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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.

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

9302 of the Balanced Budget Act of 1997, as added by section 1604(f)(3) of the Taxpayer Relief Act of 1997, is repealed.

AMENDMENT NO. 1085

(Purpose: To provide for the conduct of a study and a report on efforts to improve organ and tissue donation)

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Illinois [Mr. DURBIN], for himself, Mr. LEVIN, Mrs. MURRAY, Mr. JOHNSON, and Mr. BREAUX, proposes an amendment numbered 1085.

The amendment is as follows:

On page 49, after line 26, add the following:

SEC. . (a) STUDY.—Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the General Accounting Office, shall conduct a comprehensive study concerning efforts to improve organ and tissue procurement at hospitals. Under such study, the Secretary shall survey at least 5 percent of the hospitals who have entered into agreements with an organ procurement organization required under the Public Health Service Act and the hospital's designated organ procurement organizations to examine—

(1) the differences in protocols for the identification of potential organ and tissue donors;

(2) whether each hospital, and the designated organ procurement organization of the hospital, have a system in place for such identification of donors; and

(3) protocols for outreach to the relatives of potential organ or tissue donors.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report concerning the study conducted under subsection (a), that shall include recommendations on hospital best practices—

(1) that result in the most efficient and comprehensive identification of organ and tissue donors; and

(2) for communicating with the relatives of potential organ and tissue donors.

Mr. DURBIN. Mr. President, I ask unanimous consent those amendments be laid aside for debate at a later time.

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

AMENDMENT NO. 1086

(Purpose: To express the sense of the Senate that hospitals that have significant donor potential shall take reasonable steps to assure a skilled and sensitive request for organ donation to eligible families)

Mr. DURBIN. Mr. President, on behalf of Senator LEVIN, I would like to, on the same bill, S. 1061, offer an amendment.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Illinois [Mr. DURBIN], for himself, Mr. LEVIN, Mr. THURMOND, and Mr. INOUYE, proposes an amendment numbered 1086.

The amendment is as follows:

At the appropriate place, insert the following:

SEC. . (a) FINDINGS.—Congress finds that—

(1) over 53,000 Americans are currently awaiting organ transplants;

(2) in 1996, 3,916 people on the transplant waiting list died because no organs became available for such people;

(3) the number of organ donors has grown slowly over the past several years, even though there is significant unrealized donor potential;

(4) a Gallup survey indicated that 85 percent of the American public supports organ donation, and 69 percent describe themselves as likely to donate their organs upon death;

(5) most potential donors are cared for in hospitals with greater than 350 beds, trauma services, and medical school affiliations;

(6) a recent Harvard study showed that hospitals frequently fail to offer donation services to the families of medically eligible potential organ donors;

(7) staff and administration in large hospitals often are not aware of the current level of donor potential in their institution or the current level of donation effectiveness of the institution;

(8) under titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq; 1396 et seq.), hospitals that participate in the medicare or medicaid program are required to have in place policies to offer eligible families the option of organ and tissue donation; and

(9) many hospitals have not yet incorporated systematic protocols for offering donation to eligible families in a skilled and sensitive way.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that hospitals that have organ or tissue donor potential take prompt steps to ensure that a skilled and sensitive request for organ or tissue donation is provided to eligible families by—

(1) working with the designated organ procurement organization or other suitable agency to assess donor potential and performance in their institutions;

(2) establishing protocols for organ donation that incorporate best-demonstrated practices;

(3) providing education to hospital staff to ensure adequate skills related to organ and tissue donation;

(4) establishing teams of skilled hospital staff to respond to potential organ donor situations, ensure optimal communication with the patient's surviving family, and achieve smooth coordination of activities with the designated organ procurement organization; and

(5) monitoring organ donation effectiveness through quality assurance mechanisms.

Mr. DURBIN. Mr. President, I ask unanimous consent that the amendment be laid aside for later debate.

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

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

The Senate continued with the consideration of motion to proceed.

Mr. DURBIN. Mr. President, I would like to address the motion pending before the Senate at this time on the FDA reform bill.

I have listened very, very closely to the statements by my colleague and friend, the Senator from Indiana. I note that his comments are heartfelt about a very important agency. The Food and Drug Administration is by Federal standards a small agency. The annual appropriations is in the range of $1 billion, and by the standards of Washington, DC, it might be ignored by many. But those of us who are familiar with the important mission of the Food and Drug Administration, those of us who have worked closely with that agency and with its Commissioners over the years, and in my particular case, those of us who have had the opportunity to literally fund this agency through the Appropriations Committee of the House, understand the critical importance of this agency. Though its resources and budget may be small by Washington standards, its responsibilities are immense. There is not an American living who is not touched by the work of the FDA. They regulate things as diverse as the radar guns used by police, microwave ovens used in airplanes, and virtually all of the drugs and medical devices for sale in the United States. We count on them every day. And they are an agency, as you can tell from the previous Senator's remarks, which is not above criticism. This is an agency which has a very difficult mission. On the one hand, a person who is ill seeking a new drug or medical device wants the FDA to issue approval as quickly as possible. That is a natural reaction.

By the same token, a company with a drug or a medical device which they want to see approved is anxious for the FDA to give approval as quickly as possible. The FDA approval on a drug or medical device is better than any Good Housekeeping seal of approval. It is literally a ticket for sales, confident sales, worldwide. Once the Food and Drug Administration of the U.S. Federal Government gives its approval, you know that your medical device or your prescription drug is going to have an opportunity for a worldwide market because that approval means something.

There is another side to this ledger. The Food and Drug Administration, with the pressure to approve drugs and medical devices by not only consumers but also by manufacturers, also has an awesome responsibility to make sure that those approvals are done in the right way, so that the American consumers know that what they purchase is safe and effective.

Those are the two criteria. So the scientists and those working at the FDA put in long hours, days, weeks, months, sometimes years, to make certain that a product, before it goes on the market in the United States, is safe. While they are in the process of evaluating, there are people on the sidelines saying, what is taking so long? Why hasn't this agency moved to approve this drug or this medical device?

I have been frustrated myself when people in my old congressional district or in my State have come forward and said, it has taken months, sometimes years; why don't we have the FDA's final approval? I am sure some of that may be associated with bureaucratic slowdown, and if this bill addresses

that, then I think it is a very important step forward. But do not minimize the fact that many times the evaluations by the Food and Drug Administration are careful reviews of clinical trials to make sure, before a drug or device is released in America, it is safe and effective. Not a single one of us would want to take a drug prescribed by a doctor uncertain as to whether or not it was safe. No one would want to do that. The Food and Drug Administration tries to give us that confidence.

There has been a reference made earlier to Dr. David Kessler, the last Administrator of the Food and Drug Administration. The previous speaker obviously shares a different opinion than some about Dr. Kessler's performance and contribution. I think he is one of the most extraordinary public servants I ever had the opportunity to work with. The only holdover from the Bush administration, Dr. Kessler was reappointed by President Clinton and I think did an exceptional job. Of course, we are kindred spirits on the tobacco issue, but beyond that I think his job at the Food and Drug Administration will set an example that others will have to try to emulate, and they will find it difficult to do so. I am sorry we lost him, but he gave so many good years of service to the Federal Government we can be thankful he did.

Let me also say that this is an agency which has fallen under criticism politically. When the Republican control of the House occurred after the 1994 election, I was amazed that one of the first lines of attack by Speaker NEWT GINGRICH was on the Food and Drug Administration. He made arguments, many of which you have heard this morning, that this agency was stopping those devices which would save lives, this agency was stopping the approval of drugs which would save lives. And he went on at great length about how they were going to dismantle the Food and Drug Administration, literally to turn out the lights at this agency.

Thank God that didn't occur; saner minds prevailed, came forward and said that would be a serious mistake. A lot of the references to a more responsible approach came from the same industries that are regulated by the FDA. They realized that when you drop your guard, when you get into a no-holds-barred strategy when it comes to the approval of drugs and medical devices, the reputable companies will be the first to lose when consumer confidence is destroyed.

Let me give you three examples of what I have seen in a short period of time, of the work of the Food and Drug Administration. Some of these are forgotten, and they should not be.

There was a counterfeit infant formula on the market that was discovered by the Food and Drug Administration. It turned out that some group of individuals had decided to take one of the most popular brands of infant formula in the United States and to literally copy its label and to put contents in a can and sell them as if it was the product that it was advertised to be. In fact, it wasn't. It was a phony. Luckily, the FDA caught them and in catching them stopped the sale of this infant formula product which was grossly deficient, which if it had been given to infants across America could have caused serious health problems. The Food and Drug Administration was vigilant, caught them and stopped them.

Let me make reference to one that most people remember. It was only a few years ago that they discovered these syringes in Diet Pepsi cans. Oh, every nightly newscast told us about this discovery. What did it mean in the wake of the AIDS crisis to find a hypodermic syringe in a can of soda? Well, luckily the Food and Drug Administration stepped in and determined that this was only an isolated example and a hoax. It was important for the consumers across America, but it was equally important for Pepsi Cola. Their stock had plummeted when this occurred. But the Food and Drug Administration stepped in and said this is something the consumers do not have to worry about. We have it under control. And because they have the respect of the American people, the product went back on the market without a problem and the stock resumed its climb. I think it is important for us to make sure that we talk about what this agency brings to us.

I also took a trip to the State of Massachusetts, to review the Food and Drug Administration programs there, in particular, to review one particular company that was making heart catheters. Most people are familiar with them. Those who are not should know that they are tiny little threaded lines that the surgeon will insert in your body and then it will course through your veins to your heart, and they can literally take samples as well as photographs of the interior of our bodies—a critically important medical device. Yet, as it turns out, this company was making defective heart catheters that literally broke off inside people's bodies and then, of course, surgery was necessary to remove them. That is the type of thing the Food and Drug Administration must be constantly vigilant to watch out for and to protect us against.

I could go on—and I will not—for hours about what the Food and Drug Administration does and how important it is when we reform this agency to remember their enormous responsibility to consumers across America.

I agree with my colleague, Senator KENNEDY, that there are portions of this bill that should be reviewed and I hope changed during the course of the floor debate. I think it is wrong for us to remove from the States the authority to review cosmetics and to put warning labels on them, if a State decides it is in the best interest of its citizens. We do not have sufficient personnel at the FDA right now in the Cosmetic Section to take responsibility for complete Federal oversight of this large industry. Senator KENNEDY has made a compelling argument that we should allow the States to continue to have this authority, to put those provisions in place which will protect the health and safety of consumers.

I have three amendments which I am going to offer, and I hope that they will be amendments approved on a bipartisan basis. One seeks to reverse an area of this bill which I am afraid will weaken the strong safety protections put in place by the Safe Medical Device Act of 1990. Many of us remember the tragedy resulting from the Bjork-Shiley heart valve failure. Extensive congressional hearings were held in the late 1980's examining what had gone wrong and how we might prevent future repeats of those terrible deaths when this heart valve failed.

In the United States alone, over 300 people died because this defective medical device was implanted. Worldwide, almost 1,000 people have died as a result of fractures in this valve once it was put in place. After it was concluded these heart valves were defective, over 50 percent of the patients with these heart valves in their bodies could not be located. One widow testified before Congress about how her husband had a heart valve, suffered chest pains and the couple had no idea that it was because of the defective heart valve. They had not heard about it. They had not been notified. They lived at the time equidistant between two hospitals, only one of which was capable of performing open heart surgery. They made a mistake; they went to the other hospital. Her husband died. She didn't realize that he might need open heart surgery because the heart valve in his body was defective.

The Safe Medical Device Act of 1990 set up a system for mandatory tracking of these high-risk devices so that if problems were found, the patients with the devices could be located and notified. That is a basic protection.

There are only 17 types of devices that require mandatory tracking. They are all extremely high-risk medical devices—heart valves; pacemakers; vascular stents; jaw, shoulder, hip joint replacements; windpipe prostheses; breathing monitors and ventilators.

It is hard to imagine the tracking of such high-risk devices could ever be made optional, and yet that is exactly what this bill does. The FDA has already complained that they find it extremely difficult to enforce this provision, and yet instead of helping them with enforcement, this bill weakens their ability further by making tracking discretionary.

Isn't it curious that automobile manufacturers are required to have a tracking system so that if a safety problem is identified with your car's model, they know where to find you. It seems unthinkable to have a lower standard of consumer protection for a pacemaker or a ventilator as compared to a seat belt.

The second aspect is surveillance. This is a key part of this Safe Medical Device Act which this bill undermines. The mandatory surveillance program of high risk medical devices is especially important for consumers. These surveillance programs are important for the early detection of potential problems with medical devices. In some cases the initial breakage of a device may not cause instantaneous harm. For example, in the case of Telectronics' heart pacemaker J leads, which were found to be defective in 12 percent of the patients, breakages did not result in harm until the next bout of heart arhythmia. Surveillance of these leads identified problems in some patients. This led to the notification of patients with these leads of the need to have them checked. Such early detection and correction can prevent a health crisis.

Let me give you another example. Early detection, unfortunately, was not seen in the case of Teflon jaw implants made by Vitek in the 1980s. These implants, once put inside of a human being, were found to splinter and cause massive corrosion of jaws and skull due to the triggering of inflammation and other immune responses. By the time the patient suffered the pain, extensive damage had already been done. Many of these patients required complete resection and removal of their jaws, even some of their skulls exposing their brains.

Donna Fennema from Ames, IA, testified here late last year at an FDA hearing of how she needed 30 hours of critical major medical surgery to rectify her splintered jaw implant. She needed a rib graft to rebuild her jaw on both sides. To this day, she suffers pain from both her jaw and her rib cage. If a surveillance program had been in place prior to the Vitek jaw implant defect, many of these patients would have been able to have the implants removed prior to the deterioration of their physical conditions. This terrible tragedy that we have seen is one of the major catalysts, along with the Bjork-Shiley heart valve, for the passage of mandatory surveillance and tracking of implantable high-risk medical devices.

Yes, it is true that these programs of surveillance and tracking are burdensome to industry. Make no mistake about it. But the cost to society, the cost to each of us, the cost to American families of weakening them is far too high for us to be undermining them.

The second issue I would like to raise is one that is very typical and one that I have worked on for a long time. It is the issue of tobacco. I am concerned that section 404 of this bill, this FDA reform could undermine FDA's ability to regulate tobacco. This section attempts to limit FDA's ability to look at anything other than the manufacturer's label to determine the intended use of the product and to determine whether the product is safe and effective for this labeled use.

This section has much broader implication than just tobacco regulation. It provides a generally huge loophole through which device manufacturers can attempt to avoid FDA regulation through imaginative labeling. However, it is most worrisome for tobacco regulation given the long history of tobacco companies and their deception.

In the early seventies when there was a ban on TV advertising of tobacco products, the industry devised every imaginable way to circumvent this ban. They would purchase bill-board space at sport's events which were placed in such a manner and location, that they knew they would be televised during the sport's event. For example, they would purchase billboards behind homeplate of a baseball game or near the scoreboard. They would purchase racing cars with advertisements along their sides. No stone was left unturned, looking for ways around the ban.

Around the same time of the television ban on advertising of tobacco, the industry passed a voluntary code that none of them would use models that appeared to be under 21, and yet many of the models which were used could pass as high school students.

All this suggests to me at least that we do not want to jeopardize any type of tobacco settlement with this FDA reform bill. I suggest a very simple and straightforward fix, and I hope that the sponsors of the bill will consider it. It says as follows: Nothing in this entire bill shall be construed to alter any authority of the Secretary to regulate any tobacco product or any additive or ingredient of a tobacco product.

Mr. KENNEDY. Will the Senator yield on that issue?

Mr. DURBIN. I will be happy to yield.

Mr. KENNEDY. I welcome the Senator's focus on that particular provision. We had attempted to address that question, but it was done very unsatisfactorily. I think the Senator has raised a very important issue with regard to what we have done in the legislation and the power of the FDA to deal with tobacco in this legislation.

We will have an opportunity to address that when we move toward the legislation itself, but I think it is important and one of the principal reasons for taking the additional time on the legislation for the reasons that the Senator has just identified.

For example, I think we have heard from responsible legal authority that if the manufacture of tobacco products were to label them as ''intended for smoking pleasure'' or ''intended for weight loss'' or ''intended to be used twice weekly,'' then there is a real question whether FDA can get safety data on the addiction of those health hazards.

We know how creative—and the Senator from Illinois knows well because he has been a leader in the House of Representatives and in the Senate with regard to the activities of the tobacco industry—how creative they can be in terms of packaging, so to speak, their intercessions with the FDA in ways that can circumvent the kind of protections that all of us are so concerned about, primarily with youth, and also as part of this whole tobacco negotiation.

I commend the Senator for the work that he is doing and welcome the opportunity to join with him to try and address the actions of the tobacco industry in the recent budget item to circumvent the agreements that the tobacco industry had made with the attorneys general. That is another issue for another time. What it does reflect is how the industry is working tirelessly at every junction to try and foreclose the opportunity of meeting their responsibilities, either under the agreement or under this legislation.

I think they undermine the authority of the FDA in their agreement, which they signed with the attorneys general, and that agreement should not pass under any circumstances unless that measure is addressed. I know the Senator will work with us closely in doing that.

But the Senator has identified another potential loophole that ought to be addressed. I am very hopeful that we will be able to do that. I thank the Senator for raising this because this is another very important aspect, as we are being asked to rush through this legislation. There are only two or three Senators evidently concerned about this particular proposal. We have seen the fact that the Governors, all of the Governors, the State legislatures sent in their resolution and their letter saying, ''Go slow,'' in opposition to the legislation. As the Secretary of Health and Human Services has also indicated, go slow.

I thank the Senator for his comments on these other items, but particularly with regard to tobacco.

Mr. DURBIN. I thank the Senator from Massachusetts. Another item I would like to address on which I will be offering an amendment that I hope Senator JEFFORDS will consider is that of removing any possible money taint of the external review process.

This bill expands the ability of medical device companies to purchase their own third-party reviewers. Given the importance to the public of the approval process remaining untainted by monetary influence, it is extremely important we ensure that there are very strict anticonflict of interest standards for product reviews.

In laymen's terms, if we are going to hire companies to review medical devices to determine whether or not they are safe enough for sale in America, devices such as the heart catheter that I mentioned earlier, we want to make certain that the reviewers are truly objective; that they do not have any conflict of interest or any monetary gain associated with what they are doing.

This bill, as currently drafted, has only very limited language on the issue of preventing conflict of interest. Senator HARKIN was successful in adding

some strength to that language. His amendment which was accepted after the markup of this bill in committee, allows the FDA to look at the contractual arrangements between an outside reviewing entity and the company whose product is being reviewed.

FDA employees themselves are subject to a wide range of anticonflict of interest legislation for obvious reasons. If you are an employee at FDA, if you can purchase stock in the company of the device you are about to approve, you are in for a windfall. We don't want that to occur, and we certainly don't want it to occur when we talk about third-party reviewers.

Senator FEINGOLD and I will be offering an amendment that would codify into law basic requirements for outside reviewers. We don't seek to impose all the FDA employee regulations on outside reviewers, merely the most appropriate. We would be happy to work with Senator JEFFORDS' staff to tailor these very basic requirements specifically to outside reviewers.

Our amendment is simple. It merely asks outside reviewers not be allowed to have a financial interest in a company that they review. It further demands that no outside reviewer may receive a gift from a company whose product they review. To monitor and prevent such activities, the amendment allows FDA to require financial disclosure.

It should be obvious to all of us why it is necessary.

The money stakes are certainly higher with respect to getting FDA approval. Every day we read of how the stock market soars for a company whose product has just received FDA approval. For instance, on May 7 this year, FDA announced approval for a laser system made by a company called Premier Laser Systems, Inc., that treats tooth decay painlessly. There is something we all would like to see. Within days of this approval, the company's stock price more than doubled, and for the first time since going public in 1995, Premier hit the top 10 in trading volume on Nasdaq, far surpassing even Microsoft 5 days in a row. That is what FDA approval means.

As we farm out this responsibility to third-party reviewers, it is important that they make decisions that are objective and honest.

Failure to get approval of a product can have the opposite effect. For example, recently an FDA panel voted 9 to 2 that FDA reject an approval for a heart laser made by a company known as PLC Systems. Trading in the stock had to be halted after this announcement. Shares of PLC had risen dramatically in recent weeks on the expectation of a more favorable result. FDA denial of approval shattered the stock's profitability.

The medical device industry produces over $50 billion annually in sales. In fact, a recent article in the journal Medical Economics, entitled ''Why Medical Stocks Belong in Your Portfolio,'' the medical device industry was described as ''a hot market that is only getting hotter.''

Not only are the money stakes high for investors, however, the stakes are also high for patients who have to rely on these devices.

Reviews must be of the most stringent nature and must be carried out without outside corrupting influences.

