health-improving benefits both through prescription drugs and devices and other forms of medical assistance. They have denied people the opportunity to beneficially affect their health and have forced them to go outside the United States, forced manufacturing companies to go outside the United States, forced drug device companies to go outside the United States in order to market their product whereby they would be subject to the rules and regulations of foreign countries rather than this country.

To imply that only the United States FDA has the wisdom to be able to determine what is in the best interests of the health and safety of its citizens is, I think, a slap in the face to countries like Germany, Britain, France, and others who have similar approval processes that benefit the citizens of their own country.

FDA average review time, just taking medical devices, average review time for low- to moderate-risk medical devices, the so-called 510(k)'s in 1995 increased over the previous 6 years by over 200 percent, from 82 days to 178 days, for total review days from 66 days to 137 days for time actually in the FDA's hands. The law says they need to do this in 90 days—the law. We passed the law, a statute here that says that the FDA on low- and moderate-medical devices you have 90 days. The FDA said, OK, 90 days. In that period of time since we passed the law it has doubled in terms of the amount of time they take to review those. Those are average review times.

Specific examples show how ridiculous and how scandalous the process is or has been at FDA. Fortunately, we are in the process of looking for a new Commissioner, and hopefully that Commissioner will bring some business sense instead of simply an ideological bent to the agency and provide for some expediting of some of the devices that do not pose serious health risk to Americans at all.

We all hear about this whole idea that FDA is standing at the bridge, keeping Americans from being subjected to the most egregious of violations, drugs and devices perpetrated by a greedy industry that is concerned only about the bottom line.

I have a device manufacturer in my State that makes hospital beds. That device manufacturer, which is well respected on a national basis, that device manufacturer designed a new bed cover. This is the cover you put over a mattress, on a bed. The bed had been approved, the mattress has been approved, the old device cover has been approved. It is a piece of cloth. But they designed a new one that prevents bodily fluids from leaking into the mattress. Obviously, that could be a potential health risk to not only that patient but perhaps a subsequent patient. So they had come up with a new mattress pad which achieved significant improvement in promoting the health of patients who would use that mattress.

Of course they had to submit it to FDA for approval. This is a class I device, the lowest risk to the patient. So they submitted it to FDA, and the FDA took 476 days to review that mattress pad before it would grant approval. So we talk about the average review times and protection of the party but when you bring it down to specific examples of the ineptness and the bureaucracy that exists at FDA, there are examples on both sides.

The other side likes to use relatively rare anecdotes and of course many of these go back 20, 30, and 40 years, and no one—no one in support of FDA reform—is stating we ought to compromise on health and safety. What we are trying to do is say we think we can expedite and utilize new technology that improves health and safety if FDA could get its act together. Now, if you takes 476 days to approve a mattress pad which clearly is in the benefit of the health and safety of hospital patients because it prevents bodily fluids from seeping through the currents mattress pad, then if it takes 476 days to do that, something is wrong at FDA. Meanwhile, new 510(k) notifications have dropped dramatically, from 7,000 annually in 1989 to a projected 4,800 in 1998. So high-risk, if you look at that, and novel device review times increased from 348 days to 773 days, on average. Many are far longer than that. Some have been languishing in the system for 4 and 5 years.

Now, the statute says that FDA has 90 days on low to moderate risk, 180 days on high risk, and yet, FDA's average review time in 1995 is 773 days on high-risk and novel devices. So, clearly, something needs to be done.

What the committee has tried to do is simply say, let's take an agency that we need, an agency that is important to the health and the safety of Americans and let's see if we can improve it, let's see if we can reform it. The best step and the first step was the resignation of the Commissioner, who admitted to the committee in what was one of the most astounding statements I have ever heard any agency head ever deliver, which was basically saying, ''I am incapable of doing this. You in Congress are going to have to force me to do it. I need the pressure from Congress to do it.'' Can you imagine a CEO of a corporation coming before the board of directors and saying, ''I am not capable of running this company efficiently like you want me to, but if you will put pressure on me and force me to do it, then I can go to my vice presidents and say the board is insisting that I do this''? Is that an example of the weakest form of management and oversight that you can possibly imagine? I could not conceive that the then Administrator, Dr. Kessler, of the FDA would make such a statement. ''I am incapable of doing it, but you force me to do it and then maybe I can convince the people that work for me that we ought to do something.''

