waiting to take her to the airport, inquired about how her companions would get to the airport. When she was told they would go in a different vehicle, she declared everyone must stay together and take the bus.

To put it mildly, fame, and accolades were not important to her. What was important to her—what shaped her life from the Balkan village where she was born to the places of power where she was honored—was a devotion to the most vulnerable members of the human family, especially children, both before and after their birth.

When she first visited the Capitol back in 1981, one of our colleagues, then Senator James Buckley of New York, remarked, ''There is no telling what may be started by someone like her, who plays with fire by striking sparks off the flinty heart.''

Today, 16 years later, it is magnificently clear what she did start, literally around the world. Out of her poverty, she enriched mankind. Out of her loneliness, she showed us the heights of the human spirit. From the perspective of this century's end, we have a better understanding of what true greatness really is.

The monsters of our era—Mao, Stalin, Hitler, and the rest—they and their ideologies are in the trash heap of history. But what Mother Teresa launched, with bare hands and with an open heart, is going to last far longer than anyone can imagine.

Sad as our loss of her may be, we should not forget that her passing would not be viewed by her as a tragedy, but as a triumph. She had that assurance from the person to whom she gave her life, who surely has said to her, ''I was hungry, and you gave me to eat. I was thirsty, and you gave me to drink.''

So as we celebrate her life, let us now celebrate her joy.

Mr. President, I yield the floor.

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

The PRESIDING OFFICER (Mr. DEWINE). The clerk will report.

The assistant legislative clerk read as follows:

A bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

The Senate resumed the consideration of the motion to proceed.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. JEFFORDS. First, I want to thank the majority leader for, I think very aptly and appropriately and eloquently, expressing our thoughts about Mother Teresa. All of us were moved by her life, and all feel similarly as to his feelings about what she did for all the people of the world.

Mr. President, today, we move forward again on the motion to proceed with respect to the reform of the FDA bill, S. 830.

Under the Federal Food, Drug, and Cosmetic Act, Food and Drug Administration commonly known as FDA, has two important functions: First, the review and approval of important new products that can improve the public health, such as lifesaving drugs, biological products, and medical devices; and second, the prevention of harm to the public from marketed products that are unsafe or ineffective. Since 1938, the Federal Food, Drug, and Cosmetic Act has been amended numerous times to expand the FDA's mission to ensure that only safe or ineffective products are marketed.

But the act has been changed only once, by the Prescription Drug User Fee Act of 1992, commonly called PDUFA, to strengthen the FDA's ability to review and approve expeditiously important new products that can improve the public health.

Food and Drug Administration Modernization and Accountability Act of 1997, S. 830, is designed to ensure the timely availability of safe and effective new products that will benefit the public and to ensure that our Nation continues to lead the world in new product innovation and development.

The legislation accomplishes three major objectives: It builds upon recent administrative reforms that both streamline FDA's procedures and strengthen the agency's ability to accomplish its mandate in an era of limited Federal resources; it requires a greater degree of accountability from the agency in how it pursues its mandate; and third, it provides for the reauthorization of PDUFA.

The FDA acknowledges that its mandate requires it to regulate over one-third of our Nation's products. Within its purview the FDA regulates nearly all of the food and all of the cosmetics, medical devices, and drugs made available to our citizens.

This legislation identifies areas where improvements can be made that will strengthen the agency's ability to approve safe and effective products more expeditiously. It builds upon the numerous investigations by Congress, the FDA, the General Accounting Office, and other organizations that have identified problems with the current FDA product approval system and have recommended reasonable reforms to streamline and strengthen that system. The major provisions of S. 830 accomplishes, among others, the following purposes. The legislation:

First, establishes a clearly defined, balanced mission for the FDA;

Second, it improves patient access to needed therapies and provides expedited humanitarian access to medical devices;

Third, creates new incentives for determining better pharmaceuticals for children;

Fourth, gives patients access to new therapies more quickly through a new fast-track drug approval process;

Fifth, increases access to information by health professionals and patients;

Next, increases agency access to expertise and resources;

Also, improves the certainty and clarity of rules;

And further, improves agency accountability and provides for better resources allocation by setting priorities;

It also, simplifies the approval process for indirect food contact substances and provides a more reasonable standard for some health claims; and,

The legislation reauthorizes the PDUFA Program thus ensuring additional resource availability for the agency to conform with its necessary missions.

Mr. President, let us explore these objectives in greater detail. First, the legislation establishes a clearly defined, balanced mission for the FDA. Congress has never established a mission statement for the FDA. This bill does.

The FDA in March 1993 adopted a formal statement declaring that the agency ''is a team of dedicated professionals working to protect and promote the health of the American people.'' Although this statement defines the agency's mission in terms of ensuring that the products it regulates comply with the law, there is no reference to the importance of approving new products that benefit the public.

The legislation amends the Food Drug and Cosmetic Act by adding an agency mission statement focused on: First, protecting the public health by ensuring that the products it regulates meet the appropriate FDA regulatory standards; second, promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a manner which does not unduly impede innovation or product availability; and, third, participating with other countries to reduce regulatory burdens, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements with other countries.

The legislation improves patient access to needed therapies and provides expedited humanitarian access to medical devices. The FDA has no cross-cutting program that ensures access by patients with serious or life-threatening diseases to drugs or devices in clinical trials—even when that unapproved therapy may be the only way to save the patient's life.

The legislation would create new law whereby manufacturers may provide, under strictly controlled circumstances and in response to a patient's request, an investigational product for those patients needing treatment for a serious or life-threatening disease. The legislation also improves the existing program for the humanitarian use of medical devices for patient populations of fewer than 4,000.

The legislation creates new incentives for determining better pharmaceuticals for children. Children have for years been wrongly considered small adults when estimating the effect of prescription drugs on their overall health. Currently there is no systematic means for testing the safety and efficacy of drugs on the pediatric population.

The legislation gives the Secretary authority to request pediatric clinical trials for new drug applications and provides 6 extra months of market exclusivity to drugs when the manufacturer voluntarily meet certain conditions under the program. The Secretary must determine in writing that information relating to the use of a drug in the pediatric population is needed. In addition, the FDA may establish time frames for completing such pediatric studies before additional exclusivity is granted.

The legislation gives patients access to new therapies more quickly through a new fast-track drug approval process. I think this is important.

For several years the FDA has allowed the expedited review and approval of drugs but such review has been largely confined to treatments for HIV/AIDS or cancer. This provision facilitates development and expedites approval of new drugs for the treatment of any serious or life-threatening diseases.

The legislation increases access to information by health professionals and patients. For years, sophisticated users of health related economic information, like health maintenance organizations, have had constrained from access to important information that could help them reduce health care costs.

The legislation would apply the Federal Trade Commission's ''competent and reliable scientific evidence'' standard for FDA review of health care economic statements distributed by manufacturers to sophisticated purchasers. In the past, only a few patient groups have had access to information about ongoing clinical trials for lifesaving therapies. The legislation expands patient access to information by requiring the creation of data bases on ongoing research related to the treatment, detection, and prevention of serious of life-threatening diseases.

The legislation increases agency access to expertise and resources. Current law contains no provisions to assure that the FDA can access expertise housed at the National Institutes of Health [NIH] and other science-based Federal agencies to enhance the scientific and technical expertise available to FDA's product reviewers. The legislation requires FDA to develop programs and policies to foster such collaboration. The legislation also authorizes the agency to contract with outside experts to review all or parts of applications when it will add to the timeliness or quality of a product review, and provides for the use of accredited outside organizations for the review of medical devices.

The legislation improves the certainty and clarity of rules. The legislation makes a series of changes related to the classification, review and approval of FDA regulated products designed to ensure that sponsors of new products face consistent and equitable regulatory requirements. In addition, the legislation gives FDA 2 years to evaluate the success of its recently issued ''Good Guidance Practices'' guidance after which FDA is required to implement this policy as a regulation, making any modifications necessary to reflect experience during the 2-year trial period. The legislation provides medical device manufacturers with the ability to make recommendations to the FDA respecting initial product classifications.

It facilitates the reclassification and/or approval of device applications by allowing FDA to consider historical data in making its determinations, and the legislation more clearly states the relationship of labeling claims to approval and clearance of medical devices. It increases the certainty of review time frames by providing a definition of a day with respect to the agency's review timeclock and by requiring the agency to approve or disapprove a device application within 180 days.

The legislation also prohibits FDA from withholding the initial classification of a device because of a failure to comply with any provision of the unrelated to making a determination of substantial equivalence, and it clarifies that FDA has discretion in determining the number of clinical trials required for the approval of a drug or device. FDA would retain total discretion to require a sufficient number of trials to show safety and efficacy. The provision introduces the concept that two trials are not always necessary, establishes the primacy of quality data over quantity of data, and requires the FDA to consider the number and type of trials on a product-by-product basis.

The legislation improves agency accountability and provides for better resource allocation by setting priorities. Except as required under PDUFA, the FD&C Act provides no form of public accountability by the FDA for its performance of its statutory obligations.

The legislation requires FDA to develop a plan designed to: First, minimize deaths and injuries suffered by persons who may use products regulated by the FDA; second, maximize the clarity and availability of information about the product review process; third, implement all inspection and post-market monitoring provisions of the act by 1999; fourth, ensure access to the scientific and technical expertise necessary to properly review products; fifth, establish a schedule to bring the FDA into compliance by 1999 with the product review times in the act for products submitted after the date of enactment of this section; and sixth, eliminate the backlog of products awaiting final action by the year 2000.

The legislation also requires FDA to submit an annual report to assist Congress in assessing the agency's performance in accomplishing the objectives laid out in the agency plan.

The legislation streamlines several FDA functions with respect to certain review and inspection processes thus allowing the agency to focus its limited resources on areas of greatest need. The legislation establishes reasonable data requirements for new product approval applications, petitions, or other submissions. The legislation provides FDA with the discretion to approve drugs and biologics on the basis of products manufactured in pilot and small-scale facilities.

FDA is also directed to establish policies to facilitate the approval of supplemental applications for new uses for an approved product. Further, the legislation establishes procedures and policies to foster a collaborative review process between the agency and the sponsors of medical device applications. Finally, the legislation streamlines the review of minor modifications to medical devices.

The legislation simplifies the approval process for indirect food contact substances and provides a more reasonable standard for some health claims. Current law requires the agency to preapprove food contact substances, most of which pose little if any risk to human health.

The legislation replaces the preapproval process for these substances, primarily packaging materials, with a simple notification requirement. The legislation also provides for health claims for foods, with premarket notification, when the claims are based on authoritative recommendations by an authoritative scientific body of the U.S. Government such as the National Institutes of Health, the Centers for Disease Control and Prevention, or the National Academy of Sciences—very reliable agencies.

The legislation reauthorizes the PDUFA Program thus ensuring additional resource availability for the agency. PDUFA is reauthorized for 5 years. Performance goals beyond those set for the 1992 act will be identified in side letters between the FDA and the Senate Committee on Labor and Human Resources. The bill assumes that FDA will receive for fiscal year 1998 the 1997 level of appropriated funds for the agency.

This is important to keep in mind. For fiscal year 1999 through 2002, the bill assumes an annual inflation adjustment. I mention this because there in the present proposal by the administration is a request to cut back on the use of PDUFA.

Mr. President, I think after all of us have had time in this body to go through this legislation, Members will understand why there is so little dispute over almost all of the bill. We will be talking again today, as we did last Friday, about two areas in the bill for

which there has not been agreement, but the disagreements are not very complicated to understand.

First of all, we had a vote of 89–5 on Friday to allow us to end the filibuster under the circumstances we faced. That approval indicates what I am saying now, that for almost all of this bill there is no dispute between us and the minority or Senator KENNEDY or the Office of the President or the Secretary of HHS.

What we do have are two problems in which there is dispute. This makes up 6 pages out of a 152-page bill. Keep in mind, because we will have some vigorous arguments in those two areas, everyone agrees with the rest of the bill—almost. There will always be somebody, but there is hardly any disagreement on the matters I discussed in my statement.

The two remaining matters refer, first of all, to cosmetics. There is an increasing need, at least felt by especially some States and also by the FDA and others, that there has to be more work done in approving cosmetics or ensuring that cosmetics that are injurious to health do not get on the market. At present, most of that has been left sort of ambiguous whether the FDA should do it or not.

On the other hand, because of the realization that uniformity would be helpful, it would be useful if we could have uniformity throughout the States on cosmetics so that the people all over the country do not have to worry about going from place to place. And thus the bill does establish the FDA predominance in the field with respect to the use of cosmetics.

Now, this is met with some difficulties because some States, California in particular, had voted and had passed laws on cosmetics. Let me go through the present authority.

The FDA now has substantial authority to ensure the safety of cosmetic products. It can ban or restrict ingredients for safety reasons, mandate warning labels, inspect manufacturing facilities, issues regulatory letters, seize illegal products, enjoin unlawful activities, and prosecute violators of the adulteration and misbranding provisions of the Federal Food, Drug, and Cosmetic Act.

In addition, cosmetic products are subject to one of the most comprehensive set of Federal labeling requirements for consumer products. A cosmetic label must include the name and address of the manufacturer, packager, or distributor; a statement of product identity; net quantity of contents; a list of all ingredients in the products; adequate directions for use; and mandated warnings for specific products.

In addition to this substantial Federal regulatory authority, the cosmetic industry supports a variety of programs to ensure the safety of cosmetic ingredients. Most important is the Cosmetic Ingredient Review, a 20-year program that has reviewed the safety of almost 620 cosmetic ingredients.

The safety evaluations are conducted by an independent expert panel of seven leading academic scientists and physicians. The panel also includes three liaison representatives from the FDA, the Consumer Federation of America, and private industry.

Along with this regulatory authority, the agency has sufficient resources to police the safety of cosmetics. This year, Congress appears ready to approve nearly a billion dollars for the agency. Yet of that amount, the FDA will likely spend no more than about $6½ million on cosmetics safety and labeling. Why? Why would the agency devote less than 1 percent of its budget? Because of the outstanding safety record of cosmetic products. Numerous FDA Commissioners—including David Kessler, have stated that cosmetics are among the safest products under the FDA's jurisdiction.

Let me turn now to the language of the national uniformity provision for cosmetics included in the latest version of S. 830. First, let me emphasize that this provision in no way affects State enforcement powers, such as seizure, embargo, or judicial proceedings, that the States can now use to guard against adulterated, misbranded, or otherwise unsafe products. Let me repeat this point: The national uniformity provision would not block any State from exercising its police powers against unsafe cosmetic products.

Second, the national uniformity provision provides only limited preemption of State safety standards. Preemption would apply only when the FDA has an applicable safety standard affecting cosmetic already in place. If the FDA has not acted in a safety area, the States would still be free to impose their own particular safety regulations affecting cosmetic products. For example, individual States could ban particular ingredients or could set specified concentrations levels for ingredients used in cosmetic products when the FDA has not acted.

Preemption does apply to State labeling and packaging for cosmetic products that are in addition to or not identical with Federal standards.

This is designed to ensure a single, nationwide system for regulating the labeling for cosmetic products. This will promote efficient product distribution in interstate commerce, assure the ready availability of products in all States, and hold down costs for consumers.

Third, under this provision States and localities are clearly permitted to petition to impose a State-specific requirement if they have a situation where an important public interest is at stake, and the requirement would not violate a Federal law or unduly burden interstate commerce.

Fourth, the existing right of States, or entity or person is preserved to petition the FDA to make an certain regulation on over-the-counter drugs or cosmetics a national requirement.

And finally, the regulation of the practices of pharmacy and medicine, areas traditionally and appropriately the responsibility of the States is not modified or preempted by this provision.

This is a sensible compromise that guards against the possibility of 50 different labels in 50 different States but at the same time preserves the ability of States to protect the public against any problems that may arise over the safety of cosmetic products.