The approval of an unsafe drug or device, as I have already mentioned, can have a devastating impact. Surely, it is not too much to ask that a reviewer be prevented from accepting gifts or loans from a company they are reviewing and that they not be allowed to designate another person for acceptance of such a gift.

Furthermore, a reviewer or their spouse or minor child should not be allowed to have a financial interest in a company whose product they are reviewing. That seems basic and fundamental. I hope Senator JEFFORDS and others on the committees would consider agreeing to the Durbin-Feingold amendment. The products are too important to the American people. I believe we should take a firm stand and specifically enumerate basic standards within this legislation to prevent even the potential for corruption of this process.

Let me say, I was one of the five this morning who joined with Senator KENNEDY in suggesting that this bill should be debated at length. I hope that some of the items that I have raised during the course of this debate will give Senator JEFFORDS and others an indication of my concern. But let me say also that I respect what Senator JEFFORDS and the committee has accomplished here. FDA reform is needed, and I think what you are setting out to do, to make it a more efficient process, is a very worthy goal.

I find most of this bill to be very positive, and I am anxious to support it. I hope that during the course of the debate on my amendments and others, we can rectify what I consider to be a handful—but only a handful—of very important items which still need to be debated. I hope to be able to vote for final passage of this bill, and I hope Senator JEFFORDS and others will be open to these amendments. They are offered in good faith, and I hope we can work together to resolve some of the concerns I have.

Let me close by saying that those who are critical of the FDA often pine for those countries overseas where it is so easy to get approval for drugs and medical devices. I recommend to some of them that on their next trip to Mexico that they drop into a pharmacy and look at what is for sale on the shelves of those Mexican pharmacies. You will find products that are openly advertised as being cures for cancer and AIDS. Many countries, which have a much easier process, have little integrity in that process. We want to maintain that integrity to make sure the American consumers know that they still are getting the very best. I yield back my time.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, first of all, Senator MIKULSKI will be here shortly. I would like to make a few comments before I turn the floor over to her.

With respect to the devices, as I pointed out earlier and I just want to refresh everybody's recollection, the bill that we are dealing with is 152 pages long. The matters on devices are two pages. The matters on cosmetics are four. I thank the Senator from Illinois for bringing attention to some possible problems with respect to ensuring, as we all want to ensure, that there is no conflict of interest involved with any of the companies that they will be dealing with.

I point out, first of all, that the FDA has total control over the third parties that will be allowed for the purposes of reviewing. They have total control over that. There are already regulations which propose to correct most of the problems, although a couple others have been raised, and we certainly are going to seriously consider amendments that will take care of those problems.

Let me go through the provisions right now on the existing regulations for FDA:

Can't own a device company;

Can't have any ownership or financial interest in any medical device company;

Can't participate in the development of medical products;

Can't be a consultant;

Can't prepare advice for companies; and

Fees cannot be contingent on third-party recommendation.

In addition, I emphasize that the FDA has a list of those they have examined, have gone through to make sure that they are appropriate for the purposes of assisting—assisting—FDA in coming to conclusions on these devices.

There are some protections:

Can't obtain reviews for the same product from more than one third-party organization;

Can't contract for a substantial number of reviews, like more than 10 a year, from the same review organization on different devices; and

Can't contract for reviews from the same review organization where the sum of fees is substantially like $50,000 one year when the other organizations have the same capacity.

So there are many protections now. Of course, we are very concerned, along with the Senator from Illinois, and want to make sure we have taken care of every possible situation.

With respect to the legislatures and the Governors, I will point out that the discussion in that regard has been very limited to certain provisions, but I want to enter into the RECORD a letter

which came to the majority leader, Senator LOTT, from Gov. Tom Carper from the State of Delaware, chairman of the Committee on Human Resources, and Gov. Tom Ridge, the vice chair of the Committee on Human Resources. I will read that for the RECORD:

On behalf of the nation's Governors, we are writing to express our support for swift passage of bipartisan FDA reform and a reauthorization of the Prescription Drug User Fee Act (PDUFA).

Better health care for all Americans is a paramount national goal that is strongly supported by the Governors. An important component to improved health care delivery is the development and approval of safe and effective new medical technology. New therapies, for example, have the potential to improve the lives of millions of Americans and may, in many instances, reduce health care costs.

The Governors also recognize that the competitiveness of the U.S. pharmaceutical, biotechnology, and medical device industries—and the hundreds of thousands of people they employ in our states—is dependent on bringing products to market safely and quickly. Constructive reform will improve the efficiency of the approval process while continuing to protect the public's health and safety.

We have the support of the Governors. They are not going to go through everything. Generally, they support what we are doing. That is why we had an 89-to-5 vote today to move forward.

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:

NATIONAL GOVERNORS ASSOCIATION,
Washington, DC, July 25, 1997.

Hon. TRENT LOTT,
Senate Majority Leader,
Capitol Building, Washington, DC.

DEAR SENATOR LOTT: On behalf of the nation's Governors, we are writing to express our support for swift passage of bipartisan FDA reform and a reauthorization of the Prescription Drug User Fee Act (PDUFA).

Better health care for all Americans is a paramount national goal that is strongly supported by the Governors. An important component to improved health care delivery is the development and approval of safe and effective new medical technology. New therapies, for example, have the potential to improve the lives of millions of Americans and may, in many instances, reduce health care costs.

The Governors also recognize that the competitiveness of the U.S. pharmaceutical, biotechnology, and medical device industries—and the hundreds of thousands of people they employ in our states—is dependent on bringing products to market safely and quickly. Constructive reform will improve the efficiency of the approval process while continuing to protect the public's health and safety.

Thank you for your consideration in this important matter.

Sincerely,

GOVERNOR TOM CARPER,
Chair, Committee on Human Resources.
GOVERNOR TOM RIDGE,
Vice Chair, Committee on Human Resources.

Mr. JEFFORDS. With that, I see Senator MIKULSKI is here. I would, therefore, yield to her such time as she may desire.

Ms. MIKULSKI. Mr. President, I thank the chairman for his leadership in bringing about not only a reform structure for FDA that preserves both the safety and efficacy of pharmaceuticals, biologics and other products that the American people utilize, but also for the fact that he has been able to move this legislation to the floor.

I also extend my compliments to Senator KENNEDY for his longstanding commitment to public health, to public safety, and at the same time being able to maintain the whole idea of developing jobs in our own country.

Mr. President, I have been working on FDA reform for a number of years. I worked on FDA reform when I was a Member of the House of Representatives on the Energy and Commerce Committee, serving under then Congressman DINGELL, where we embarked, on a bipartisan basis, to ensure consumer protection and that we did not dump our drugs that did not meet our standards on third world countries.

Coming to the Senate, I joined with my colleague from Massachusetts and the Senator from Utah, [Mr. HATCH], in fashioning legislation called PDUFA, the Prescription Drug User Fee Act, which enabled a very important tool to go into place in which we could hire more people to come to FDA to examine the products that were being presented for evaluation, to be able to move them to clinical practice in an expeditious way. The leadership of Kennedy-Hatch on PDUFA has not only stood the test of time, but has really been shown as a test for being able to expedite approval processes and maintaining safety and efficacy.

But it was clear that PDUFA was not enough, that more staff operating in an outdated regulatory framework, without a clear legislative framework, was deficient. That is when we began to consult with experts in public health, those involved in public policy related to food, particularly with drugs and biologics. And in the meantime, while we were considering all this, something came into the world which was the revolution in biology. We had gone from a smokestack economy to a cyberspace economy. We had gone through basic discoveries in science from the field of chemistry and physics to a whole new explosion in biology, which is truly revolutionizing the world, whether it is in genetics or other biologic materials. These offer new challenges to ensure their safety and efficacy, new staff and a new legislative framework.

What we then said is that we needed an FDA with a new legislative framework and a new culture. This is then when we tried to put together what we called the sensible center, working with Republicans and Democrats alike, because we certainly never want to play politics with the lives of the American people to come up with it.

Senator Kassebaum chaired the committee during this initiative. We took important steps forward. I say to Senator JEFFORDS, you have assumed that mantle, and I think you have improved on the original legislation that Senator Kassebaum had written.

I was proud to participate for several reasons.

One, I have the pleasure and the honor of having FDA located in Maryland. I cannot tell you the enthusiasm to be able to have the National Institutes of Health in Bethesda and FDA in Rockville, really looking at the life science endeavors, the ingenuity, creativity and scientific know-how, to come up with basic knowledge, to work extramurally in these wonderful institutions in Maryland, in Massachusetts, and Vermont, academic centers of excellence, to come up with fantastic new ways of saving lives and at the same time generating jobs.

Through the work, then, of Secretary Shalala and the Vice President, we did make some improvements. But we must codify those improvements. So this is where we come to today. What I like about the legislation here is that it streamlines and updates the regulatory process for new products, it reauthorized that highly successful Prescription Drug User Fee Act, and it creates an FDA that rewards significant science and evaluation while protecting public health.

Now, what is the end result of the legislation that we will pass? It will mean that new life-saving drugs and devices will get into clinical practice more quickly, and it will enable us to add products that we can sell around the world and, through this, save lives and generate jobs.

FDA is known the world over as kind of the ''gold standard'' of the approval of products. We want to maintain that high standard. We want to maintain its global position. At the same time, we want to make sure that FDA can enter the 21st century. This bill gets us there. It sets up a new legislative and regulatory framework that reflects the latest scientific advancements. The framework continues FDA's strong mission to protect public health and safety and at the same time sets a new goal for FDA, enhancing public health by not impeding innovation or product availability through unnecessary processes that only delay the approval.

We are considering a very important issue today. I would just like to reiterate the importance that no matter what the outcome of this bill, we must pass the reauthorization of the Prescription Drug User Fee Act. This has enabled them to hire 600 new reviewers and cut review times from 29 to 17 months over the last 5 years. If we fail to act, it means that people who have been working on behalf of the American people will get RIF notices because we have not been as quick to approve FDA reform as we have asked them to approve products that do meet the safety standard.

Who benefits from this legislation? Most of all, it is the patients. Safe and effective new medicines will be getting to the patients early. It will meet the

performance standards in PDUFA, and we will be able to again provide this great opportunity for patients.

By extending PDUFA, we can make further improvements in the drug approval process. Currently, PDUFA only addresses the review phase of the approval process. Our bill expands PDUFA to streamline the early drug development phase as well. This expansion will be covered in a separate letter. This letter is very significant in how PDUFA will work. The letter includes performance goals that have been worked out between FDA and the biological and pharmaceutical industry.

What are the kinds of things that this will do that will help? Electronic submissions. It means that instead of a carload, whether it is UPS, IPS, or whatever, pulling up at FDA, with stacks and stacks and stacks of material, it can be done electronically. That not only reduces paperwork, but actually provides a more facile, agile way for the scientific reviewers to get through the data. Also, we are talking about meeting management, in other words, FDA meeting to discuss what are the appropriate protocols; reducing the response time on clinical holds; having written protocol agreements; predictable appeal processes; and reducing manufacturing supplement review times, along with some others.

These are management tools, and I cannot understand why the naysayers are saying no to this.

I want to make it clear that these goals that we are outlining should be binding on the agency. It is my intent that the letter that will accompany this legislation should be considered as a minimum, not a maximum, commitment. The agency can do better; it should by all means do better. The agency did a great job exceeding its commitments in the 1992 letter along PDUFA compliance. I am sure they can do it this time.

Updating the approval process for biotech is another critical component. Biotech is one of the fastest growing industries in our country. There are over 143 biotech companies like that in my own State of Maryland. They are working on AIDS, Alzheimer's, breast and ovarian cancer, other life-threatening infections such as whooping cough.

I know during the NIH discussion the other day we passed additional money for Parkinson's. I am proud to report that there is a biotech firm in Maryland that also has a joint venture with brilliant neurological scientists from Johns Hopkins. And we anticipate either a cure for Parkinson's—a cure for Parkinson's—or certainly the ability to stretch out the ability of people to function both intellectually and in terms of their motor skills.

You know what? That cure could very well come from Maryland. My gosh, can you understand the joy that I will have the day that I can come to the U.S. Senate and announce that we have found a cure for Parkinson's, that it is in my own home State, and that we have a pharmaceutical that can help people gripped by this devastating and debilitating disease?

That is what we are here for. We do not find the cure, but we fund the research to look for the cure. We do not invent the product; that is up to the genius of our private sector working with our scientific community. We cannot ensure the safety and efficacy of that idea to make sure it is not only a dream, but also has the ability to really work in clinical practice in a way that enhances in patients. And that is the job of FDA. But our job is to fund the research and to have the regulatory and legislative framework to evaluate it, to get it out to clinical practice. That is why I am fighting for this. This is exactly why I am fighting for this.

My dear father died of Alzheimer's, and it did not matter that I was a U.S. Senator. I watched my father die one brain cell at a time, and it did not matter what my job was. My father was a modest man. He did not want a fancy tombstone or a lot of other things, but I vowed I would do all I can for research in this and to help other people along these lines. And we can go around the Senate. Every one of us has faced some type of tragedy in our lives where we looked to the American medical and pharmaceutical, biological community to help us.

When my mother had one of her last terrible heart attacks that was leading rapidly to a stroke—there is a new drug that is so sophisticated that it must be administered very quickly. You need informed consent because, even though it is approved, it is so dramatic that it thins the blood almost to the hemophilia level. I gave that approval because my mother was not conscious enough to do it.

Guess what? That new drug approved by FDA, developed in San Francisco, got my mother through her medical crisis with the hands-on care of the Sisters of Mercy in Baltimore at Mercy Hospital. We were able to move that through. Mother did not have a stroke because we could avoid the clotting that would have precipitated it.

Thanks to the grace of God and the ingenuity of American medicine, we had my mother with us 100 more days in a way that she could function at home, have conversations with us and her grandchildren.

Do you think I am not for FDA? You think I am not for safety? You think I am not for efficacy? You bet I am. And that is what this is all about. It is not a battle of wills. It is not a battle over this line item or that line item. It is really a battle to make sure that the American people have from their physicians and clinical practitioners the best devices and products to be able to administer to save lives.

So that is what we are all about. I do really hope that we can approve this FDA reform. I am glad that we invoked cloture, not because I want to stifle debate, but I hope that for whatever ways can be done to improve the bill, let us offer those amendments on the floor, let us have a robust debate, and then let us vote on this, because at the end of next week we will make sure we have had adequate staff to be able to deal with work at FDA and an adequate framework to save lives and generate jobs.

So, Mr. President, I thank you for the time. If I seem a little emotional about it, you bet I am. I love FDA. I am really proud they are in my State. I thank God for the ingenuity of the American medical community. And I really look forward to moving the bill.

I yield the floor.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. I thank the Senator from Maryland whose untiring efforts have enabled us to come forward here with an excellent piece of legislation, her undying efforts on behalf of FDA and the people of Maryland and the rest of the country to ensure that they are an effective, efficient operation and they do all that is possible and appropriate to protect the interests of others. There is no one I relied on more who has done more to bring about this bill in the shape that it is in and in a position where I feel confident that it can pass. So I thank the Senator very, very much for her effort.

Mr. President, I know of no other Members on my side of the aisle who desire to speak and I do not believe there are those on the other side, other than Senator KENNEDY.

I make a point of order that a quorum is not present for the purpose of allowing other Members to notify me if they do desire to come and speak and we will certainly accommodate them. I will wait for at least 5 minutes for a response.

I suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. GRAMS). The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

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

Mr. JEFFORDS. Mr. President, we have given Members time to notify us that they desire to speak. I have received no requests from my side or supporters of the bill for a presentation here. I believe the same is true for Senator KENNEDY, but I defer to him for that.

Mr. KENNEDY. Mr. President, there is a possibility of one speaker but not more than that, although I have some remarks related to the legislation which I will look forward to presenting.

Mr. JEFFORDS. My present intention is to make some final remarks myself and then to yield back the time on behalf of the majority. It is my understanding, as the Senator has said,

that he intends to proceed for some time and perhaps have one additional speaker, and it is my understanding at that time that he will yield back his time. I am not concerned for the presentation of the majority because we have another 4 hours on this on Monday morning, I believe, so we will have ample time—just to reassure the majority—we will have ample time on Monday to take care of any situation which may arise.

Before I complete my remarks, I want to refresh people where we are, especially on the critical issues that have been raised by the Senator from Massachusetts. I understand there are concerned people, and I am well aware of editorials and groups who have raised issues, most of which I have found not to be relevant to the bill which we are considering. Many of those problems were related to last year's bill and we are assured the whole country has available to them the bill before us here by having it on Web pages and all. I am hopeful those groups who have expressed their deep concerns will review the legislation that is before the Senate and not make conclusions or alarm the public based upon provisions which were in the bill which did appear before this body last year but of course were not voted on.

First, I remind everyone we voted 89–5 to proceed on this legislation. It is clear that the large majority of the Members here believe and have full confidence that any problems that may exist in the bill will be taken care of. I remind everyone, as I hold this bill up, it is 152 pages long. The areas we are concerned with are two, basically. One is cosmetics. That is an area of deep concern to all of us and the present status of things without this legislation. That is four pages in the bill. There are another two pages on the problems which some see with respect to medical devices and the approval process for them. The issues there have been narrowed down to very small issues, but they are important. I do not diminish that at all.

With respect to the cosmetics, and that is where the most concern has been expressed, and rightfully so because of the present situation with respect to cosmetics, there is little or no assistance or help to the public in understanding as to whether there are problems, health problems, created by cosmetics. The industry itself has done a great deal to work within the industry to try and ensure they have adequate understanding of what the contents of the cosmetics are and they have tried to eliminate to the extent possible any potential harm to individuals. That has apparently been fairly successful.

On the other hand, the present situation with respect to governmental influence in trying to protect the public or trying to allow people to determine the safety of the utilization of cosmetics, there has really been no effort to do this which is satisfactory to us and to the American public generally. The issues are raised in a way that explain what the present situation is and make it look like that is what the bill is. That is not what the bill is. The bill is trying to take care of the concern that the public has with the present situation of not being aware or officially find ways to determine whether or not cosmetics are harmful.

What the bill does is to say not only should the FDA get into this and reassure the public on cosmetics but that they should do that with an eye toward uniformity so that if you buy something in Vermont it does not tell you one thing and you find if you buy it in California, something else, or other places have no warnings. You do not have any way to judge if the product you may be using is one that is safe.

Now, the States have had authority to move into this area and thus to point out that this will somehow interfere with the States. You have to remember they have had this authority forever, I guess, and only one State has taken it upon themselves to really do anything in this area to try and solve the problem—not the best of ways, to determine what cosmetics are good or bad for your health.

What did we do? We said, ''OK, California, fine, we will not get involved with preempting you with respect to your laws that are on the books. We will allow those laws to stand. The FDA can work around that.'' But on the other hand, we will tell the other States that you are free, too, unless the FDA has moved in on those specific products and has made a determination and has exercised its authority, in which case you would be preempted.

Now, that leaves a narrow problem we are dealing with and is one of the reasons, perhaps the only reason, we are here, and that is suppose a State should say no, not only is that cosmetic going to cause possibly skin cancer, it may also cause blood poisoning, and the FDA only includes skin cancer. Can we not tell our people they should be protected against blood poisoning? We have not quite resolved that. It does not seem irresolvable to me or make the bill horrible because I have that much confidence in the FDA.

With respect to the devices, again, that is two pages of the bill. With respect to that, it gets down to another problem for the industry, and that is, when they have a device and they say we have studied it and this is the intended purpose of that device and the studies have gone on and it shows it is effective and safe for this purpose, FDA says, yes, but there may be some other uses of that, so we want to do studies on all possible uses of that device. The industry says, well, wait a minute, it is being produced for this purpose, being sold for this purpose, intended for this purpose; we should not have to run all these studies on other things that somebody dreams it may be used for.

The issue of tobacco has been raised. We were concerned, also, that the tobacco devices—I don't know what they might be, but obviously filter-type things, or whatever else, I don't know. Anyway, we were concerned about that. So, first of all, we asked the CRS as to whether or not the bill, as presently drafted, in the device areas would in any way allow tobacco devices to be sold out from under the bill and, therefore, create problems and a very serious situation in tobacco. I have the CRS study that was done.

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

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

CONGRESSIONAL RESEARCH SERVICE,
THE LIBRARY OF CONGRESS,
Washington, DC, September 4, 1997.

To: Senate Committee on Labor and Human Resources, Honorable James M. Jeffords, Chairman.

Attention: Jay Hawkins.

From: American Law Division.

Subject: Discussion of Possible Effects of Sections of S. 830, the ''Food and Drug Administration Modernization and Accountability Act of 1997,'' On FDA's Ability to Regulate Tobacco.