Well, let me talk about another example of intolerable delays. This isn't a mattress pad. This goes to life and death. The product was a stent, a small, mesh, spring-like device used to keep coronary arteries from closing. A new stent product that was developed by a manufacturer was submitted to the FDA in November 1986. In August 1987, FDA said, ''We need more paperwork.'' It took them that long to figure out they needed more paperwork. In April 1988 and in August 1989 and in June 1991 were additional requests for more paperwork. An FDA panel meeting was held in May 1992, and they gave unanimous approval to the product. Four years after it was first submitted, an FDA panel gave unanimous approval to the product. It then took the agency an additional year to issue a letter allowing the device to go to market.

Now, have you ever heard of such bureaucratic ineptness? After 4 years of reviewing paperwork on a life-saving device, on which the statute said the FDA had 180 days—after 4 years, the FDA panel met and gave unanimous approval. From that time, it took 1 year for the FDA to issue the letter saying, ''Congratulations, you have been approved.''

Now, critics of reform talk about the potential threat to American health and safety for approval of devices. But

they never talk about the demonstrated not only threat but consequence to the safety and health and even life of Americans for ineptness and delay in the approval of drugs. How many people died or suffered serious incapacity because a life-saving stent on which we could not get a letter of approval from FDA, which approved it, until 1 year later? How many people, over a 5-year period of time, lost their lives because a life-saving device didn't receive FDA approval for 5 years? Let's say it took 4 years; let's grant them that it took 4 years of reviewing paperwork to make sure that this life-saving stent device was worthy of FDA approval. There is no excuse. What possible excuse could there be for a delay of 1 year in submitting the letter so the company could go ahead and market the product?

Dr. FRIST, who is a member of our panel, said, ''I would have loved to have had that stent. I known what that stent does. I've used that stent. Had I known that stent was available before approval * * *''—to think that it was languishing in FDA 1 year after FDA approved it unanimously—it took them a year to get the letter out so that they could market the device. So there are people lying in their graves.

This Senator is tired of hearing about FDA being the guardian of the health of Americans and we should not move forward with any kind of reform at all. When you touch the words ''reform of FDA'' and try to move up their approval process or expedite the process at all, why, then you are jeopardizing the health and safety of Americans. The burden of that lies on the shoulders of those who won't move forward with responsible reform.

Fortunately, today, this Senate, in an overwhelming bipartisan vote—only five people opposed—said it is time to move forward with reform and it is past the time to move forward with reform. We owe apologies to the families of the Americans who have been denied life-saving treatments and devices because people have blocked reform and efforts to move forward.

A Hoosier who attended one of our FDA hearings recently had a life-saving vascular graft implanted in his body. Mr. Friar testified before our committee. He was one of the fortunate patients to receive the graft because he needed the product only after it was approved. Other patients who were denied that before FDA got around to approving it, were not so fortunate.

I could go on and on with examples, but I won't. I do get exercised over it because it is unfair to characterize those that try to seek meaningful reform as those who somehow don't care about the health and safety of American people. We care so much we want to get something done. We want to get some reform underway.

The Hudson Institute, in late 1995, surveyed this question and came up with an estimate. It is difficult to talk about an estimate when we are talking about human life. The Hudson Institute is a respected institution. Let me cite an example from their study. Delay in approving the coronary stent, they say, reached 27 months. The FDA gave access to this product to American patients 27 months after European patients had access to the product. Depending on how one attributes responsibility to the agency, partial or total, the regulatory delay is estimated to have resulted in 1,600 to 2,900 lives lost, patients whose lives were lost because of bureaucratic excess.

So we stand on this floor and talk about it being irresponsible to move forward with FDA reform and we delay FDA reform. We won't even allow a disputed issue to come to a debate on FDA reform, when we are talking about a potential loss of lives of Americans who are denied products because of FDA ineptness.

That is the human side of the question. I am not even going to get into the business side of the question because the two don't even begin to compare. We have lost manufacturing and jobs to overseas facilities in record numbers because manufacturers are throwing up their hands and saying they will go broke waiting for FDA to approve their products. It means a significant number of jobs. Sixty-one percent of U.S. device companies plan to market offshore first. We lead the world in drug and device product development. But they are being pushed out of the country by the FDA. They are being aggressively lured by foreign governments who know that our bureaucratically bloated system provides them the competitive advantage they need to draw those American companies and employees and the brain power away from the United States.

A Netherlands foreign investment company has a publication out highlighting the oppressive climate in the United States. They say, ''Come over here and we will provide a much more favorable climate.'' Now, we will hear in rebuttal about some product that was approved and later turned out to be a mistake. Well, there are exceptions and there will be exceptions, whether they are in the Netherlands or in the United States. We are talking about human beings. We can't guarantee 100 percent perfection. But that is no excuse for not reforming FDA and trying to give it the tools and give it the wherewithal to do a better job.