Mr. President, we will go forward with another lengthy dissertation on this aspect of this. I hope people will keep in mind that there is broad, broad agreement among all of us—Senator KENNEDY and those who support it—that this bill has come a long way. It has gone a great distance toward bringing together what we can pass and be very proud of. There are just two areas where there is disagreement, which we will hear about, I am sure, now. But I hope that everybody will keep in mind that this is in the area of 6 pages of a 152-page bill.

Mr. President, I yield the floor.

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER (Mr. GREGG). The Senator from Massachusetts is recognized.

Mr. KENNEDY. First of all, I want to just comment about the devotion and duty of our friend and colleague from Vermont. I am sure there may be those who are watching the proceedings this morning who may not know, as many of us know, the Senator and his daughter were rear-ended last Friday morning. Nonetheless, he came in here during the course of the consideration of this legislation, and now he is here doing his duty in spite of the inconvenience and discomfort he is feeling. So I think all of us have great respect for Senator JEFFORDS. His devotion to duty is again reflected in his presence here this morning and his commitment in moving ahead this legislative process.

Mr. President, I also want to, as I did at the opening of the discussion and debate, congratulate Senator JEFFORDS on his efforts in the consideration of this legislation. We considered this legislation—FDA reform—in the last Congress. We reported legislation out of the committee. It did not move toward a successful resolution. There were a number of features there that were extremely troublesome in terms of the protection of the public. There were areas of strong difference. Although the process did move forward, it was not successful.

Senator JEFFORDS has built upon a strong record and made every effort to try to work through an important public policy area, reform of the Food and Drug Administration, in ways that recognize its primary responsibility, which is to protect the public. As we go forward with this debate, FDA reform should serve the public interest and also take into consideration the innovation of the pharmaceutical industry and the medical device industry in bringing new products onto the market

in ways that can improve the health care of the American people. That is always a balance.

Men and women of good judgment can differ. There are two important provisions in this legislation, which eventually will be subject to further debate and discussion, dealing with what we call sections 404 and 406, labeling and manufacturing. I will come back to those measures a little later in the course of the debate. We heard references to those items by our friends and colleagues, Senator REED and Senator DURBIN, on Friday last. We will have a chance to outline at least some of the concerns about those measures, and, ultimately, the Senate and the conference will have an opportunity to deal with those.

I personally feel that they pose important public health issues that need to be addressed. But I agree with what Senator JEFFORDS has outlined, which is the broad sweep of this legislation, and the areas of broad agreement that have been an impressive legislative achievement. Senator JEFFORDS should receive commendation for that because all of us who were part of that process feel that there are many features in here that should move forward.

Some of us are hopeful that we can address the medical device legislation and also address what I consider to be one of the important amendments that was passed in the consideration of the legislation in one of the last markups—passed with a strong vote, after some discussion, but nonetheless, poses what I consider to be an important and unnecessary health hazard to the American people. That is, the provisions which are known as the cosmetic preemption provisions, which were added to this legislation, not included in the original mark of the chair, not included in the original mark of Senator Kassebaum a year ago, but added at the behest of the industry. As a matter of fact, the language itself was drafted by the industry. It was advanced in the committee considerations and now is part of the legislation.

As I mentioned last week, I am absolutely convinced that if this had been introduced as a separate bill, it would be far back in the recesses of the Labor and Human Resources Committee, in terms of its consideration. But nonetheless, action was taken by the committee and that action has resulted in the inclusion of the cosmetic preemption provision. If this legislation is passed, it will effectively say to the 50 States that you virtually have no rights or opportunities for protecting your consumers from unsafe or dangerous cosmetics.

Now, I listened with interest to what the Senator outlined in regards to the powers of the FDA, in terms of protecting the public. But the fact is, as we know, the food and drug law has 126 pages that relate to drugs or prescription drugs and medical devices, it has 55 pages dealing with labeling and nutrition labeling, it has 8 pages dealing with definitions in the food and drug law, and it has a page and a half on cosmetics.

There are only two members of the Food and Drug Administration who oversee cosmetic packaging, labeling and warning. We have seen where the various studies that have been done by governmental agencies, like the General Accounting Office, have stated that what is necessary to give assurance and protection to the American people regarding cosmetics is more significant regulatory authorities for FDA to make sure that the ingredients that are going into cosmetics are going to be safe. We do that with the pharmaceutical industry; we do it with the medical device industry. We do not do that with cosmetics.

The American people go into their drugstore and get a prescription drug or an over-the-counter drug. They know that, in effect, there is a warranty from the FDA that bears the gold standard for safety in the world, that those products are going to be safe. They get a medical device and they know it is going to be safe. But the fact of the matter is, Mr. President, we are not so sure when it comes to cosmetics. For example, when we consider the safety of our cosmetics, we know that, the Consumer Product Safety Commission, more than 10 years ago—and the utilization of cosmetics has grown exponentially since that time—reports 47,000 emergency room visits as a result of the use of cosmetics and cosmetic products in one single year. Does that sound very safe to all of you? What is the record? Where is the testimony to say how safe it was? You do not have it. You do not have it because we have not had any hearings. It would have been a good hearing if we had two or three former heads of FDA that appeared before the committee and said this is what the safety issues are, these are what the health issues are, these are why either we agree or we differ on the issues of preemption. But we didn't have them in the Senate. And you have not had them in the House. You didn't have them in this Congress. You didn't have them in the last Congress. You have not had them in the Congress before. You have not had them for 20 years. The only documents you have are from the GAO. And they don't talk about how safe everything is. They have a series of recommendations, which I have read into the RECORD, that say what we ought to be doing in order to guarantee safety and security.

That is what the GAO said. That isn't the Senator from Massachusetts. That isn't the four other Senators that said let's stop, look, and listen. But we are going to go ahead pell-mell with this particular provision. We have looked at the results of the GAO study. They have not been refuted, and we have not had any hearings providing evidence that can refute the GAO.

Mr. President, is this something that just now a single Senator, or three, or four, or five Senators should be concerned about?

It is interesting that the administration has targeted this provision, as well as the two to three other provisions that I mentioned earlier, as matters that have to be addressed.

The National Governors' Association: This is what they say about this provision.

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

All the Governors are saying virtually the same thing. Let us, in the 50 States, be able to take actions with regard to cosmetics, allow us to protect our people. That is what all the Governors are saying. But oh, no. ''Washington knows best.'' Remember those old statements that we used to hear all across the country by many of our colleagues. Let's not have a one-solution-fits all. Let's not have that. Let's not have ''Government knows best.'' Well, here you have Government knows best. They don't know best. They can't handle and protect their people in California, or Ohio, or Massachusetts. Absolutely not, even though there have been strong efforts in each of these States to try and move ahead and to protect their people. But we are saying not after we pass this law.

Mr. President, as I said last Friday here on the floor of the U.S. Senate, we are making tough decisions on matters over which reasonable people can differ. And these are in many instances heartrending decisions. I mentioned last Friday, the decisions that we had in our Human Resources Committee where you have a limited amount of money. You have to make a decision for Meals on Wheels; whether you are going to provide all of the money to the congregate sites to feed elderly people—and you can feed more elderly people if you put it in the congregate sites—or are you going to take a third of that money and feed people that are shut-ins? The money will not go as far. You are not going to reach as many people if you take those scarce resources and reach the shut-ins. What should be the public policy question? Should we give the money to feed more people, or should we allocate some to the shut-ins, or should we just leave this up to the local community?

These are important public policy issues that affect the lives of real people. But not on this cosmetic issue. What are the public policy considerations on the other side? Money. Greed. Cosmetic industry. Greed. What are the public health considerations of preemption? How are they advanced? How are they preserved? How are the American people further protected by a preemption? They are not. We have not heard that

argument made on the floor of the U.S. Senate. We have not heard it, because it is not there.

This legislation is proposed because of what has been happening in the area of California, and some of the other States which have been looking at the kinds of concerns being raised by so many consumers day in and day out—I will mention those in just a few moments—that are really wondering whether some of these products are safe. And there is good reason to ask whether they are safe because as we have seen from the GAO, many of these products are potential carcinogens. What is a carcinogen? It is a cancer-causing agent. We wouldn't permit these products to go into processed food because the Delaney clause would protect the American people from carcinogens in processed food. But can you add them to cosmetics? You can add them to cosmetics. They are added to cosmetics today.

That is another reason, Mr. President, why the Environmental Defense Fund says no to this provision; why the Natural Resources Defense Council says no to this provision; why the Patients Coalition Consumers Union says no to do this provision; why the Consumer Federation of America says no; why AIDS Action says no; why the American Public Health Association, the association to protect the American public health, says no to this provision. All of these organizations say no to this provision. Why? Because it doesn't protect and advance the interests of the public health in the States. It advances the bottom line of the cosmetic industry, but it does not advance the interests of the public health.

Mr. President, I will mention what the National Women's Health Network says in a letter that I will include.

I ask unanimous consent that this letter be printed at an appropriate place in the RECORD.

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

NATIONAL WOMEN'S HEALTH NETWORK,
September 8, 1997.

Hon. EDWARD M. KENNEDY,
U.S. Senate,
Washington, DC.

DEAR SENATOR KENNEDY: On behalf of the 13,000 individual and 300 organizational members of the National Women's Health Network, I am writing to express our opposition to damaging provisions in S. 830, the FDA Modernization and Accountability Act of 1997 which would preempt state regulation of cosmetics. I commend you for speaking out about this potential threat to women's health.

The spectrum of the cosmetic industry is broad and not simply limited to lipstick, mascara, or eyeshadow. Hair gels and dyes, soap, toothpaste, baby powder, and lotions also fall under the umbrella of this $20 billion dollar industry. Most women use one or more of these products everyday, and assume that they are safe for themselves and their families.

Sadly, this is not the case. There is virtually no federal oversight of cosmetic products which, according to a 1987 Consumer Product Safety Commission study, led to an estimated 47,000 emergency room visits in one year. Additionally, the General Accounting Office reported that a number of cosmetic products marketed in the United States ''may pose a serious hazard to the public.''

Because the FDA has virtually no authority to regulate this very profitable industry; in fact the FDA has less than 30 employees overseeing the safety of cosmetics, states have initiated their own efforts to protect their residents. These state consumer protection laws have alerted women to products containing carcinogens or the presence of ingredients which may cause allergic reactions.

The Network believes that S. 830 puts the financial bottomline of the cosmetics industry ahead of the health of millions of women by banning states from regulating the industry's products. The bill would even bar states from establishing public communication campaigns which would inform women of a cosmetic's safety and effectiveness. This would mean no warning labels, no data on carcinogens, no ''keep out of reach of children'' notices.

It is absolutely crucial that provisions in S. 830 preempting states' rights to regulate cosmetics be removed from the bill. Women and their families deserve to have complete information about the safety and effectiveness of these products and states who are willing to step forward to safeguard the health of their residents must be allowed to do so. The National Women's Health Network stands ready to work with you to educate members of the Senate and the American public about this very serious women's health issue.

Sincerely,

CYNTHIA A. PEARSON,
Executive Director.

Mr. KENNEDY. They say:

The spectrum of the cosmetic industry is broad and not simply limited to lipstick, mascara, or eye shadow. Hair gels and dyes, soap, toothpaste, baby powder, and lotions also fall under the umbrella of this $20 billion industry. Most women use one or more of these products every day, and assume that they are safe for themselves and their families.

Sadly, this is not the case. There is virtually no federal oversight of cosmetic products which, according to a 1987 Consumer Product Safety Commission study, led to an estimated 47,000 emergency room visits in one year.

Just to depart for a minute, if you have 47,000 people going to the emergency room, how many other thousands are going back to see their doctors? How many other thousands have gone to their dermatologists? How many other thousands have gone to their own doctors, and not to the emergency room and willing to pay the other $150, $175, or $200 to just visit the emergency room? How many others knew that? There were 47,000 emergency room visits in one year.

Additionally the General Accounting Office reported that a number of cosmetic products marketed in the United States ''may pose a serious hazard to the public.''

That is the GAO— ''* * * may pose a serious hazard to the public.''

It would seem to me this morning that we ought to be debating how we are going to advance public health, and how we are going to protect those individuals whose health may be in danger. Are we debating that? No. To the contrary. We are going to say as a result of this legislation that the health of the consumers of cosmetics are going to be at greater risk. That is the only conclusion, and that the bottom lines of the cosmetic industry are going to be higher.

I continue:

The Women's Health Network ''* * * believes that S. 830 puts the financial bottom line of the cosmetic industry ahead of the health of millions of women by banning states from regulating the industry's products.''

There it is. There is the heart of the argument right there by the National Women's Health Network, one of the effective organizations that looks out after the public health of American women. Does it get it right here?

The Network believes that S. 830 puts the financial bottom line of the cosmetic industry ahead of the health of millions of women by banning states from regulating the industry's products.

That is it. That is what we got tagged onto this bill that is dealing with pharmaceuticals and prescription drugs, dealing with medical devices, dealing with the extension of PDUFA, which is a source of revenue to ensure that the FDA can be tops in the world in terms of approving new products. We support those various provisions. But now we have added onto this train this cosmetic preemption that the principal organizations that are dealing with public health say to the U.S. Senate: ''Stop. Say no. Do not move ahead with that.''

It continues, Mr. President:

It is absolutely crucial that provisions in S. 830 preempting states' rights to regulate cosmetics be removed from the bill. Women and their families deserve to have complete information about the safety and effectiveness of these products and states who are willing to step forward to safeguard the health of their residents must be allowed to do so.

Mr. President, let me just continue on with the groups just so that we understand the breadth of the opposition. It isn't just a few Senators. As I mentioned, the principal public health associations, those that are primarily concerned about women's health, the ones that use these products to the greatest extent—the administration, the State legislators. The State legislators were joined by the Association of State and Territory Health Officials. They emphasized State laws provide consumers with important protections in areas where the FDA has insufficient resources to act and represent a legitimate exercise of State authority.

As I mentioned before, Mr. President, if we were debating the regulatory authority of the FDA to protect the public health, that is a legitimate debate. But that is not where we are. We are not out here debating what would be appropriate power for the FDA to have to ensure protections for the American consumer on cosmetics.

If there are those that can say with a straight face with the $6 million budget that they are allocating through FDA

and two people that are overseeing the areas of packaging and labeling, which is the only thing that the States can do in terms of trying to get at these health considerations—if we were out here to say, ''Look, they have too much power, they have been abusing that power, and they are inefficient with that power,'' that would be one thing. But we are not out here debating that. We are just saying we know, as the cosmetic industry does, that the agency does not have the wherewithal in order to protect the consumer, that the historical protections for the consumer on health and safety have been the States and local communities, and what we are out here now saying is that we are going to take all of their power away. That is the issue. It isn't that we have a strong FDA. We don't have it. It is not represented. It was never discussed in the course of our markup. We had no hearing that would be able to represent it.

Let me just take a few minutes to indicate how we have gotten to where we are with regard to the FDA power on drugs, pharmaceuticals, and on cosmetics.

As I mentioned, the FDA has less than two people to regulate the labeling, packaging, and warning for a $20 billion a year industry. The FDA has less than 30 people to work on cosmetics, and FDA's authorities are grossly inadequate. The FDA regulation of cosmetics is a dinosaur, an anachronism from the time when drugs didn't have to be effective, when food additives didn't have to be safe, and when medical devices didn't have to be safe or effective. Just go back with me in terms of the times so we understand where we are.

I chaired the hearings that we had in the 1970's about medical devices. Twenty-three women died from perforated uteruses as a result of the Dalkon shield. And that was the beginning of the changes in our medical device legislation—in the mid-1970's. Because of the danger with the sophistication of medical devices, we were going to have to make sure they were going to be safe and efficacious. And we did.

Mr. President, in 1938, the last and only time the Congress acted specifically to regulate cosmetics—1938 is the last time—FDA was given authority to regulate products that were misbranded or adulterated. FDA had the burden. FDA had to find the problem. FDA had to do the studies. FDA has to bring a court action.