This memorandum responds to your request for an examination of various claims and the effect that certain provisions of S. 830, the ''Food and Drug Administration Modernization and Accountability Act of 1997,''[1] may have on FDA's current authority to regulate cigarettes and smokeless tobacco products. Specifically, you are concerned with provisions of S. 830, as reported out of the Senate Committee on Labor and Human Resources, that may interfere with FDA's ability to regulate these products or have serious, unintended consequences. Two memoranda by different commentators have been prepared and have examined S. 830's provisions as they may relate to the FDA's regulation of cigarettes and tobacco.[2] The following highlights and discusses the main provisions of S. 830 that were discussed in the two memoranda and concludes that it would not appear that S. 830, in its current form, would interfere substantially or negatively with the FDA's tobacco authority. To a certain extent, this discussion is speculative considering that a hypothetical new cigarette product is discussed herein and that a new product application is not pending or known to be the focus of this inquiry.

RELEVANT PROVISIONS OF S. 830 AND DISCUSSION

Section 404 of the bill, as reported out of full committee, would amend the Federal Food, Drug, and Cosmetic Act (FFDCA)[3] and provides, in pertinent part:

''Consideration of labeling claims for product review.

''404(a) PREMARKET APPROVAL . . . In making the determination whether to approve or deny the application, the Secretary *shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness*, if the proposed labeling is *neither false nor misleading.* In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate *all material facts pertinent to the proposed labeling.''*

''404(b) PREMARKET NOTIFICATION . . . Whenever the Secretary requests information to demonstrate that the devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary

Footnotes at end of article.

to make a substantial equivalence determination. . . . The determinations of the Secretary under this section and section 513(f)(1)[Initial classification and reclassification of certain devices] with respect to the *intended use of a device shall be based on the intended use included in the proposed labeling of the device* submitted in a report under section 510(k) [of the Act].''[5]

Section 404(a) of the bill relates to agency action on an application for premarket approval of a device intended for human use.[6] This section of the bill primarily relates to the classification of devices, findings of substantial equivalence to prior approved products, and, premarket notification requirements under 510(k) of the Act. With reference to 404(a) and (b) of S. 830, several concerns and responses were raised in the commentators' memoranda. Regarding 404(a), Mr. Westmoreland asserts that the bill may limit the Secretary's ability to determine whether there is a ''reasonable assurance of safety and effectiveness'' if the Secretary's evaluation for approval is tied only to ''conditions of the use included in the proposed labeling'' of the product.[7] This concern is raised in light of the tobacco industry's history of dealing with the agency, consumers, and others. The commentator notes that, hypothetically, the manufacturer could develop a cigarette that reduces nicotine intake levels and state on the proposed labeling that the product is for occasional consumption, weekend use, or once-a-week use. Under this scenario and the language of 404(a), he claims that the Secretary would assess safety and effectiveness only in light of the proffered ''conditions of use'', when in reality, addicted smokers would most likely consume many more cigarettes than the occasional one or two. Under this scenario, the memorandum states, ''the FDA may be required to approve the product as safe (inasmuch as there are probably few data about smoking once a week.)[8]

The question is raised whether this provision would reduce or negatively interfere with the FDA's authority and result in the approval of a cigarette that would have the agency's imprimatur of ''safe and effective'' for the conditions of use listed on the label. By way of background, the FDA currently regulates cigarettes as delivery devices and nicotine as the drug in the device under the Act, recent rulemakings and other relevant statutes. The agency has been granted broad statutory and regulatory authority, as well as a great degree of agency discretion, when evaluating an application for approval of a device or drug, particularly in light of strong public health concerns.

Section 404(a) does appear to limit the Secretary's examination to the proposed label, to a certain extent, however, it provides an exception for ''false or misleading'' labeling and authorizes the Secretary to ''fairly evaluate all material facts pertinent to the proposed labeling.'' This exception is bolstered further by other important provisions of the FFDCA. The Act currently defines ''label'' to include a display of written, printed, or graphic matter upon the immediate container of the article and defines ''labeling'' to include all labels and other written, printed or graphic matter upon any article or its containers or wrappers or accompanying such article.[9] Additionally, under the misbranding provisions of the Act, an article may be deemed misbranded because the labeling or advertising is misleading. When determining if the labeling is misleading, the Secretary shall take into account, ''among other things'', not only representations made or suggested by statement, word, design, etc., ''but also the extent to which the labeling . . . fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use as are *customary or usual.*''[10]

Additionally, section 515(d) of the Act currently authorizes the agency to deny the approval of an application if, ''upon the basis of the information submitted . . . and any other information before [the Secretary],'' that ''based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular.''[11] Thus, even though current law does constrain the Secretary to ''conditions of use on the proposed labeling'', much in the same manner as S. 830, other relevant provisions grant the Secretary authority and discretion to examine other material facts and information when evaluating the product application. This permits the agency to view different facets of the product, the manner in which it is commonly used, the presence of misleading or false information on the label, or the absence of appropriate information.

When viewed in the context of the agency's broad statutory and discretionary authority under the FFDCA, it would appear that section 404(a) of the bill would not necessarily confine the FDA to look only at the label thereby compelling the agency to make a favorable decision on a product like the hypothetical new cigarette offered for ''occasional use.'' Relying on its statutory authority and recognizing its mandate to protect the public health, the agency would most likely evaluate the new product for safety and effectiveness by considering numerous issues it considers material. Thus, the agency would not necessarily be confined to a narrow reading of only the proposed labeling. Although this approach may be objectionable to some, it is likely that the agency would examine material issues beyond the proposed labeling, particularly in light of the scientific data that indicate the addictive nature of cigarettes, especially for young people, and the debilitating, serious health effects of cigarette ingredients and smoking. While the intent of 404(a) seems to be aimed at limiting or confining the agency to a certain degree and clarifying rules of procedure[12], it does not appear that this section would operate in a vacuum and result in a catastrophic, unintended consequence involving cigarettes or tobacco products.

Section 404(b) of the bill focuses also on the label but presents slightly different issues that involve the classification of devices[13] and the finding of ''substantial equivalence'' between a new device and a device already on the market, i.e., predicate device.[14] This subsection would amend section 513(i)[15] of the Act by adding new provisions relating to what types of information the Secretary may request to demonstrate that devices with differing aspects are ''substantially equivalent'' to a product already on the market. To generally explain, current law provides that any device intended for human use that was not introduced into interstate commerce for distribution before the date of enactment is classified in class III (triggering high risk controls) unless (1) the device (a) is within a type of device (i) which was introduced into interstate commerce before the enactment date and which is to be classified under 515(b) [classification panels] or (ii) which was not introduced before such date and has been classified in class I or II *and* (b) is ''substantially equivalent'' to another device within such type *or* (2) the Secretary, in response to a petition, has classified the device as class I or II. In sum, under current law all devices are class I, II or III, however, the manufacturer can petition to have its product placed in class I or II.

Examining the text of section 404(b) of the bill (see above), the thrust of the provision appears to be that the Secretary, when requesting certain information concerning substantial equivalence, must request only the amount of information that is necessary to the decision and is the least burdensome to the manufacturer. Among other things, this provision would operate during the agency's assessment of substantial equivalency and classification for controls. Section 404(b) would appear to limit the Secretary's inquiry concerning ''intended use'' of the device, and ultimately substantial equivalency, to only information of intended use that the manufacturer includes in the proposed labeling (submitted in a report under 510(k) of the Act.) At the same time, this provision appears to be aimed at lifting perceived information and demonstration burdens borne by manufacturers.

The question has been raised whether 404(b) is constructed in such a way that it, albeit unintentionally, could limit the FDA's authority to regulate cigarettes, tobacco, and nicotine by limiting the agency's decision only to the intended uses listed on the proposed label. Mr. Westmoreland raises the concern that clever labels and such a restricted authority might pave the way for cigarette products to enter the market, with less stringent controls, having (apparently) met the tests for safety and effectiveness. The commentator states, ''Under the terms of subsection (b), the FDA would not be allowed to look behind the conditions of use. Consequently, a cigarette manufacturer with a clever proposed statement of use may be able to force the FDA to classify or reclassify the cigarette as an approved Class I or Class II medical device with relatively few controls.''[16]

Under the bill, to a certain extent, the Secretary would be required to make the relevant determination based on the ''intended use included in the proposed labeling.''[17] However, the result proposed by Mr. Westmoreland may be unlikely since the hypothetical product would need to have the same intended uses as the predicate device upon which the claims of substantial equivalence are based. Current law provides that substantial equivalence means that the device has the same intended use as the predicate device and that the Secretary by order has found that the device (i) has the *same technological characteristics* as the predicate, or (ii) has *different technological characteristics* and the information submitted that the device is substantially equivalent to the predicate contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that the device is safe and effective as a legally marketed device and does not raise *different questions* of safety and efficacy that the predicate device.[18]

The more likely scenario would be that based on the prongs of the substantial equivalency test, the agency would not find substantial equivalence to a predicate device that had different characteristics or raised different questions without the requisite supporting data. And, under the Act, in most cases, a new or the hypothetical product would be automatically classified in class II.[19] A new type of cigarette that, say, reduces nicotine levels or has a unique filter, could very well have ''different technological characteristics'' that would probably not give rise to a finding of substantial equivalence. Thus, under this prong of the substantial equivalent assessment, the agency would not be overly confined in its judgement. In the context of cigarette and tobacco issues, S. 830 could potentially, but would not appear to affect drastically these determinations by the FDA.

The FDA's final tobacco rule and explanatory statements in the *Federal Register* shed

some light on the FDA's view of ''intended use'' for tobacco products. In the ''label'' section of the rule, the FDA requires that each cigarette or smokeless tobacco package that is offered for sale, sold or otherwise distributed shall bear the following statement: ''Nicotine-Delivery Device for Persons 18 or Older.''[20] The explanatory statement that accompanies the final rule indicates that initially, in the proposed rule, the agency indicated that it would exempt these products from the statement of identity and labeling for intended use. However, based on comments received, FDA reconsidered and concluded that it is appropriate to require that the intended use statement noted above must appear on the label. The FDA stated that as with all over-the-counter devices, cigarettes are required to bear the common name of the device followed by an accurate statement of the principal intended action/s of the device. ''As over-the-counter devices, cigarettes . . . are legally required to comply with this provision.''[21] To reflect the ''permitted intended uses'' of these products, the agency requires the statement: Nicotine Delivery Device for Person 18 or Older. The agency stated further: ''The statement of intended use, in essence, incorporates the statement of one of the principal restrictions FDA is imposing on these products.'', i.e., restrict and eliminate youth smoking.

These agency statements tie in with what are considered ''adequate directions for use'' of the products. The FDA acknowledged in the final rule that it is very difficult to establish adequate directions for use for cigarettes and smokeless tobacco, primarily because of the inherent nature of the products, their addictiveness, the numerous hazards associated with their use, and because the behavior of each user, e.g., depth of inhalation, duration of puff, whether the filter holes are covered, length of time in mouth, determines the amount of tar and nicotine delivered to the user from the device. The FDA has stated:

''Tobacco products have a very long history of use in this country, and they are one of the most readily available consumer products on the market today. Consequently, the way in which these products are used is common knowledge. FDA believes that the public health would not be advanced by requiring adequate directions for use. . . . In the agency's view, the warnings mandated by the Cigarette Act and the Smokeless Act satisfy this requirement. Additionally, the Surgeon General's warnings provide information warning against use in persons with certain conditions, i.e., pregnant women.''[22]

The FDA has chosen to regulate tobacco products as ''restricted devices'' under section 520(e) of the Act and is authorized to require that a device be restricted to sale, distribution or use only upon the written or oral authorization of a practitioner licensed by law to administer or use such device or *upon such other conditions as the Secretary may prescribe in regulation* if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. Moreover, as a restricted device, the label of the product shall bear ''appropriate statements'' of the restrictions required by regulations under the noted paragraph as the Secretary may prescribe.

Returning to section 404(b), the current text would not appear to obviate or reduce the agency's authority in a manner that would ensure that the hypothetical cigarette product (for occasional use) would reach the market with little controls or by default. The agency could utilize the full range of its authority, briefly discussed above, with regard to the test for substantial equivalency, classification or reclassification of these products, as well as the enforcement and definition sections of the FFDCA. Moreover, the agency has been granted additional authority reserved for restricted devices under section 520.

Section 604 of the bill as reported raises similar issues regarding the Secretary's authority and discretion to evaluate a product and assign its classification. Mr. Westmoreland's memorandum indicates that this section, operating with section 404(b) of the bill, may limit the Secretary's authority and force the agency to rely only on the manufacturer's statement of intended conditions of use when classifying or reclassifying the product. In brief, this section allows manufacturers who have a class III designation to request the agency to reclassify the product to less stringent control levels, e.g., class I or II. The Secretary then has 60 days to respond to the request. Based on the foregoing and the current provisions of the FFDCA, the view expressed by the second commentator would appear to be the more likely scenario. The FDA would not be limited to the proposed labeling and would employ what it considers to be the appropriate evaluation of safety and effectiveness for class designation.

Additionally, the concern was raised that the bill, particularly section 402, may interfere with the FDA's regulation of ''combination products'', e.g., a combined drug and device product. This is raised in light of the fact that the FDA intends to regulate, and is regulating, cigarettes and smokeless tobacco products as combination products whereby the nicotine is the drug and the cigarette is the delivery system and device. The bill would establish a procedure for the FDA when assigning the product is appropriate designation, e.g., drug, device biologic, etc., thereby placing it within the proper sphere or center for regulation within FDA's structure. Many features of the bill are currently being performed via inter-center memoranda of understanding of FDA. Section 402 does not expressly state a person may request the designation of combination product. Further drafting attention may be merited to add that clarity, however its absence would not appear to remove that authority from FDA's powers. Under current law and policy, the FDA is authorized to designate and regulate combination products and assign the product to the appropriate center for its primary regulation. More express language may be desirable in order to remove any hint of ambiguity and to avoid some unintended or unforeseen consequences.

CONCLUSION

Based on the foregoing analysis and the current text of S. 830, it appears that the bill would not interfere with or lessen the agency's authority to regulate tobacco products by the agency. Current provisions of statutory and regulatory law upon which the FDA basis its jurisdiction to regulate tobacco, would continue to be viable and would appear to support the FDA's actions regarding these products. The two memoranda raise valuable insights by discussing and relating various sections of the law so that a more clear understanding is gained. However, it is reasonable to conclude that the highlighted provisions of S. 830 would not appear to operate in a manner that would reduce the agency's tobacco authority in a weakening manner. Although some issues await judicial resolution, the explanatory statements that accompanied the proposed and final tobacco rules issued by the agency, as well as other subsequent analysis indicate that the provisions of the law upon which the FDA bases its jurisdiction, would continue to support, as least at this point the FDA's regulatory actions governing cigarettes and smokeless tobacco products. Notwithstanding some unforeseeable circumstance, S. 830, in its current text, would not appear to alter drastically that approach. Finally, in addition to any drafting changes or clarifications of text, further explanation of congressional intent regarding these sections or the bill in its entirely may be included in report language, in order to guide a legal challenge in which the court might be called upon to discern the intent of the law, if enacted.

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FOOTNOTES

[1] As ordered to be reported by the full committee.
[2] Memorandum of Tim Westmoreland, July 23, 1997 and memorandum of an unknown or undisclosed source.
[3] 21 U.S.C. §§301 *et seq.*
[4] Emphasis added.
[5] In the text of S. 830 supplied to CRS, there is additional handwritten language added to the end of 404(b) which reads''. . . provided however that nothing in this paragraph shall prohibit the Secretary from determining that a device is not substantially equivalent to a predicate device within the meaning of paragraph (A)(ii).'' This language does not appear to be included in the reported-out version of the bill, according to text in Sen. Rept. No. 105–43. However, I have included it here because it was included in the text supplied to CRS and also because it may benefit your examination of these issues.
[6] Section 404 proposes to amend section 515(d)(1)(A) of the FFDCA.
[7] Westmoreland memoranda, pp. 1–3.
[8] Westmoreland memorandum, p. 2.
[9] FFDCA, section 201 [Definitions].
[10] Id. Regarding the ''customary and usual'' phrase, even if one argued that a new cigarette product could be introduced where the ''customary and usual'' use would not be apparent, the agency has stated in the final tobacco rule issued in the *Federal Register*, the tobacco products have a very long history of use in this country and ''the way in which these products are used is common knowledge.'' 61 Fed. Reg. 44464 (Aug. 28, 1996).
[11] FFDCA, section 515(d)(2).
[12] Title IV of the bill is entitled, ''Improving Certainty and Clarity of Rules.''
[13] Devices are classified according to risk and then subject to various controls. For instance, class I trigger general controls; class II products present more risk to the user and are subject to tighter controls; class III present the highest risk and are subject to the most stringent controls on the products. The FDA stated in the final tobacco rule that it would apply the general controls provisions of the Act to cigarettes and smokeless tobacco, including restrictions on their distribution, sale, and use under section 520(e) of the Act governing restricted devices. These controls will be in place while the agency's decision on classification is pending. The FDA will, in a future rulemaking, classify cigarettes and smokeless tobacco in accordance with section 513 of the Act. ''In the meantime, the general controls will apply.'' 61 Fed. Reg. 44464 (Aug. 28, 1996).
[14] In brief, the finding of substantial equivalence permits the device to be marketed without going through the longer, more stringent premarket approval process for new devices.
[15] Section 513(i) relates to substantial equivalence in classification and reclassification of devices into categories I, II and III. This section also references section 520(l) that relates to transitional provisions for devices considered as new drugs or antibiotics.
[16] Westmoreland memorandum, pp. 3–4; [footnote omitted].
[17] This hypothetical again would involve the reduced nicotine cigarette that is labeled for once-a-week use or occasional use.
[18] Act, section 513(i). The Act defines ''different technological characteristics'' to mean that there is a significant change in the materials, design, energy source or other features of the device from those of the predicate.
[19] However, the agency's current classification of cigarettes is class I pending a rulemaking and final articulation of what class of controls these products will be under.
[20] 61 Fed. Reg. 44617 (Aug. 28, 1996).
[21] 61 Fed. Reg. 44464 (Aug. 28, 1996).
[22] Id.; citations omitted.

Mr. JEFFORDS. This clearly sets out that, in their opinion, it would appear

that, in its current form, our bill would not interfere or substantially negatively affect any of the FDA tobacco authority.

In addition to that, just to be double and triple sure, we, in the bill, say it can't apply to tobacco and that the FDA has full authority in the tobacco area. So that is why we got the 89 to 5 vote today. Yet, I certainly commend the Senator from Massachusetts, and others, who want to make darn sure that we are really doing the job we think we are doing. I appreciate that and I think it is healthy. The harder that Senator KENNEDY fights, the more the public will be aware of that, and I hope we have as good a vote this time.

Mr. President, with that, on behalf of the majority, I will yield back the time that we have today, except that I will provide the Senator from Minnesota 5 minutes at his disposal, at such time as he is appropriately available to make a statement. I would be happy to make that time available for the Senator.

Mr. GRAMS. Mr. President, I rise today in support of S. 830, the Food and Drug Administration Modernization and Accountability Act.

While this legislation covers many areas under the FDA's jurisdiction, as chairman of the Medical Device Caucus, I want to focus primarily on the provisions relating to the regulation of medical devices.

The medical device industry is an important asset to Minnesotans. I am proud to say that many of the world's leading and most innovative medical device companies call Minnesota home. In fact, there are over 500 medical device manufacturers in Minnesota.

In my State, the medical device industry has created more than 16,000 manufacturing jobs. Minnesota ranks fifth nationally in total employment for medical devices—and since 1988, the number of medical device manufacturing jobs has grown faster in Minnesota than in the rest of the Nation. In 1994 alone, 53 new medical device companies were created in Minnesota.

Yet, despite all the successes, there are significant hurdles the industry must clear in order to succeed in the increasingly competitive global marketplace.

Medical device manufacturers face incredible barriers that too often prevent them from marketing new products, creating jobs, researching and developing the latest technologies, and most tragically, from providing U.S. patients the best medical technology in the world.

Mr. President, it is easy for debates on reforming or modernizing the FDA to develop into an FDA bashing session which does nothing to persuade or accentuate the positive results of suggested changes made in the FDA reform measure, S. 830.

I want to be very clear: The individuals charged with ensuring the safety of medical devices, drugs, biologics, food, and cosmetics are good people, trying their best to do a difficult job. The pace at which new technologies are introduced in the medical community is staggering—and at best, difficult to keep up with.

This legislation will give the FDA the tools they need to keep pace with technology and ensure the safety and effectiveness of drugs, medical devices, food, and cosmetics well into the 21st century.

I would like to thank the Labor and Health and Human Services Committee for drafting what is a well-balanced and meaningful FDA modernization package in addition to reauthorizing the Prescription Drug User Fee Act.

