9302 of the Balanced Budget Act of 1997, as added by section 1604(f)(3) of the Taxpayer Relief Act of 1997, is repealed.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

DIANE T. DUFFY,
Legislative Attorney,
American Law Division.

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.