It has been estimated that the delay in U.S. availability of products threatens a loss of 50,000 jobs in the next 5 years. This is one of the greatest industries we have ever had in this country, in terms of promoting job growth, but beyond that, providing health-improving and life-saving benefits for the American people. Why do we make it so difficult for them?

I don't want to go any further with that because, as I said, you can't compare economic benefit with health benefit. We ought to be focusing on the denial of benefits, the loss of life for failure of the FDA to meet its statutory requirements. We are not asking the FDA to compromise; we are not asking them to compromise on health and safety. We are saying: Do what you said you could do, or at least let's look at alternatives. I proposed an alternative to try to help the FDA. You would have thought I was proposing an amendment to disband the FDA and let the free market sort it out. It was nothing of the sort. That is not what we are after here. I thought we would try to give them some assistance with a third-party review, the FDA certified agencies or organizations outside of the FDA. But FDA looked at it and said: You have the testing wherewithal and the scientific wherewithal to help us expedite approval of these products, and as long as we certify you and as long as we approve the process, and as long as we have a veto power, even if you approve it, if we have a veto power and say, no, we have changed our mind, or we are not sure about that—not even that was acceptable to the opponents of this bill. But it is acceptable, fortunately, to the majority of the committee. It is acceptable to a majority of the American people. It is acceptable to a majority—not a majority but a supermajority—of this Congress. But yet with all of that debate, there is delay and withholding of moving forward, and procedural delays, all in an effort to oppose an honest effort at trying to help the FDA do its job. The irony is the FDA was already doing some of this. We are trying to provide a way that they can do more of it. So the FDA couldn't come forward and say, ''Well, we think everything ought to be done within the FDA.'' They admitted they needed help from the outside, and we structured the statute in such a way that you even wonder if it is going to work because the FDA has so much preapproval, during the process approval, postapproval, veto, and everything else on the thing. But at least it is a start. At least it is a movement in the right direction.

FDA has made all kinds of promises about internal approval, approval, improvement, reinventing itself, and so forth and so on. The record speaks for itself. Prescription drug user fee types have improved, and we are grateful for that. And they have improved because we taxed the industry. The industry said, ''We are so anxious to try to get some of these drugs to market we will pay for it. Not only the development of the drugs, which is enormously expensive, not only the approval of the drug but we will tax us some more and we will give the money to FDA, and you can hire more people so you can look at it. If you turn it down, you turn it down. But at least get an answer one way or another so we can move on to something else, if you don't approve it.''

People say, Why don't you do the same thing with devices? Let's tax the device industry. We are not talking about American-owned products, or

Merck, or Pfizer, Glaxo, major international companies with the funds able to do this. The device companies are often small organizations—startup venture capital organizations. To tax them at this stage is going to just accelerate driving them offshore, and in many cases they in no way have the wherewithal to provide a tax for that. It is not their responsibility. It is a governmental responsibility.

The President's budget hasn't helped much either. The President's budget proposal for fiscal year 1998 reflects something other than an effort to strengthen the agency. In fact, it proposed a cut of funding for the agency. They wanted to cut the Device Center budget by 27 percent. Clearly that calls for congressional action to address the issue, to ensure that the bureaucracy, and the old ways of doing business give way to some efficiencies and accountability in this era of tight budgets.

So that alone is reason for us to move forward. Here we are now in September on PDUFA and a jeopardy of laying off—expiring and laying off—a whole bunch of people. And we are way behind the timetable that we ought to be on in terms of moving this forward.

Just on another point about the size of device companies. Of roughly 8,000 device companies that exist in United States, 88 percent have fewer than 100 employees and 72 percent have fewer than 50 employees. User fees are clearly not workable in a situation like this. And I am pleased that the bill doesn't impose those.

I have all kinds of statistics here, and all kinds of anecdotes and all kinds of stories. The bottom line is we are attempting to bring the FDA into this century. This century is almost over. We are attempting to try to take a tired, inefficient bureaucratic ideologically driven agency and introduce it to the modern era. We are trying to take advantage of these marvelous technological breakthroughs in drugs and devices and products that are occurring at an ever increasing rate around the world, but particularly in the United States, and make them available to American consumers to improve their health, to ensure their safety, to prolong their lives, to save their lives. That is why we have formed an extraordinary coalition between Republicans and Democrats. This has nothing to do with party lines, liberals, conservatives, and everybody in between. There was an almost unprecedented vote in committee of 14 to 4, and we would have had even a better vote than that if we went back and did it now because we have resolved some of the concerns that those four had. We wouldn't get all four. But we would have even a better vote—probably more like 16 to 2 because we have addressed those concerns that were raised in committee. Those Members thought that they had better reserve their vote and negotiating ability. And we resolved that.