The User Fee Act has proven itself as an example of how an agency and an industry can work together to bring highly regulated products to the market more quickly and more efficiently—without sacrificing safety.

However, the regulatory burdens imposed on the medical device industry have had a chilling effect on the industry and its customers—the patients. As a result of regulatory delays, device manufacturers are falling behind their foreign competitors or moving their production and development overseas.

While approval of devices in Europe takes only 6 to 8 months, the same device can be caught up in the regulatory process for years here in the United States. What this means is that Europeans have access to the most up-to-date technologies while patients in the United States are forced to wait.

If this continues, we will not be able to claim that the United States has the world's best health care for very much longer.

Many will say we need a strong FDA. I agree. I would argue, however, that far too many Americans have become victims of the Government's bureaucracy because they were denied access to devices which have been available and safely used in Europe for years.

We can no longer allow ourselves to perpetuate out-of-date rules and regulations which ultimately harm the patient, nor can we allow those same rules and regulations to force American jobs, technologies, and health care overseas.

The FDA Modernization and Accountability Act is a solid piece of legislation which will ensure American patients' access to the most advanced medical devices as well as create jobs and strengthen the economy.

I urge my colleagues to support this important legislation.

Mr. President, I understand that there are no other speakers on our side of the aisle wishing to come to the floor and talk about the subject today. So, on behalf of the manager of the bill, the Senator from Vermont, and the majority, I yield my time and the remainder of the majority's time.

Thank you.

Mr. KENNEDY. Mr. President, I wonder if the Senator would yield for a question on my time?

As I understand, Minnesota has passed a hazardous product labeling bill requiring warning of all products that are ignitable, corrosive, reactive, or toxic, and that that this legislation will effectively be preempted—Minnesota's passage of that particular legislation.

I was just interested in the Senator's reaction to that. That has been a judgment made in Minnesota by Minnesotans and passed by their legislature, is now current law, and has not been grandfathered into this legislation. It effectively would be eliminated.

Mr. GRAMS. I would have to defer to the author of the bill and to the Senator from Massachusetts. I am not aware of the details of that. I would have to look that up to understand it fully.

Mr. KENNEDY. I thank the Senator. I think we had earlier comments by our chairman, which we welcome, about the fact that California has been able to be grandfathered in and they will have the protections. But Massachusetts, my State, is about to pass this legislation. The people of my State of Massachusetts are concerned about the public health of citizens in that State, and want to provide the protection for those people. The action here in this legislation, as it is prepared, will basically wipe out those protections.

I have been on this floor so often and have heard that we want to get away from the Washington solution to these problems, that what we want to do is get away from this one-form-fits-all solution; what we want to do is let the States make judgments and decisions. And here we are writing legislation that is going to preempt States from taking action in the future. We grandfather in one State, California, but are denying any other State the opportunity to take action.

I find that very difficult to understand, or to be able to accept.

(Mr. JEFFORDS assumed the chair.)

Mr. KENNEDY. I will give my assurance that if there is a Senator on the other side coming over here on the floor and wants some time, we will be delighted to make sure they have an opportunity to do so.

Mr. President, again, I thank my friend and colleague from Vermont. We have worked long and hard on this issue, although there are areas where we do have differences, and I mentioned those here today. It is very important. It doesn't negate the point of the substantial progress that has been made on a wide variety of different matters, which we all believe will make a difference in terms of the health of the American people.

Mr. President, I want to just, first of all, address and respond to some of the comments made by my friend from Indiana, Senator COATS, about the FDA, come to their defense because it was a rather blistering assault on the FDA. I have heard those comments made by the Senator on previous occasions. But as we are here on the floor of the U.S. Senate, I want to say a few words

about the FDA and where it is now. Perhaps those comments might have been relevant some years ago. I don't believe that they are relevant today.

Out of fairness not only to the men and women that work at FDA day-in and day-out and toil to protect the American consumer because the protection for the American consumer sets an example for the rest of the world, and for the agency itself, and for respect for that agency, I would like to point out that there are few more important agencies of the Federal Government than the Food and Drug Administration. The FDA is responsible for assuring that the Nation's food supply is pure and healthy. The FDA provides a guarantee that the drugs and devices we rely on to cure and treat diseases are safe and effective. It does its job.

The FDA can speed miracle drugs from the laboratory bench to the patients' bedside. If the agency does its job poorly, it can expose millions of Americans to unsafe devices and medical products and jeopardize our food. I think even the most zealous supporters of the FDA recognize that there have been troubles in the past. But we would also recognize there has been the sincerest effort to address those deficiencies in the past. To listen to some of the speeches we have heard on the floor today, you would think that the FDA was a regulatory dinosaur, mired in the past, cumbersome and bureaucratic, imposing unnecessary and costly regulatory burdens on industry and denying patients speedy access to lifesaving drugs. That is a myth. Those who want to destroy the FDA in the service of an extreme ideological agenda, or in the interest of higher profits at expense of patients' health, would love you to believe that. But it isn't true.

The FDA's regulatory record is the envy of the world. It sets the gold standards for the protection of patient health and safety. The agency's recent performance under the leadership of former Commissioner David Kessler and the Clinton administration represents a model of how to transform the regulatory process so that it is more flexible, responsive, and speedy, while maintaining the highest standards of patient protection. Indeed, a large number of the positive elements of this legislation simply codify or extend actions the agency has undertaken administratively.

The landmark PDUFA reauthorization contained in this bill was essentially negotiated by the agency and the industry, working collaboratively with the bipartisan efforts here in the Senate and in the House of Representatives. I welcome the chance to work closely with Senator HATCH in the passage of this legislation to improve the review process.

In recent years, in partnership with Congress and the administration, FDA has responded to growing criticisms of delay in approving new products by taking impressive steps to improve its performance. The PDUFA Act of 1992 was one of the most effective regulatory reforms ever enacted. The bill established a new partnership between the agency and the industry. The industry agreed to provide additional resources and agreed to measurable performance standards to speed the review of products. This was unique instance where, in receiving the additional funding, they established criteria to be measured by over a period of time and those were strict criteria and a strict challenge. Every goal set by the legislation has not only been met, but it has been exceeded.

Today, the FDA is unequaled in the world in its record of getting new drugs quickly to market without sacrificing patient protection. In fact, last year, the average review times in the United States were twice as fast as in Europe. Fifty new drugs were approved in both the European Union and in the United States. In 80 percent of the cases, the United States approved the new drugs either first or at the same time as the European Union. More companies chose the United States for the introduction of breakthrough drugs than any other country.

In addition, to speeding the review times, the FDA has taken far-reaching steps to reduce unnecessary regulatory burdens on industry and modernize its regulatory process. More needs to be done, but these steps have added up to a quiet revolution in the way the FDA fulfills its critical mission. When PDUFA was originally passed, the device industry refused to agree to user fees that would give the FDA the additional resources and performance standards that have contributed to so much to the agency's outstanding record on drugs and biologics.

I remember the negotiations. They were unsatisfactory, regrettably. But even in the device area, the FDA's recent achievements have been impressive. The so-called 510(k) applications, devices approved based on their substantial equivalence to a device already on the market, accounts for 98 percent of all the device admissions. FDA has now essentially eliminated its backlog. Last year, it reviewed 94 percent of these devices within the statutory timeframe, compared to only 40 percent just 4 years ago.

Even in the area of class 3 devices, where the most problems remain, the FDA has improved its performance substantially. According to a study by the General Accounting Office, median review times dropped 60 percent between 1991 and 1996. In a recent survey of device industry executives reported that the business climate for the industry is in the best shape in the 5-year history of the survey. I introduced that in the RECORD in our markup. The industry publications are virtually uniform in terms of the progress that has been made and the atmosphere that has been created and the current very positive atmosphere. The sponsor of the survey attributes this favorable response in large measure to improvements at FDA and concludes that the agency has not only reduced the delays to allow new products to be introduced but, more importantly, has also greatly reduced executives' and investor's uncertainty about the timeliness of future product introductions.

So, Mr. President, the FDA must continue to improve many of the provisions in this legislation. The idea that the reforms in this legislation must be passed at whatever cost, because the agency is doing a bad job, is simply incorrect.

Now, Mr. President, I want to just return to what I consider the most troublesome part of our legislation. We have had very important discussions and representations by our colleagues and friends, the Senator from Rhode Island, Senator REED and Senator DURBIN, on particulars of the legislation, which I think need further attention. In my remaining time here, I would like to talk again about the whole issue of protection of the health and safety of the American consumer as it relates to cosmetic products. That is the most egregious and, I believe, unjustified provision in the bill, which would effectively cripple consumer protections by preempting State regulations on cosmetics.

I note for the RECORD that these provisions, as I mentioned, were not in the chairman's mark, they were not the subject of significant hearings, and they have no place in the bill, whose primary purpose is to reauthorize the Prescription Drug User Fee Act. That is the principal purpose of the bill, the reauthorization of that program and to try and accept these adjustments, incorporate into the law some of the measures which have been so successful administratively by the FDA. And also to incorporate the great majority of the measures which have been included in the bill that relate to pharmaceutical products and device products.

If the Congress were earnest about addressing over-the-counter drug and cosmetic regulation, it would have undertaken a serious and detailed inquiry into the regulatory structure and authorities which assure that consumers are adequately protected before even remotely contemplating the possibility of preempting active and essential State protections.

The preemption of cosmetic regulation is especially outrageous and shows a callous disregard for the health of American men, women and children. Cosmetics are broadly used by Americans, far more broadly than prescription drugs and medical devices and biological products.

Mr. President, I want to mention why we find ourselves where we find ourselves today and why this issue is of such importance. I have here the testimony of Commissioner Young from some years ago, 1988. It points out that Congress, in 1938, recognized the public health problems associated with cosmetics and addressed them in the laws

they enacted based on the science available to them. But science and the cosmetics industry have changed. In 1938, at most, only a few hundred ingredients were used to formulate cosmetics, and the industry was small in numbers of manufacturers that marketed products. Today, tens of thousands of cosmetics are in distribution, and the number of ingredients used has risen to an estimated 4,000 for producing a multitude of base formulation in equal number for compounding fragrances. Regulatory sciences have also progressed. When the law regulating cosmetics was enacted in 1938 the science was based on a less sophisticated concept for evaluating the safety of chemicals used on the skin. If you saw a reaction, you treated it; then avoid it. Today, science can take into account the effects produced under chronic long-term exposure to trace contaminants in addition to acute toxic effects, such as immediate skin irritations, contact allergic reaction, systematic reaction resulting from inhalation and ingestion. In 1938, the skin was considered to be an impenetrable barrier to cosmetics or other substances.

As the number of ingredients and products has multiplied through scientific and technological innovation, our ability to measure minute amounts of residual contaminants and unwanted substances also has taken a quantum leap. At the same time science has developed more precise ways to assess risk, taking into account relevant factors such as use and exposure over a lifetime.

(Mr. GRAMS assumed the chair.)

Mr. KENNEDY. Mr. President, I was pointing out how the change in the complexity of the different products had taken place from 1938 and the number of products that were out there; the number of potentially dangerous products that were out there and the progress that had been made from the time when there were only a few hundred of them; back to 1938.

Listen to what we have now at the present time. This is according to the Food and Drug Administration and the studies that have been done. The number of cosmetic ingredients in the industry's own inventory is over 7,500. The industry has been adding new ingredients at a rate of 1,000 per year for the last few years. Virtually none of these ingredients have been properly tested for safety. The industry's safety review process has reviewed only 450 of the most commonly used cosmetic ingredients. That is about 20 a year. At this rate, even using the industry's own process, it will be many years before new ingredients are considered for safety.

So the sheer number of cosmetic ingredients in products makes safety assurance difficult. And most adverse reactions for cosmetics are immediate burns or irritation—long-term effects which do not show up for many years, such as cancer or reproductive effects are even more difficult to determine. They require special studies designed to measure this risk, while many ingredients are studied for only short-term effects when they are added to products. Risk of cancer or reproductive effects are not available for the vast majority of cosmetic ingredients.

Mr. President, we have been talking here this morning and this noontime about the authority and responsibility of different agencies. We have been talking about the power of the States. We have been talking about rules and regulations. But, when we are talking about health and safety, we are talking about real people.

Let me give you the kinds of examples that we are dealing with.

A woman from Santa Rosa—this is 1995, April 22—complained about an acrylic product which is for nails. She had the product applied to her nails. The product burned, and the cosmetician tried to remove it. Since the incident, six of her nails have fallen out.

That was according to the California Department of Health Services, in April 22, 1995.

Here is another one.

On her 29th birthday, a woman from New Jersey was supposed to retire from the career she loved. She was a hairdresser for 11 years until a series of ailments, including difficulty breathing, burns in her sinuses and severe headaches prompted her to quit in August 1985. Her doctors had concluded that the beauty products she used on the job led to her medical problems. She had no idea what was actually in the products which she used in her beautician job. Lack of labeling is neither unusual nor illegal, although cosmetic manufacturers are required to list ingredients containing products sold to consumers. They need not do so for products sold for use only by professionals.

Another case is Carolyn, a secretary from Rockville, MD. She arrived at a wedding shower and realized the permanent she had received at a beauty salon the day before resulted in a red swollen, face. Carolyn's is a case of cosmetic contact dermatitis, also known as acute allergic inflammation of the skin caused by contact with various substances found in cosmetics, including materials used by the hair stylist. This is a case that was reported to the FDA.

A 33-year-old housewife consulted her dermatologist because of inflammation of her hands, face, and neck. She had experienced two similar episodes earlier in the year. After the skin properly healed, the physician determined through appropriate testing, that Swedish formula lotion had caused the adverse reaction.

A telephone company supervisor was hospitalized after a 2-year history of chronic irritation of her eyelids. She received a variety of topical medications without relief. Her contact history revealed a long list of cosmetic eye drops, and multiple spray perfumes. All the cosmetics were removed from her hospital environment, and after her skin healed, patch testing showed lanolin in her creams—lanolin in her creams—was causing her condition.

That is from a subcommittee hearing on health.

The use of chemical skin peeling products caused severe injuries, including reports of skin burns from using a product called Peel Away. FDA sources said such products can penetrate the skin too deeply causing severe skin damages. In several cases persons have been hospitalized with severe burns, swelling, and pain. In one case, a California woman suffered seizures, shock, and second-degree burns after a combination of skin peel chemicals was applied to her legs by a beautician. Skin peeling procedures used to be carried on by plastic surgeons.

However, they are now being done by nonmedical professionals, by beauticians and some using newly marketed preparations. Many have inadequate instructions. None has been approved by the FDA as being safe and effective. Again, an FDA consumer report.

A letter from the CDC cited nine cases of eye infections due to microorganisms contained in mascara. One was a 47-year-old woman who developed a corneal abscess within days of scratching her eye with a mascara wand. The woman eventually needed a corneal transplant.

As I understand it, it is because of the failure to be able to indicate that mascara needs an expiration date.

So, Mr. President, this list goes on. I want to show what the States have been doing with regard to the protection for the American consumer. The issue now that is before the Senate on the FDA reform deals with the medical devices and pharmaceuticals and the extension of what we call the PDUFA, which will help to expedite the consideration of those measures.

By and large, there is strong bipartisan agreement to those provisions. There are several that have been identified today that need further attention, but men and women of good will can work that out and work it out with the administration so that we can have a successful conclusion. But what was not considered in the original bill is the provisions that apply to preempting the States from giving protections to their consumers on the use of cosmetics. What we have recognized in this debate is that the Food and Drug Administration does not today have the authority, power, or personnel to protect the American consumer on the issue of these cosmetics.

What we know overwhelmingly today is that the number of dangerous and toxic products and the number of carcinogens has expanded exponentially and is continuing to expand. All you have to do is look at the past record, of the numbers that have been introduced, and it is continuing and continuing to grow and those products are not being tested adequately today.

So who has been protecting the American consumer? Who has been protecting the American public? The States have been doing it, and primarily California has been doing it, under the legislation which they have passed. How important that has been. It has not ended up with actions that have been taken by the State of California as the result of very extensive studies that products have been removed. What has happened is that the producers and the manufacturers have withdrawn the product, addressed the problem, put it back on the market, and by and large, if you look at the advertising, they would say the product is better today than it was yesterday.

That has been the record. That has been the record. And that is why this is so important. Just review with me, Mr. President, the extent of this preemption—as I mentioned before, the extent of this preemption of the cosmetic industry in the States. This is the language that there will be the preemption for—''labeling of cosmetics 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 in the legislation. They are effectively saying no to the States in providing public information or any public communication relating to safety. If the States are trying to protect their people and they develop public information on the basis of scientific studies, they are prohibited under this legislation. I don't know what the penalties are. I don't know what the civil penalties are, but they must be in there. They are prohibited from providing public information or any form of public communication relating to safety or effectiveness.

That is what the cosmetic industry is doing in this legislation. That is the disdain that the cosmetic industry has for those in the States who are trying to protect the public. That is the arrogance that this industry has for legislators or Governors or attorneys general or medical professionals who are interested in the public.

This is what this says. You cannot do it. You cannot provide public information even with regard to safety. That is arrogance. That is greed. That is the greed of a $20 billion industry.

What do the States say? Well, why are you so worked up, Senator? It isn't just myself. Again, we have shown we have the letters from the Governors, the State legislators. This is not just one Senator's position. This happens to be the position of the Governors and the State legislators.

Yes, I listened to the comments of my friend and colleague, Senator JEFFORDS, about the general statements of two of the Governors with regard to the health provisions on pharmaceuticals and devices, that is, an admirable job has been done. I think we still have areas to deal with. But I would certainly sign on to that. But what we are talking about is what we are saying to the States. The cosmetic industry is saying to the States you are not going to stick your nose in and protect the consumers there. What have they done in the past? Why are the other Governors worked up about it? Because of what these two charts demonstrate, Mr. President.

Here we have the issue of lead which is known to cause birth defects and has also been found in hair dye. That is the result of State action, of State analysis, of various hair dyes that are out there that contain lead product. Initially, when there was the analysis, they said, well, this really isn't dangerous because it is just on the scalp. Then they did additional kinds of studies and found that the lead got into the individuals, obviously, who were using it. That lead was passed on to pets, children playing with pets, children ingesting it and when people are washing their hair day after day after day it causes a birth defect. Lead is one of the principal causes of mental retardation among children, period. We find, as a result of State activity, they have found it and it has been changed in many, many of the products—not all of them, because the cosmetic industry was able to get an exclusion from some participation.

Mercury, which can cause mental retardation, has been found in lipstick and nail polish—lipstick and nail polish, mercury. With all the implications that has in terms of women's health and in terms of safe pregnancies, it is found in lipstick and nail polish. That was another study that was done in California.

Alpha hydroxy, a known carcinogen, has been found in face creams. That was not done by the Food and Drug Administration. That is a result of State activities. There is not a physician in this country who does not know the dangers of lead and mercury and the alpha hydroxy to the American consumer, primarily women. There isn't a doctor who will not tell you that. Yet this legislation is saying, no more. This legislation is saying, no more. ''Any requirement relating to public information or any other form of public communication relating to safety or effectiveness of the drug or cosmetic''—preempted. So we are saying, if you find this out, we are preempting you. You are not going to have to tell the public.

As a result of State regulation protecting consumers, we have seen that States forced the removal of reproductive toxins from lipstick and nail polish. That is a result of State action. You have to admire the resourcefulness, the innovativeness, the persistence of the leaders in States that have had the courage and the determination and have been willing to take on the cosmetic industry, the cosmetic industry that by its own agreement spends 70 percent of its lobbying dollars in the States rather than on the Federal Government. You can understand that, because we haven't got any power over it, so they have targeted it in the States. Yet you find the courage of State public health officials who have been willing to force the removal of reproductive toxins from lipstick and nail polish. They didn't take the products off the markets. The manufacturers took them off the market and they addressed those issues.

States forced the removal of harmful lead from hair dyes and antacids and calcium supplements. The States forced the removal of mercury from suppositories. These are just examples.

How do we know how many other dangers there are out there when we have an explosion of dangerous products that have been agreed to by Republican and Democratic leaders of the FDA over the period of years—increasing exponentially with the dangers of toxins and carcinogens. The problem isn't getting less. The problem and the danger is getting more as every consumer understands the range of additional kinds of products that are out there and available to them. Nonetheless, we are asked on the floor of the Senate to say no to the States. We are not doing it at the Federal level.

As I mentioned before, if you said, well, we are going to have a whole review, regulatory review, we are going back to say, OK, we will preempt the States but we will find out what we are going to do with regard to providing protection—we have had, as I mentioned earlier, the GAO studies that have been done 10 years ago which made a series of recommendations to the Congress about steps we ought to take if we are going to protect the public—then maybe, maybe then it makes some sense. But we have not done that. We have not done that. The FDA has been starved in resources to even fulfill its requirement for protection in terms of the American consumers in medical devices and with regard to pharmaceuticals.