The entire burden is on the agency. In the last 60 years, we have progressed in other areas of public health and safety. In 1954, we passed the Miller pesticides amendment. In 1958, we passed the Food Additives Amendment requiring manufacturers of food additives to demonstrate safety before putting potentially harmful chemicals in the food supply. Now manufacturers have to demonstrate that their products are safe in order to go in the food supply.

Do you have to do that with regard to cosmetics? No, you do not have to do that with regard to cosmetics. Two years later, we passed the color additives amendment to establish a premarket approval system for additives used in food, drugs and cosmetics. The drug amendments of 1962 fundamentally restructured the way FDA required premarket approval of safety and effectiveness for every new drug. Prior to that it was not there, not necessary. They have to prove safety and effectiveness.

In 1976, we enacted the medical device amendments following long years of study and debate. So now we have the agency requiring that each of the products in terms of the prescription drugs and with regard to medical devices have to be proven safe and efficacious. Do they have to do that with regard to cosmetics? No. No, they do not have to do that today.

Among the most recent changes in FDA's authority were the infant formula amendments of 1980 and the 1990 Nutrition Labeling and Education Act, and the 1990 Safe Medical Device Act. Under these laws Congress held manufacturers responsible for safe and effective products. We asked the manufacturers to provide data to FDA to demonstrate safety before they could sell the products.

We went ahead again with regard to prescriptions and again with regard to medical devices. Do we do it with cosmetics? No. Despite all this progress and advance in public health and safety, cosmetic regulation has lagged far behind. FDA's authority and regulation of cosmetics is still stuck in the framework of the 1938 law that Congress found it necessary to update in every other product area. This is not to say that Congress has not revisited the area of cosmetic regulation. In fact, every time that Congress has revisited cosmetic regulation it has resulted in a call for additional protection and additional safety measures—every single time. But here we are on this FDA reauthorization bill, to reauthorize the FDA and bring it up into the modern period in terms of medical devices and pharmacy. Here we are with a change, significant change in terms of the relationship of the protection of the American people from cosmetics.

And here we are without the hearings, using the exact language of the cosmetic industry which is going to mean health threats to the American consumer—at what benefit? Well, as I mentioned, the bottom line of the cosmetic industry. So we have each and every time, with regard to pharmaceuticals and medical devices, we see what we have done and we have seen each time that Congress has gotten into it or the GAO studies have gotten into it, they say it is an area which cries out of the need for greater protection of the public.

In 1948, George Larrick, who became the Food and Drug Administrator, said:

> Real scientific appraisal of cosmetic ingredients should be made before an ingredient is marketed.

Did we do that? No. In the 1952 hearings, James Delaney in the House found that partial regulation of cosmetics resulted in insufficiently tested cosmetics that are a source of discomfort and disability. Further, the House report found that cosmetics should be subjected essentially to the same safety requirement as applied to new drugs. Yet today that is far from the case.

In 1978, the U.S. GAO report strongly recommended the FDA be given adequate authority to increase safety of cosmetics. Among its findings: Although there is increasing evidence that some cosmetic products and ingredients may carry a significant risk of injury to consumers, the FDA does not have an effective program for regulating cosmetics. Some coal tar hair dyes may pose a significant risk of cancer because they contain colors known to cause or are suspected of causing cancer in humans or animals. However, the exemptions granted to coal tar hair dyes in 1938 prevented FDA from effectively regulating hair dyes. The industry was sufficiently powerful at that time to write an exemption in the law. And there is increasing evidence that people with darker hair who use these darker colors have higher incidence of troubles in terms of not only their scalps but also their general health conditions and there are increasing studies concerning the exposure these individuals may have had to carcinogens and cancer.

Serious burns have been reported from the use of flammable cosmetics. Among those likely to ignite at the time of application are perfumes and colognes which usually contain a high concentration of alcohol and nail polish removers which contain flammable ingredients such as acetone and ethyl acetate.

In 1975 FDA sponsored a 3-month survey of 35,000 users of cosmetics. Participants kept a diary and reported adverse reactions. These reports were reviewed by a team of physicians to determine if the injuries were cosmetically related. One of every 60 participants suffered an injury confirmed by a physician as cosmetically related. One in every 450 participants suffered a severe or moderate injury.

These are studies that were done back in 1975 by the FDA. Do you think we have updated those studies? No. Do you think we have had hearings about that? No. And yet each and every time there is a serious evaluation we are finding these incidents involving health hazards. We have seen the varying degrees of the hazards in the examples and in the pictures that are here behind us. And we could go through picture after picture of the damage done by various kinds of products.

The GAO report concludes that cosmetics are being marketed in the United States which may pose a serious hazard to the public.

That is not the Senator from Massachusetts. That is the GAO, not Democrat, not Republican. In drawing on the best scientific information, this is what they conclude.

Cosmetics are being marketed in the United States which may pose a serious hazard to health. Some contain toxic ingredients which may cause cancer, birth defects or other chronic toxic effects and contain contaminants known to cause cancer in animals because exposure to these ingredients can occur through skin absorption and inhalation as well as oral ingestion. It is important that the hazards posed by them be carefully assessed.

I tell you, Mr. President, if this provision passes, those hazards are not going to be assessed by the States because of the way the language is written in the legislation. I am talking about what will be preempted on page 119, line 8:

Shall be deemed to include—

This is the preemption—

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. Here you have the last studies being done, nonpartisan. Individuals are reviewing the most recent, up-to-date scientific studies. Cosmetics which are being marketed in the United States which may pose a serious hazard to the public.

Why are we asked to take a chance on it, Mr. President? Why are we being asked to take this action? One reason and one reason only—the bottom line for the cosmetic industry. There is no public health argument that can be made on the other side—absolutely none—just the greed of the cosmetic industry.

Every American ought to understand that. Here you have the GAO saying cosmetics are being marketed which may cause a serious hazard to your health. You have the several States: Texas, California, Ohio, my own State of Massachusetts, and a number of other States that are attempting to deal with some of these potential and real hazards to us and they are going to be preempted. Sure, we exempted California from this provision, but there are other health protections in California that are going be precluded.

I have my differences with the attorney general, Dan Lundgren out there in California, but you read through his letter about this action and about the efforts California is making trying to protect its public and how it is completely contrary to the interests of California. Here is the Attorney General of California:

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.

And he says:

As noted above, S. 830 would, in the absence of specific FDA exemption, appear to prevent the State of California from enforcing their Sherman Food Drug and Cosmetic Law which is there to protect the people of California. And it goes on to make the case in opposition to this particular provision.

So now we have the GAO report and we have what this statute does.

The 1988 hearings held in the House of Representatives raised the same issues about the FDA's lack of authority and resources in this important area. Nothing has been done. Let me review one more time what FDA cannot do under its current authority.

It cannot require cosmetics manufacturers to submit safety data on their products—cannot require that. It can require it with regard to pharmaceuticals. It cannot require cosmetic manufacturers to register their plants or establishments or require cosmetic manufacturers to register their products or require premarket approval of any cosmetic or cosmetic ingredient even when such approval is necessary to protect the public health; cannot require manufacturers to submit consumer complaints about adverse reactions to cosmetics; cannot require manufacturers to perform specific testing necessary to support the safety of a cosmetic or an ingredient.

So, Mr. President, this is what we have under current law. I would like to mention just some of the dangers associated with this limited authority. We have talked in generalities. We talk about jurisdiction. We talk about preemption. We talk about inspection. But here are examples of dangerous cosmetics. These injuries took place this year, and there are dozens and dozens of them in graphic detail. I want to read a few of them for you.

Do any of you use Alberto Hot Oil Treatment for your hair? There was a complaint just last month of eye dermatitis from this product. Do you know what that means? It means blisters, chemical burns, rash, redness, swelling, and inflammation. All that from a simple hair treatment.

Everybody in America uses toothpaste every single day. In August, a consumer used a type of Colgate toothpaste with baking soda and peroxide. What happened? Mouth pain and dermatitis. That's a fancy way of describing itching, burning, and swelling of the lips, tongue and gums.

In case you are thinking of switching brands, think again. Somebody else used Crest Tartar Control toothpaste in January and developed the same symptoms of burning, itching, and swelling in the mouth—not what you would expect from brushing your teeth in the morning.

Here is another example. In August somebody used Gillette Cool Wave clear stick deodorant. Instead of being clean and presentable, they ended up with armpit dermatitis and bleeding. Can you imagine bleeding from using deodorant.

How about a product called Revlon Outrageous Shampoo and Conditioner? It is outrageous all right. The user developed scalp sores, swelling, and inflammation from the shampoo.

Have you ever used Bath salts? You may not want to after you hear this. In March, someone developed ''nervous system and urogenital tract reactions'' from Essential Elements Bath Salts. Can you imagine expecting a nice relaxing hot bath and end up with dizziness and headaches.

These examples go on and on.

Prestigious manufacturers L'Oreal, Avon, Clairol, Neutrogena, familiar names like Procter and Gamble, Revlon, Maybelline, Mr. President, this list provides a dismaying parade of horrors from products we rely on every single day.

Here are just a few examples of the injury complaints received by the FDA. Dermatitis includes rash and redness, swelling, blisters, sores, weeping and lumps, inflammation, chemical burns, and irritation. Pain ranges from itching and stinging to soreness and tingling. Tissue damage, other than thermal burn, can include dryness and peeling, splitting, cracking, hair and nail breaking, hair and nail loss, ulcerations, hair matting, and scars. Nervous system reactions range from dizziness, and headache to irritability, nervousness, and numbness.

How many people using these products have symptoms like dizziness, headache, irritability, nervousness, or numbness, and wonder where in the world this is all this coming from? It may very well be coming from their cosmetics, from their shampoos and toothpastes and other types of cosmetics.

If these examples aren't striking enough, there are respiratory system reactions, like upset stomach, nausea, loss of appetite, vomiting, and diarrhea. Or urogenital tract reactions: painful urination, discharge, stopping of urination, and on and on it goes.

Mr. President, I asked for the complaints that we have gotten in just the last few months. Here in my hand is the list of them from the FDA. It is interesting to note that, a number of years ago, we tried to get authority for an FDA hotline so people could call up with their cosmetic injuries. It was struck out in the Appropriations Committee at the behest and intervention of the cosmetic industry. We tried to get a hotline so that at least we would be able to get more information and the FDA would be able to act on that information about specific products.

What is the lesson we can draw from this? The industry does not want more information about cosmetic injuries. They don't want others to have that information. So they eliminated funding of the cosmetic hotline. We have successful and important hotlines in many other areas. They have been a strong success. I have been a strong supporter of them, because they assist people in obtaining information and, most important, help in a timely way. But they also allow the Government to register various complaints and gauge the seriousness of public health problems.

We tried to get the hotline. We had it authorized, it went on to the Appropriations Committee a few years ago,

but it was knocked out by intensive lobbying. So I am truly amazed that the FDA has the kinds of reports I will describe, and the sheer number of cases that they do. The truth is, most people who suffer injuries or adverse reactions from cosmetics simply don't know who to tell, other than their doctors. They in turn don't have anyone to tell or don't know who to tell. Certainly, the companies are under no obligation to tell the FDA—nor do they.

I will return a little later to the efforts that were made to try to get the manufacturers to voluntarily assist the FDA in reporting complaints. At the end of the day, only about 3 percent of the manufacturers cooperated in that effort. When hearings were held in 1988, there appeared to be a consensus to do more to protect the public. The industry itself said, give us an opportunity to voluntarily provide the FDA the complaints that we receive. Well, it ended up being about 3 percent of the companies that actually participated. I will get to this in just a few moments.

Let's begin with the injury complaints. In August, Alberto Culver & Co.'s hot oil treatment for color-treated and permed hair: Eye dermatitis, including rash, redness, swelling, blisters, sores, weeping, lumps, inflammation, sunburn, chemical burn, and irritation. Clairol Helene Curtis, the brand was Nice N Easy Natural Lite Ash Brown No. 114 and Degree antiperspirant; upper trunk and shoulder pain, including burning and stinging. Clairol's Nice N Easy Medium Brown No. 118: Hair tissue damage other than thermal burns. Procter & Gamble's Covergirl Makeup Master, facial and nose injury including dermatitis; Revlon's Professional Nail Enamel Remover: Finger injury, including cuticle, irritation, dermatitis. Neutrogena's Clear Pore Facial Treatment, facial injury; Dixie Health, Dermal KK is the brand: Face, including nose bleeding.

In July, Maybelline's Great Lash Mascara: Face pain and dermatitis in the nose. Realistic's, which is Roux Labs, Revlon Super Fabulayer Hair Relaxer Conditioner: Scalp dermatitis; Shark Products' Africa Pride Relaxer is the brand: Hair tissue damage. Procter & Gamble's Pantene Shampoo: Upper trunk dermatitis, neck tissue damage. Vidal Sassoon Shampoo: Upper trunk dermatitis. Clairol Hydrience Permanent Hair Color: Permanent discoloration of the hair. I can't imagine a product that could unintentionally make hair permanently discolored, but that is what has been reported.

The list goes on. It lists the names of just about every major kind of cosmetic maker in the book. Andrea International's eyelash adhesive: Eye pain. You have perfume from Stern & Co., the product is Oscar: Respiratory system reactions. And the list goes on. I have page after page of these kinds of complaints.

It seems to me if the States want to bring these matters up and it was the desire of the States to try to protect their consumers, they should have the opportunity to do so. Just as California has done and just as other States which are presently studying these issues will do. These States could go and talk to the manufacturers and the manufacturers can make changes, which they have on product after product sold in California. Proposition 65 is the basis for this California system, which works by inducing product improvements without having to remove products from the market or even putting labels on them. That is the way it has worked in California. Safer products. And time in and time out, the manufacturer comes out and advertises that they have upgraded their product. It is a better product now than it ever has been—an interesting and desirable outcome.

But in this bill we say no. We just say no. We tell consumers, you cannot have the remedy of the State and you cannot have the remedy at the Federal Government. The result will be more individuals like the 59-year-old California woman who was almost killed by an allergic reaction to hair dye. Or the woman who lost her hair and was horribly scarred when her hair caught fire from a flammable hair treatment gel. The 6-year-old daughter of an Oakland, CA, woman who used a hair product on her child who suffered second-degree burns. Two women who used eyelash dye, one of whom died and the other who went blind. A 16-month-old toddler died of cyanide poisoning after swallowing artificial nail remover, and a 2-year-old child from Utah was poisoned by the same cosmetic. If there is a State that wants to do something about children, like putting a warning label on these items in order to protect children, it will never happen under this bill. We know that children get into all kinds of products in the household and there is the chance of them ingesting some of these items. Obviously, some may be considerably more dangerous than others, and consumers will want to have labeling that says if the child ingests this, take the following steps or contact the following people. But under this bill, if the State wants to do that, they are virtually prohibited from doing so. They are denied the opportunity to protect their children in their own States.

What if a review is made of the scientific information in these States on these products if ingested by children, asking do they present serious threats of poisoning among children that may be life-threatening? Should warnings be placed on the labels? The result under this bill will be: No, you are out. You can't do that. I just find it difficult to understand why can't the States do this? Why can't they if they want to in Massachusetts or any other State? The reason will be because the Congress of the United States, at the request of the cosmetic industry, says you can't do it. Congress and the industry say you can't do it. That is what we are dealing with, Mr. President. It is just why I think this makes absolutely no sense.

We reviewed earlier this morning some of the groups that were opposed to this provision: The Governors and State legislatures, virtually all of the public health and consumer groups like the National Women's Health Network, the wide range of agencies and officials with primary responsibility over the public health. They are virtually unanimous in their opposition. I will happily wait to hear from public health groups in support of the provision. We will have time during the course of the debate for other Members who are able to get that kind of information and place it in the RECORD. In the face of such unanimous opposition, they will be few and far between.

Here is a letter from the United Food and Commercial Workers, Beth Shulman, the international vice president.

> We are appalled that the Senate is considering preempting state cosmetic safety regulation in the almost complete absence of any Federal protection.
>
> Unlike all other products governed by the Food and Drug Administration, such as food and drugs, the FDA has essentially no authority to assure the safety of cosmetic products prior to entry into the marketplace. The FDA has no legal authority to require manufacturers to conduct safety testing, submit lists of ingredients to the agency, company data, or consumer complaints. Most consumers would be shocked to learn that there is no Federal government regulation or testing to assure the safety of cosmetics before they appear on store shelves or are used by hair care professionals. It is scandalous that the Senate is now considering stripping states of their legal authority, so that the safety of cosmetic products used by millions of consumers will now be completely unregulated.
>
> The United Food and Commercial Workers Union, which represents barbers and cosmetologists among its 1.4 million members, has a long history of campaigning for stronger Federal regulation of cosmetic products. Over the past twenty years we have testified repeatedly about the hazards of cosmetic products and the need to protect not only the 750,000 professional cosmetologists, but the millions of consumers that use these products daily.

They point out they take strong exception to those protections. Now, why should they be concerned? They gave some excellent testimony several years ago to the Congress. Let me give an example. After 2 years as a wig stylist, a cosmetologist from San Francisco began to experience memory loss, nausea, and dizziness. She had troubles with vision and balance. She stated, ''I can't remember things I did just a short while ago. I have to write everything down.'' Her condition was blamed on the ingredients in hair spray and other products she was using in her work. She appeared as one of the witnesses where Congress was working to regulate the largely unregulated industry.

Another example: Christy Smith enrolled in a beauty college in 1984. Christy began to have trouble breathing, a problem that worsened over the

years. She dropped out of beauty school after 10 months. She was found to have irreversible occupational asthma. Again, her condition was attributed to cosmetics present at her school.

A 1997 study in the Journal of Environmental Medicine found evidence to support the claim that female hairdressers are at a higher risk of asthma as a result of occupational exposure to chemicals found in various hair products. This prompted a related study by the Palmer Group, which found an increased prevalence of respiratory symptoms and diseases among female hairdressers. These diseases included asthma, bronchitis, emphysema, and other chronic lung diseases.

Female hairdressers face daily exposure to many harmful chemicals that are used in a wide array of hair care products on the job. I will give a few examples. These chemicals include persulfates, which are used in hair bleaches and can cause allergic skin and respiratory symptoms. Several indications of occupational asthma among hairdressers have been reported. Polyacrylates mixed with chemicals and hydrocarbons in hair styling agents can cause irritation of airways and adversely affect other respiratory functions.

Ammoniac and sulfur compounds released in hair dying and permanent waving can cause irritation of the airways.

The relative risk of asthma and chronic bronchitis among hairdressers was measured almost twice that of a reference group between 1980 and 1995. This study found that the youngest cohort of female hairdressers experienced the greatest occurrence of asthma, 42 percent; and chronic bronchitis, 44. These women ranged in age from 35 to 44.

Mr. President, this is what is happening in the beauty parlors among beauticians across the country. Why? Because they are inhaling these products. They suffer from the higher concentrations of these toxins, but the women of this country who use these products at home are also inhaling them and endangering their health.

I am not here to say precisely what the extent of this problem is, but we know now that it is happening as a result of studies that the compounds that are being used are more toxic and there are more of them being used every year. The health hazards have to be greater. At a time when the health hazards have to be greater, why are we taking away the rights of the States to render judgments to protect their citizens? This is especially true in an area of traditional State authority.

What if the States want to take some kind of action? We are prohibiting them from doing so. We are denying them that chance to do so. It makes absolutely no sense—no sense at all. It does make dollars and cents because the industry is going to benefit from it, but it doesn't make any sense in terms of the public health. That is why virtually every public health agency committed to protecting women and women's health wants this provision out. It undermines their ability at the State level to give additional protections to consumers, and for no other reason than the financial interest of the cosmetic industry.

Mr. President, I will mention here how the United States compares with the rest of the world. That doesn't happen to be the most important argument made this morning, but we heard on the floor of the Senate last Friday about how we have fallen behind other countries in terms of the FDA's work. In reality, the United States has been compared with the rest of the world, and impartial sources such as the General Accounting Office have found that the United States has the fastest and most vigorous product approvals. American consumers expect the best and that is what they get from the FDA.

But when it comes to cosmetics, the U.S. motto should be: ''Expect the best, but settle for less.''

Looking around the world, it is remarkable how inadequately the United States stacks up against other countries. The European Union requires documented proof of good manufacturing practices and similar proof that extensive testing be carried out on all its products. What do they know that we don't know? What are their scientists and research scientists finding? Are we taking the time of the Senate to go through their various studies that point out the health hazards in their communities? They have done it, and they are providing additional protection.

Let us examine another major economic power: Japan regulates cosmetics likes drugs, requiring the companies to do safety tests before marketing. Why? What is it they understand about cosmetic safety? Is it possible they have reviewed and found the same things that we have talked about this morning? The same things that the GAO has found out about the dangers posed by cosmetic products?

Japan requires testing before marketing. That is exactly what the Congress said in 1952 we should be doing in the United States. Forty-five years later, we are still waiting for safety testing. The Japanese are not.

Let's look at North America. Mexico adopted a regulation mandating expiration dates on all cosmetics. To the north in Canada, manufacturers submit data to show the product is safe under normal use conditions.

The Scandinavian countries: Sweden and Denmark are initiating product registration for cosmetics, something the FDA can't require.

Malaysia already requires mandatory registration of cosmetics. That is something the cosmetics industry would fight tooth and nail.

The bottom line is that the American consumers have less protection than consumers in any other country that I have mentioned. The United States is a First World country with a Third World cosmetics safety system. That is the way it is today, and this legislation is going to make it worse. Much worse. That, Mr. President, is wholly unacceptable.

I want to mention more specifically the products of which I think people should have some awareness. These are five common cosmetics products with potentially devastating health effects:

Alpha-hydroxy acid, used in face cream, causes skin cancer.

Feminine hygiene products cause infertility in young women;

Talc used in baby powder that may cause cancer; and

Mascara that can cause blindness.

Alpha-hydroxy acid is one of the hottest selling cosmetics on the market with sales of roughly $1 billion a year. This product is sold to erase fine lines and tighten the skin, but has devastating health effects that are unknown to most consumers. The agency has received 100 reports of adverse effects with alpha-hydroxy acid products ranging from mild irritation and stinging to blistering and burns. More importantly, these products make users more sensitive to ultraviolet radiation from sunlight which causes skin cancer.

To find out if a cosmetic contains an alpha-hydroxy acid, the consumer has to look for one of the following ingredients: glycolic acid, lactic acid, malic acid, citric acid, L-alpha-hydroxy acid, mixed fruit acid, triple fruit acid, sugar cane extract. All of these are alpha-hydroxy acids, although you'd hardly know from their names.

The cosmetics industry sponsored a study linking alpha-hydroxy acids to increased ultraviolet sensitively and, most likely, skin cancer. An industry panel concluded that alpha-hydroxy acid cosmetics are safe at concentrations less than equal to 10 percent at a pH of greater than or equal to 3.5 percent when directions for use include daily use of Sun protection.

Equal to less than 10 percent. This is what the cosmetic industry says will be safe if used along with these other items.

Wouldn't it be useful for someone else or someone impartial to get a chance to look at the basic science and research that the industry has used to make a judgment? Wouldn't that be worthwhile? Wouldn't it be valuable if the FDA had a chance to have that data submitted to them? They could have their researchers look at it and see whether they come to the same conclusion as to the safety.

But, no, there is a recognition by the industry itself that if there is something wrong, they want to do their own study and make their own recommendations. We, the public, don't know. We don't know whether they are accurate. We don't even know whether there is going to be any kind of enforcement, or by whom. By the industry? How? All we have is the industry's

record and their willingness to comply voluntarily with the FDA. We have less than 3 percent of them willing to submit adverse kinds of reactions to the FDA. So we have no way of knowing about the true safety of cosmetics. What we do know is that the industry itself understands that there are health hazards with this specific product and want to control what's on the warning label.

Don't we want researchers out in the great centers of research in this country to say, ''Look, we'd like to try to find out if and how we can protect people.'' Maybe States with broad exposure to the Sun, such as the South and Southwest, should have particular interest in trying to do this. They might want to do some studies to find out.

Would they be able to try to make some kind of a judgment under this bill? Mr. President, the answer is no. We are preempting those States. Let us look at alpha-hydroxy acids again. Here we have one of the most highly advertised products on the market today. We have the industry's own recognition of their health hazards. Again, are we doing something on the floor of the Senate to protect the consumer from those hazards? Absolutely not. We are undermining what protection there is out there among the States.

Consumers should be aware that alpha-hydroxy acid concentrations and pH are generally not noted on these products, not unless FDA's two employees find the time and resources to initiate rulemaking to establish such a regulation. FDA is reviewing the industry report, as well as other data, about these products and may initiate rulemaking sometime in the future, but do not expect the States to protect their citizens from alpha-hydroxy because under the law, States could not warn their citizens about alpha-hydroxy acid creams.

Feminine hygiene products are other harmful, largely unregulated products, with roughly $100 million a year in sales. Many women who buy these products will be surprised to find the overwhelming majority of these feminine hygiene products are regulated only as cosmetics. These products have been known to cause upper reproductive tract infection, pelvic inflammatory disease, ectopic pregnancies, infertility in women. This reduction in fertility is even greater in young women.

Researchers at the Center for Health Statistics in Seattle, WA, have published studies regarding the risk of pelvic inflammatory disease from the use of feminine hygiene products. These researchers have found that the risk of ectopic pregnancy doubles in women who use feminine hygiene products. Researchers at Brigham and Women's Hospital, Harvard Medical School also published data regarding the adverse health effects of feminine hygiene products. We had better hope that those two people at FDA working on cosmetics labeling and warnings have time to work on adequate labeling for feminine hygiene products.

The National Women's Health Network has testified before an FDA advisory committee that more has to be done to protect the reproductive health of women, which is clearly affected by these cosmetics. Just look at the science. But the industry doesn't want the States to have the authority to warn consumers. So, for the women of the State of Washington, we should say goodbye to the research studies conducted in Seattle and what they found out—because we are preempting what those States can do with them.

Even in my own State, research conducted at Brigham and Women's Hospital found that the risk of ectopic pregnancy doubles in women who use feminine hygiene products.

It is worthwhile to inquire if there are other researchers who come to contrary conclusions. These are studies being done. What State is going to go out and perform studies, and which research centers, when they know they are preempted from doing anything about it? That is why the Women's Health Network is opposed to this provision. And for what reason are we risking women's health? Why are we risking lives? It is because of the cosmetic industry. It is going to be cheaper for them, allegedly, when they don't have to deal with warnings and disclosure of health risks. It's too much trouble for them. Talc is something widely used in baby powder and other body powders.

In 1992, the National Toxicology Program published a study of the effects of talc inhalation in animals and an epidemiology study on exposure to talc and ovarian cancer risk. The researchers reported an elevated risk of ovarian cancer associated with talc use. Workers at Columbia University have reported the detection of talc particles in the ovaries of patients undergoing surgery.

The Cancer Prevention Coalition has submitted a citizen's petition to FDA addressing their concern about the possible health risks posed by talc and requested the agency establish regulations to require carcinogen warning labels on cosmetics containing talc as an ingredient. FDA is reviewing the information and may respond sometime in the future. Those two workers are going to be hard pressed with this one, too. If the State wanted to warn its consumers about the potential carcinogen, they would be prohibited under S. 830.

A technique that has been used to extract ovarian tumor material found talc particles in approximately 75 percent of ovarian tumors examined. Subsequent evaluations have appeared to support the contention of an association between talc and ovarian carcinoma.

The most recent study reported by the American Cancer Society has validated the claim that talc exposure increases the risk of ovarian cancer. Since the use of talcum powder is not an unusual practice for women, further studies need to be conducted to further understand the effects on a woman's female reproductive system. We had hoped that perhaps some of these research centers, some of these States would be interested in this. They might have done some work and might have been able to provide some health and safety recommendations in this area.

But now we are saying that if the State of Washington, that was interested in alpha-hydroxy, or if we are going to find out from Columbia University the work they have done with regard to the finding of talc particles in the ovaries of patients undergoing surgery, if they wanted to do something in warning people in the State of New York, those would effectively be off the table. Why are we not debating how we are going to provide greater protection for women?

We have seen important research done up in Seattle, WA. Why are we not out here debating what we are going to do about it? How can we provide protections? What about these kinds of recommendations in terms of the talc? How dangerous is that to our children? Why are we not out here debating that rather than saying, look, even though we have seen this kind of study, we are not going to permit the States to get into this—into this at all—because the cosmetic industry does not want it.

On mascara, the FDA had numerous reports of corneal ulceration associated with mascara products, some of which caused partial blindness of the infected eye. In addition, many other reports of conjunctivitis caused by contaminated mascara were received.

In a 1969 FDA survey of hand and body lotions and creams, about 20 percent of the products sampled contained microbial contamination. Researchers at the Medical College of Georgia demonstrated that 10 percent of eye cosmetics were contaminated when sold. Bacteria were isolated from about 50 percent of all used eye cosmetics. Popular brands of mascara were marketed without preservative systems and are particularly vulnerable to contamination.

Mascara cosmetics can become easily contaminated during customary use because human skin is not sterile, and contact between the skin and a cosmetic leads to microbial contamination of the products. FDA published a notice asking the industry to provide information covering microbial testing methods and standards of performance suitable to assure that cosmetics do not become contaminated with microorganisms during manufacture as well as use. However, FDA's request for information resulted in no substantive response from the industry. The industry just said no. What can FDA do about it? Since FDA has no authority to request the safety data from the manufacturers or look at industry records, FDA's inquiries likely stops

there. Can the States perhaps do something down the line? Perhaps they could have at some point, but not under this proposal.

Expiration dates would help remind consumers to get rid of cosmetics before the bacterial contamination becomes dangerous. Under this legislation, States could not act to require expiration dating on cosmetics.

So, Mr. President, the cosmetic provision of the bill is utterly irresponsible. It is a flagrant example of a special-interest lobby using its back room muscle to attain unfair advantage over the public interest.

You bring that bill out separately, Mr. President, and let us have an opportunity to debate that on the floor of the U.S. Senate. The votes are not there to carry that individually. And they should not be there. But now we have seen that the cosmetics industry has added this on to legislation that was initially devised for the extension of PDUFA, to ensure adequate funding for FDA's drug review program so that the United States can be first in the world in terms of approving new products in the pharmaceutical industry.

It is time for the Senate to stand up for the health of the American people, reject this unjustified, unwise, unacceptable provision that is nothing more than a tribute to the greed and recklessness of the cosmetic industry. The political power of the cosmetic industry is not a license to ride roughshod over the rights of the States and the health of the Nation's men, women, and children who use their products every day.

The American people deserve safe cosmetics. They have a right to full and fair information about the actual and potential danger of their products. The last thing Congress should do in a bill called the FDA reform is to give the cosmetic industry a blank check, poisoning the American people with its products.

Mr. President, we allow States to decide whether their bottles will be recycled or buried or whether their barbers are going to be licensed, whether their pets will be registered, how close to a crosswalk you can park your car, what hours the stores can be open. But this bill prohibits the States from protecting the consumers from cosmetics that can give you cancer, catch on fire, or cause birth defects.

As I mentioned, the language broadly preempts any public information or public communication. That is an ironclad guarantee that the consumers will know less about their cosmetics. States will not be able to require warnings to parents or children about the dangers of a particular product. American consumers are going to know less about their products. The cosmetic industry introduces 1,000 new ingredients every single year into our cosmetics, everything from lipsticks, hair creams, soap, deodorant, and hair dyes.

Do you think we will know how safe they are if this language becomes law? Who will be looking out after the public interest under this language? I suppose it is left to the two employees at FDA—an agency with limited authority and resources—who are charged with regulating $20 billion worth of cosmetic labeling and packaging. This language that we are considering was drafted by the cosmetic industry itself so make no mistake who it is intended to benefit.

Many challenges to State action have been rejected by the Federal appellant courts because the courts interpret preemption narrowly. This is because the courts cannot imagine that Congress would want to preempt the States from protecting their citizens. So what does the cosmetic industry do? They carefully drafted this language to give them their broad preemption. They have admitted that they drafted this law specifically to force the Federal judges to interpret preemption very broadly.

Mr. President, this provision should not become law.

Mr. President, beyond this issue, I will mention two other important items that I hope we will have a chance to debate in the form of amendments when we move to the bill itself. Others have spoken to them, and I will work with them or introduce legislation on these particular provisions.

The overall legislation includes a number of provisions that will significantly improve and streamline the regulation of prescription drugs, biologic products, and medical devices. I am pleased that, through a long process of negotiation both prior to and subsequent to the markup of the legislation, many provisions that seriously threaten public health and safety were dropped or compromised.

But despite our best efforts, this legislation includes several Trojan horses that I think undermine important positive proposals in this bill. I would like to discuss the changes in the regulation of devices that put consumers at unacceptable and unnecessary risk. They should be removed from the bill before it goes forward. The administration has made it clear that these provisions put the whole bill at risk.

A great deal of negotiation has taken place on the medical device provisions of this bill. I compliment Senator JEFFORDS and Senator COATS and other colleagues in the committee for resolving most of the divisive provisions in a way that is consistent with the protection of the public health. I see in the chair Senator GREGG. We worked with Senator GREGG on the health claims issues in a constructive manner.

But there are at least two medical device provisions in the bill which still raise substantial concerns that could be corrected very simply with negligible effect on the basic purpose and intent of the bill. Yet these corrections have not been made. My colleagues deserve a clear description of the hazards they pose. A brief explanation of how the FDA regulates and clears the medical devices for marketing may be first in order.

Under the current law, manufacturers of new class I and class II devices can get their products onto the market by showing that they are substantially equivalent to devices already on the market. For example, the manufacturer of a new laser can get that laser onto the market if they can show the FDA that the laser is substantially equivalent to a laser that is already on the market.

Similarly, the manufacturer of a new biopsy needle can get that biopsy needle onto the market by showing that it is substantially equivalent to a biopsy needle already on the market. And the manufacturer of new patient examination gloves can get those gloves onto the market by showing that they are substantially equivalent to patient gloves already on the market.

Mr. President, these manufacturers are obliged to demonstrate substantial equivalence to the FDA by showing that the new product has the same intended use as the old product and that the new product has the same technological characteristics as the old product. If the new product has different technological characteristics, these characteristics must not raise new types of safety and effectiveness questions in order for the product to still be substantially equivalent to the older product.

The logic of this process for bringing medical devices onto the market is quite simple: If a product is very much like an existing product, it can get to market quickly. If it raises new safety or effectiveness questions, those questions should be answered before the product can be marketed.

This process for getting new medical devices on the market, commonly known as 510(k), is considered by most to be the easier route to the market. Devices that are not substantially equivalent to a class I or class II device already on the market must go through a full premarket review. Thus, device manufacturers have an incentive to get new products on the market through the 510(k) process. In effect, well over 90 percent of all new devices get on the market through the submission of a 510(k) application.

This legislation seriously compromises the FDA's ability to protect the public health through its regulation of medical devices that are marketed through the 510(k) process. Of the dozens of provisions that we have negotiated and discussed which affect medical devices in this bill, these two still raise fundamental public health problems. Although few in number, these provisions raise substantial risks to public health which simply cannot be ignored.

The first problem raised by the bill relating to medical devices is a prohibition on the FDA from considering how a new device will be used if the manufacturer has not included that use in its proposed labeling.

You may think this approach makes sense. Why should the agency consider the use of a device if the manufacturer has not specified the use on the label? I'll tell you why—because that proposed label may be false or misleading. How would the FDA know that? Because the design of the new device may make it perfectly clear that the new device is intended for a different use.

Let me provide my colleagues with a few examples. Let's talk about the biopsy needle I mentioned before used on breast lesions. Most biopsy needles for breast lesions currently on the market take a tissue sample the size of a tip of a lead pencil. Assume the manufacturer of a new biopsy needle comes to the FDA with a 510(k) submission. But the new biopsy needle takes a tissue sample 50 times as big, the size of a 1-inch stack of checkers.

The manufacturer of this new needle has proposed labeling that says that the needle will be used like the old, marketed needles to biopsy breast lesions. But FDA knows the chunk of tissue being ''biopsied'' will exceed the size of the lesion. This makes it clear to FDA—and any impartial observer—that the needle in most cases will be used to remove the lesion.

Under these circumstances the FDA should be able to ask the manufacturer to provide information on this use. Is it safe to remove lesions? Does it really work? The bill, however, categorically bars FDA from asking these essential questions. This means the FDA would be unable to make a complete review of the device and the public would be deprived of existing assurances that devices are truly safe and effective.

The proponents of this provision have argued that the FDA could simply say that the change in device design or technology—such as the change and size of the biopsy needle—renders the new product not equivalent to the old product. But that is not always true. The manufacturer could argue that there are no new questions of safety or effectiveness for the purpose claimed on the label. In the case of the biopsy needle there are times when a large sample is needed—a sample larger than a pencil tip.

So long as the larger needle is safe and effective for removing a sample, FDA could be barred from obtaining data about the new use of removing lesions and to the extent the needle is used for the new use, women could be put at risk for effective or unsafe treatment of breast cancer.

Another example is surgical lasers that have been used for decades to remove tissue. Several years ago, a manufacturer added a side-firing mechanism to their laser to improve its use in prostate patients. While the manufacturer did not include this specific use in its proposed labeling, it was transparently clear that the new side-firing design was intended solely for this purpose of treating prostate patients.

As a result, FDA required the manufacturer to submit data demonstrating the laser's safety and effectiveness in treating prostate patients. This is precisely how the device review process should work. Manufacturers must prove their devices live up to their claims, while patients and doctors receive all of the information needed to make the best possible treatment choices.

Under this bill, FDA would be prohibited from getting adequate safety data on the laser's use on prostate patients, even though that would be the product's primary use. This defies common sense, yet this is the result of one troubling and indefensible provision. Other examples in the way this provision could allow unsafe and ineffective devices onto the market abound. A stent designed to open the bile duct for gallstones could be modified in a way clearly designed for treatment of blockages in the carotid artery. Without adequate testing, it could put patients at risk for stroke or death. But under this bill, the FDA would be prohibited from looking behind the label to the actual intended use of the device. A laser for use in excising warts could have its power raised so it was also possible for use in smoothing facial wrinkles, but without FDA's ability to assure adequate testing, the use of the laser for this purpose could lead to irreversible scarring.

Most companies, of course, will not try to bypass the process in this pay. But some bad actors will. This legislation should not force the FDA to fight these bad actors with one hand tied behind it. This provision is like asking a policemen to accept a known armed robber's assurance that the only reason he is wearing a mask and carrying a gun is that he is going to a costume party.

The second way this bill undercuts the FDA's ability to protect the public's health and adequately regulate medical devices is the way it forces the FDA to clear a new device for marketing even if the agency knows that the manufacturer cannot manufacture a safe device.

Let me repeat that. It sounds, frankly, preposterous but it is true. One of the bill's provisions actually requires the FDA to allow a new device on to the market even if the manufacturer is producing defective devices. Surprisingly, the proponents of this provision freely admit that this is true.

Under the current law, let's assume that a maker of a new examination glove submits a 510(k) to the Food and Drug Administration and claims that the new gloves are substantially equivalent to gloves already on the market. If the FDA knows for a fact from its inspectors that the company uses a manufacturing process that often results in the gloves having holes, FDA would simply not clear the gloves for marketing. FDA would find that these gloves are not substantially equivalent to gloves on the market because gloves on the market don't have holes. That is common sense, and fortunately that is also the law.

In contrast, this bill would force FDA to clear the gloves for marketing. These defective gloves would be sold to hospitals, clinics, and HMO's where they would be used routinely by doctors, nurses, paramedics, and other health professionals every single day. Every single glove would expose these professionals needlessly to AIDS and hepatitis.

Here is the response of the provision's supporters. They argue that once these defective gloves are in the market and being used by health professionals, FDA can simply institute an enforcement action to remove them from the market. But when hundreds or thousands of defective devices have been distributed, and when dozens or hundreds of facilities may be using these devices, an enforcement action entails more than blowing a whistle or picking up the phone to place a simple call.

In reality, FDA must coordinate with the U.S. Attorney's Office, U.S. Marshal's Office, and persuade the court of jurisdiction to issue appropriate papers. As any attorney or law enforcement professional can tell you, that takes precious time. In the case of a defective device which is exposing people to unnecessary risk, time is absolutely critical. The sooner a defective glove is pulled from the market the sooner the public is protected.

All this makes no sense when the FDA can prevent this from arising. If this provision becomes law, the debater's point distinguishing between different forms of FDA authority will be paid for in the health and safety of American consumers, placed at needless risk of death and injury. In fact, even the regulated industry is willing to compromise on this provision because they recognize it is so unreasonable and should be removed from this bill.

In the end, there is simply no justification for these troubling medical device provisions. Our overriding priority in regulating medical devices should be distinguishing between reforms which preserve the public health and protections and those which endanger the public health.

Mr. President, we have had arguments on the other side of that provision which say, well, on the labeling provision are we going to have to require the manufacturer to dream up every possible use and be able to answer the charges that some nameless person at FDA can possibly imagine that a particular medical device would be used for?

We say, no, that is not what we are looking for. We are looking for what would generally be defined as the predominant or dominant use of the device as a criteria. That ought to be the key. We know many devices are used in different kinds of ways. We are looking here at the predominant or dominant use for the device. That is what we are concerned with.

You might have a pacemaker which can speed up the activities of the heart

and some treatment might require that you slow down the beat of the heart. You might have one pacemaker that has already been approved, and someone else wanted to get on stream and say that they have a pacemaker that speeds up the heart but also may slow it down. So they come in and say, ''We want this approved because it will speed up the heart but it also has the possibility of slowing it down,'' in order to circumvent the safety requirements.

It seems to me we ought to be able to work that out. We are looking, as I said, as a criterium of the predominant and dominant device use as the key. We are not looking for these other, incidental uses. It seems to me we ought to be able to work that through. For the reasons I outlined in discussing the good manufacturing practices provision, it seems to me we also ought to be able to find some common ground in that area, as well, but we are not there yet.

I suggest the absence of a quorum.

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

The bill clerk proceeded to call the roll.

Mr. GREGG. 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. GREGG. Mr. President, I ask unanimous consent to consume as much time as I may require under the pending debate.

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

Mr. GREGG. Mr. President, today, we are debating, in part, the FDA Modernization Act, which is a very important piece of legislation because it goes to the issue of the health and safety of the Nation. I congratulate the Senator from Vermont for having the foresight, ability, and acumen to bring this bill to the floor after a considerable amount of negotiations and debate and discussion and activity within the committee. In fact, we have been working on this ever since I have been on the committee. I believe that would be almost 5 years now.

The need to modernize the FDA is obvious. I think it is obvious to anybody who represents any group of people, as we hear constantly from folks in our States about problems that they have had with getting drugs, getting devices in a prompt way and in a manner that will help them live better lives. I, for example, had an instance where Helen Zarnowski came to my office fairly regularly over the years as she sought to get approval, or wanted to be able to use various Alzheimer's drugs, drugs being developed that were experimental, in order to help her husband, who, unfortunately, had Alzheimer's. She would come and talk about how terrible this disease is—and it is a horrible disease—and how much she would like to be able to try this drug she had heard about, or that drug which she knew was having positive effects. She had heard about some in Europe that had positive effects, which had been approved there. Yet, unfortunately, the process of approval in the FDA involved considerable delay, delay really well beyond what one would consider to be common sense. Regrettably, her husband died in 1995. Some of the drugs that might have been able to be helpful were not approved by then.

Of course, we all, I suspect, have friends or people we know who have contracted the AIDS disease and have had problems with AIDS. They are historic. The FDA has started to address that more aggressively in the last few years. In the latter part of the 1980's, that was not the case. Approval was delayed for an extended period of time in a variety of other areas, especially the device area, where people's lives could be improved dramatically by getting a medical device that would assist in their rehabilitation. Or the testimony which was so heart rending and stark, given within our own committee by our own committee member, Senator FRIST, a nationally prominent heart surgeon prior to becoming a U.S. Senator. He made it so clear that if he had simply had a device that was available in Europe, he could have possibly saved some of his patients. But he could not get it because the FDA would not approve it in a manner that was timely enough to have it available for those patients.

So this is a very personal issue. It is brought up in the context of the bureaucracy and the question of this huge institution called the FDA, but when you get right down to it, like most Government, this is a very, very personal issue of people being impacted by their need to obtain care, by their belief that certain types of care that are available maybe in other countries would help them, and their inability to get it in a timely manner in the United States. The FDA has had some real problems. There has been, without question, an attitude that ran well into the early part of this decade that caused FDA to be ponderously bureaucratic in the manner in which it dealt with drug approvals and especially device approvals. That has changed. It has changed for the better. It hasn't gone as far as it needs to go, no. But that is what this bill is about—to give the FDA the capacity to go even further down the road toward being a positive force for the approval of drugs that may help people live longer, live better lives, and for the approval of devices that would help people live better lives. So especially for those individuals who are going to be impacted, this is a very significant piece of legislation.

In addition, of course, it has the PDUFA language in it, which is critical because PDUFA is the manner in which we fund the expedited approval process for all intents and purposes. And we need to have that fee system reauthorized so that we can keep on board the 600 or so people who are employed through the PDUFA fee process to help us expedite approvals. So that is one approval. In addition, it deals with the question of a variety of questions such as health plans and what can be said. And we approve that language in the bill. The issue of uniformity and how we deal with that—we have improved that language in the bill for a variety of areas. But, most importantly, it is a piece of legislation which will—to use a nice term— ''modernize'' the FDA and help us move more promptly to the approval of drugs and devices which will cause for better caring for Americans.

There has been a lot of discussion on this floor about the question of national uniformity in the area of over-the-counter drugs, and national uniformity in the area of cosmetics. Certainly the Senator from Massachusetts has expanded considerably on this topic. I must say that at an entry point I do find it ironic that this bill would be filibustered because when this bill is filibustered it slows down the approval process for people who have problems, for people who confront diseases and who need new drugs and new devices. And the filibuster by very definition when it was initiated on this floor in opposition to this bill means people are going to have further delays—delays beyond just the bureaucratic delays, which are bad enough —delays which are created by the politics of the process. That is just not right. If the Senator from Massachusetts has a serious concern, which he, obviously, does about one or two items in this bill, he shouldn't be filibustering this bill. He should be offering amendments to the bill letting us vote them up or down and decide whether or not his position has the support of the body, or the bill as it was reported has the support of the body. Clearly a filibuster is totally inappropriate and tremendously ironic in the context of an issue which we are trying to expedite the approval of. And we run into a filibuster. It is bad enough, as I said, to have a bureaucratic slowdown of the approval process. But to have a political slowdown of the approval process is really, I think, unconscionable.

Independent of that point, let's go to some of the specifics here of the concerns. The issue of uniformity is an issue which has been addressed and discussed at dramatic depths and lengths over the last decade, at least—probably prior to that. That is the only time I recall over the last decade. There have been commissions of very thoughtful people who are extraordinarily expert on the issue of how we deal with the approval process and management of the drug and device delivery system in this country, and who have looked at this. In fact, there was a study, a group, a commission put together headed up by Carl Edwards, who was at one time head of the FDA, and the conclusion of that commission, which was

put together at the request of the Congress as early as 1991, was that Congress should enact legislation that preempts additional and conflicting State requirements for all products—not a few, all products—subject to the FDA jurisdiction. States should be permitted to seek a preemption in areas where the FDA has acted based on convincing local needs. States should in addition be allowed to petition for the adoption of national standards.

That is exactly what is proposed in this bill relative to the two items that the Senator from Massachusetts appears to have problems with—over-the-counter drugs and cosmetics. It should, also, according to this language, have been proposed for food. We should have done uniformity for food if you follow the presentation of this commission proposal. And maybe there will be an amendment coming as we move forward on FDA reform which addresses the issue because I know there is a lot of support on both sides of the aisle for the issue of uniformity on food regulation as well as drugs—over-the-counter drugs and cosmetics.

But the point here is that an independent, thoughtful, congressionally supported commission headed up by the former head of FDA concluded that this type of uniformity is exactly what we need in order to effectively administer and protect—administer the issue of food and drugs and protect the public. In their 1-year review of their report—1 year later. That was a unanimous agreement, I should have mentioned, reached by the commission, and 14 of the 17 people on this commission said, ''We reaffirm our original recommendation that Congress should enact legislation preempting conflicting or additional requirements for products subject to FDA regulation with provisions for the States to be able to demonstrate a genuine need for distinctive requirements to seek an exemption. Failing action by Congress, FDA should adopt regulations to accomplish the same rules for national uniformity.''

They went a step further. They said even, ''If the Congress doesn't go the uniformity route, the FDA ought to do it unilaterally with regulation.''

I don't agree with that. I think it is the prerogative of the Congress to decide this type of issue. But the fact is they felt so strongly about this as a group of commissioners who had expertise in this area that they asked for that type of an extraordinary action. That would have meant uniformity for drugs, food, over-the-counter drugs, and uniformity for cosmetics.

Then Commissioner Edwards reaffirmed this point in a letter that he sent to Chairman JEFFORDS by saying ''national uniformity should play a greater role in FDA-State relations. If not, the agency's ability to protect''—this is the issue; how do you protect?—''to protect consumers will be further eroded and unnecessary concerns will be imposed on the national Congress.''

Former Commissioner Arthur Paul Hayes wrote in July 1997, ''I write in strong support of the national uniformity provisions in S. 830 for the nonprescriptive drugs and cosmetics, I have long believed that a single national system for regulations for these FDA-regulated products is essential and now overdue.''

So you have a commission which was the brainchild of the Congress to determine what FDA should do and how they should manage the issue of drugs, cosmetics, over-the-counter drugs, and food; a commission saying: Use uniformity. Why did they say that? They said it because they believe that to have 51 FDA's running around the countryside—50 States plus the Federal FDA—would create chaos. It would confuse the consumer and create a situation where a consumer in one State was to be given one piece of advice and the consumer in the next State was being given another piece of advice, and as a result, rather than having an encouragement of a comprehensive, thoughtful approach to health protection, you would have confusion and anarchy in the public's mind as to what was correct in the area of health care and protection.

It is a pretty logical position. I have to say as someone who comes from the States' rights viewpoint, and who has spent most of my life defending States' rights, that it runs against my grain to want one Federal agency to run the country on one issue but, when you think about it, to do it any other way would be to undermine the health, and certainly the veracity and the confidence of the public on the issue of health care provided.

This is especially true in the area of FDA because even though the FDA has been excessively bureaucratic, nobody would argue that they haven't been extremely professional. They are an agency which has and maintains the view that they are the world's premier reviewer and protector of public health. And I think they have credibility in taking that position.

That is why I think as a States' rights advocate I am willing—or one of the reasons I am willing—to say yes in this area. The role of the FDA is unique, and to undermine the role of the FDA—that is what you would be doing—to undermine the role of the FDA by allowing the 50 States to basically pursue arbitrary independent views in areas where the FDA has the authority to regulate would be a big mistake. It would run counter to the basic goals of having a strong system of health protection in this country.

So we are talking here about how you protect the public health. And what we have is a commission set up with the support of the Congress which concluded—we have experts; they weren't Members of Congress on this—concluding that the way to protect the public health is to have uniformity.

So let's give that a fair amount of credibility. Let's not just discard that. I think that is a fairly persuasive point in favor of the language in this bill which tracks the proposal of the commission, the Edwards Commission, for all intents and purposes, and which was brought forward out of committee with a vote of something like 14 to 4—overwhelming support because the people on the committee who have taken a long time looking at this sort of thing understand that the commission made sense when it came to these conclusions.

Before I get into the specific responses to some of the points made here, there is another general theme that comes out which is that if you take the argument coming in opposition to the uniformity standards in this bill you are essentially taking an argument that says the FDA can't do its job; the FDA isn't competent; that the States are more competent than the FDA. The corollary to that is you are saying the FDA doesn't care; the FDA isn't really interested in health and safety; that there are areas of health and safety under its regulatory responsibility, under its portfolio, that it has no responsibility, and that it is going to walk away from it. Those are heavy charges to make against the FDA.

But that is essentially the subtlety of the position in opposition to uniformity: It is that the FDA isn't capable of administering its portfolio and it doesn't care about safety. I personally disagree with that. If anything, the FDA consistently errs in favor of safety, which is probably the right way to do it. We are asking in this bill that they streamline their efforts, that they expedite their procedures, but we are not asking that they do it at the expense of safety. And to imply that they aren't going to fulfill their obligations—which is not an implication but basically a statement made here on numerous occasions—citing that only two people are doing this, three people are doing that, to imply that they are not going to fulfill their obligations is I think incorrect. I think the track record shows that the FDA does fulfill its obligations in many ways, and it maybe is a little slow in doing it sometimes. But it sure does get into the issue of safety. And to presume that it would not is I think inappropriate or inaccurate. ''Inappropriate'' is not correct. Obviously, you can presume anything you want. So that is another point.

First, we have the commissions' support for this proposal.

Second, we have the logic of the committees' support for this proposal.

Third, we have the fact that the FDA is perfectly capable of pursuing this proposal and should be pursuing this approach because a single uniform approach is what makes sense for the health and safety of the American citizenry.

There were a number of specific points made in representations relative specifically to cosmetics. But you have

to remember that cosmetics isn't any different here than over-the-counter drugs for all intents and purposes. Thus, I am surprised with the intensity of opposition of the colleagues; that we don't have the same intensity of opposition to over-the-counter drugs. It seems to be inconsistent to me. And it may just be that the photographs are better for cosmetics than over-the-counter drugs. I doubt that. You can probably find some pretty heinous photographs that relate to over-the-counter drugs. But the fact is that, I think, that is inconsistent.

In specific, the statement was made that the States will no longer be able to regulate, or to paraphrase it, the States will no longer be able to regulate the packaging and labeling of cosmetics. That isn't really accurate. Nothing preempts State enforcement powers. States may seize, embargo, or pursue judicial proceedings whenever necessary to enforce the law; Federal law; the FDA law.

(Ms. COLLINS assumed the chair.)

Mr. GREGG. States are also free to publicize any information or warning they deem necessary. They simply cannot force the manufacturers to post warnings unless they can get the FDA to agree that that warning is legitimate.

What is wrong with that? Nothing. FDA is certainly going to want a warning on a bottle if it is proven to cause cancer. It is absurd to think they will let the bottle or whatever it is out on the market. If there is some threat that is created by something, the FDA is going to step forward.

States will have two specific options under this legislation. The States may use the existing authority provided under 21 CFR 10.30 to petition the FDA to make any requirement a national requirement. So they can ask that their proposals, their ideas, be moved up to the national level. Under this provision, States may seek an exemption. If you have a law or requirement that is different from the FDA's, the States can come to the FDA and say we think there should be a national protection.

For example, the Senator from Massachusetts was talking about the studies in the State of Alaska and what the State of Massachusetts was doing in the area of caring for women. If they feel strongly about that, they can go to the FDA and ask that those types of disclosures which they think are appropriate in the State of Washington and the State of Massachusetts be national. Why shouldn't they?

The other side of that argument is that, well, women in Washington and women in Massachusetts should get a different warning label than women in New York State or women in Oregon. Why? If it is that serious, why would you want the people in Washington to know something different than the people in Oregon? Obviously, you would not. The logic is that the FDA should make the determination as to whether or not it is serious enough to require national disclosure or to make a determination whether it isn't so that you don't arbitrarily scare the people in one State versus another State. It really makes no sense to have a hodgepodge of disclosures on these over-the-counter drugs and cosmetics, requiring that over-the-counter drugs and cosmetics are not drugs in the traditional sense that they are defined by the statute. Drugs are clearly something that the FDA is going to be involved in.

So it is just an inconsistency here to this argument that the FDA should not be making the decisions but that the States should be making decisions because you end up with inconsistency from State to State by definition. So I don't think that argument really applies.

Now, there was another representation that I believe 47,000 injuries resulted last year from cosmetics use. This calculation was not analyzed in its representation, the specifics of it. I think it should be.

The Consumer Product Safety Commission's National Electronic Emergency Injury Surveillance System came up with this figure in a 1988 House hearing. I believe that is what is being referred to here. Their calculation included things such as slipping on soap in the shower, suicide attempts, injuries from broken bottles, plus in the context of total usage 47,000 injuries, some of which clearly weren't involved in the character of a cosmetics, represents .00044 percent, which I believe is less than five ten-thousandths—five ten-thousandths—of the number of products sold in the country; 10.5 billion products sold in the country and 47,000 potentially caused injuries, some of which involved slipping on soap or broken bottles or possibly ingesting things intentionally to cause harm, and that represented .00044 percent or less than five ten-thousandths of the products sold.

You have to put that in a little bit of context here because, as studied by the same group, injuries caused by couches and sofas were 70,000. Almost twice as many injuries were caused by couches and sofas as were caused by cosmetics. And 117,000 were caused by drinking glasses. Are we going to have that be State regulated—drinking glasses? And 253,000 were caused by pillows, mattresses, and beds. What is that, almost six times the number caused by cosmetics studied by the same group. So when that number is thrown out here, I think it has to be put in context, and I think that puts it in the context of ''less than persuasive'' would be the adequate term to put to that statement.

Now, also, the point was made that cosmetics pose an inherent threat to a person's health and safety. I think we just saw from the numbers it is not very inherent if it is less than five ten-thousandths of a percent that are impacted.

But cosmetics by definition are inherently the safest products FDA regulates. Cosmetics, as defined by the Federal Food, Drug and Cosmetics Act, section 201(I), means:

> Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

We are not talking about products that affect the structure of any function of the body. Such products are viewed as drugs. So if it affects structure, if it affects function of the body, it is a drug; it is not a cosmetic.

In fact, former Commissioner Kessler stated in a hearing in the House, again in 1991:

> People can take comfort from the fact that the cosmetics industry is as safe as they come.

So cosmetics are not inherently dangerous, which would be what you would think if you listened to the debate here for the last couple of days.

There are problems with cosmetics. Nobody is going to deny that. And that is what we have the FDA for. When there is a problem, that is what the FDA is there for.

Now, there was another statement, I believe, made that 884 cosmetic ingredients have been found to be toxic. That is a pretty strong statement. Of course, we all know that things that are toxic are things that we deal with every day. Salt is toxic if you take too much of it. In fact, that list included chemicals such as water, salt, and vinegar. This was a list derived from a list published by the National Institute of Occupational Safety and Health Registry of Toxic Effects of Chemical Substances, which list, as I mentioned, included such things as water, salt, and vinegar.

So toxicity depends on the manner in which it is used and the manner of application as versus by definition that the substance is toxic. ''Many substances that are common in everyday life are obviously toxic.''

Mr. President, 884 ingredients were evaluated by the Cosmetic Ingredient Review Expert Panel to determine if they were toxic. This was not mentioned, I don't think, during the debate. They found no significant health effects with the cosmetic use of any of them. So, again, I don't think that argument is persuasive.

Then there is the GAO report on which a considerable amount of discussion has been spent. I believe the Senator from Massachusetts was referring to the 1978 GAO report that listed 125 ingredients which were then available for use in cosmetic products that were suspected of causing cancer, 25 that were suspected of causing birth defects, and 20 that were suspected of adversely affecting the nervous system.

The GAO report goes on to state that:

> Neither we nor NIOSH—

Which is the other Federal agency that would have responsibility here; I just quoted their numbers—

has reviewed the adequacy of the tests performed or the applicability of the tests performed or the applicability of the results to exposure to the ingredients through the use of cosmetics.

They haven't reviewed that. In fact, much of the limited scientific work done before this list was first compiled by NIOSH was done at extremely high exposure levels, rather than against a relative baseline.

Anytime the FDA would like the Cosmetics Review Panel, in its capacity as an independent expert panel meeting the same criteria as any FDA review board, to review the data, to review the safety data on anything that can be used as a cosmetic ingredient, they may request that it be done. But the FDA has never asked them to do that. The CIR has never denied such a request. The FDA may have asked, but the CIR has never denied the request. The fact is that if something causes cancer and if it were being used in some sort of cosmetic and as a result cancer was being generated, you would have FDA action.

What do we think the FDA is, a potted plant? They are not going to sit around if there were any cancer-causing substances that were being generated by any cosmetic that were a threat. The idea that a State is going to step up and do a better job of evaluating whether or not there is a carcinogenic effect to anything is, I think, a bit of an affront to the FDA. The fact is the FDA takes cancer pretty darned serious. And they aren't about to walk away from anything or not get involved in anything that has a cancer issue, a serious cancer issue. So bandying around numbers like that may create headlines, but I don't think it is persuasive if you look at the substance of this.

Now, there has been some representation that FDA doesn't have a whole lot of regulatory authority here. It has a lot of regulatory authority, as was shown again by the Edwards Commission. FDA is the regulatory agency, and that's why there should be uniformity.

Just let me read a few of these.

Section 301 prohibits the introduction into, or receipt of, any cosmetic that is adulterated or misbranded in interstate commerce.

Section 303 lists the penalties for violating section 301, starting at imprisonment for up to 1 year and a $1,000 fine.

Section 601 defines ''adulterated''—if it contains a poisonous or deleterious substance; contains a filthy or decomposed substance—we are not even talking about things that are going to cause you cancer here; we are talking about a filthy or decomposed substance—if it was prepared, packaged or stored under unsanitary conditions; its container is made of an adulterated substance; or if it contains a color additive not approved by the FDA.

We heard a lot about color additives earlier.

Section 706 requires FDA to approve color additives as safe before they can be used in cosmetics.

Again, we heard a lot about color additives, but the FDA has authority here.

Section 602 defines ''misbranded'' as: False or misleading labeling; if the package is not labeled with the name and place of business of the manufacturer, packer, or distributor, and with accurate quantity; if any word required by Federal law or regulation to appear on the label is not prominently displayed in a readable and understandable manner; if the container is misbranded; if the color additives don't conform with requirements; or if the packaging or labeling violates the Poison Prevention Packaging Act.

Section 201(n) states that misbranding must also calculate the extent to which the required facts are not revealed.

The FDA has broad authority—broad authority—here. And they will use that authority.

The FDA can ban or restrict ingredients for safety reasons, mandate warning labels, inspect manufacturing facilities, issue warning letters, obtain court orders to seize illegal products, obtain court orders to enjoin activities, prosecute any violators, publicize public health issues, and work with manufacturers to implement nationwide recalls.

There are 41 pages—41 pages—in the FDA, in the Federal Food, Drug and Cosmetic Act applying to cosmetics—41 pages. There are 32 pages of FDA regulations of cosmetics in the Code of Federal Regulations. The fact is that the FDA knows this issue and has the capacity to deal with this issue. The idea that the States are going to do a better job—well, I suppose that if they are they can come to the FDA, under the law as proposed in this bill and say, ''We have done a better job. Change the Federal rule.'' And the FDA will do that, because that is what the law gives them the authority to do. Or if they think it is a unique situation, then the States can come and say we want special treatment for this, and the FDA will give them that authority.

But the point here is that you should not have—and my colleague uses the term women or children a great deal. I think it is just about anybody who would be impacted. But you should not have women in Washington State getting a different instruction from women in the State of Oregon, because it is going to confuse people. Who is going to know who is getting the better instruction, the people in New York versus the people in Massachusetts? Let's have it done consistently, across the country. That is why the commission decided in favor of uniformity. Uniformity on over-the-counter drugs, uniformity for cosmetics, uniformity for food. We don't have food in this bill. Maybe we will. Maybe there will be an amendment.

There is some representation—I couldn't get it clear but I think there was a representation relative to California's status. Let's define California's status. This law is prospective. It doesn't affect the California situation at all. Prop 65 remains effective in California. So that bit of red herring should be put to bed.

There has been this representation there are only two people over at the FDA doing this or that. The FDA regulates cosmetics. It has the financial capability—and we will give it the financial capability if it feels it doesn't have it—to have the personnel to do the job right. And I believe that, as part of its portfolio, the leadership of the FDA will do the job right. To say they will not or imply they will not, which is the representation, I think, as I said earlier—the subtle undercurrent of these representations in opposition to this language that the FDA cannot do its job is, I think, incorrect. I think the FDA has shown its capacity. So, resources, here, is not really an issue at all. Resources may be an issue for us as the Congress. But I can assure you that, as a member of the Appropriations Committee—sitting not on the FDA subcommittee but on the overall committee—I would have no problem funding whatever is needed in this area. I suspect none of my colleagues would either. In fact, this bill is about that, with the PDUFA language. It is about funding the FDA in a more effective way. In fact, I put an adjustment in this bill so we would not end up cutting FDA, as a result of the PDUFA funding from base funding, which is critical.

There was also, I believe, a representation that this prevents the States from providing public information. No, it does not. Under this provision, the States remain free to publicize any information or warning they deem necessary. They simply cannot force manufacturers to post the warning unless the FDA says they agree with it. As I said earlier, what's wrong with that? If a State decides that something needs to be put on a warning label, they can come to the FDA, say, ''This is important.'' The FDA will evaluate it and tell them, ''Yes, it works,'' or, ''No, it doesn't work.'' If you do it another way, you get into this confusing, anarchic situation I spoke about earlier. This is a transient society. People coming from different States are going to see different statements, different warnings. They are not going to know what to think, and that undermines health because it undermines confidence. It's better to have a single agency making that decision because, when you are dealing with health, you have to have confidence.

There are a couple of specific claims—lead in hair dye was one, I believe. In 1980 the FDA approved the use of lead acetate as a color additive, ''safe for use in cosmetics that color the hair.'' That approval was based on extensive testing that showed there was no toxicological risk of lead absorption through the skin from lead acetate in hair dye. Hair dye is one of the most stringently tested products on

the market today. The FDA has the authority to impose any warning it chooses to promote the continued safety use of hair dye. The fact is, the FDA is engaged in the issue and has made the decisions which it deems appropriate for safety. We should have a consistency across this country, based on what they have decided.

Mercury in lipstick and nail polish was also cited as an example. Mercury, through the Code of Federal Regulations, has been affirmatively banned for use in all cosmetic products except eye area preservatives, so I am not sure why this idea was thrown out. Maybe it was a red herring.

''Alpha-hydroxy in face creams causes cancer.'' That was, I believe, the representation. Certainly it has been discussed at considerable length as a concern. In 1995, the Office of Cosmetics and Colors' Director stated that appropriate actions can be taken in product characterization or through proper label warning statements in regards to reactions to alpha-hydroxy. So the FDA stepped up to this issue. He noted that the adverse reactions reported—often allergy-type symptoms—could be due to the pH factor in the product and not the actual concentration. He did not raise any concerns about it causing cancer.

If the FDA is concerned that this type of product is causing cancer, it already is investigating such products generally and why would it leave this product on the market? Obviously, it would not. Alpha-hydroxy has been used literally for 3,000 years, in hundreds of different ways. Just this past June the Cosmetic Ingredient Review of this independent group I mentioned before, unanimously confirmed after public debate that alpha-hydroxy is safe for use in a variety of products. However, if there is evidence now, or that comes to light later to the contrary, I am certain that the decision would be reversed and these products would be prohibited nationally. And they should be prohibited nationally if they are that much of a problem. Why should they be prohibited in just one State? Obviously, they should not be. Why would you protect one State over another State? If the legitimacy of the science is such that it is determined that the product is a problem, then obviously the FDA is going to sign on to that debate at that point, and you are going to have a national ban or national warning.

But to have the people in the State of Washington told one thing and the people in the State of Oregon told another thing and the people in the State of Nevada told another thing—six States in New England that sit right on top of each other such that you can't go shopping without going to one of the other States. At least that is what we hope. We hope that everybody from Massachusetts goes to New Hampshire to go shopping. The fact is, What are you going to do? Are you going to tell them they are going to get a different labeling than they get in Massachusetts? Foolish, worse than foolish, because it undermines confidence in the health care delivery system and the safety and efficacy of it, which has always been the core, always been the core, really, of one of the great strengths of our health care system in this country, which is that we have public confidence in its safety, primarily as a result of the work of the FDA.

If you have a lot of different States moving into this area you have confusion, and confusion leads to lack of confidence and that is why, again—it was not my idea. It was not the committee's idea to go to uniformity. It was a commission, set up by the Congress, with professionals, who said uniformity makes sense. It not only makes sense, it's essential—essential. So the alpha-hydroxy, I think is, again, a matter of hyperbole, maybe, in this debate. Certainly the photographs have been aggressively used. But is it substantively an issue? No. Because the FDA is already involved in that debate, has made initial decisions on that debate, and if it were determined that there were further decisions that had to be made on that product, it would make them.

A side point—I believe there was a statement there is no cosmetic hotline. There is a cosmetic hotline. It's at the FDA. In fact I'll give it to people, 1–800–270–8869. Call it up if you have a question.

As I mentioned, Prop 65 has been addressed.

So, overall this goes, not only to uniformity of cosmetics, that's just one, the uniformity of over-the-counter drugs, uniformity of management of our health care system in the area of drug protection and quality of the drug delivery system in our country is something that has been concluded to be essential. This bill tries to accomplish that and pursues that course.

I am not sure what energizes the opposition with such enthusiasm, except the leader of the opposition is an enthusiastic individual. But I do not feel the facts or the substance support any of the—or even a marginal amount of the presentation made from the other side. The facts and the substance support the position of the committee; the position of the committee, which it passed out 14 to 4, which is that uniformity protects the public. It protects the public health, maintains confidence in the public system, and allows us as a nation to deliver better health care.

I yield the floor to the Senator from Vermont.

Mr. JEFFORDS. Madam President, I commend the Senator. His expertise in this area has helped us greatly and I am sure will lead us to a final conclusion here.

I would also like to point out as another member of a small State, how we would suffer if we had to rely upon others, since we have no resources to do any of this investigation ourself. We would be placed in a position without uniformity to have to rely on some big State or something to tell us what we should or should not do. We really have no ability in ourselves to protect our citizens, that we would like to. I wonder if you would agree with that as well?

Mr. GREGG. I agree 100 percent with what the Senator from Vermont is saying, being from New Hampshire, an equally small State, and knowing it would be confusing to our consumers who cross the borders all the time to purchase products, if they were not able to rely on a nationally regarded, highly expert agency to evaluate their health care products instead of a hodgepodge from the States.

The PRESIDING OFFICER (Mr. ROBERTS). Who yields time?

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

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

The Senator from Vermont is recognized.

Mr. JEFFORDS. Mr. President, I only anticipate speaking for a few minutes. I know Senator COATS will follow me.

This legislation to modernize the Food and Drug Administration and reauthorize the Prescription Drug User Fee Act will, upon enactment, streamline the FDA's regulatory procedures. This modernizing will help the agency review medical devices and drugs more expeditiously and will let the American public have access sooner to newer, safer, and more effective therapeutic products.

I am disappointed that some of my Democratic colleagues are still attempting to block this bill.

I am especially chagrined given the months of bipartisan negotiating that have led to this bill. Each major provision—every drug issue and all but one medical device provision of this measure, represents long-sought agreements with the minority and with the FDA itself. We have made significant concessions on the uniformity provision objected to by the Senator from Massachusetts to ensure that a State may act on cosmetic safety issues in the absence of FDA action. I do not understand this continued objection and delay. In particular, I am disappointed that after countless hours and many concessions to his point of view, the ranking minority member is opposing progress in passage. And I must add that I wish to applaud his willingness—and his tenacity—in working through several difficult issues to reach a consensus on 99 percent of this legislation. In addition Secretary Shalala and the FDA itself, has worked diligently, to reach reasonable, sensible agreements.

This is a good, bipartisan measure that represents moderate, yet real reforms. There is no reason for further delay.

On June 11, prior to the committee markup of S. 830, I received a letter from Secretary Shalala outlining the Department's key concerns. In her letter the Secretary stated:

> I am concerned that the inclusion of non consensus issues in the committee's bill will result in a protracted and contentious debate.

Before and since our committee markup, we have worked hard to achieve a consensus bill. And the measure before us today accomplishes that goal. Bipartisan staff have worked diligently with the agency to address each of the significant nonconsensus provisions raised by the Secretary.

The American people will hardly believe that anyone would suggest that disagreement over 6 pages out of a total of 152 is grounds for holding up consideration of this important bill. A little over a month ago, we all joined together to further the economic health of the country by voting for an historic budget bill, despite our many misgivings, on each of our part, on far more than 6 pages of that legislation. We must do no less here to promote the physical health of our citizens by moving forward to approve S. 830.

In her letter, Secretary Shalala felt the legislation would lower the review standard for marketing approval. Key changes have been made to the substitute to address these concerns. With respect to the number of clinical investigations required for approval, changes were made to assure that there is not a presumption of less than two well controlled and adequate investigations—while guarding against the rote requirement of two studies. The measure clarifies that substantial evidence may, when the Secretary determines that such data and evidence are sufficient to establish effectiveness, consist of data from one adequate and well-controlled clinical investigation and confirmatory evidence, totally under the control of the FDA.

Concerns were raised also about allowing distribution of experimental therapies without adequate safeguards to assure patient safety or completion of research on efficacy. Changes to accommodate those concerns were made. We tightened the definition of who may provide unapproved therapies and gave the FDA more control over the expanded access process.

Other changes will ensure that use of products outside of clinical trials will not interfere with adequate enrollment of patients in those trials and also give the FDA authority to terminate expanded access if patient safeguard protections are not met. The provision allowing manufacturers to charge for products covered under the expedited access provision was deleted also.

In mid-June, the Secretary argued that S. 830 would allow health claims for foods and economic claims for drugs and biologic products without adequate scientific proof.

In response, Senator GREGG agreed to changes that would allow the FDA 120 days to review a health claim and provide the agency with the authority to prevent the claim from being used in the market place by issuing an interim final regulation. In addition, the provision allowing pharmaceutical manufacturers to distribute economic information was modified to clarify that the information must be based on competent and reliable scientific evidence and limited the scope to claims directly related to an indication for which the drug was approved. That problem is taken care of.

This bill was further changed to accommodate the Secretary's opposition to the provision that would allow third party review for devices.

Products now excluded from third party review include class III products, products that are implantable for more than 1 year, those that are life-sustaining or life-supporting, and products that are of substantial importance in the prevention of impairment to human health. In addition, a provision advocated by Senator HARKIN has been incorporated that clarifies the statutory right of the FDA to review records related to compensation agreements between accredited reviewers and device sponsors. I would add that FDA's existing stringent regulations which protect against conflicts of interest in today's third-party review program would apply to the expanded program created by this bill.

Finally, the Secretary was concerned about provisions that she felt would burden the Agency with extensive new regulatory requirements that would detract resources from critical agency functions without commensurate enhancement of the public health. This legislation now gives FDA new powers to make enforcement activity more efficient, adds important new patient benefits and protections, and makes the review process more efficient.

First, we give FDA new powers and clarify existing authority, including mandatory foreign facility registration, seizure authority for certain imported goods, and a presumption of interstate commerce for FDA regulated products.

Second, to assist patients with finding out about promising new clinical trials, we establish a clinical trials database registry accessed by an 800 number. Patients will also benefit from a new requirement that companies report annually on their compliance with agreements to conduct post-approval studies on drugs.

Third, FDA's burden will be eased by provisions to make the review process more collaborative. Collaborative review will improve the quality of applications for new products and reduce the length of time and effort required to review products. We also expressly allow FDA to access expertise at other science based agencies and contract with experts to help with product reviews.

Lastly, by expanding the third-party review pilot program for medical devices, we build on an important tool for the agency to use in managing an increasing workload in an era of declining Federal resources.

In closing, I would echo another part of Secretary Shalala's June 11 letter:

> I want to commend you and members of the Committee on both sides of the aisle on the progress we have made together to develop a package of sensible, consensus reform provisions that are ready for consideration with reauthorization of the Prescription Drug User Fee Act . . .
>
> . . . a protracted and contentious debate . . . would not serve our mutual goal of timely reauthorization of PDUFA and passage of constructive, consensus bipartisan FDA reform.

From the beginning of this process, all of the stakeholders have been committed to producing a consensus measure—and we have accomplished that goal. There is overwhelming agreement on this bill. For those who still oppose a few pages of this bill I can only say that we will continue to bend over backward to accommodate their concerns and to bring about an even closer consensus. Dozens and dozens of changes have been made. The Secretary of Health and Human Services knows that we will continue to work with her—this is not the end of the line. But at some point, the Senate must move on, and we have reached that point, Mr. President.

Mr. COATS addressed the Chair.

The PRESIDING OFFICER. Who yields time?

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

The PRESIDING OFFICER. The Senator from Indiana is recognized.

Mr. COATS. Mr. President, I know this debate today doesn't have the fireworks that the debate on Friday had about FDA reform. I know we are today detailing some of the specifics of the reform legislation that is before us, but I think it is important for us to lay out this record as to why it is important to go forward with FDA reform and what the FDA reform bill that is before this Congress actually proposes.

On Friday, I laid out the why of the need for reform, but I didn't lay out the what it is that we are actually doing to bring about this reform and what is included in this bill. I think it is important for our colleagues and Members to focus on the constructive things that we have done through our exhaustive process in the Labor and Human Resources Committee to conduct an FDA reform bill that can truly bring greater efficiency to this agency.

On Friday, I indicated how much many of us resent the charge that we are somehow gutting the FDA. FDA is an important agency. It is an agency that does protect the health and safety of Americans, and we want to do all that we can to give that agency the kind of resources and the necessary support that it needs to continue that effort. Yet, clearly, I think the case

that was laid out Friday indicates the need for substantial reform of the agency on how it does its business, how it is going to proceed in the future.

Senator KENNEDY from Massachusetts has stated the agency has improved so much in the last few years—and others have said the same thing, including a former commissioner—that it doesn't need congressional reform. I think the facts indicate otherwise. As I outlined on Friday, the agency can't come close to meeting its statutory deadlines for approval of either drugs or devices. There have been egregious examples of delays that have affected people's safety and health, and we want to do everything we can to minimize those delays and to make the agency a more constructive force in terms of dealing with these questions.

The President's latest budget is outlined in this publication I have entitled ''Department of Health and Human Services Food and Drug Administration, Justification of Estimates for Appropriations Committee.'' This is a backup document, material facts in terms of the President's budget decision, as to how much we should fund FDA for the next fiscal year.

Having outlined all of these problems that exist at FDA in approving drugs, in approving devices and expediting the process and even beginning to attempt to meet their statutory requirements, it is astounding that the President's budget for next year does not only not strengthen the agency, it diminishes its effectiveness.

The proposal here plans to cut the agency's total appropriated budget by 8 percent and cut the device center budget—that is the center that reviews and approves medical devices—by 27 percent. This is at a time when, if we need to do anything, we need to increase the funding for the agency or at least find ways to help the agency with outside sources to try to do its job more effectively and more efficiently.

So that alone—I guess this was designed to meet some budget numbers, but it certainly doesn't square with the assertions that the agency is well on the way to solving its problems and, given a little more time and few more resources, those problems will be solved. It also flies in the face, I think, of the facts that have been presented on this floor in terms of the agency's inability to meet its statutory requirements for review and approval of devices.

In just a couple of areas, with respect to the 510(k) submissions, the agency itself predicts that it will complete 6 percent fewer applications in fiscal year 1998 over fiscal year 1997 because it has fewer resources. It also predicts that it will review them 20 percent slower than it did in fiscal year 1996. In fiscal year 1996, it took them an average of 110 agency days for review; in fiscal year 1997, 120 days; for fiscal year 1998 it is predicted to be 130 days and will only complete 40 percent of the submissions in the statutory 90-day period compared with 60 percent last year.

So it makes no sense whatsoever to assert that the agency is well on the way to reforming itself and this legislation isn't needed when the agency's own predictions, own plan for what it is able to do with the resources it has for next year, indicates that it is going in the other direction, not toward reform, not toward more efficiency, not toward meeting their statutory requirements, but in the opposite direction.

With respect to PMA applications, the agency has said, while it expects to receive slightly more PMA applications than in recent years, it will complete 27 percent fewer applications. In fiscal year 1997, they completed 75. But for fiscal year 1998, they predict they will only complete 55, and that they will review those applications 15 percent slower than last year, 250 days of review as opposed to 220 days, that they will complete only 35 percent within the first 180 days—that is the statutory limitation—as compared with 53 percent last year, and they will have a 17 percent increase in the backlog.

If there has ever been justification for reform of FDA, it is in looking at their own estimates of what they will be able to do next year as compared to previous years. And so they are certainly not reforming themselves, certainly not going in the right direction. They are going in exactly the opposite direction.

What we are trying to do here with this legislation that Senator JEFFORDS is leading the effort on—I might add with a lot of bipartisan support, both Republicans and Democrats, as indicated by the cloture vote last week with I think only five votes in support of Senator KENNEDY's support of a filibuster. People want to move forward here. We know that hanging in the balance are decisions that can affect people's health and safety and their very lives. We want to do this in a more efficient and effective manner. So I think there is certainly justification for going forward with this reform bill.

I just point out, for the benefit of my colleagues, that even after extensive debate and markup in the committee, which produced a vote of 14 in favor and only 4 against on the legislation that we are discussing today, there has been considerable negotiation. I have in my hand here a list of 33 separately negotiated compromises to try to accommodate the Senator from Massachusetts, four pages of single-spaced negotiations on 33 separate items to try to address the concern of the Senator from Massachusetts and a couple of other Senators on the committee who thought that perhaps we should have addressed these in committee.

In good faith, we sat down with them and attempted to address their concerns. I know that Senator HARKIN had a particular concern during the markup, and we were very close to getting an agreement on that. And I take responsibility for not accepting it at the time. In retrospect, I think Senator HARKIN was correct. I think what he was suggesting in terms of how we classify medical devices and what devices will be eligible for outside third-party review was correct. And so we notified him of that. We worked with his staff, and we made the change.

So the bill before us incorporates the change that he thought we should have made in committee. In retrospect, I wish I had made that change in committee. I think it probably would have changed the Senator's vote. And I think it would have been wise for us. We would have then had a 15 to 3 vote or maybe even a 16 to 2 vote if that was the case. In review of that action, that was one of the compromises or one of the negotiations that were made.

But to say that, you know, we are standing here on the floor unwilling to look at reasonable requests for some of the concerns and objections of the Senator from Massachusetts, or from others, I think this undermines that assertion. Mr. President, 33 changes have been made to address the concerns raised by the Senator from Massachusetts and from others.

Mr. President, I sincerely hope that we do not have to engage in another filibuster effort as we move to the bill itself and open the bill up for amendment and consideration. With that vote on Friday, only five votes in favor of proceeding with discussion of the bill, I think it would be a disservice to the American people, a disservice to the FDA, and to this body for us to engage in additional lengthy filibusters of this where we have to go to another cloture vote.

So I hope that as soon as we finish the Labor-Health and Human Services appropriations bill, we can move with a definitive timetable which will allow amendments to be offered, hopefully debated with some kind of limitation on the time so we can move and then vote on, and then move forward with this. It makes no sense to continue to delay it.

Mr. President, let me just talk a little bit about what the bill includes—we talked about why we need it—about what the bill includes.

Back in 1990, I authored legislation which would allow some expedited provisions within FDA for review of what is called humanitarian devices. These are devices that affect only a small class of people and really are not in the manufacturer's financial interest to proceed with these devices because there is not a broad enough market for them. But yet there are individuals that can benefit from these devices, and it makes no sense to have the same convoluted, time-consuming process, and particularly some of the specifics of what the FDA requires for approval of these devices, if the sum total of all of that discourages the manufacturer from going ahead because there is such a limited class for whom these devices

are applicable. Then the only losers in this are the people for whom the devices could have improved their quality of life or perhaps have been of great benefit to their health.

And so in 1990 we enacted some humanitarian device provisions. But since that time, as a result of I think what can only be described as bureaucratic delay and inefficiency, since that time only one company has been able to take advantage of this provision. The bill that we have before us expedites certain agency procedures. It allows a waiver of prior hospital review committee approval if the patient would suffer harm or death while waiting for supervised approval. So if a patient is in a position where waiting for approval could result in their death, it allows for the provision for a waiver of the agency procedures.

In addition, the agency is ordered under this legislation to review the application in 75 days, and that is one of those compromises. We originally had 60 days. The agency thought they needed a little more time. We agreed to allow them to have 75 days. And the agency was no longer allowed to arbitrarily force the manufacturer to seek reapproval of the product. In the past legislation the approval was only good for a limited period of time and then they had to go through the whole procedure again to get reapproval. We are saying once the agency approves it, absent evidence to the contrary, that approval sticks.

In addition, the humanitarian device provision is made permanent whereas before it had a sunset. Now, perhaps one of the most important parts of this legislation is the increased access to expertise, outside expertise, to allow the agency to accomplish its reviews and approval process in a much more expeditious timeframe.

We, in the bill, require the FDA to enter into contracts with nongovernmental experts—non-FDA scientists and reviewers—to assist in product approvals. We are still talking about medical devices here to assist in product approvals if the agency determines that doing so would improve the timeliness or the quality of the review.

It is important to understand that the agency is going to retain final approval authority over the review, but for the first time we are requiring them to utilize outside experts, outside resources to help them with that review. They are saying, ''We're overwhelmed. We have all these applications. We don't have enough employees to review it. And that's why we have the delay.'' We are saying, ''There are organizations, institutions, agencies outside of the FDA that can help provide these reviews. We are asking you to look to these to provide some assistance. But you, the FDA, have approval authority.'' In other words, it does not automatically go to an outside reviewing group, but it can go to a group that the FDA approves of.

I do not see what the problem is with that. I mean, final authority rests within the FDA. But if there is an organization outside the FDA that the FDA can contract with or that the manufacturer can contract with, to expedite it, as long as FDA retains approval authority, then why not utilize this? It is going to expedite the process.

The agency currently has a pilot program in place with which it is testing out this concept. We want to expand that pilot program. We would like to require that 60 percent of the nonexempt 510(k) submissions be included in the pilot. We also have language in here which limits the agency's ability to write all the guidance documents for these organizations. Sometimes the writing of the guidance documents takes months, if not years, and in a sense is unnecessary because the agency can allow the outside organization to go forward without that as long as it retains authority.

We are concerned about a manufacturer contracting with an outside agency just to seek approval. And if the manufacturer were allowed the contract with that outside agency, and they just said, ''OK, we reviewed it. Here is the approval. You have to take it,'' there would be legitimate grounds for objection to that. But we have built in total oversight authority and control into the FDA so that they really are not giving up jurisdiction here, they are just utilizing that outside source to help them do their work. It is not like somebody subcontracting work out if they do not have the capacity to do it within their factory or within their business.

But because public safety and public health is at risk here, we want to make sure that FDA retains sufficient authority to oversee all of this. FDA is given the authority in the bill to establish conflict of interest protections because we do not want to get into a situation where there is a conflict of interest between the manufacturer and the review authority. FDA decides what those protections are. FDA accredits the pool of qualified organizations. In other words, a manufacturer cannot go to any organization unless FDA has preapproved that organization, that outside agency for review. They have to get FDA's stamp of approval, good seal of approval, before they are even eligible to do the work to assist FDA.

FDA selects from a pool of two or more accredited parties from whom the product sponsor may select. In other words, FDA says these agencies are certified to do this work; the company selects one or two or a pool of accredited parties, and FDA then makes that selection. FDA has authority to revoke the accreditation if it feels that it is not proceeding according to the way they want it to go. It has the ability to investigate any kind of conflict of interest and it has final approval authority.

Now, this is important, this final approval authority. At one point, I threw up my hands and said the FDA has so much authority why are we going outside? Are we not just defeating the purpose? But in order to get the legislation addressed, we built in all these protections, additional protections, and of course the best protection of all for FDA is that it has final approval authority.

If it does not like what comes back from the outside agency despite all these other steps where it accredits and so forth it can say we do not approve because we do not think the agency did such and such. So it has preapproval authority. It has process approval authority. It has final approval authority. That is plenty of protection.

All of what you hear about how risky it is to American health and so forth, some agency which is not part of the Federal Government is involved in approving a particular product, that is not the case, because we have built into the legislation approval authority for FDA all up and down the line.

Title III improves the collaboration and communication between FDA and the various drug and device companies. There is a list of items that I will not take time to detail.

Title IV clarifies a lot of the rules currently in place and improves the certainty of the process. We address the whole question of policy statements. In recent years, FDA has increasingly developed informal policy statements without involving the public and has failed to make the policies available to the public. In response to a petition from citizens in my State, a group of Indiana manufacturers, the agency published guidance that radically changed these practices. The bill requires the FDA to make this ''Good Guidance Practices'' document permanent by promulgating it as a final regulation in 2 years.

In the area of labeling claims for medical devices, in the past the agency has looked beyond a manufacturers' legitimate labeling claims and requires that the company making the product provide extensive data on a variety of claims for which the company never intended the product to address. The product was designed for a specific purpose. The FDA said we want you to conduct all kinds of trials and provide extensive data for what other things it might be used for, not for what the company is marketing it for, not for what the company has designed it for, but what it might be used for. That has clearly delayed the ability to review products and to get them approved.

The bill clarifies the relationship of labeling claims to approval and clearance of products, and it further limits FDA's review of device submissions to the intended use of the device set forth in labeling.

We tried to build in certainty of review timeframes. I will not go through the details of that, but that is extensive and brings some certainty to the process.

We have placed some limitations on initial classification determinations.

Recently the agency denied due process of law to manufacturers by withholding a substantial equivalence determination even when the product was in fact substantially equivalent whenever the manufacturer was determined to have even a technical defect in the GMP inspection. The bill prohibits the FDA from withholding the initial classification of a device based on failure to comply with unrelated provisions of the act, including good manufacturing practices. The agency is directed to use its ample existing enforcement authority to ensure that products that have the GMP violations at the time of classification do not reach the market.

Title V, improving the accountability. It sets an agency plan for statutory compliance in an annual report so we have a better handle on what is going on within the FDA.

Title VI, better allocation of resources by setting priorities. We exempt certain classes of devices from premarket notification requirements. This really expands on the administration's reinventing Government initiative that exempts class I and class II medical devices that pose little risk by exempting all class I devices, the least risk devices, except those that are important in preventing impairment of human health or presents potential unreasonable risk of illness or injury.

We had extensive discussion on this. This is an area where Senator HARKIN raised what I believe are legitimate concerns and we have tried to address those concerns in this legislation.

We have evaluation of automatic class III designations. Current law requires that all new devices not substantially equivalent to a device already on the market must be automatically classified in a highest-risk category. This does not make sense. If a very simple device that would otherwise be a class I or class II device is not substantially equivalent to a device already on the market, it has to be automatically classified as the riskiest of all devices and therefore falls into class III for the review process, and the approval process, which takes an extraordinary amount of time and requires an extraordinary amount of data, clinical trials and so forth. That is not necessary. So we have changed that so that it does not automatically fall into class III.

It says ''if it is not substantially equivalent,'' what we have done here is allow the agency to make a determination as to which category it would fall in rather than automatically go to class III. So the agencies could look at it and say we think this is class I or class II and is subject to those review procedures rather than automatically moving into class III. It is a sensible change in the current status of how this is handled.

We made changes regarding health care economic information, health claims for food products, and pediatric studies of drugs.

Title VII, we have extended, and of course this is the engine that drives the train here, and another reason why it is so necessary to move forward with this legislation. We have reauthorized the Prescription Drug User Fee Act for 5 years. That is the so-called PDUFA legislation which the prescription drug companies have agreed to support. It is a tax on those companies for the specific purpose of providing extra funds for FDA to hire personnel to expedite the reviews of drugs which are submitted for review and approval to the FDA.

It has worked out very, very well in response to an overwhelmed FDA who could not begin to meet their statutory requirements for review of drugs. A proposal was made that we would enact a tax against the companies submitting the product and the proceeds of that tax will be used to hire personnel and establish procedures whereby we could expedite the approval drugs. It was needed. It was supported. It has worked. We need to reauthorize it because it expires October 1 this year. That is why it is so important to move forward with this legislation.

There are other things in the bill, Mr. President, but in the interests of time I will not detail them unless the President wants me to go through them point by point, but I do not think we have the time still allotted. I know the majority leader is anxious to move back to the Labor-Health and Human Services appropriations bill.

Again, I thank the Senator from Vermont for his leadership on this issue. It has been a cooperative effort that has reached across the aisle and involved Members from both parties in a very substantial number. Hopefully, we can move forward now in getting to the bill itself and the amendments and move this very needed legislation forward. I will be involved in this. I know there are a number of discussions coming up with some of these amendments.

I appreciate the leadership and support of the Senator from Vermont, who is not testing but actually utilizing a medical device to address an unfortunate accident he had just last week.

I yield the floor.

Mr. JEFFORDS. I commend the Senator from Indiana who has been extremely helpful on this whole bill in helping us bring it to conclusion. He made many offers, very reasonable, and I hope we can find the magic one to bring us to fruition very quickly.

I yield the floor and I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk called the roll.

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

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

Mr. JEFFORDS. I have the authority to yield back the balance of the time for the minority, as well as the majority on this side.

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

Mr. JEFFORDS. I suggest the absence of a quorum.

The PRESIDING OFFICER (Ms. COLLINS). The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS ACT, 1998

The PRESIDING OFFICER. The clerk will report the bill.

A bill (S. 1061) making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 1998, and for other purposes.

The Senate resumed consideration of the bill.

Pending:

Gregg amendment No. 1070, to prohibit the use of funds for national testing in reading and mathematics, with certain exceptions.

Coats-Gregg amendment No. 1071 (to amendment No. 1070), to prohibit the development, planning, implementation, or administration of any national testing program in reading or mathematics unless the program is specifically authorized by Federal statute.

Specter amendment No. 1069, to express the sense of the Senate that the Attorney General has abused her discretion by failing to appoint an independent counsel on campaign finance matters and that the Attorney General should proceed to appoint such an independent counsel immediately.

Nickles-Jeffords amendment No. 1081, to limit the use of taxpayer funds for any future International Brotherhood of Teamsters leadership election.

Craig amendment No. 1083 (to amendment No. 1081), in the nature of a substitute.

The PRESIDING OFFICER. The Senator from Minnesota.

AMENDMENT NO. 1087

(Purpose: To increase funding for the Head Start Act)

Mr. WELLSTONE. Madam President, I send an amendment to the desk and ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Minnesota [Mr. WELLSTONE] proposes an amendment numbered 1087.

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

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

The amendment is as follows:

On page 61, after line 25, insert the following:

SEC. . If the amount appropriated to carry out the B–2 bomber program for fiscal year 1998 is more than $579,800,000, then notwithstanding any other provision of law—

(1) the total amount appropriated under this Act to carry out the Head Start Act shall be $4,636,000,000, and such amount shall