We have done an extraordinary amount of negotiating from the time the committee passed the bill out until this point. We were that far away in July from resolving this. In the negotiations with Senator KENNEDY, we made 30-some concessions on a bill that passed 13 to 4 in order to get the approval of one person because one person could tie this thing up procedurally. We made 30-some concessions—concession after concession after concession by the chairman, this Senator, and other Senators. What is the problem? How can we fix it? Can you work it out? Can you go along with the bill, if we did that? Can you do that?

We finally threw our hands up in total exasperation because every time we thought we were at the goal line, no, move the ball back another 15 yards to another position. Take that up. Will that do it? Yes. Solve that. Then they thought of another one. There was always a reason to delay and delay. And then we went through the August recess. If we were talking about making a widget, if we were talking about something that didn't affect the health and the safety of the American people—I suppose that is just part of the process here—but we are talking about people waiting for steps that would save their lives; waiting for approval from FDA of drugs that can potentially keep them from dying, waiting for products that can make their life a little more tolerable while we play games in the U.S. Senate because one person doesn't think it is a perfect bill in front of him, even though there is a widespread majority in support of it. That is wrong.

So I am glad we are moving forward. I am sorry that we had to invoke a procedure to cut off a filibuster to do it.

I understand people may have some concerns about this bill. It is not a perfect bill. It passed through months of arduous negotiation. There has been give and take. Every Senator is free to come down here and make his point and raise his objection and offer an amendment and take a vote. If it passes, the bill will be modified. If it fails, instead of taking the ball and going home and saying we are not going to play anymore, let's just say apparently I wasn't persuasive enough, or maybe I got my facts wrong, or maybe that is not what the majority wants to do. But let's not deny health improvements and safety improvements for the American people and the American consumer just because we don't get our way. Let's move forward. We will now.

We have invoked cloture. I regret that we had to do that. I regret we had to go through the month of August waiting to reconvene, because there are people out at FDA that are going to be laid off if we do not get this thing moving. All the efforts that we have done to try to hire additional people out there will be undermined in terms of drug approval because we can't get this bill moving.

So let's move forward. Let's raise our objections. Let's have a debate. Let's have a vote and accept the result, and let's move forward with FDA reform.

Mr. President, I will have more to say about this at a later time. I have not gotten into the ''what.'' I was talking about the ''why'' here—why do we need reform. I have not gotten into what the bill includes. It is a broad bill with a lot of depth. It covers a lot of areas. It is significant reform. It is not as much as this Senator would like. It is more than some other Senators would like. But it is a big step in the right direction.

I just note for the RECORD that I don't know what is going on, Mr. President, at the White House. We have been without a commissioner now at FDA for some time. They nominated someone this week, and then withdrew the nomination 24 hours later. I don't know why. But I urge the administration to continue its search. I am going to suggest a couple of names to them of people, if they need people to look at. I don't do it with any hope that they think anybody I would suggest ought to head up FDA—not this administration. But we ought to get somebody in there who is willing to exercise the oversight and the administrative ability to work with the Congress in bringing this agency into the modern era and improving the way things are done there. There are a lot of dedicated, competent, hard-working scientists and researchers and medical personnel at FDA who deserve to have competent leadership, competent management, and deserve to have the support of this Congress in providing the funds and providing the technology and providing the assistance in expediting in an appropriate manner the bringing to market of drugs and devices that can make a difference in people's lives.

Mr. President, there is more to come later. I yield the floor.

Mr. DURBIN addressed the Chair.

The PRESIDING OFFICER (Mr. HAGEL). The Senator from Illinois.

UNANIMOUS-CONSENT AGREEMENT—S. 1061

Mr. DURBIN. Mr. President, I ask unanimous consent that it be in order to offer two amendments to S. 1061, even though the bill is not pending, and that those two amendments be laid aside.

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

AMENDMENT NO. 1078

(Purpose: To repeal the tobacco industry settlement credit contained in the Balanced Budget Act of 1997, as amended)

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Illinois [Mr. DURBIN], for himself and Ms. COLLINS, proposes an amendment numbered 1078.

The amendment is as follows:

At the appropriate place, insert the following:

SEC. . REPEAL OF TOBACCO INDUSTRY SETTLEMENT CREDIT.—Subsection (k) of section