So we have a situation where we have limited, limited, limited authority under the FDA to protect the public for a range of these cosmetics. We find a record today where you are getting the explosion of these dangerous products, of toxins and carcinogens. Carcinogens cause cancer—cause cancer. We are seeing those numbers expand. We are finding completely inadequate policing by the cosmetics industry. We find the only breath of air that is out there to protect the public is the States. California is leading the way. Thank God, at least California has been grandfathered in.

What we are saying is California is grandfathered in, but my State of Massachusetts, which is just about to pass a similar law, is out. We cannot protect people. Washington knows best. Washington is saying to Massachusetts, no matter how you want to protect your consumers up there, you can't do it because we are preempting you.

Come on, Mr. President. This is a health issue. This is a safety issue.

This involves primarily women, it involves children, and to some degree men in our society. But it involves health and safety.

We have thousands and thousands of complaints about various products. I indicated earlier today—maybe I didn't—about the number of people—there were 47,000 cosmetic-related injuries in the emergency rooms in American hospitals in 1987—47,000. I wonder how many today, with greater utilization of cosmetics, greater danger, more toxins, more carcinogens. These are just the emergencies. These are not the kinds of situations that maybe—they may be—have long festering, long lasting kinds of implications and have been festering for a long period of time.

That is what is happening out there—47,000 cosmetic-related injuries in the emergency rooms. How many others where people go back to their doctor and do not go through the emergency room? How many others?

We have scores, scores and scores of complaints that have come to the FDA, and they go down the list. Thousands of consumer complaints in 1996 alone: Equate Baby Oil—these are complaints to the FDA—their complaints are eye tissue damage. Disney Kid Care Bubble Bath: urogenital track reactions. Nat Robins Eye Shadow Pencils: eye rash, burns and irritation. Flame Glow No Mistake Eyeliner Pen, black magic color: Rash, burns, and irritation. Incredible Lex Mascara, Eye Perfector, Dramatic Timing Faceneck, Covergirl Professional Advanced Mascara: rash and burns.

These are the companies. You have the Disney Co., the Reckitt & Colman Co., Softsoap Enterprises, Great American Cosmetic. They produce Nat Robins eye shadow pencils.

You have Del Laboratories, Estee Lauder eye shadow; Avon products; Procter & Gamble, rash and burns.

You have Helene Curtis, Salon Selective Styling, flammable, resulting in thermal burns.

You have American Pride, hair relaxer, Alberto Culver lotions, hair tissue damage and hair loss.

You have Clairol, Clairol Infusion 23 Shampoo, hair loss and hair tissue damage;

Del Laboratories;

You have Products Naturistics Mango Shampoo, hair loss and damage;

Helene Curtis, Suave Balsam and Protein Shampoo, hair loss, hair damage.

Vigoral—we find hair loss and tissue damage.

Alberto Culver Co., VO5, hot oil concentrated treatment, hair loss and tissue damage;

Hydrox Laboratories, Fresh Moment Mouthwash, mouth infections—mouth infections;

Carter Wallace, Arrid deodorant, bleeding and infection with utilization;

Apollo Health Care, Baby Bear Lotion, pain, including itching, stinging, burning, and soreness.

Mr. President, these are just some of the items. I may very well include the whole list in the RECORD on Monday. These just give an example of some of the leading companies.

Some may say, these are not really accurate. We would know whether they are accurate if we were able to give the assurances that we had those in the States who were looking into this and be able to say, ''Look, this isn't a problem.'' But now we are not going to know because all the States are preempted. Now we are going to find these reports are going to come in more and more. We will have to just presume that they are accurate, because the cosmetic industry will not let us find out whether they are or are not accurate. They will not permit the publication of information that is going to reflect poorly on either safety or effectiveness.

Mr. President, these are just some of the items that I think form the compelling case for State action. I think we will on Monday go through some of the particular cases in more detail on the California situation, because I think that they have really had the soundest record. It isn't easy to get this kind of information, but we will go through it. These that I just mentioned are some of the thousands of consumer complaints to Government agencies. This is only for a few months of the year, and I have read just a very few of them. I will perhaps get into even more of them later on.

Mr. President, I mentioned earlier a study by the General Accounting Office which reported that more than 125 ingredients used today are suspected of causing cancer. We have scores of cosmetic ingredients that can damage the nervous system, including headaches, drowsiness, convulsions.

To all of those watching this program I would say, ''don't discount the fact that perhaps some of your ailments—headaches, drowsiness, and convulsions—may actually be resulting from the use of cosmetics.'' Don't discount that, because the record shows that cosmetics manufacturers are including ingredients that can cause those symptoms. You don't know, your State won't know, the Federal Government won't know, we won't be able to tell you because of the power of the cosmetic industry in foreclosing that kind of study and the publication of information about the real health implications.

The GAO found that additional Federal authority is necessary to protect the public. That is the General Accounting Office. It is not this Senator from Massachusetts, not a Democrat, it is not a Republican. Here is the General Accounting Office reaching the conclusion, after reviewing this whole subject matter, that if you want to protect the public, you need greater Federal authority—we are not getting that today. The only authority that we have out there is at the State level, and this bill is taking that away.

How much do we have to yield to the greed of this industry? How much? And why? Why should we do it? We patch together something that will take care of California because they passed their law a couple of years ago. But we say to the other 49 States, ''You can't, you are never going to be able to do it again, never be able to do it again, ever.'' They have been able to protect their consumers. Hopefully, they will be protecting the people of Massachusetts, because that is the only way we are going to be protected, not at the Federal level, but through their own leaders, legislature, and representatives. No, we are just saying absolutely not.

So, Mr. President, the cosmetic industry wants the public to believe that no effective regulation is necessary or desirable. They are masters of the slick ad and expensive public relations campaign, but all the glamour in the world cannot obscure the facts.

Mr. President, I just showed what the results of some of these actions are in terms of affecting people. I mentioned the peelaway product. This is a before and after appearance and complaint of the peelaway product. You can take a look and see what happens to people.

These are various ingredients which have been put on an individual's feet. Look at the reactions to it. We are saying, no, we are not going to permit the States to try and do something about that kind of activity. And we could have had a whole series of charts up here.

I mentioned just a few moments ago what was happening in terms of burns and irritations that are occurring with skin products and what is happening to eye tissue and what is happening with rash and burns and hair tissue and hair loss and mouth infections and bleeding—the list goes on and on.

We could have had charts all around this room. Generally speaking, when you have this kind of circumstance, we would be in here debating what to do about it. Instead of thinking about what we are going to do about it, we are talking about what we are not going to do about it.

Mr. President, here we have seen what the States have done, what the problems have been, what the dangers are to the American consumer in terms of mercury, lead, and other substances in products that everyone knows are dangerous and are health hazards. Here we have a problem, and it is getting bigger. The products that are being produced for the market are more dangerous. Yet, we are doing less and less and tying the hands of the local communities to act in our stead.

We allow States to decide whether your bottles are going to be recycled or whether they are going to be buried. We permit the States to decide what they are going to do about licensing barbers. States decide and have rules and regulations and laws about pets. We have States that have rules and regulations about how close to the crosswalk you can park your car. We have regulations in the States about

what store hours are going to be, how late a store can be open. But this bill would prohibit the States from protecting consumers from lipsticks, hair creams and the soaps, hair dyes, mascara, and deodorants that can give you cancer or can catch you on fire as a result of flammable ingredients, or cause serious birth defects.

Now, does that make any sense at all? Does that make any sense at all? When you have the most serious dangers in terms of health and safety, we are denying States the opportunity to do something about it, but we will let them go ahead and look after these other kinds of issues which are not related in any particular way to health and safety.

It just doesn't make any sense. It makes no sense at all. The proponents of this provision know they couldn't pass this legislation if it wasn't tagged on to the Food and Drug Administration bill. They wouldn't dare bring this legislation out here on its own. The reason they tagged it on this bill is because they knew the importance of food and drug reform. They knew that we had to pass the extension of PDUFA, which is a key program to provide sufficient resources to the Food and Drug Administration to get the qualified people who can help expedite the more rapid consideration of new products, new pharmaceuticals in the Food and Drug Administration and has been very creatively utilized over there.

So what do they do? They tag this on to that train. This legislation would be laughed out of this body if it came up here on its own. Why don't they try to bring it up on its own? We have Members in the Senate say, ''We don't understand, there are just one or two Senators troubled by this.'' All the Governors seem to be troubled by it, and you can't blame them. They have the fundamental responsibility for protecting health and safety. That has been fundamentally a responsibility at the State and local level. It is a fundamental responsibility that is as old as this country. So the Governors don't buy into this.

The administration understands that this thing is a phony grab, a greedy grab for profit, because that is what it is. It will mean that the various cosmetic industries are not going to have to be altering or changing their products because you are not going to have the research being done or the authority in the States to bring changes that would make products safer. It is going to mean more profits. On the one hand, more profits for the cosmetic industry and much greater health threats in terms of safety, in terms of potential birth defects for infants, for various kinds of ingested products with a whole range of sensitivity to the body—eyes, mouth, ears, hair—and the problems of lips and the ingestion of various products that are dangerous.

(Mr. COVERDELL assumed the chair.)

Mr. KENNEDY. It just defies any logic. So, as we all know—we have been around here—hopefully even the newer Members understand this one, where you get something that is going through and can't make it on its own, and is added at the last or next-to-last markup with just a fraction of the discussion as we have had to date out here today during this consideration, and it is locked in.

That cosmetic industry is just smiling. They are smiling now with the votes that they had down there saying, ''Well, it seems we've got through this hurdle.'' I am just telling you, this is a long, long process. And they better get used to the fact there is going to be a long process, because this issue is not going to go away. It is not going to go away today, and it is not going to go away when we talk about this some more on Tuesday and get more information. It is not going to go away on Tuesday and not going to go away in terms of the consideration of the legislation. It is not going to go away for a long, long time.

Amazing about how a measure like this can slow something down over a long time so that the American people can begin to understand what is really at risk. I do not believe that they do. I wonder how many Members of this body have read through the legislation and understood exactly what was included in terms of the cosmetic program.

So with this particular proposal in there, we are going to have to ensure that we are going to have the kind of full awareness and understanding, not only by our colleagues here but the American people as well, as to what the health implications are.

This has important and significant health implications. We deal with a variety of different proposals in terms of education—the HOPE scholarship, the tuition credit, the work-study programs—and we debate those and discuss those and allocate resources to those, trying to decide how much we are going to provide in terms of the Head Start Program. Will it be 59,000 new children this year or 100,000? At the end of the day we may understand that our side does not win, others prevail on it, but we know that we have made the battle and made the fight, and the people that are going to be disadvantaged may be those children who are not going to get that benefit in terms of education. And that is a tragedy in terms of a mind developed.

But here we are talking about something else that is even much more important. You are talking about the vital health of the American people and the safety of the American people. You are talking about the dangers to children and infants and about the birth of healthy children. You are talking about the dangers to children's eyes, and you are talking about the dangers to people who are trusting just what they see on the shelves of American pharmacies across the country.

I would say that 9 out of 10 Americans who walk into any pharmacy this afternoon and see a product on the shelf are saying, ''Well, this is just sort of like my medicine or just about like the other products that I'm buying here. Somebody's looked at it, the Food and Drug Administration or somebody's looked at it, and it is safe or it wouldn't be out there.'' That is baloney. It is true for prescription drugs. And by and large it is true about over-the-counter drugs. True about medical devices, by and large. You can flyspeck and find instances, but that is true about those. We have the safest regulatory systems in the world. But it is not true for those products that are on those shelves that so many millions of people are using and have resulted in, in 1 year, 46,000 people going to the emergency room.

People do not go to the emergency room unless it is serious. I do not know whether it is $300, $800 to go to an emergency room to get any kind of attention. People might go back to their doctors with good health insurance, go back to their dermatologists to ask them to do it, but how many people are going to the emergency room? Someone with a little burn is not going to that emergency room. Particularly if you are working families and have children and you do not have health insurance, you are not going to be going down. How many other people did not go and still were adversely affected? But we say, ''Oh, no, no, no, we're not going to do anything about that.'' Whatever was being done out there by the States—that is out now. You cannot go forward with it.

So, Mr. President, the cosmetics industry wants the public to believe there is no effective regulation that is necessary or desirable. They are masters of the slick ad and expensive public relations campaign. But all the glamorous pictures in the world cannot obscure the facts. This is an industry that is underregulated and its products are too often hazardous.

The severe reactions may be only the tip of the iceberg. Long-term illnesses, ranging from cancer to birth defects, may not be linked to their underlying cosmetic-related causes. As the GAO 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, injury estimates generally account for only acute toxic effects.''

The GAO is saying that with those 46,000 people that are going to the emergency room, that is only the tip of the iceberg. And Lord only knows, if you did not have State action in taking away the lead and the mercury and the other kinds of poisonous products that are cancer forming there would be even a much more dramatic number for it.

Here we have the GAO effectively saying that because the symptoms of

chronic toxic effects may not occur until months after exposure, injury estimates generally account for only acute toxic effects. We see that in 1987 we had 46,000 of what we know now was the exponential increase in the danger of all these products. We can imagine the dangers that exist out there today.

In light of this limited authority and even more limited resources to protect the public, you would think Congress would want to encourage States to fill the regulatory vacuum. You would think we would be out here asking, what can we do to help, if anything, the States that are trying to address protections for their consumers? What can we do with the Centers for Disease Control to help Massachusetts, to help Georgia, help North or South Carolina? What are the resources that are out there to assist your State legislatures, Republican and Democrat, to provide protection from some of these toxic or carcinogen problems?

But, oh, no, we are not out there asking that this afternoon. We are out there putting more roadblocks in front of the States in their attempt to do so. In fact, the language is so extreme the States have been barred, as I mentioned, from establishing ''any requirement relating to public information or any other form of public communication relating to the safety and effectiveness of a drug or cosmetic.''

So, Mr. President, the last time the Senate looked at the issue of cosmetic regulation was in the late 1970's. We held extensive hearings, and we debated the issue, and we passed a comprehensive bill that included additional authorities for the FDA. Today, we are considering a bill that resulted from no hearings, where there has been little debate, no expert testimony in a product area that touches the American public every day.

It should be made clear to anyone that cosmetics are as deserving of adequate regulation as they were 20 years ago. It defies logic that our single action in this important consumer product area is to preempt the States from acting where there is wide agreement that FDA has neither the authority nor the resources to adequately fill the field. An attorney, now with Procter & Gamble, wrote in a 1996 Food and Drug Law Journal article that although cosmetics are regulated by the Food and Drug Administration, ''the agency's regulation is extremely lenient.'' If lenient regulation led to the chamber of horrors documented in the Senate hearings 20 years ago, it is difficult to imagine the impact of preempting the States from acting.

The proponents of the bill will tell you their language preempts State safety regulations only—remember we heard that during the course of the day—that their language preempts safety regulations only where the Federal Government has acted. But the actual statutory language is very broad and demonstrates a different intent. The industry admits that the language is drafted specifically to undermine Federal judges that have narrowly interpreted the Federal preemption.

For instance, if FDA sets a standard for lead in hair products, this bill would direct a conclusion that the lead level sets the standard for other, unrelated products that might have different routes of exposure. So we know what the industry was doing. You can talk about these issues in generalities, but you have to look at the specific language here.

Mr. President, I have no doubt the industry will argue that any little action on FDA's part will preempt State action. Yet we have no assurance the FDA is actually up to the task of filling the void left by the States. Again, we have had no hearings, no public record, no expert testimony. In fact, the industry cannot cite one example of a burdensome State regulation that this law preempts. I hope that if that is not the case, that this record will be clarified. The industry cannot cite—you have not heard in this debate here this afternoon the industry citing one example of a burdensome State regulation. Instead, they suggest that the benefit of this law is prospective. They claim they are concerned about what the States might do in the future. This is legislation for a problem that does not exist. But they see that this was the chance to get on this particular train, and they are riding it.

The stark reality is that, according to the cosmetic industry itself, the industry spends 70 percent of its lobbying dollars influencing State legislatures. I suppose we should really call this the FDA Lobbying Relief Act. I find scarce comfort in the fact that this bill will relieve cosmetic lobbyists from having to lobby 50 States, who can now focus on Congress. Even worse, if this provision is enacted, the cosmetic lobbyists will spend their time getting FDA to act in some small way on a safety issue simply to create a broad scope of Federal preemption of the State in that area.

This is irresponsible deregulation, putting the proverbial cart before the horse. Let me emphasize that if we want to truly reform the FDA's regulation of cosmetics, we should start with ensuring they are protecting the American public from unsafe cosmetic products. Once the American people can be confident that FDA has the authority and the resources to protect them, that FDA is up to the task, then we can talk about State preemption. That is the way we have always approached State preemption in the past, and that is the only way to approach it now.

The proponents of this provision claim that by permitting States to petition for exemptions, there is adequate protection for States rights. In reality, the high procedural hurdles in this provision, especially the extreme, burdensome requirements of formal rulemaking, ensures a lengthy process where industry will entangle States in years of hearings. Given the lack of Federal presence in the area of cosmetic regulation, it is unconscionable to make the States jump through hoops in order to continue to protect and warn their citizens.

They finally say, ''Well, OK, you can make some progress and deal with this, but you're going to have to jump through all these hoops.'' How many times have we been hearing on the floor about rules and regulations and the bureaucracy of Federal regulatory agencies, and here we have those that support this proposal on cosmetics setting up hoops for any of the States to jump through—hoops and landmines—hoops for the States to jump through in order to continue to protect and warn their citizens?

I assure my colleagues that this is only the first instance of where you will witness efforts at sweeping preemption in the absence of significant Federal activity. We will be faced with a barrage of bills seeking to preempt State authority in the area of public health regulation. It is certainly ironic that this Congress is so determined to undermine States rights.

Mr. President, let me emphasize again how this provision hinders States from protecting their citizens at the end of the day. The labeling and packaging of a cosmetic is preempted completely under this language. States will be unable to communicate safety concerns in the most effective and sensible manner—through labeling and packaging. Even if the States retain some vestige of authority over cosmetic safety, this bill ties their hands and prevents them from giving the public the information it needs to make informed choices. ''Right to know'' under this provision means ''right to no information.''

What about the FDA? Today, the FDA has fewer than two people working on labeling and packaging. In fact, most of the 30 people working in the FDA Office of Cosmetics work on the regulation of color additives and not actually on cosmetics. The reason for this underwhelming presence is simple: FDA has put limited resources in the cosmetic program because they simply do not have adequate legal authority to address cosmetic safety. If you can't enforce the law because there is no enforcement authority and because the standards are basically nonexistent, you are not going to squander valuable personnel where there are drugs and medical devices to approve, and foods to keep safe.

For example, if the FDA suspects a cosmetic safety problem exists, as they do with the use of alpha-hydroxy, acid face creams, the agency faces high hurdles in bringing any kind of regulatory action. The FDA bears the burden of demonstrating by its own testing that the product is injurious to health. The FDA cannot make the company demonstrate they are selling a safe product. That is important, Mr. President. The FDA cannot come in and say to the company, ''Show us the information for the product you are testing to

demonstrate this is a safe product.'' No, they do not have that power or authority. The FDA cannot require the companies to come in, and the FDA, by its own testing has to demonstrate that the product is injurious to health.

Today, the FDA knows how many milligrams of aspirin are in a tablet and they know how much sodium is in human or animal food and can require disclosure of this information to consumers, but the FDA does not have to know how much alpha-hydroxy acid is in face cream. The agency cannot even require the cosmetic companies to disclose the presence of a known carcinogen like alpha-hydroxy acid to consumers. We need to understand, Mr. President, that the agency cannot even require the cosmetic companies to disclose the presence of a known carcinogen—they cannot do it—like alpha-hydroxy, to consumers.

It is, frankly, no wonder that 70 percent of the cosmetic industry lobbying takes place in the States because that is where the action is. That is where the standards are being set. That is where the standards are being set and enforced.

My colleagues do not have to take my word. We have a letter from the National Governors' Association, Association of Food and Drug officials, and the Association of State Legislatures, voicing strong opposition to this whole provision. We have a letter from the conservative Republican Attorney General of California, Dan Lundgren, strongly opposing this provision, and speaking eloquently about the importance of State laws on cosmetic safety.

In my own State we have a bill that would extend the same public health protections enjoyed by California under their right-to-know law, Proposition 65. Proposition 65 is so successful and so popular with California voters that the committee has excluded it from preemption. No one has refuted the positive impact Proposition 65 has had on the public health. No one has. But instead of taking a law that is working so effectively to protect the public and encourage other States to emulate California today, we are debating whether to preempt every State but California.

Some of my colleagues have expressed satisfaction with grandfathering Proposition 65. They should delay their celebration. This bill grandfathers Proposition 65 in its current form, which applies to reproductive toxins and carcinogens. But California cannot react to future scientific developments by warning its citizens against other hazardous substances.

I will include the whole letter and I ask unanimous consent the complete letter be printed in the RECORD.

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

STATE OF CALIFORNIA,
DEPARTMENT OF JUSTICE,
Los Angeles, CA, July 14, 1997.

Re S. 830, FDA Modernization and Accountability Act of 1997—Potential Preemption of California Health and Safety Laws.

HON. JAMES M. JEFFORDS,
Chairman, Senate Labor and Human Resources Committee, Hart Office Building, Washington, DC.

DEAR SENATOR JEFFORDS: It has come to our attention that S. 830, the FDA Modernization and Accountability Act of 1997, is moving rapidly through Congress. We understand that this omnibus bill, which covers the entire gamut of FDA authority, also contains language in section 761 on National Uniformity for Non-prescription Drugs to the effect that no state may establish or continue in effect any requirement ''that relates to the regulation of a drug intended for human use that is not subject to the requirements of section 503(b)(I) or a cosmetic'' unless is it identical to the Act. While this is only a small portion of a major piece of legislation, we are concerned that this provision may be construed to preempt states from imposing any requirements on cosmetics or over-the-counter drugs, and could therefore prevent the State of California from enforcing significant laws dealing with the health and safety of its citizens in the absence of a specific FDA exemption. California laws which could potentially be affected by the FDA Modernization Act in its current form include the Sherman Food, Drug and Cosmetic Law, and the Safe Drinking Water and Toxic Enforcement Act of 1986 (''Proposition 65'') as they apply to manufacturers of cosmetics and over-the-counter drugs.

Regulation of health and safety matters has historically been a matter of local concern and the federal government has been reluctant to infringe on state sovereignty in these traditional areas of police power. As noted by the Supreme Court in *United States* v. *Lopez*, 154 U.S. 151, 131 L.Ed.2d 626, 633 (1995), ''a healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front.''

Thus, many federal statutes that preempt state regulation in the traditional health and safety area do so narrowly, if at all. For example, the Federal Insecticide Fungicide, and Rodenticide Act and the Federal Hazardous Substances Act preempt only labeling requirements and the Medical Device Amendments to the federal Food, Drug and Cosmetics Act preempts state requirements only if there is an existing, very specific federal requirement in effect. In contrast, the ''National Uniformity'' provision of S. 830 as currently proposed, appears to generally preempt all state requirements, not just labeling requirements, even when there is no existing federal requirement in effect.

As noted above, S. 830 would, in the absence of specific FDA exemption, appear to prevent the State of California from enforcing both the Sherman Food, Drug and Cosmetic Law as well as Proposition 65, a state ''Right to Know'' statute, passed by the voters of California in 1986. Proposition 65 requires that persons who expose others to certain levels of carcinogens or reproductive toxins give a clear and reasonable warning.

Proposition 65 has been used successfully to reduce toxic contaminants in consumer products and has repeatedly been instrumental in creating positive changes in products regulated by the Food and Drug Administration. The federal government has at least twice in the past ten years followed the lead of the State of California after the state entered into various settlement agreements under Proposition 65 that required lower levels of contaminants in various products. For example, in 1990, after California filed suit under Proposition 65 concerning lead leaching from ceramic dishes, the Food and Drug Administration (''FDA'') adopted stricter lead standards for dishware. In 1991, the state brought an action concerning lead-foil wine bottle caps, resulting in industry-wide agreement to convert to tin or plastic caps. A year later, the FDA adopted a standard barring lead-foil caps.

Most recently, this office entered into settlements, just approved by the court, with the major manufacturers of calcium supplements and antacids (a non-prescription drug), both of which are taken in large quantities by pregnant women and many of which contained lead at levels that caused concern for the health of the fetus. The settlements require the manufacturers to lower the lead levels in their products substantially below previously mandated food and pharmaceutical levels. The manufacturers intend to make these changes on a nationwide basis. As has been the pattern in the past, the calcium settlements have served as a model for federal action, and the FDA is now considering changes to the federal standards for lead in calcium supplements and antacids.

While we appreciate the need for national uniformity of regulation in certain areas, the provisions of Proposition 65 have been in existence for over ten years and have repeatedly been found not to be preempted by federal law.[1] In June of this year, the Federal Occupational Safety and Health Administration approved Proposition 65 in the California workplace, ruling that it did not impose an undue burden on interstate commerce. (U.S. Department of Labor, Occupational Safety & Health Administration 62:31159–31181—Supplement to California State Plan, Approval (June 9, 1997)).

Propostion 65 as well as the Sherman Food, Drug and Cosmetic Law are examples of the type of state regulation that protects the health and safety of its citizens and that coexists comfortably with federal regulation. The states should be permitted to continue in their historical role as guardians of the welfare of their citizens. We therefore respectfully urge you to seek modification of your bill to address this issue.

Sincerely,

DANIEL E. LUNDGREN,
Attorney General.
THEODORA BERGER,
Assistant Attorney General.

Mr. KENNEDY. Reading from the last paragraph:

Proposition 65, as well as the Sherman Food and Drug Law are examples of the type of State regulation that protects the health and safety of its citizens and that coexist comfortably with Federal regulation. The States should be permitted to continue in their historic role as guardians of the welfare of their citizens. We therefore respectfully urge you to seek modification of your bill to address this issue.

There it is, Mr. President, from the attorney general of California, a conservative Republican, who understands as a person that has been working and implementing this legislation why this proposal is rotten and why it ought to be adjusted.

Mr. President, a few years ago, the agency proposed establishing a cosmetics hotline to receive consumer complaints. The FDA hoped to fill in gaps

[1] See, e.g., Committee of Dental Amalgam Manufacturers v. Stratton, 92 F.3d 807 (9th Cir. 1996) (no preemption by Medical Device Amendments to Federal Food, Drug and Cosmetics Act); Chemical Specialities Manufacturers, 958 F.2d 941 (9th Cir. 1992) (no preemption by Federal Insecticide, Fungicide and Rodenticide Act and Federal Hazardous Substances Act (''FHSA''); People v. Cotter, 53 Cal.App.4th 1373 (1997) (no preemption by FHSA).

because their voluntary cosmetics adverse event reporting systems had dismal compliance rates of well below 40 percent. The majority of all cosmetics health problems were going unreported, and here was an ingenious solution. The reason the reporting systems were all voluntary is because the FDA does not have the authority to require companies to tell consumers what kind of problems consumers are having. Put Congress and some heavy lobbying together and you get a congressional prohibition forbidding FDA from establishing the hotline. So we were denying the FDA from having a hotline.

When will it stop, Mr. President? We are preempting all of the States, except California, from taking any steps to give the FDA any kind of additional authority. Then when there was the effort to just establish a hotline so people could call in and register their complaints, the funding for that hotline was dropped. I wonder why? I can tell you why. I gave you some examples of why, just a few moments ago, with the consumer complaints to various agencies, including the FDA, with people writing in. No, we are not going to hear from the public.

Finally, Mr. President, there was some reference earlier about medical device legislation in Europe. We often hear about FDA's regulation of drugs as the international gold standard. I refer to our country's regulation of cosmetics as the fool's gold standard. Cosmetic regulation in other countries is far superior to our own. The European Union requires full ingredient listing on packaging, documentary proof of good manufacturing practice, and similar proof that extensive testing has been carried out on all products. Mexico recently adopted regulation mandating expiration dates on all cosmetics. Although New York recently adopted just such a rule, it may live a short life—the bill before the Senate would preempt that regulation even if FDA does not have its own regulation in place.

Let's continue on our world tour. Canada requires that manufacturers submit data showing that a product is safe under normal use conditions. Sweden is initiating product registration for cosmetics and Denmark is considering a similar law. Malaysia requires mandatory registration of cosmetics. The list goes on, but the point is clear. We are not content to lag behind other countries in protecting our citizens. We prefer to buck the trend and expose them to greater hazards. As experience has shown in other countries and in California with Proposition 65, the industry can readily comply with meaningful safety standards when they are imposed.

Unlike food or drugs, cosmetics are not essential to our health. We use them because their benefits are so clear. We need only mention this summer's unprecedented beef recall to illustrate that our food supply is not perfectly safe. But cosmetics are a different matter. We are not compelled to use them. For that reason, we should be far less willing to accept injury and death from such products.

I suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. HELMS). The clerk will call the roll.

The bill clerk called the roll.

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

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

Mr. KENNEDY. Mr. President, earlier I reviewed for the Senate the actions that have been taken by the States which have resulted in additional kinds of protections for safety for the American consumer in those States, primarily in California. I reviewed some of the items that posed the principal health hazards for citizens—the lead, the mercury, and other items and what has happened by the States when removing those items.

Then I also mentioned, Mr. President, the limitations we have in terms of the Food and Drug Administration in taking any actions to protect people and the power of the cosmetic industry in refusing to even have a hotline. We have hotlines in so many different and important areas for American people. We have them with regard to battered women, as one of the principal sponsors for that. We are not comparing that need with this one but there is enormous importance and enormous justification and that has been a powerful, powerful instrument for battered women in our society.

We wanted to try and have at least a hotline for people that might be able to have been impacted adversely by these cosmetics. We mentioned already that there are 46,000, at the last count, people going to emergency rooms—46,000. And we know the dangers which are out there in terms of impacting the American consumer and they have increased dramatically with the increase in products. It has been recognized by the companies and the industry itself by the number of products and the complexity and the toxins that have been included.

So the only real opportunity that we have other than going to the States and reviewing the kind of complaints that they have has been from the various agencies of government. I mentioned just a few moments ago about these various items and I will go into greater detail with the companies and what the allegations are and what the results are on Monday. I have them here but I will not take the additional time.

The fact is, these are the kind of results we are having, Mr. President. When California runs into those circumstances they can do something about it. When California found out about a particular product, the State was able to do something about it. Now, under this legislation, on this preemption, 49 States will not be able to do something about it. California has been grandfathered in, but all of the rest of us that come from other States will not be able to get that kind of a protection.

Now, I just mention the kind of injury complaints that have been included. They include, going through this code which we are gradually going through, injury code 14 includes rash, redness, swelling, blisters, sores, weeping, lumps, inflammation, sunburn, chemical burn and irritation; code 19, pain, to include itching, stinging, burning, soreness, and tingling; injury code 20, tissue damage—other than thermal burn, peeling, splitting, cracking, hair, or nail breakage; code 21, discoloration; code 22, infection; code 23, nervous system reactions, to include dizziness, headache, irritability, nervousness, numbness; injury code 24, respiratory reaction, to include choking, coughing, sneezing, shortness of breath, wheezing; code 25, digestive system reaction, upset stomach, nausea, loss of appetite, vomiting, diarrhea; code 26, bleeding, code 27, urinary tract infections; code 28, flammability resulting in thermal burns; code 29, blurred vision; code 30, death as a result of inhalation or sniffing deaths, and code 31.

These are serious, Mr. President. These are serious health hazards. Before we in this body and the House of Representatives see a piece of legislation tagged on to the important Food and Drug Administration, the medical device and the pharmaceuticals which are so important, on which we have made so much progress, on which all of us are hopeful will finally result in a bipartisan agreement, we see the greed of the cosmetic industry go right out there and tag on this amendment as one of the last amendments to preclude the States—they have gotten the Government effectively precluded, unlike the European countries. The European Union, and most of the other industrial countries of the world, have some protections. They have been able to preclude the Federal Government, and now they are precluding the States from protecting the consumers and putting them at risk for all those kinds of illnesses and sicknesses that I have talked about here that are resulting from all of those products.

That is what we are being asked to embrace. That is what we are being asked to embrace. For those that understand the importance—the Attorney General of the State of California, who has been working on this, makes it so clear: Don't do it, Senator. Don't do it, Senate of the United States. Don't do it in the Congress and Senate. Mr. President, don't sign that legislation. He wants to be able to protect the people in California, as other public health officials want to be able to protect their people in the other 49 States. That is the issue. That is the issue.

We are going to come back to it again and again and again, Mr. President, because it is of such enormous importance to the health and safety. The other side of the balance is the

question of greed by the cosmetics industry. Usually, when we are making tough decisions around here—and we have made them—we have limited funding; for example, for the food programs for our elderly people. We have to make a judgment, are we going to treat more people in congregate sites where you can feed more elderly people with limited resources, or are we going to carve out some and feed them at home, which means you will get to less people, you will get those people that are homebound. What do you do under those circumstances? You are placing needy people of one side against needy people on the other.

No easy answers on this. Painful judgments and decisions on that. We don't always get it right. We understand that. People of good will can differ on that and feel strongly about it, and we respect them here in this body. But under this circumstance, we are talking about the profits of the cosmetics industry and the risk to the American consumer. That is what the balance is. That is what is unacceptable. That is what is outrageous and that is why that cloture vote was necessary, so we begin to wake up America as to what is happening to these States. That is what we are going to have an opportunity to debate as we go to this bill, plus the other measures.

Mr. President, the last unacceptable element of this bill is an assault on the basic environmental protections contained in the National Environmental Protection Act, which is a key Federal environmental statute that regulates the Government's own actions through environmental impact statements. Under NEPA, Federal agencies must undertake a comprehensive environmental planning process for every major action they take. This law is a crucial statutory assurance that the work of the Government, the actions of regulated industries are consistent with the guiding principles of environmental protection.

Section 602 of the bill broadly exempts FDA's activities from environmental impact assessment under NEPA. This is the first preemption of NEPA in a regulatory agency and is the beginning now of cutting back very, very important environmental issues. For what reason? Why are we, in our committee that is responsible in terms of the education and the health and basic research, and the basic oversight of laws dealing with labor and management, pensions, and some of the older Americans activities —why in the world are we going around here in terms of preempting NEPA from the FDA? Who do you think was interested in that? Perhaps some of the industries who want to get out from under filing the environmental impact statement. If we are starting off with this agency, we know exactly what is going to happen in each of the other agencies.

This week, I spoke with the Vice President who expressed his serious personal concerns about this provision. Just a few sentences: This bill opens the door to weakening environmental protection, and lays a welcome mat down for future exemptions and attacks on the effective and essential environmental statute. This is an act of environmental extremism, which should have no place in this or any other bill.

The reauthorization of the prescription drug and user fee is tremendously important to assure that the FDA will have the resources to review the new drugs. That is what we ought to be addressing.

Mr. President, what is the parliamentary situation?

The PRESIDING OFFICER. The Senator from Massachusetts has 55 minutes 28 seconds remaining.

Mr. KENNEDY. Fine. I thank the Chair. I want to prepare to yield back the balance of my time this afternoon. As I understand, from a previous agreement, we will have time to continue this debate, I believe, on Monday next for a period of 4 hours, with the time evenly divided, starting at 11 o'clock, is that correct?

The PRESIDING OFFICER. Yes.

Mr. KENNEDY. I yield back the remaining time this afternoon.

FOREIGN OPERATIONS, EXPORT FINANCING, AND RELATED PROGRAMS APPROPRIATIONS

The PRESIDING OFFICER. Under the order of July 16, 1997, the Senate having received from the House of Representatives the bill H.R. 2159, all after the enacting clause of H.R. 2159 is stricken, and the text of S. 955, as amended, is inserted in lieu thereof. H.R. 2159 is read for the third time and passed, and a motion to reconsider is laid upon the table.

The bill (H.R. 2159), as amended, was passed.

The PRESIDING OFFICER. The Senate insists on its amendment, requests a conference with the House on the disagreeing votes of the two Houses on H.R. 2159, and the Chair appoints the following conferees.

The Presiding Officer appointed Mr. MCCONNELL, Mr. SPECTER, Mr. GREGG, Mr. SHELBY, Mr. BENNETT, Mr. CAMPBELL, Mr. STEVENS, Mr. COCHRAN, Mr. LEAHY, Mr. INOUYE, Mr. LAUTENBERG, Mr. HARKIN, Ms. MIKULSKI, Mrs. MURRAY, and Mr. BYRD conferees on the part of the Senate.

PASSAGE VITIATED AND MEASURE INDEFINITELY POSTPONED—S. 955

The PRESIDING OFFICER. Under the previous order, passage of S. 955 is vitiated and the bill is indefinitely postponed.

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, may I proceed for 2 minutes?

The PRESIDING OFFICER. Yes.

THE DEATH OF MOTHER TERESA

Mr. KENNEDY. Mr. President, I have just been notified about the death of Mother Teresa. I think I speak for all of the Members of the Senate, and I know that I speak for all of the members of my family and the people of Massachusetts that feel a sense of loss with Mother Teresa. She was really an extraordinary, inspirational, spiritual person whose life was devoted to others. She was a woman of enormous tenderness, gentleness, faith, and spirituality.

I had the chance to visit with her in Calcutta in the late 1970's and was first exposed to her extraordinary work with the homeless and destitute in that community. I saw how she was able to minister unto the poorest of the poor in ways that were absolutely inspiring, in terms of her gentleness and in terms of her capacity for caring. Anyone whose life she touched will never forget her. She was really a very, very special person. This world is a better world because of her life. I know that all Americans will feel deeply about the loss of Mother Teresa. I just hope that we will all say a prayer for her. Thank you very much.

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

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

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

MORNING BUSINESS

Mr. STEVENS. Mr. President, I ask unanimous consent that there now be a period for the transaction of morning business, with Senators permitted to speak therein for up to 5 minutes each.

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

TRIBUTE TO MOTHER TERESA

Mr. DASCHLE. Mr. President, we just received word that Mother Teresa has died in Calcutta of cardiac arrest. With Mother Teresa's death, another bright light has gone out in the world.

Someone once asked St. Francis what a person needed to do to please God. He answered, ''Preach the Gospel every day. If necessary—use words.'' Mother Teresa lived just that sort of life. She was a living reminder to all of us that faith is more than words. It is the good deeds we do in this world.

She was a tiny woman, but she was an enormous inspiration. In the same way we can best show our respect for Princess Diana by supporting the ideals she believed in, the best way to honor Mother Teresa is to reach outside of ourselves and try to show a little more compassion in our own lives.

THE VERY BAD DEBT BOXSCORE

Mr. HELMS. Mr. President, too many Americans have not the foggiest notion about the enormity of the Federal debt. Every so often, I ask various groups, how many millions of dollars are there in a trillion? They think about it, voice some estimates, most of them not even close.

They are stunned when they learn the facts, such as the case today. To be exact, as of 10:08 a.m. today, September 5, 1997, the total Federal debt—down to the penny—stood at $5,414,792,993,913.96.

Another astonishing statistic is that on a per capita basis, every man, woman, and child in America owes $20,203.80.

As for how many millions of dollars there are in a trillion, there are a million in a trillion, which means that the Federal Government owes more than five million million dollars.

MESSAGES FROM THE HOUSE

At 12:01 p.m., a message from the House of Representatives, delivered by Mr. Hays, one of its reading clerks, announced that the House has passed the following bills, in which it requests the concurrence of Senate:

H.R. 2159. An act making appropriations for foreign operations, export financing, and related programs for the fiscal year ending September 30, 1998, and for other purposes.

PETITIONS AND MEMORIALS

The following petitions and memorials were laid before the Senate and were referred or ordered to lie on the table as indicated:

POM–218. A resolution adopted by the Advisory Board of Directors of the Methodist Medical Center of Oak Ridge, Tennessee relative to proposed National Spallation Neutron Source; to the Committee on Commerce, Science, and Transportation.

POM–219. A resolution adopted by the Midwestern Legislative Conference of the Council of State Governments relative to global climate change; to the Committee on Energy and Natural Resources.

POM–220. A resolution adopted by governing body of the Township of Little Egg Harbor, New Jersey relative to the Mud Dump site; to the Committee on Environment and Public Works.

POM–221. A resolution adopted by governing body of the City of Brigantine, New Jersey relative to the Mud Dump site; to the Committee on Environment and Public Works.

POM–222. A resolution adopted by the Midwestern Legislative Conference of the Council of State Governments relative to monopolization of agriculture production; to the Committee on the Judiciary.

POM–223. A joint resolution adopted by the Legislature of the State of Nevada; to the Committee on Labor and Human Resources.

ASSEMBLY JOINT RESOLUTION NO. 12

Whereas, within the State of Nevada, the sport of rodeo has great historical, cultural and social significance, and is an important attraction for domestic and foreign tourism; and

Whereas, professional rodeos generate substantial economic activity and are significant sources of income, employment, recreation and enjoyment for Nevadans; and

Whereas, the sponsors associated with rodeos of the Professional Rodeo Cowboys Association assist in sustaining rodeos, making this sport affordable and accessible to millions of rodeo fans; and

Whereas, despite the importance of such events to the economy of Nevada and to the economies of other western states, federal agencies have proposed restrictions upon the activities of sponsors, programs and advertising connected with rodeo events; and

Whereas, such restrictions, if adopted, would jeopardize the financial viability of rodeos, causing considerable loss to tourism and related industries and interfering with the enjoyment of rodeo events by the millions of Americans who attend rodeos annually; and

Whereas, these restrictions would impose unconstitutional limitations on both commercial speech and the freedom of association of the membership of the Professional Rodeo Cowboys Association; and

Whereas, during their 104th session of Congress, Senators Richard Bryan and Harry Reid jointly introduced the ''Rodeo Freedom Act of 1995,'' which, if enacted, would have prohibited the regulation by the Secretary of Health and Human Services and the Commissioner of Food and Drugs of any activity of sponsors or sponsorship programs connected with, or any advertising used or purchased by, the Professional Rodeo Cowboys Association or any other professional rodeo association; now, therefore, be it

Resolved by the Assembly and the Senate of the State of Nevada, Jointly, That the Nevada Legislature supports the efforts of Senators Richard Bryan and Harry Reid in this regard and urges the Nevada Congressional Delegation to continue to bring this issue before Congress; and be it further

Resolved, That the members of the 69th Session of the Nevada Legislature do hereby urge Congress to enact legislation patterned after the ''Rodeo Freedom Act of 1995''; and be it further

Resolved, That the Chief Clerk of the Assembly prepare and transmit a copy of this resolution to the Vice President of the United States as the presiding officer of the Senate, the Speaker of the House of Representatives and each member of the Nevada Congressional Delegation; and be it further

Resolved, That this resolution becomes effective upon passage and approval.

REPORTS OF COMMITTEES

The following reports of committees were submitted:

By Mr. LUGAR, from the Committee on Agriculture, Nutrition, and Forestry, without amendment:

S. 1150. An original bill to ensure that federally funded agricultural research, extension, and education address high-priority concerns with national multistate significance, to reform, extend, and eliminate certain agricultural research programs, and for other purposes (Rept. No. 105–73).

INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second time by unanimous consent, and referred as indicated:

By Mr. LUGAR:

S. 1150. An original bill to ensure that federally funded agricultural research, extension, and education address high-priority concerns with national multistate significance, to reform, extend, and eliminate certain agricultural research programs, and for other purposes; from the Committee on Agriculture, Nutrition, and Forestry; placed on the calendar.

By Mr. DODD (for himself, Ms. SNOWE, and Mr. KENNEDY):

S. 1151. A bill to amend subpart 8 of part A of title IV of the Higher Education Act of 1965 to support the participation of low-income parents in postsecondary education through the provision of campus-based child care; to the Committee on Labor and Human Resources.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. DODD (for himself, Ms. SNOWE, and Mr. KENNEDY):

S. 1151. A bill to amend subpart 8 of part A of title IV of the Higher Education Act of 1965 to support the participation of low-income parents in postsecondary education through the provision of campus-based child care; to the Committee on Labor and Human Resources.

THE CHILD CARE ACCESS MEANS PARENTS IN SCHOOL ACT

Mr. DODD. Mr. President, I am pleased to rise today to introduce legislation to provide new support to needy college students struggling to balance their efforts in college with their role as parents. The CAMPUS—Child Care Access Means Parents in School Act will support the participation of low-income parents in college by supporting campus-based child care. I am pleased to be joined in this effort by Senator SNOWE and Senator KENNEDY.

The stereotypical college student is no longer an 18-year-old high school graduate. Increasingly, nontraditional students—older, with children and various job and life experiences—are filling the ranks of college classes. These students recognize the importance of college to future success.

But these students face new barriers unheard of in earlier times. Many are parents and must provide for their children while in school. Campus-based child care is a vital necessity for parents attending college. It is conveniently located, available during the right hours, and of high quality and lower cost. Unfortunately, it is unavailable at many schools. Even where programs exist, they are often difficult to access, particularly for low-income parents who struggle with the costs.

In the wake of welfare reform, new pressures are also coming to bear on low-income student parents. With the work requirements of the welfare reform bill, it will become increasingly difficult for students who are low-income parents to obtain Federal child care funds. States are likely to shift these funds to support welfare recipients returning to work, rather than to support low-income parents pursuing higher education. This outcome is particularly perverse given the impact of obtaining a college education on family earnings over time. Studies are clear: public assistance recipients who attend college are significantly more likely to leave welfare permanently.

This bill will offer new hope to these students. It will provide support to campus-based child care programs serving low-income parents. Colleges can apply for these 3-year grants to assist the institution in supporting or establishing a campus-based child care program serving the needs of their low-income students. Funds will be targeted to institutions serving low-income students and programs focused on meeting these needs.

Mr. President, this is a modest measure that will make a major difference to students. I am hopeful that it can be considered and enacted as part of the Higher Education Act which we will consider later this year. I look forward to working with my colleagues to move this important measure forward.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 1151

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. CAMPUS-BASED CHILD CARE.

Subpart 8 of part A of title IV of the Higher Education Act of 1965 (20 U.S.C. 1070f) is amended by adding at the end the following:

''SEC. 420C. CAMPUS-BASED CHILD CARE.

''(a) SHORT TITLE.—This section may be cited as the 'Child Care Access Means Parents in School Act'.

''(b) FINDINGS.—Congress finds that—

''(1) earning potential increases significantly when individuals attend college for any period of time;

''(2) public assistance recipients who complete college are more likely to leave public assistance permanently;

''(3) students who are parents and receive campus-based child care are more likely to remain in school, and to graduate more rapidly and at a higher rate than students who are parents and do not receive campus-based child care;

''(4) students who are parents rate access to campus-based child care programs as an important factor affecting their college enrollment;

''(5) children placed in high quality child care programs exhibit significant positive results from the experience, including—

''(A) higher earnings as adults;

''(B) higher rates of secondary school graduation;

''(C) lower rates of retention in grade level;

''(D) lower rates of teenage pregnancy; and

''(E) reduced need for special education or social services;

''(6) the public saves $7 for every $1 invested in quality child care; and

''(7) campus-based child care programs may have an increasingly difficult time accessing Federal child care funds under the structure of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Public Law 104–193; 110 Stat. 2105).

''(c) PURPOSE.—The purpose of this section is to support the participation of low-income parents in postsecondary education through the provision of campus-based child care services.

''(d) PROGRAM AUTHORIZED.—

''(1) AUTHORITY.—The Secretary may award grants to institutions of higher education to assist the institutions in providing campus-based child care services to low-income students.

''(2) AMOUNT OF GRANTS.—

''(A) IN GENERAL.—The amount of a grant awarded to an institution of higher education under this section for a fiscal year shall not exceed 1 percent of the total amount of all Federal Pell Grant funds awarded to students enrolled at the institution of higher education for the preceding fiscal year.

''(B) MINIMUM.—A grant under this section shall be awarded in an amount that is not less than $10,000.

''(3) DURATION; RENEWAL; AND PAYMENTS.—

''(A) DURATION.—The Secretary shall award a grant under this section for a period of 3 years.

''(B) RENEWAL.—A grant under this section may be renewed for a period of 3 years.

''(C) PAYMENTS.—Subject to subsection (f)(2), the Secretary shall make annual grant payments under this section.

''(4) ELIGIBLE INSTITUTIONS.—An institution of higher education shall be eligible to receive a grant under this section for a fiscal year if the total amount of all Federal Pell Grant funds awarded to students enrolled at the institution of higher education for the preceding fiscal year equals or exceeds $1,000,000.

''(5) USE OF FUNDS.—Grant funds under this section shall be used by an institution of higher education to support or establish a campus-based child care program serving the needs of low-income students enrolled at the institution of higher education.

''(6) CONSTRUCTION.—Nothing in this section shall be construed to prohibit an institution of higher education that receives grant funds under this section from serving the child care needs of the community served by the institution.

''(7) DEFINITION OF LOW-INCOME STUDENT.—For the purpose of this section, the term ''low-income student'' means a student who is eligible to receive a Federal Pell Grant for the fiscal year for which the determination is made.

''(e) APPLICATIONS.—An institution of higher education desiring a grant under this section shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require. Each application shall—

''(1) demonstrate that the institution is an eligible institution described in subsection (d)(4);

''(2) specify the amount of funds requested;

''(3) demonstrate the need of low-income students at the institution for campus-based child care services by including in the application student demographics and other relevant data;

''(4) contain a description of the activities to be assisted, including whether the grant funds will support an existing child care program or a new child care program;

''(5) identify the resources the institution will draw upon to support the child care program and the participation of low-income students in the program, such as accessing social services funding, using student activity fees to help pay the costs of child care, using resources obtained by meeting the needs of parents who are not low-income students, and accessing foundation, corporate or other institutional support, and demonstrate that the use of the resources will not result in increases in student tuition;

''(6) contain an assurance that the institution will meet the child care needs of low-income students through the provision of services, or through a contract for the provision of services;

''(7) in the case of an institution seeking assistance for a new child care program—

''(A) provide a timeline, covering the period from receipt of the grant through the provision of the child care services, delineating the specific steps the institution will take to achieve the goal of providing low-income students with child care services;

''(B) specify any measures the institution will take to assist low-income students with child care during the period before the institution provides child care services; and

''(C) include a plan for identifying resources needed for the child care services, including space in which to provide child care services, and technical assistance if necessary;

''(8) contain an assurance that any child care facility assisted under this section will meet the applicable State or local government licensing, certification, approval, or registration requirements; and

''(9) contain a plan for any child care facility assisted under this section to become accredited within 3 years of the date the institution first receives assistance under this section.

''(f) REPORTING REQUIREMENTS; CONTINUING ELIGIBILITY.—

''(1) REPORTING REQUIREMENTS.—

''(A) REPORTS.—Each institution of higher education receiving a grant under this section shall report to the Secretary 18 months and 36 months after receiving the first grant payment under this section.

''(B) CONTENTS.—The report shall include—

''(i) data on the population served under this section;

''(ii) information on campus and community resources and funding used to help low-income students access child care services;

''(iii) information on progress made toward accreditation of any child care facility; and

''(iv) information on the impact of the grant on the quality, availability, and affordability of campus-based child care services.

''(2) CONTINUING ELIGIBILITY.—The Secretary shall make the third annual grant payment under this section to an institution of higher education only if the Secretary determines, on the basis of the 18-month report submitted under paragraph (1), that the institution is making a good faith effort to ensure that low-income students at the institution have access to affordable, quality child care services.

''(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $60,000,000 for fiscal year 1998 and such sums as may be necessary for each of the 4 succeeding fiscal years to carry out this section.''.

Ms. SNOWE. Mr. President, I am extremely pleased to join my colleague from Connecticut, Senator DODD, to introduce the Child Care Access Means Parents in School Act [CAMPUS Act]. Senator DODD and I have worked together to ensure access to quality child care, and this bill represents the next step in our shared commitment to this important issue. I am also pleased Senator KENNEDY has joined us as a cosponsor of this legislation, which provides grants to colleges in order to provide child care for low-income students.

Mr. President, this is the time of year when countless American students return to college. At this time, we should remind ourselves that many Americans face obstacles that prevent them from participating in higher education. The absence of affordable and accessible child care is, unfortunately, one such obstacle.

For many parents with young children, the availability of oncampus

child care services is central to their ability to attend college. Campus-based child care is conveniently located, available at the hours that fit students' schedules and often available at a lower cost than community-based child care centers. Student parents rate access to campus-based child care as an important factor affecting their college enrollment. Unfortunately, such services are often in very short supply, particularly for low-income parents who may find the cost of existing services prohibitive.

Moreover, in order to meet the high demand for child care created by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, States may divert funds away from programs currently providing campus-based child care services for low-income students and use the funds to provide child care to welfare recipients, because educational activities do not count as work under the act. This may leave students with less access to child care services. If we want to fulfill the goals of the welfare reform act and ensure that families are able to remain financially self-sufficient, we need to ensure that low-income parents have access to higher education and affordable and convenient child care. This is crucial given that people who receive public assistance and then complete college are far more likely to leave welfare permanently than those who do not.

There is no question that a person's earning potential increases dramatically with a college degree. According to the Census Bureau, in 1990 the average income for high school graduates was almost $18,000. Those who had 1 to 3 years of college education, however, earned an average of $24,000. And those who graduated from college received an average salary of $31,000.

Higher education is crucial to getting a job in today's global job market. More than half of the new jobs that have been and will be created between 1995 and 2000 will require education beyond high school. While nearly 40 percent of American jobs are currently in low-skill occupations, only 27 percent will fall in that category by the year 2000. Over the same period, high-skill occupations will grow from 24 to 41 percent of the work force. Getting the skills necessary to meet these market demands simply requires higher and higher levels of educational achievement.

For many low-income students who are parents, the availability of campus-based child care is key to their ability to receive a higher education and thus achieve the American dream. Student parents are more likely to remain in school, and to graduate sooner and at a higher rate if they have campus-based child care. Child care services are particularly critical for older students who choose to go back to school to get their degree or to improve their skills through advanced education. This is especially important in today's economy where people need to continuously train and retrain in order to meet the demands of high-technology jobs.

Children placed in campus-based child care also reap numerous benefits, given its very high quality. In fact, children in high-quality child care exhibit higher earnings as adults, higher rates of secondary school graduation, lower rates of teen pregnancy, and a reduced need for special education or costly social services. We also know that quality child care is cost efficient—the public saves $7 for every $1 invested in child care.

The bill we are introducing today will help bring the American dream within the reach of numerous American parents who need child care in order to attend college. The CAMPUS Act will amend title IV of the Higher Education Act to help provide campus-based child care to low-income parents seeking a college degree. Under the bill, the Secretary of Education will award 3-year grants to institutions of higher education to support or help establish a campus-based child care program serving the needs of low-income student parents. The Secretary will award $60 million in grants—equal to 1 percent of total Pell grant funding—based on an application submitted by the institution, and the grant amount will be linked to the institution's Pell grant funding level.

Under the bill, Pell grant recipients will be eligible for child care, to ensure that services target low-income students. In 1995–96, there were approximately 3.6 million Pell grant recipients, and almost 17,000 Maine residents received Pell grants. Students typically qualify for Pell grants if their income is under $30,000 per year. This bill will make a true difference in the lives of many low-income students who need child care to attend school.

I urge my colleagues to support this important legislation which will truly make a difference in the lives of numerous American parents who wish to attend college.

ADDITIONAL COSPONSORS

S. 224

At the request of Mr. WARNER, the name of the Senator from Montana [Mr. BURNS] was added as a cosponsor of S. 224, a bill to amend title 10, United States Code, to permit covered beneficiaries under the military health care system who are also entitled to Medicare to enroll in the Federal Employees Health Benefits Program, and for other purposes.

S. 496

At the request of Mr. CHAFEE, the name of the Senator from New Jersey [Mr. TORRICELLI] was added as a cosponsor of S. 496, a bill to amend the Internal Revenue Code of 1986 to provide a credit against income tax to individuals who rehabilitate historic homes or who are the first purchasers of rehabilitated historic homes for use as a principal residence.

S. 1096

At the request of Mr. GRASSLEY, the name of the Senator from Alabama [Mr. SHELBY] was added as a cosponsor of S. 1096, a bill to restructure the Internal Revenue Service, and for other purposes.

S. 1103

At the request of Mr. MOYNIHAN, the name of the Senator from Pennsylvania [Mr. SPECTER] was added as a cosponsor of S. 1103, a bill to amend title 23, United States Code, to authorize Federal participation in financing of projects to demonstrate the feasibility of deployment of magnetic levitation transportation technology, and for other purposes.

SENATE CONCURRENT RESOLUTION 30

At the request of Mr. HELMS, the names of the Senator from Oklahoma [Mr. INHOFE] and the Senator from Georgia [Mr. CLELAND] were added as cosponsors of Senate Concurrent Resolution 30, a concurrent resolution expressing the sense of the Congress that the Republic of China should be admitted to multilateral economic institutions, including the International Monetary Fund and the International Bank for Reconstruction and Development.

AMENDMENTS SUBMITTED

THE DEPARTMENT OF LABOR APPROPRIATIONS ACT FOR FISCAL YEAR 1998

GRAHAM AMENDMENT NO. 1084

(Ordered to lie on the table.)

Mr. GRAHAM submitted an amendment intended to be proposed by him to the bill (S. 1061) making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 1998, and for other purposes; as follows:

At the end of the bill, insert the following:

TITLE ___—NATIONAL COMMISSION ON PUBLIC EDUCATION FACILITIES CONSTRUCTION AND REHABILITATION

SEC. ___01. FINDINGS.

Congress finds the following:

(1) The condition of our Nation's public pre-kindergarten through grade 12 school facilities play an enormous role in the educational development of our children as there is a relationship between the condition of school facilities and student achievement. In addition to their educational value, neighborhood public schools that are structurally safe and sound, and well-supported by the community can act as important civic and social institutions within our communities.

(2) The financing of public pre-kindergarten through grade 12 school construction and renovation has historically been primarily a local function. Typically, tax-exempt bond issues must be approved through a referendum reliant on local property taxes and are sold to finance capital spending. However, recent national trends indicate a decrease in bond referenda approval to pay for school construction projects. The General Accounting Office reports that 33 percent of school districts have had an average of 2 bond issues fail in the past 10 years.

(3) The United States is currently experiencing a 20-year rise in public elementary and secondary school enrollments which is projected to peak at over 54,000,000 students by 2006 from less than 40,000,000 in the mid-1980's.

(4) The General Accounting Office has reported the following conditions regarding education facilities construction in the United States:

(A) Approximately $112,000,000,000 is needed in order to make necessary infrastructure repairs to our Nation's schools and to comply with current Federal mandates.

(B) One-third of schools nationwide are in need of extensive repair or replacement and 60 percent of schools nationwide reported needing at least 1 major building feature extensively repaired, overhauled, or replaced with most of these schools requiring multiple features repaired.

(C) 60 percent of students in the United States attend school in buildings with at least 1 unsatisfactory environmental condition, with heating, ventilation, and air conditioning systems being the most frequently reported building feature in need of repair. It is estimated that nearly $2,400,000,000 is required to comply with new regulations on asbestos management.

(D) Often the schools with major renovation and rehabilitation needs are least prepared for 21st century technology learning and teaching needs, with over 14,000,000 students attending approximately 40 percent of our schools which report not being able to provide facilities to well meet the functional requirements of laboratory science or large-group instruction.

(5) As the result of the school enrollment increases, the need to prepare postsecondary academic institutions for the influx of these new students will be ever more important.

SEC. ___02. ESTABLISHMENT OF NATIONAL COMMISSION ON PUBLIC EDUCATION FACILITIES CONSTRUCTION AND REHABILITATION.

There is established a Commission to be known as the ''National Commission on Public Education Facilities Construction and Rehabilitation'' (in this title referred to as the ''Commission'').

SEC. ___03. MEMBERSHIP OF COMMISSION.

(a) APPOINTMENT.—The Commission shall be composed of 7 members as follows:

(1) Two individuals shall be appointed by the Speaker of the House of Representatives.

(2) One individual shall be appointed by the Minority Leader of the House of Representatives.

(3) Two individuals shall be appointed by the Majority Leader of the Senate.

(4) One individual shall be appointed by the Minority Leader of the Senate.

(5) One individual shall be appointed by the Secretary of Education.

(6) One individual shall be appointed by the Secretary of the Treasury.

(b) ADDITIONAL QUALIFICATIONS.—Each of the individuals appointed under subsection (a) shall be an individual with expertise and experience in public education facilities construction and financing (including financing the construction of public institutions of higher education).

(c) CHAIRPERSON AND VICE CHAIRPERSON.—The members of the Commission shall elect a Chairperson and a Vice Chairperson of the Commission. In the absence of the Chairperson, the Vice Chairperson will assume the duties of the Chairperson.

(d) QUORUM.—A majority of the members of the Commission shall constitute a quorum for the transaction of business.

(e) APPOINTMENTS.—All appointments under subsection (a) shall be made within 30 days after the date of enactment of this Act. In the event that an officer authorized to make an appointment under subsection (a) has not made such appointment within such 30 days, the appointment may be made for such officer as follows:

(1) The Chairman of the Committee on Education and the Workforce may act under such subsection for the Speaker of the House of Representatives for 1 of the Speaker's appointments, and the Chairman of the Committee on Ways and Means may act under such subsection for the Speaker of the House of Representatives for the second.

(2) The Ranking Minority Member of the Committee on Education and the Workforce may act under such subsection for the Minority Leader of the House of Representatives.

(3) The Chairman of the Committee on Labor and Human Resources may act under such subsection for the Majority Leader of the Senate for 1 of the Leader's appointments, and the Chairman of the Committee on Finance may act under such subsection for the Majority Leader of the Senate for the second.

(4) The Ranking Minority Member of the Committee on Labor and Human Resources may act under such subsection for the Minority Leader of the Senate.

(f) VOTING.—Each member of the Commission shall be entitled to 1 vote, which shall be equal to the vote of every other member of the Commission.

(g) VACANCIES.—Any vacancy on the Commission shall not affect its powers, but shall be filled in the manner in which the original appointment was made.

(h) PROHIBITION OF ADDITIONAL PAY.—Members of the Commission shall receive no additional pay, allowances, or benefits by reason of their service on the Commission. Members appointed from among private citizens of the United States may be allowed travel expenses, including per diem, in lieu of subsistence, as authorized by law for persons serving intermittently in the government service to the extent funds are available for such expenses.

(i) INITIAL MEETING.—The initial meeting of the Commission shall occur within 40 days after the date of enactment of this Act.

SEC. ___04. FUNCTIONS OF COMMISSION.

(a) SPECIFIC FINDINGS AND RECOMMENDATIONS.—The Commission shall study and make findings and specific recommendations regarding the following:

(1) The extent, degree, and national implications of the needs in public education construction and rehabilitation.

(2) The role of public education facilities with respect to the education of children and its impact on performance and achievement.

(3) The existing financing options available for school construction and rehabilitation, and how and to what extent the options are being utilized, including the identification of new sources of finances to assist with school construction.

(4) The adequacy of current State and local programs and policies to meet school construction and rehabilitation needs.

(5) The extent to which creative financing options are being explored and what yet-to-be utilized options could and should be formulated.

(6) The trends and practices in the construction and renovation of public school facilities, including the modernization of facilities to access and utilize new technologies.

(7) The cost of current construction practices and the impact of modernization and technological advances on these costs.

(8) The unmet needs of 21st century technology for education.

(9) Other related topics determined to be appropriate by the Commission.

(b) SPECIAL RULE.—The Commission primarily shall study and make findings and specific recommendations regarding the matters described in subsection (a) with respect to pre-kindergarten through grade 12 public schools, but also may study and make findings and specific recommendations regarding the matters with respect to public institutions of higher education.

(c) FINAL REPORT.—

(1) IN GENERAL.—Subject to paragraph (2), the Commission shall submit to the President and to Congress, not later than 120 days after the date of the first meeting of the Commission, a report which shall contain a detailed statement of the findings and conclusions of the Commission, including the Commission's recommendations for administrative and legislative action that the Commission considers advisable.

(2) MAJORITY VOTE REQUIRED FOR RECOMMENDATIONS.—Any recommendation described in paragraph (1) shall be made by the Commission to the President and to Congress only if such recommendation is adopted by a majority vote of the members of the Commission who are present and voting.

SEC. ___05. POWERS OF COMMISSION.

(a) HEARINGS.—The Commission may, for the purpose of carrying out this title, hold such hearings and sit and act at such times and places, as the Commission may find advisable.

(b) RULES AND REGULATIONS.—The Commission may adopt such rules and regulations as may be necessary to establish the Commission's procedures and to govern the manner of the Commission's operations, organization, and personnel.

(c) ASSISTANCE FROM FEDERAL AGENCIES.—

(1) INFORMATION.—The Commission may request from the head of any Federal agency or instrumentality such information as the Commission may require for the purpose of this title. Each agency or instrumentality shall, to the extent permitted by law and subject to the exceptions set forth in section 552 of title 5, United States Code (commonly referred to as the ''Freedom of Information Act''), furnish such information to the Commission, upon request made by the Chairperson of the Commission.

(2) FACILITIES AND SERVICES, PERSONNEL DETAIL AUTHORIZED.—Upon request of the Chairperson of the Commission, the head of any Federal agency or instrumentality shall, to the extent possible and subject to the discretion of such head—

(A) make any of the facilities and services of such agency or instrumentality available to the Commission; and

(B) detail any of the personnel of such agency or instrumentality to the Commission, on a nonreimbursable basis, to assist the Commission in carrying out the Commission's duties under this title.

(d) MAILS.—The Commission may use the United States mails in the same manner and under the same conditions as other Federal agencies.

(e) CONTRACTING.—The Commission, to such extent and in such amounts as are provided in appropriation Acts, may enter into contracts with State agencies, private firms, institutions, and individuals for the purpose of conducting research or surveys necessary to enable the Commission to discharge the Commission's duties under this title.

(f) STAFF.—Subject to such rules and regulations as may be adopted by the Commission, and to such extent and in such amounts as are provided in appropriation Acts, the Chairperson of the Commission shall have the power to appoint, terminate, and fix the compensation (without regard to the provisions of title 5, United States Code, governing appointments in the competitive service,

and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title, or of any other provision, or of any other provision of law, relating to the number, classification, and General Schedule rates) of an Executive Director, and of such additional staff as the Chairperson deems advisable to assist the Commission, at rates not to exceed a rate equal to the maximum rate for level IV of the Executive Schedule under section 5332 of such title.

SEC. ___06. EXPENSES OF COMMISSION.

There are authorized to be appropriated to pay any expenses of the Commission such sums as may be necessary not to exceed $1,000,000. Any sums appropriated for such purposes are authorized to remain available until expended, or until 1 year after the termination of the Commission pursuant to section ___07, whichever occurs first.

SEC. ___07. TERMINATION OF COMMISSION.

The Commission shall cease to exist on the date that is 60 days after the date on which the Commission is required to submit its final report in accordance with section ___04(c).

DURBIN (AND OTHERS) AMENDMENT NO. 1085

Mr. DURBIN (for himself, Mr. LEVIN, Mrs. MURRAY, Mr. JOHNSON, and Mr. BREAUX) proposed an amendment to the bill, S. 1061, supra; as follows:

On page 49, after line 26, add the following:

SEC. . (a) STUDY.—Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the General Accounting Office, shall conduct a comprehensive study concerning efforts to improve organ and tissue procurement at hospitals. Under such study, the Secretary shall survey at least 5 percent of the hospitals who have entered into agreements with an organ procurement organization required under the Public Health Service Act and the hospitals' designated organ procurement organizations to examine—

(1) the differences in protocols for the identification of potential organ and tissue donors;

(2) whether each hospital, and the designated organ procurement organization of the hospital, have a system in place for such identification of donors; and

(3) protocols for outreach to the relatives of potential organ or tissue donors.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report concerning the study conducted under subsection (a), that shall include recommendations on hospital best practices—

(1) that result in the most efficient and comprehensive identification of organ and tissue donors; and

(2) for communicating with the relatives of potential organ and tissue donors.

LEVIN (AND OTHERS) AMENDMENT NO. 1086

Mr. DURBIN (for Mr. LEVIN, for himself, Mr. THURMOND, Mr. DURBIN, and Mr. INOUYE) proposed an amendment to the bill, S. 1061, supra; as follows:

At the appropriate place, insert the following:

SEC. . (a) FINDINGS.—Congress finds that—

(1) over 53,000 Americans are currently awaiting organ transplants;

(2) in 1996, 3,916 people on the transplant waiting list died because no organs became available for such people;

(3) the number of organ donors has grown slowly over the past several years, even though there is significant unrealized donor potential;

(4) a Gallup survey indicated that 85 percent of the American public supports organ donation, and 69 percent describe themselves as likely to donate their organs upon death;

(5) most potential donors are cared for in hospitals with greater than 350 beds, trauma services, and medical school affiliations;

(6) a recent Harvard study showed that hospitals frequently fail to offer donation services to the families of medically eligible potential organ donors;

(7) staff and administration in large hospitals often are not aware of the current level of donor potential in their institution or the current level of donation effectiveness of the institution;

(8) under titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq; 1396 et seq.), hospitals that participate in the medicare or medicaid program are required to have in place policies to offer eligible families the option of organ and tissue donation; and

(9) many hospitals have not yet incorporated systematic protocols for offering donation to eligible families in a skilled and sensitive way.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that hospitals that have organ or tissue donor potential take prompt steps to ensure that a skilled and sensitive request for organ or tissue donation is provided to eligible families by—

(1) working with the designated organ procurement organization or other suitable agency to assess donor potential and performance in their institutions;

(2) establishing protocols for organ donation that incorporate best-demonstrated practices;

(3) providing education to hospital staff to ensure adequate skills related to organ and tissue donation;

(4) establishing teams of skilled hospital staff to respond to potential organ donor situations, ensure optimal communication with the patient's surviving family, and achieve smooth coordination of activities with the designated organ procurement organization; and

(5) monitoring organ donation effectiveness through quality assurance mechanisms.

ADDITIONAL STATEMENTS

TRIBUTE TO COMDR. SEAN FOGARTY

● Mr. KEMPTHORNE. Mr. President, I rise today to recognize and say farewell to an outstanding naval officer, Comdr. Sean Fogarty, who has served with distinction for the past 24 years in naval service. It is a privilege for me to recognize his many outstanding achievements and to commend him for the superb service he has provided this legislative body, the Navy, and our great Nation.

A native of Idaho Falls, ID, and a 1977 graduate of the U.S. Naval Academy, Commander Fogarty comes from a patriotic family who has contributed immeasurably to our Nation's defense. His father was a career submariner and also a U.S. Naval Academy graduate.

Commander Fogarty's service at sea includes a division officer tour aboard U.S.S. *Harold E. Holt* FF–1074, department head tours as Operations Officer aboard U.S.S. *John Young* DD–973 and U.S.S. *Callaghan* DD–994, and an executive officer tour aboard U.S.S. *Downes* FF–070.

Commander Fogarty's duties ashore included scheduler for the commander in chief, U.S. Pacific Fleet, exercises and plans officer for the commander, U.S. Sixth Fleet, and the Office of Legislative Affairs.

As Assistant Director of the Navy's Senate Liaison Office for the last 5 years, Commander Fogarty has provided timely support and accurate information on Navy plans and programs. Working closely with the U.S. Senate, he has helped maintain the best trained, best equipped, and best prepared Navy in the world. His consummate leadership, integrity, and tireless energy serve as an example for us all.

Mr. President, Sean Fogarty, his wife, Anita, and daughters, Larissa, Colleen, and Megan have made many sacrifices during his 24-year naval career. They have made significant contributions to the outstanding naval forces upon which our country relies so heavily. During his illustrious career, Commander Fogarty has been the recipient of many awards and commendations including the Legion of Merit. He is a great credit to both the Navy and the country he so proudly serves. As he now retires from the naval service, I call upon my colleagues from both sides of the aisle to wish him fair winds and following seas.●

CHARLES A. HORSKY

● Mr. MOYNIHAN. Mr. President, Mr. Charles Horsky, former adviser to Presidents Kennedy and Johnson on the District of Columbia, passed away during the August recess. I rise today to pay honor to this man who devoted himself to improving our Nation's Capital.

Charlie Horsky was the ''Mayor of Washington.'' And yet, he looked forward to giving that up and getting home rule for the city of Washington. He accomplished a great deal toward that end. Mr. Horsky was instrumental in redeveloping Pennsylvania Avenue, in promoting the construction of a metropolitan subway system, and he played a crucial role in establishing the initial home rule for the citizens of Washington.

Further, he led the establishment of the National Building Museum, the John F. Kennedy Center of the Performing Arts, the University of the District of Columbia, and urged the preservation of Union Station.

I first arrived in Washington over three decades ago. Since those initiatory days, I was most fortunate to have known and worked with Charlie Horsky. He was as fine a gentleman as we have seen in our Capital, and his tireless efforts are reflected in so many rejuvenated aspects of the city around us. When thinking of this great man we do well to recall the epitaph of Sir

Christopher Wren at St. Pauls Cathedral, London: ''Si monumentum requiris, circumspice.'' (If you would see his monument, look around).

I ask that an obituary from the New York Times from August 24 be printed in the RECORD.

The obituary follows:

CHARLES A. HORSKY, 87, DIES; LEFT IMPRINT ON U.S. CAPITAL

(By Irvin Molotsky)

WASHINGTON—Charles A. Horsky, a lawyer and former Government official who helped redevelop the nation's capital during the Kennedy and Johnson Administrations, died Wednesday at Holy Cross Hospital in Silver Spring, Md. He was 87 and lived in Silver Spring.

The cause was kidney failure, said his daughter, Margaret Horsky Burns.

Mr. Horsky argued many cases and held many important positions in a law career that began in 1934, but it was his work as adviser to the President for national capital affairs from 1962 to 1967 that had the greatest impact on those who live in or visit Washington, an impact that will be felt for years to come.

President John F. Kennedy appointed him to the White House job and Lyndon B. Johnson carried him over when Johnson succeeded to the Presidency in 1963. During Mr. Horsky's time at the White House, he pressed for switching money from a highway project to the construction of a subway system, and the resulting Metro is now regarded as one of the best in the world.

He worked on the redevelopment of Pennsylvania Avenue, a project that was begun after the 1961 inaugural parade and Kennedy determined that America's Main Street had become seedy and unworthy of a great nation. That project is just being completed with the opening soon of the Ronald Reagan Building.

Senator Daniel Patrick Moynihan, who served in the Kennedy Administration with Mr. Horsky, recalled that they were reviewing plans for the redevelopment of Pennsylvania Avenue on Nov. 22, 1963, when they received the word that the President had been shot. The plans were to be presented to Kennedy for his approval the next day.

Another of Mr. Horsky's accomplishments is enduring a melancholy chapter. For years, Washington was run as a virtual fiefdom of Congress, with residents having no say in its government. During the Johnson Administration, a push was made to establish home rule for Washington and it was Mr. Horsky who played the pivotal role in getting legislation for it through Congress.

Mr. Moynihan, reached at his home in upstate New York, said: ''Charlie Horsky was 'Mayor of Washington.' He looked forward to giving that up and getting home rule for the city of Washington, and he accomplished a great deal toward that end.''

In recent years, however, with the District of Columbia's budget deficit ballooning out of control, Congress has taken back much of that power and placed it in the hands of a control board.

Mr. Horsky's other activities included establishing the Kennedy Center for the Performing Arts, rescuing Union Station and opening both the National Building Museum and the University of the District of Columbia.

He was born in Helena, Mont., graduated from the University of Washington 1931 and received a law degree from Harvard University in 1934. He served as a lawyer in the Solicitor General's office until 1939, when he joined Covington & Burling, one of Washington's leading law firms, staying there for the rest of his career except for his White House years.

After World War II, Mr. Horsky served as an assistant prosecutor at the Nuremberg war crimes trials and argued many cases before the Supreme Court, including a case that challenged the wartime internment of Americans of Japanese ancestry.

''I was trying to persuade the Court that there was no legitimate basis for the Army to arrest citizens,'' Mr. Horsky said in a 1989 interview with The Washington Post. ''I couldn't get enough information to make it stick.''

Mr. Horsky lost his argument before the Supreme Court, but in 1988, Congress approved and President Ronald Reagan signed a bill that offered the nation's apologies to Japanese Americans and provided payments to those who were interned.

A partner at the firm, David B. Isbell, said that Mr. Horsky took senior counsel status, that is, a reduced work load, in 1981 and that until he was slowed down by illness two years ago, he had kept active in the firm by arbitrating railroad disputes.

His wife of 58 years, Barbara Egleston Horsky, died two years ago.

Besides his daughter, Ms. Burns, a resident of Falls Church, Va., Mr. Horsky is survived by a sister, Flora Wertz of Missoula, Mont., and two grandchildren.

Despite his advancing years, Mr. Horsky maintained a rugged regimen. ''He never wore an overcoat, even on the coldest day,'' Mr. Isbell said of his colleague. ''I don't think he had one. It may have had something to do with his coming from Montana.''

That Great Plains frame of mind prevailing as recently as 1989, when he drove around in the middle of winter in his 1962 Ford convertible, often with the top down. When asked in the interview in The Post about his lack of an overcoat, he said, ''I am sure I had one in college.''●

MAYOR DONALD ARONSON

● Mr. TORRICELLI. Mr. President, I rise today in recognition of the mayor of my hometown, Englewood, NJ. Mayor Donald Aronson's dedication to the Englewood community and the State of New Jersey make it an honor to be able to recognize him. After being elected mayor of Englewood three times he has decided not to stand for reelection. As his term comes to an end, I would like to convey my good wishes to a friend and valued colleague.

Donald has made innumerable contributions to the residents of Englewood and to the State of New Jersey as a whole through numerous community service positions. He has served as commissioner and secretary of the Palisades Interstate Park Commission, president of the Bergen County League of Municipalities, and he has sat on the board of trustees for the American Red Cross. In addition, he has been a member of the Englewood Board of Adjustment, Englewood Chamber of Commerce, and Englewood Economic Development Corp. The list of his community activities is endless. The extent of his service to State and local organizations is evidence of his lifelong commitment to public service.

Now, Donald is preparing for a new position as the president of the Englewood Chamber of Commerce. I ask that you join me in recognizing Mayor Donald Aronson for all of his hard work and his service to the State of New Jersey.●

EXECUTIVE SESSION

NOMINATION OF ROBERT CHARLES CHAMBERS TO BE U.S. DISTRICT JUDGE FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

Mr. STEVENS. Mr. President, I ask unanimous consent that the Senate immediately proceed to executive session to consider the nomination of Robert Chambers, of West Virginia; that the nomination be confirmed, the motion to reconsider be laid on the table, any statements relating to the nomination appear at the appropriate place in the RECORD, the President be immediately notified of the Senate's action, and the Senate then return to legislative session.

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

The nomination was considered and confirmed, as follows:

THE JUDICIARY

Robert Charles Chambers, of West Virginia, to be U.S. District Judge for the Southern District of West Virginia.

STATEMENT ON THE NOMINATION OF ROBERT C. CHAMBERS

Mr. LEAHY. Mr. President, I am pleased that the majority leader has moved the nomination of Robert C. Chambers to be a judge of the U.S. District Court for the Southern District of West Virginia. Mr. Chambers has the strong support of Senator ROBERT C. BYRD and Senator JOHN D. ROCKEFELLER IV. Mr. Chambers has been engaged in the private practice of law for almost 20 years and served as a delegate in the West Virginia House of Delegates, chairman of that body's judiciary committee, and speaker of the West Virginia House of Delegates. The ABA found him to be qualified and the Judiciary Committee unanimously reported this nomination to the Senate in July.

I congratulate Mr. Chambers and his family and look forward to his service on the Federal court.

As I noted yesterday, we have a good deal of work ahead of us if we are to fulfill our responsibilities and confirm the other fine nominees who are pending before us and are needed in the Federal courts around the country. I commend the majority leader for returning to the Executive Calendar today to take up this judicial nomination.

LEGISLATIVE SESSION

The PRESIDING OFFICER. Under the previous order, the Senate will now return to legislative session.

ORDERS FOR MONDAY, SEPTEMBER 8, 1997

Mr. STEVENS. Mr. President, I ask unanimous consent that when the Senate completes its business today, it

stand in adjournment until the hour of 11 a.m. on Monday, September 8; I further ask unanimous consent that on Monday, immediately following the prayer, the routine requests through the morning hour be granted and the Senate immediately resume consideration of the motion to proceed to S. 830, the FDA reform bill.

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

Mr. STEVENS. Mr. President, I also ask unanimous consent that following the expiration or yielding back of time on the motion to proceed to S. 830, the Senate resume consideration of S. 1061, the Labor, Health and Human Services appropriations bill.

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

PROGRAM

Mr. STEVENS. Mr. President, for the information of all Members, on Monday, the Senate will resume debate on the motion to proceed to S. 830, the FDA reform bill. Under the previous order, there are 4 hours of debate remaining on the motion to proceed, equally divided between Senators JEFFORDS and Senator KENNEDY. Following the expiration or yielding back of that time, the Senate will resume consideration of S. 1061, the Labor–HHS appropriations bill. Also under the order, a vote on an amendment relating to S. 1061 is expected at 5 p.m. on Monday. In addition, under the consent agreement, all amendments remaining in order to the Labor, Health and Human Services appropriations bill must be offered during Monday's session of the Senate. Also, all votes ordered on those amendments will be stacked to occur at a time to be determined on Tuesday. In addition, under the previous order, the Senate will begin consideration of S. 830 following the disposition of S. 1061, but not before 4 p.m. on Tuesday. As a reminder to all Members, the next rollcall vote is expected on Monday at 5 p.m. on an amendment relating to the Labor, Health and Human Services appropriations bill.

ADJOURNMENT UNTIL MONDAY, SEPTEMBER 8, 1997, AT 11 A.M.

Mr. STEVENS. Mr. President, if there is no further business to come before the Senate, I now ask unanimous consent that the Senate stand in adjournment under the previous order.

There being no objection, the Senate, at 3:38 p.m., adjourned until Monday, September 8, 1997, at 11 a.m.

CONFIRMATION

Executive nomination confirmed by the Senate September 5, 1997:

THE JUDICIARY

ROBERT CHARLES CHAMBERS, OF WEST VIRGINIA, TO BE U.S. DISTRICT JUDGE FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA.