

Massiah-Jackson, for the eastern district of Pennsylvania, Federal court. Judge Massiah-Jackson has a very distinguished record on the State Court of Common Pleas in Philadelphia County. Although some questions have arisen, a couple of intemperate remarks, I think, do not disqualify her. If intemperate remarks were disqualifiers, there wouldn't be any Federal judges, there wouldn't be any Senators or anybody in any other positions. Questions have arisen about her sentencing. Out of 4,000 cases, 95 appeals were taken and reversals in only 14 cases. I urge my colleagues to support Judge Fred-erica Massiah-Jackson so we can fill a vacancy on the Federal court.

Several Senators addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

UNANIMOUS-CONSENT AGREE-
MENT—CONFERENCE REPORT AC-
COMPANYING S. 830

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the Senate now turn to the conference report accompanying the FDA reform bill; that it be considered as having been read; that there be 30 minutes for debate equally divided between the chairman and ranking minority member, with an additional 5 minutes for Senator REED of Rhode Island; and that following the conclusion or yielding back of time, the Senate proceed to vote on the adoption of the conference report, all without further action or debate.

The PRESIDING OFFICER. Is there objection?

Mr. HARKIN. Reserving the right to object.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. As I understand this, we now have an hour of debate?

Mr. JEFFORDS. Half hour; 30 minutes.

Mr. HARKIN. And then we will vote.

Mr. JEFFORDS. Right.

Mr. HARKIN. It will be a recorded vote.

Mr. JEFFORDS. No, it will not be. It depends on the body, but it is intended to be a voice vote.

Mr. HARKIN. Thirty minutes of debate, a voice vote and then there will be no pending business after that? What will the pending business be after that voice vote?

The PRESIDING OFFICER. The pending business is the fast-track bill. My understanding of the request of the Senator from Vermont was 30 minutes equally divided, plus an additional 5 minutes for the Senator from Rhode Island.

Mr. HARKIN. Mr. President, since everybody else seems to be getting in line, I wonder if I can amend that to ask unanimous consent that after the disposition of this bill, after the voice vote, which I understand is included in your disposition, after the disposition of this bill, that the Senator from Iowa be recognized.

The PRESIDING OFFICER. Is there objection?

Mr. KENNEDY. Mr. President, I was wondering if we could ask for 40 minutes. I have a couple of Senators on our side who would like time, who have been very active on this issue. Perhaps we could have a few more minutes so that we could accommodate their requests. Would that be agreeable?

Mr. JEFFORDS. Does that include the Senator from Iowa?

Mr. HARKIN. No.

Mr. KENNEDY. No.

Mr. JEFFORDS. Yes. I have an objection to the request from the Senator from Iowa.

Mr. KENNEDY. Mr. President, could we have 40 minutes then on the bill?

Mr. JEFFORDS. I have no objection to the Senator from Iowa being recognized as in morning business for a period of 10 minutes after the vote.

Mr. HARKIN. I understand that after the vote on this bill, the pending bill is the fast-track bill.

The PRESIDING OFFICER. The Senator is correct.

Mr. HARKIN. I ask unanimous consent that after disposition of this bill, the Senator from Iowa be recognized to speak on the fast-track bill. That is all.

The PRESIDING OFFICER. Is there objection to the request?

Mr. JEFFORDS. It would have to be in morning business.

Mr. HARKIN. I don't understand why it has to be in morning business.

Mr. JEFFORDS. It is my understanding from the majority leader that the 10 minutes the Senator is requesting should occur as in morning business. That is all I can tell you.

Mr. KENNEDY. If the Senator would be recognized for 10 minutes—

Mr. JEFFORDS. I believe the Senator would be recognized for 10 minutes, but it would be in morning business.

Mr. HARKIN. I want to ask unanimous consent that the Senator from Iowa be recognized for up to 20 minutes after the disposition of this bill.

The PRESIDING OFFICER. Is there objection to the unanimous-consent request?

Mr. JEFFORDS. Objection. I object.

Mr. HARKIN. Then I will object to that unanimous-consent request.

The PRESIDING OFFICER. Objection is heard.

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. Is there objection? Without objection, it is so ordered.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the Senate now turn to the conference report to accompany the FDA bill, and the conference report be considered as having

been read, and that there be 40 minutes of debate equally divided, and that following the conclusion or yielding back of time, the Senate proceed to a vote for adoption of the conference report, all without further action or debate.

The PRESIDING OFFICER. Is there objection?

Several Senators addressed the Chair.

Mr. HARKIN. Reserving the right to object.

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. REED. Reserving the right to object, I don't know what I did, but a few minutes ago I had 5 minutes. There wasn't 5 minutes—

Mr. JEFFORDS. Then I will amend it to ask unanimous consent to add an additional 5 minutes for the Senator from Rhode Island, Senator REED.

Mr. REED. I thank the Senator.

The PRESIDING OFFICER. Is there objection to the unanimous-consent request?

Mr. HARKIN. Reserving the right to object, I ask unanimous consent to amend that unanimous consent so the Senator from Iowa would be allowed 20 minutes in morning business after the disposition of it.

The PRESIDING OFFICER. Is there objection to the unanimous-consent request by the Senator from Iowa?

The PRESIDING OFFICER. Without objection, the entire unanimous-consent request is agreed to.

FOOD AND DRUG ADMINISTRATION
MODERNIZATION ACT OF 1997—
CONFERENCE REPORT

Mr. JEFFORDS. Mr. President, I submit a report of the committee of conference on the 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, and ask for its immediate consideration.

The PRESIDING OFFICER. The report will be stated.

The legislative clerk read as follows:

The committee on conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 830), have agreed to recommend and do recommend to their respective Houses this report, signed by all of the conferees.

The Senate proceeded to consider the conference report.

(The conference report is printed in the House proceedings of the RECORD of November 9, 1997.)

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, before us is the conference report on S. 830, the Food and Drug Administration Modernization Act. This is really an excellent moment to bring this up and consider what has been accomplished.

This bill represents the first major reform of the Food and Drug Administration in some 30 years. For our committee, it is the second major reform

that we have accomplished this session, the first one being special education, which was the first major reform for that program in some 20 years.

I am very pleased to be able to say to my colleagues that the FDA measure embodies the objectives we originally sought to accomplish.

This legislation achieves two important goals.

First, it helps the FDA to get medicine and medical devices to patients and doctors sooner and safer.

And, second, it will extend and improve the Prescription Drug User Fee Act, commonly known as PDUFA.

I am pleased to report that the conference report has the unanimous support of the conferees. It deserves the unanimous support of this body as well.

The conference report is the culmination of 3 years of hard work by dozens of Senators. It offers the most substantial reform of the Food, Drug and Cosmetic Act in decades and will have a positive impact on the lives of millions of Americans for decades to come.

Think how the world of medicine has changed over the past two or three decades. The law that governs much of that world, and nearly \$1 of every \$3 spent by consumers, must change and adapt as well.

The measure makes scores of changes in the law that ensures the safety of the food we eat, of the drugs we use to fight disease, and the medical devices we use to improve the health of Americans. It will help patients gain access to new therapies sooner without weakening either safety requirements or the authority of the FDA. It gives the agency needed tools and resources to manage an increasing workload more efficiently. In addition, it contributes to our maintaining America's technological leadership in producing pharmaceuticals and medical devices.

Achieving these reforms is a win-win situation for consumers, for the FDA, and for manufacturers. It is a win for patients and consumers, who will gain access to previously unavailable information and obtain better therapy sooner. It is a win for the FDA, which will receive new, sorely needed resources and streamlining and modernization of bureaucratic processes that have not changed in decades. And it is a win for the manufacturers, who will have a certainty that the review and approval processes applied to their innovative products will be applied in a collaborative and consistent manner.

About 10 months ago, Mr. President, we embarked anew on an effort that some characterized as foolish—an effort to modernize the regulatory processes of the FDA. Many thought it could not be done. Some urged we merely extend PDUFA or we tackle only a few issues related to drug regulation and leave the comprehensive modernization to another day.

I am glad we did not choose either of these paths. Instead, we chose to forge

a bill with broad, bipartisan support, one that took a broad view of the changes needed at the FDA.

In that regard, I particularly want to acknowledge the Democratic members of the Labor Committee, and especially Senators DODD, MIKULSKI, WELLSTONE, and MURRAY. They have made countless contributions to this legislation, large and small. Their tireless support has been critical in our success.

This measure is the result of the process to consult with individuals of all points of view and to benefit from the expertise needed to craft legislation on this complex issue. Patients, physicians, consumer groups, the FDA, and the manufacturers of medical devices and pharmaceuticals all contributed to this effort through their participation in hearings and in discussions with the staffs.

This effort was parallel to that of our colleagues in the House of Representatives, which, under the outstanding leadership of Chairman BLILEY, also produced a strong bipartisan bill with overwhelming support. The collaboration and consensus building has continued right up to the present, and the quality of this conference report we are considering today reflects that process.

Mr. President, we would not be here today if it were not for the effort of my predecessor as the chair of the Labor and Human Resources Committee, Senator Kassebaum. Her efforts to advance reform in the last Congress paved the way for our work here today. We owe her an enormous debt.

This year, there have been many Members in both Chambers who have contributed to this effort. Foremost among them has been Senator COATS. The list of provisions of this bill that bear his imprint is far too long to recite. But, as an example, the third-party review provision has been developed under his leadership, and he has played an important role in advancing FDA modernization throughout this process.

Senator GREGG is to be commended for his proposals to streamline the FDA process for consideration of health claims based on Federal research and his amendments to establish uniformity for the over-the-counter, OTC, drugs and cosmetics. Senator MCCONNELL also suggested improvements in the regulation of food.

I am especially grateful to Dr. FRIST. He and Senator MACK led the way to compromise on the issue of the dissemination of medical information to health professionals, an important advance forward.

Senator DEWINE, joined by Senator DODD, offered an important amendment to establish incentives for the conduct of research into pediatric uses for existing and new drugs, a needed change. The bill was improved by Senator HUTCHINSON's amendment to establish a rational framework for pharmacy compounding, which respects the State regulation of pharmacy while allowing an appropriate role for the FDA. And

Senator HARKIN has made many contributions to this legislation.

Finally, the ranking minority member, Senator KENNEDY, has played an important role in bringing this conference report to the floor in a manner that draws support from all quarters.

In the House, Chairman BLILEY and Congressmen DINGELL, BURR, BURTON, GREENWOOD and WHITFIELD have contributed immense energy and leadership in reaching this agreement.

Mr. President, it has been a remarkable year, crowned by a remarkable, bipartisan achievement. And I thank my colleagues for their support.

Mr. President, I yield the floor and reserve my time.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, we have waited a very considerable time for this moment this afternoon in the U.S. Senate as well as action in the House of Representatives and, hopefully, the President's signature in the next few days on a matter of very significant importance to the issues of quality health for the American people.

It has been a very considerable process that we have followed over a number of years to get to this point.

I congratulate the chairman of our committee, Senator JEFFORDS, for his leadership all along this long and difficult passage, because I think without his perseverance, without his knowledge and awareness and his strong commitment on this issue, we would not have this important legislation available for the Senate and for the American people.

Mr. President, one could wonder why it has taken so much time. But we have a natural tension between bringing new innovation and creativity and breakthroughs in the areas of pharmaceutical drugs and medical devices to the market and, on the other hand, protecting the public by approving only safe and efficacious products. We have well-intentioned, brilliant medical researchers in our country who are absolutely convinced that their particular product can provide life-saving opportunities for our fellow citizens, members of our families, who are suffering extraordinary illness. And we have brilliant researchers at FDA that examine scientific information and clinical studies and believe that a very significant potential danger is out there for those who might use a particular pharmaceutical or medical device. Achieving a balance between these two concerns is a difficult task.

The one who has really balanced these conflicting views has been our chairman, Senator JEFFORDS, working diligently with other members of the committee, Democrats as well as Republicans, over a long period of time.

I am convinced that as a result of this legislation the health of the American people will be enhanced through faster availability to pharmaceutical drugs and medical devices while maintaining important protections for the

American people. I join in supporting this landmark FDA conference report.

This is a very important piece of legislation. I think in many respects this will be one of the most important pieces of legislation of this year, and possibly of this Congress.

Mr. President, I want to commend Chairman BLILEY, JOHN DINGELL, as well as Chairman BILIRAKIS, SHERROD BROWN and other members of the House committee for their bipartisan work. We had a good conference where Members were knowledgeable and very committed in terms of finding common ground. I believe as a result of this conference we have an even stronger bill than was passed earlier.

In addition, I commend the Patients' Coalition and Public Citizen, who worked to assure that the needs of patients were fully and fairly considered in the legislation. I appreciate the assistance of the Massachusetts biotechnology and medical device industries, who provided me with valuable insight into these complex issues and their concerns.

I also commend Secretary Shalala, the dedicated men and women at the FDA, and the Clinton administration for their skillful and impressive role in developing so many aspects of these needed reforms.

The most important part of the bill is the extension of the Prescription Drug User Fee Act [PDUFA] which was originally enacted in 1992. PDUFA is one of the most important FDA reform measures ever enacted. It provides funds for FDA to hire hundreds of new reviewers who, in turn, are able to expedite the review and approval of pharmaceutical products. A critical element of PDUFA's success was the establishment of measurable performance targets, which was negotiated between the industry and the FDA.

Under the PDUFA provisions in this bill, in addition to moving products through the regulatory process more quickly, the FDA and industry will also establish a cooperative working relationship and shorten drug and device development times, which now represent the most significant delay in bringing new products to market.

In addition, the bill includes a number of other constructive provisions to enhance cooperation between industry and the FDA to improve regulatory procedures.

I am particularly gratified that the bill includes broader use of fast-track drug approval. The streamlined accessibility procedure now available primarily to cancer or AIDS will be available for drug treatments for patients with all life-threatening diseases.

The bill provides for expanded access to drugs still under investigation for patients who have no other alternatives. The compromise combines protections for patients with expanded access to new investigational therapies, without exposing patients to unreasonable risks.

The bill includes a new program to provide access for patients to informa-

tion about clinical trials for serious or life-threatening diseases.

It provides incentives for research on pediatric applications of approved drugs and for development of new antibiotics to deal with emerging, drug-resistant strains of disease.

It requires companies to give patients advance notification of discontinuance of important products. And in that connection, I am disappointed that we were not able to address the issue of assuring that asthma patients and others will not be put at risk by any abrupt discontinuance of inhalers containing CFCs. I have been informed by FDA that no notice of proposed rulemaking will be issued before this summer, which will give Congress plenty of time to return to this question, if necessary.

Mr. President, the current legislation is an improvement over the bill approved by the Labor Committee earlier this year—that bill included a number of provisions that as originally proposed could have jeopardized public health.

The original bill provided a pilot program for third-party review under which private third parties, certified by the Food and Drug Administration but selected and paid by the manufacturer, would have reviewed the safety and effectiveness of medical devices to determine whether or not they could be sold.

The original proposal would have included many of the most complex and risky devices, such as digital mammography machines, and a host of other devices to detect and treat cancer and other dread diseases.

Under the final bill, these devices may not be included in the pilot program.

The original bill required the Food and Drug Administration to approve devices for marketing even if the Food and Drug Administration knew defects in the manufacturing process would make the devices unsafe or ineffective. The final legislation eliminates this requirement.

The original bill would have prevented the Food and Drug Administration from looking behind the label proposed by a device manufacturer seeking approval of a product, even if the product was false or misleading. The final legislation assures that the Food and Drug Administration will be able to require full and complete information for physicians and consumers on any potential use of the device, not just the one claimed on the label submitted with the application for approval.

And the final legislation preserves the State authority to regulate cosmetics, an area of significant potential hazard to consumers.

The legislation includes an important compromise on information on off-label use of drugs. This compromise will allow companies to circulate reputable journal articles about off-label use of drugs but will ultimately en-

hance the public health and safety because the FDA will be given the opportunity to review, comment on, and approve articles which the companies will circulate. The compromise also requires companies to undertake studies on the safety of their drugs for the specific off-label use and submit applications to the FDA for approval of their drugs for these uses within 3 years. Currently, too many off-label uses of drugs have never been reviewed for safety and effectiveness.

The bill assures the Food and Drug Administration will continue to conduct appropriate environmental impact statements, rather than be exempted from the standards that apply to every other governmental agency.

The compromise included in the bill assures the Nutrition Labeling Act is not undercut or weakened, and any health claims by food manufacturers have to be substantiated.

The legislation maintains existing standards for approval of supplemental use of drugs while streamlining the process by which they can be approved.

In summary, the current legislation is a vast improvement over the bill approved by our committee earlier this year. As a result of extensive discussion since then, including the 3 weeks of debate in the full Senate and our subsequent negotiations with the House, I believe every one of these problem issues has been resolved satisfactorily.

The bill we enact will get safe and effective products to market while assuring the Food and Drug Administration will have the tools it needs for public health. It is a landmark achievement. I urge all of my colleagues to support it.

Mr. JEFFORDS. Mr. President, I yield 4 minutes to the Senator from Tennessee.

Mr. KERRY. Mr. President, my understanding is when this business is completed that Senator HARKIN has unanimous consent for 20 minutes, and I ask unanimous consent, following Senator HARKIN, I be permitted to speak in morning business for 20 minutes.

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

Mr. COATS. Reserving the right to object, I don't intend to object, but I know there is an effort underway to try and bring the omnibus appropriations bill forward and I know a lot of Members are waiting around so they can take that vote. In fact, I was discussing that.

This isn't my call, but I ask the Senator if he could withhold until we can get some understanding of when that vote might be. It might be that it won't come before the Senator's 20 minutes, but if we add time here, 20 minutes there, and an additional 20 minutes, it could delay past the time when they now have commitments. I want to make sure we check that out.

Mr. KERRY. If I could allow my order to stand, I would be sensitive to

the need for a vote, and if need be, I will respond.

Mr. COATS. I accept that, and withdraw my objection.

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

The Senator from Tennessee is recognized.

Mr. FRIST. Mr. President, 3 years of hard work, which was begun by Senator Nancy Kassebaum, have resulted in the passage of the conference report to the Food and Drug Administration Modernization Act of 1997 in the Senate today. This legislation represents the first major, comprehensive reform effort since the initial amendments outlining regulation for drugs in 1962 and for medical devices in 1976. This major reform will help improve the FDA by strengthening its efficiency, accountability, and its ability to safeguard the public health.

There are several provisions contained in this bill that constitute significant reform and improvements to increase the efficiency of product review. For example, this legislation gives FDA authority to increase its access to scientific and technical expertise outside the Agency by allowing interagency collaboration with Federal agencies such as the NIH and CDC, and with the National Academy of Sciences. Also, the bill gives FDA the explicit authority to contract with outside reviewers and expand its current third party medical device review pilot program.

To help alleviate the confusion and frustration that many applicants feel when working with the FDA, the bill will require the FDA to codify evidence requirements for new drug and medical device application submissions and encourages improved communication between the agency and industry. And after 60 years, the FDA will be made more accountable by giving it a mission statement and requiring the FDA to develop a plan of action to meet its requirements under law. The bill will also reauthorize for 5 years the Prescription Drug User Fee Act, known as PDUFA, which has been tremendously successful in improving and speeding the review of much needed pharmaceutical products.

Most importantly, the bill Congress sends to the President will help patients. Individuals with a serious life-threatening disease or condition will have access to a new clinical trial database providing information on investigational therapies. Patients will benefit from the expansion of the fast-track drug approval process for new drugs intended for the treatment of serious or life-threatening conditions built on the existing program for AIDS and cancer drugs. And, patients that have no other alternative but to try an unapproved investigational product will have access to investigational therapies and medical devices.

The bill also includes a provision that will allow reprints of scientifically, peer-reviewed medical journal

articles and medical textbooks about off-label uses of FDA-approved drugs and devices to be shared with physicians and other health care practitioners. This provision will help get life-saving information to doctors, so they can be better informed when making decisions about how to treat their patients.

As a physician, I have used off-label uses to treat my patients in the past and understand its tremendous importance to the patient. Over 90 percent of treatments for cancer patients are off-label and the American Medical Association has estimated that between 40 percent and 60 percent of all prescriptions are for off-label uses of prescription drugs. I would like to acknowledge the tremendous work on this provision during the last few years by my friend, Senator CONNIE MACK and Mark Smith of his staff.

There are a number of people who worked hard to insure passage of this reform effort. I would like to thank Senator JEFFORDS, the chairman of the Labor and Human Resources Committee, for leading the bipartisan effort on FDA Reform in the Senate. I also acknowledge the leadership of Senator COATS, who has done significant work on provisions affecting medical devices in the bill. I also thank Senators GREGG, DEWINE, DODD, MILKULSKI, KENNEDY and HARKIN and their staffs for their hard work in conference. I would like to thank our House colleagues and their staffs who worked with us in conference and I especially recognize the able leadership of the chairman of the House Commerce Committee Representative TOM BLILEY and the ranking member JOHN DINGELL. I would also like to acknowledge and thank Secretary Donna Shalala and the FDA for working with us to help modernize and improve the FDA.

In particular, I would like to thank Jay Hawkins, Mark Powden, and Sean Donohue of Senator JEFFORDS' staff, Vince Ventimiglia of Senator COATS' staff, and Kimberly Spaulding of Senator GREGG's staff who were critical to the development of the bill. I thank them for their dedication and tireless effort on this important bill.

I especially want to thank the tireless work and outstanding leadership of Sue Ramthun, my staff director for health affairs, who has been so instrumental in passage of this bill.

I believe we have made a step in the right direction that will improve patient care and that this bill begins the debate on the long-term investment necessary to move the agency forward in areas such as regulatory research, professional development, and collaborative efforts between Government and academia, and I hope to continue working with my colleagues in a bipartisan manner to further improve the FDA in the following years.

Mr. KENNEDY. I yield 2 minutes to the Senator from Maryland.

Ms. MILKULSKI. Mr. President, I am so happy this day has finally come, in

which the U.S. Senate, and I believe the House, will pass a conference report to modernize the Food and Drug Administration and to bring it into a 21st century framework.

I want to thank Senator JEFFORDS for the patient leadership he has provided in moving this bill, and a special thanks for the collegiality of his staff in working with mine. I also would like to acknowledge the special role that Senator COATS has played. I have enjoyed working with him these last 3 years. We will miss him here as he undertakes next year a new life in encouraging faith-based community groups to become more involved. I think in this bipartisan collegial exchange we have come up with an outstanding bill that is going to save lives, save jobs in the United States of America, give us a product to export around the world that is translingual, transcultural, but certainly helps our people and at the same time puts patients first.

I want to particularly thank my own staff, Lynne Lawrence, for the active work she has done, and Roberta Haerberle and Kerry O'Toole in the excellent backup they have provided.

Why do I like this bill? First of all, we reauthorize the Prescription Drug User Fee Act. What this will mean is we will be able to have 600 reviewers who will be able to work at the Food and Drug Administration making sure that we cut the review time, streamline the process, be able to move drugs, biologics and devices for clinical practice in a more expedited fashion, and at the same time be able to protect safety and efficacy. We do protect safety and efficacy while we move along at a quicker step with more people.

A reauthorization of PDUFA gives us the right people and now we have the right legislative framework to do it. One of the important aspects of this legislation is the streamlining process, and yet at the same time maintaining safety and efficacy upon the approval process so more and more clinical things will be able to go into clinical practice.

I am delighted that this day has finally arrived. It is a great day for patients and physicians. They will get new medical products in a more timely and efficient manner. It is a great day for American business. They won't have to go through unnecessary regulatory hoops to get these new products on the market.

This legislation, carefully crafted between the House and Senate, represents a solid, bipartisan effort. We could not have reached this point without the incredible dedication and persistence of the chairman of the Labor Committee, Mr. JEFFORDS. I thank him for his heartfelt devotion to this bill, and for never giving up. I also thank his staff, Jay Hawkins, Sean Donohue, and Mark Powden for all their hard work.

Let me also acknowledge the tremendous contributions of our ranking

member, Mr. KENNEDY. There is no doubt this is a better bill because of his efforts. I also want to acknowledge the hard work of our counterparts in the House, the chairman of the Commerce Committee, Mr. BLILEY and the ranking member, Mr. DINGELL. Many thanks also go to the fine staff of the Commerce Committee for their excellent work.

Mr. President, I have worked on FDA reform for a number of years. When I was a Member of the House of Representatives, we embarked, on a bipartisan basis, to ensure consumer protection and to prevent dumping drugs that did not meet our standards on Third World countries.

Coming to the Senate, I joined with my colleague from Massachusetts, Mr. KENNEDY, and the Senator from Utah, Mr. HATCH, in fashioning the Prescription Drug User Fee Act [PDUFA]. PDUFA has enabled FDA to hire more people to examine products that were being presented for evaluation and get them to patients more quickly.

The leadership of KENNEDY-HATCH on PDUFA has not only stood the test of time, it has shown that we can expedite the drug approval process while maintaining safety and efficacy. I am so pleased that this successful legislation will be reauthorized for 5 years.

But while PDUFA has made a huge difference, it became clear PDUFA was not enough. More staff operating in an outdated regulatory framework, without a clear legislative framework, was deficient.

That is when we began to consult with experts in public health, particularly those involved in drugs and biologics. While we were considering all this, the world of science was changing. We experienced a revolution in biology. We went from a smokestack economy to a cyberspace economy. We went from basic discoveries in science from the field of chemistry and physics to a whole new explosion in biology, in genetics and biologic materials.

It became clear we needed an FDA with a new legislative framework and a new culture. This is when we began to put together what we called the sensible center on FDA reform. We worked with Republicans and Democrats alike, because we certainly never want to play politics with the lives of the American people.

Senator Kassebaum chaired the committee during this initiative. We took important steps forward. I say to Senator JEFFORDS, you assumed that mantle, and you brought us to the point today where we will achieve final passage of FDA reform. I thank you for that.

What will this legislation do? Why is it so important? It streamlines and updates the regulatory process for new products. It reauthorizes the highly successful Prescription Drug User Fee Act. And it creates an FDA that rewards significant science while protecting public health.

It will mean that new lifesaving drugs and devices will get into clinical

practice more quickly. It will enable us to produce products that we can sell around the world, and through this, save lives and generate jobs.

FDA is known the world over as the gold standard for product approval. We want to maintain that high standard. At the same time, we want to make sure that FDA can enter the 21st century.

This legislation gets us there. It sets up a new legislative and regulatory framework that reflects the latest scientific advancements. The framework continues FDA's strong mission to protect public health and safety. At the same time, it sets a new goal for FDA, enhancing public health by not impeding innovation or product availability through unnecessary redtape that only delays approval.

There has been an urgency about reauthorizing PDUFA. Its authority expires at the end of September. PDUFA has enabled FDA to hire 600 new reviewers and cut review times from 29 to 17 months over the last 5 years. Acting now means that people who have been working on behalf of the American people can continue to do their jobs. We won't risk losing talented employees and slowing down the drug approval process.

Delay would have hurt dedicated employees, but more importantly, it would have hurt patients. Patients benefit most from this legislation. Safe and effective new medicines will be getting to patients quicker.

We're not only extending PDUFA; we're improving it. Currently, PDUFA only addresses the review phase of the approval process. Our legislation expands PDUFA to streamline the early drug development phase as well.

Instead of a carload of paper—stacks and stacks of material—being deposited at the FDA's front door, companies will be able to make electronic submissions. This not only reduces paperwork, but actually provides a more agile way for scientific reviewers to get through the data.

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

The job of FDA is to make sure that safe and effective products get to patients. Our job as Members of Congress is to fund scientific research and to provide FDA the regulatory and legislative frameworks to evaluate new products and make them available to doctors and patients.

This is why I fought so hard for this. This is exactly why I fought for this. My dear father died of Alzheimer's, and it did not matter that I was a U.S. Senator. I watched my father die one brain cell at a time, and it did not matter what my job was.

My father was a modest man. He did not want a fancy tombstone or a lot of other things, but I vowed I would do all I can for research in this and to help other people along these lines.

Every one of us has faced some type of tragedy in our lives where we looked to the American medical and pharmaceutical, biological, and device community to help us.

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

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

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

Do you think I am not for FDA? You think I am not for safety? You think I am not for efficacy? You bet I am. And this is what this is all about. It is not a battle of wills. It is not a battle over this line item or that line item. It is really a battle to make sure that the American people have from their physicians and clinical practitioners the best devices and products to be able to save lives. That's why I'm so pleased that we were able to achieve a bipartisan bill.

So, Mr. President, I thank you for the time. If I seem a little emotional about it, you bet I am. I love FDA. I am really proud they are in my State. I thank God for the ingenuity of the American medical community. And that is why I am so pleased we will be voting on the conference report today.

All of us are happy that this bill will finally pass.

Mr. JEFFORDS. Mr. President, I yield Senator COATS 4 minutes. He is a man whose tenaciousness and ability have made this a better bill.

The PRESIDING OFFICER. The Senator from Indiana is recognized for 4 minutes.

Mr. COATS. Mr. President, as the Senator from Vermont has said, this is the first reform in 30 years at FDA. Obviously, a lot has changed in the industry. New drugs and new devices, new methods of bringing life-saving and health-improving benefits to the American people, and the people of the world. I think it is remarkable, particularly given the fact that it has been nearly 2½, 3 years now that we have been specifically working on this legislation in the committee, through a

number of hearings, through a considerable, lengthy, and complex committee consideration, extensive floor debate. There were very difficult procedural hurdles to overcome and a difficult conference. We now arrive at this point with a bill that, very shortly, will be passed. This has only been done with a bipartisan effort.

I want to return the compliment to the Senator from Maryland. I thank her for that. I am not sure that everyone is going to miss me around this place, given my role in this bill, in trying to bring it forward. But I thank her for her kind words. Senators DODD, MIKULSKI, HARKIN, and WELLSTONE joined Republicans in the committee to produce a bipartisan piece of legislation, and they supported us on the floor. I thank Senator JEFFORDS and his leadership, and Senator GREGG, Senator FRIST, Senator DEWINE, and others on the Republican side, who contributed to the effort in moving the bill forward.

I would be remiss not to acknowledge the extraordinary work of so many staff people that helped to move this forward.

I thank my chief of staff, Sharon Soderstrom, and particularly Vince Ventimiglia, someone whose tireless efforts and thorough knowledge of the issues at hand, and at whose persistence we continued through all of the obstacles placed in the way of this legislation, and it was all accomplished in a manner of courtesy and respect, which is, unfortunately, all too rare around this place. He is an exceptional person. I don't believe we would be here without his efforts—even though he is not here right now; he is probably digging through the bill to make sure all the t's are crossed and the i's are dotted. He was exceptional in this whole effort.

This bill provides help to the Food and Drug Administration, who did not have the capacity nor, I believe, in the past, the managerial leadership that allowed FDA to keep pace with the marvelous breakthroughs we have had in the pharmaceutical and medical device area, which brings life-saving benefits and health-improving benefits to people. Six-hundred additional people, paid for by the industry in a tax against them to reauthorize PDUFA, will help speed up the drug approval process.

Now, for the first time, we give assistance to FDA on medical devices because we have a procedure where outside parties can, with FDA certification, approval and oversight, review medical device applications. This is going to provide for the medical device section what PDUFA provided for the drug section. This was a very critical part of the legislation, and I am pleased that it was retained in our efforts.

We are here and it is a victory for the American people. It took a lot of effort by a lot of people. It is a testament to the persistence of many, some of whom

are speaking here on the floor today. I am proud to play a role in this effort because I believe we are addressing some fundamental concerns, going to the very health and safety and very lives of the American people and people throughout the world. Mr. President, it is with that, I yield whatever remaining time I have.

Mr. KENNEDY. Mr. President, I will yield 5 minutes to the Senator from Rhode Island, but first I yield myself 15 seconds.

I want to give the assurance to my friend and colleague from Indiana, as one that didn't always see eye to eye with the good Senator on some of these issues, I pay tribute to him for the strength of his commitment and the power of his logic and argument, and the passion which he has demonstrated out here.

I have enjoyed his friendship and have always valued the opportunity to exchange ideas with him.

Mr. COATS. I thank the Senator. We have had some interesting exchanges of ideas.

Mr. REED. Mr. President, I believe I have 5 minutes.

The PRESIDING OFFICER. The Senator is correct.

Mr. REED. Mr. President, I rise today in support of the conference report on S. 830, the Food and Drug Administration Modernization and Accountability Act of 1997. This is an important bill with serious implications for the protection of the health of the American people. Although I did not support this bill when it was first considered on the floor of the Senate, I am pleased that significant changes have been made and that this final version of the legislation is worthy of support.

This FDA reform bill is the result of ongoing negotiations both prior to and subsequent to the Labor Committee's markup of the bill. Through this process, a number of provisions that seriously threatened public health and safety were dropped or otherwise resolved. I am particularly pleased that improvements made include important protections to the third party review process. Significant changes and additions also include provisions regarding health claims for food products, health care economic claims, a notice of discontinuance when a sole manufacturer stops producing a drug, and a range of other items.

The original Senate-passed bill contained a provision regarding the FDA device approval process that posed a serious threat to public health. In effect, the Senate-passed bill would have limited the FDS's current authority to ask device manufacturers for safety data. It would have prohibited the FDA from considering how a new device could be used if the manufacturer has not included that use in the proposed labeling. As a general matter, the FDA does not consider uses that the manufacturer has not included in its proposed labeling. However, there are instances when the label does not tell the whole

story. It is these instances—when the label is false or misleading—that my and Senator KENNEDY's amendment addressed.

I was not alone in my concern about this issue. Indeed, this provision was also identified as worthy of a veto threat by the administration. The Secretary of the Department of Health and Human Services said on numerous occasions that if this provision were not changed, that she and other top Presidential advisers would recommend that President Clinton veto this bill.

By accepting the House language on this device labeling issue, the conferees have struck a reasonable compromise that will give the FDA the authority it needs to ensure that medical devices are safe and effective. In this case, the legislative process has worked, and worked well. I commend the conference committee for the sensible compromise they reached on this important issue.

The FDA is responsible for assuring that the Nation's food supply is pure and healthy and to provide a guarantee that drugs and devices are safe and effective. The FDA has an immense impact on the lives of all Americans. Indeed, the FDA's mandate requires it to regulate over one-third of our Nation's products. Few Government agencies provide this kind of important protection for the American people. On a daily basis, the FDA faces the delicate balance between ensuring that patients have swift access to new drugs and devices while guaranteeing that those new products are safe and effective.

The bill we are considering today contains many positive elements. It reauthorizes the important Prescription Drug User Fee Act, one of the most effective regulatory reforms ever enacted. The legislation also includes a number of provisions that will improve and streamline the regulation of prescription drugs, biologic products, and medical devices. I believe that these important reforms to the operation of the Food and Drug Administration will increase its efficiency and speed the delivery of important new medical treatments to patients.

One of the most important elements of this legislation is the aforementioned reauthorization of the Prescription Drug User Fee Act, often referred to as PDUFA. PDUFA established an important partnership between the agency and the industry, and has successfully streamlined the drug approval process.

I am pleased that this bill will provide expedited access to investigational therapies. This provision builds on current FDA programs related to AIDS and cancer drugs. Another important element will allow the designation of some drugs as "fast-track" medications, thus facilitating development and expediting approval of new treatments of serious or life-threatening conditions. The bill will also require the Secretary of the Department of

Health and Human Services to establish a data base on the status of clinical trials relating to the treatment, detection, and prevention of serious or life-threatening diseases and conditions. Patients have long needed access to such information, and I am pleased that this bill provides a mechanism to grant it.

I am also pleased that this bill contains my amendment requiring that within 18 months of the date of enactment, the FDA must issue regulations for sunburn prevention and treatment products. In August 1978, the FDA published an advance notice of proposed rulemaking to establish a monograph for over-the-counter sunscreen drug products. To date—almost 20 years later—while progress has been made, this rule has not been made final.

Sunburn prevention and treatment products can go far to help prevent sun exposure related to skin cancer. The facts on skin cancer are compelling: one person an hour dies of malignant melanoma; half of all new cancers are skin cancers; one million Americans will develop skin cancer this year, making it nearly as common as all other types of cancer combined.

The Food and Drug Administration has a key role in our response to this skin cancer epidemic through the regulation of safe and effective sunburn prevention products that are vital to avoiding skin damage from the sun's rays.

Mr. President, I am pleased that this compromise is a bill that I can support. I look forward to working with my colleagues to oversee the implementation of this important legislation and to ensure that its provisions streamline FDA processes while also protecting the public health of the American people.

I compliment Chairman JEFFORDS, Senator KENNEDY, and many other colleagues in both the Senate and the House of Representatives who have worked hard on this bill together to eliminate many other troublesome provisions in the bill as originally introduced.

Mr. President, again, I support the conference report on S. 830, the FDA reform bill. The challenge throughout this process has been to balance a more efficient, streamlined, and productive FDA with their obligation to protect the public health. It has been a difficult task, but we made remarkable progress over the last several months. At the committee level, there was a serious discussion and debate. I could not support that version because at that time there were still outstanding issues which I thought could jeopardize the public health and safety.

When we reached the floor, there was another serious and productive debate about this legislation. Once again, I felt there were issues that had to be further addressed before I could support the measure. Today, happily, through the work of the conferees and colleagues on the floor today, we have

reached a point where we have legislation that both provides for a streamlined, productive, and efficient FDA, and continues to give FDA the authority to protect the public health.

With specific regard to the debate on the floor, there was one major issue that I felt was very important, and that was to allow the FDA to have the authority to carefully review medical devices that may be used by the public. The legislation at that time circumscribed significantly the ability of the FDA to look beyond the label, look beyond the listed use by the manufacturer, to contemplate possible other uses that may take place when the product is in the stream of commerce. Fortunately, through the work of the conferees, this situation has been resolved.

Indeed, on the floor I offered an amendment with Senator KENNEDY. It did not pass, but I think that effort helped spur a concentrated effort during the conference to develop a legislative formula to give the FDA the power to regulate these devices appropriately.

We have many, many things to be thankful for in this bill. One issue I would like to address, also, which does not rise up, in some respects, to the major reforms, PDUFA or these issues, but it is critically important; that is, the issue of protecting the public with respect to sunscreen products and sunburn products. I am pleased to note that the FDA has been directed to promulgate regulations within 18 months with respect to these products which are sold to the public to protect them from the Sun. This might seem like an innocent product, but, in fact, we are seeing a remarkable growth in incidence of skin cancer throughout the United States. One person an hour dies of malignant melanoma, skin cancer. Half of all the new cancers developing are skin cancer. One million Americans will develop skin cancer this year alone. So we have to begin to focus our attention on those products which are advertised to protect the American public.

Once again, I think this is totally consistent with the role of the FDA. I am pleased that this provision has been included in the legislation.

Let me conclude by saying, again, I believe we have struck the vital balance between an efficient, productive FDA and their obligation, historically and statutorily, to protect the public health. We have done that through the work of Senators JEFFORDS, KENNEDY, and many others. I personally thank them and applaud them for their efforts today.

I would be remiss if I didn't also thank my staff member, Bonnie Hogue, for her help through this entire process. I yield the balance of my time.

Mr. JEFFORDS. Mr. President, I will now yield to the Senator from Utah, who has been a tremendous help over the years on FDA. In fact, I am going to give him all the rest of my time—all 3 minutes.

Mr. HATCH. Mr. President, I wanted to take this brief opportunity to commend Chairman JEFFORDS for a job well done—for producing a bill which will dramatically improve the way the Food and Drug Administration does business as we move into the 21st century.

That has been one of my top priorities during my service in the Senate. I am proud that we are having the opportunity today to vote on this historic legislation which will have so many benefits for my State of Utah.

Utah is the home to over 100 medical device manufacturers, and several pharmaceutical manufacturers as well. We also are the Nation's leading producer of dietary supplements.

The Utah Life Sciences Industries Association, the leading trade association for Utah device and drug manufacturers, has worked closely with the Congress in formulating this legislation, which will have many positive effects for Utah.

On behalf of our Utah drug and device manufacturers, let me thank you Chairman JEFFORDS, and our colleague in the House, Chairman TOM BLILEY, for producing a bill which has encouraged the FDA to work in a more collaborative manner and to get the job done, to get it done professionally and expeditiously, without all the bureaucratic hassles we have experienced in the past.

And on behalf of the dietary supplement manufacturers, and most importantly the 100 million or so consumers—most of whom seem to have called our offices in the last few weeks—let me thank you for making sure that the bill does not undo the Dietary Supplement Health and Education Act in any way and that dietary supplements will remain what they are, food products, not drugs.

Finally, I wish to thank all of the staff who worked literally through the night to make today's passage of the conference report for S. 830 possible. You can be proud of your work.

RETIREMENT OF KATHLEEN "KAY" HOLCOMBE

Mr. HATCH. Mr. President, I could not let this opportunity pass without recognizing the extraordinary contribution that Kay Holcombe has made during almost 25 years of Government service.

Kay, who currently serves as the top health staffer on my good friend Representative JOHN DINGELL's Commerce Committee staff, has worked in a variety of positions in Government, including 6 years on Capitol Hill. Unfortunately for us, she plans to retire at the end of this session—while a fantastic opportunity for her, a regrettable loss the Congress and the Nation.

I grew to know and appreciate Kay in 1984, when I was chairman of the Labor Committee and Kay joined our staff as an American Political Science Association congressional fellow. What Kay

brought to that job was considerable. She is bright, witty, an expert on any issue she studies, and, above all, a true professional who puts good policy above politics.

What I recall most vividly about Kay's period on the Labor Committee was her incredible ability to juggle lots of balls without dropping any of them. I could always count on her to get the job done, and, in fact, to do her job and the job of three others.

I believe that Kay stands out among Government employees for the common sense she brings to any position and for an ability to bring consensus to the most difficult of issues.

We are witnessing that ability today with passage of the conference report on the FDA reform bill, a bill which—quite simply—would not have been possible without Kay Holcombe.

Her work on the Dietary Supplement Health and Education Act also stands out in my mind, where Kay's knowledge and skills as a tactician helped us overcome many an impasse. And, I might add, she was, and I suspect is, the only staffer in the Capitol who understands many of the words we wrote into that act, the most memorable of which was "lyophilize".

Her background as a bench scientist at NIH, with subsequent experience in almost every one of the Public Health Service agencies, is a record of accomplishment and experience that cannot be matched on Capitol Hill.

I, for one, will miss Kay's expertise sorely. And while I am thrilled for her as she enters this challenging new period in her life, and I am saddened at our loss here in the Congress.

To Kay, her husband Frank, her daughter and son-in-law Anne and Tony, and her mother Ginny, I wish the best as the family enters a new period of life after Capitol Hill. I hope it will be happy indeed.

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

The PRESIDING OFFICER. The Senator has 8 minutes 33 seconds.

Mr. KENNEDY. I yield 4 minutes 33 seconds to the Senator from Connecticut.

Mr. DODD. Mr. President, I want to begin by thanking my colleagues who have spent innumerable hours creating a bill that will bring lifesaving drugs and medical devices to the American people more quickly and efficiently, without compromising safety or effectiveness.

First, Senator JEFFORDS is to be commended for his leadership. His staff, most notably Jay Hawkins and Sean Donahue, also deserve our appreciation for their hard work and dedication to seeing this legislation enacted.

Although the process was at times a difficult one, I'm pleased to say that a spirit of bipartisanship and compromise ultimately prevailed, as evidenced by the overwhelming Senate vote of 98 to 2 in September on this bill.

I'd also like to thank my fellow Senate conferees—Senators KENNEDY,

COATS, HARKIN, GREGG, MIKULSKI, FRIST, and DEWINE for their successful efforts to negotiate a workable compromise with our colleagues in the House.

We should take pride in the legislation that has been created—the first substantial update of FDA's rules for regulating drugs and devices since the 1970's.

We should take pride in the fact that this bill will speed critical products to patients without compromising the high safety standards that Americans have come to rely on.

Mr. President, I'd like to speak for a moment about some of the positive reforms contained in this bill.

At the heart of the bill is the 5-year reauthorization of PDUFA, the Prescription Drug User Fee Act—a piece of legislation remarkable for the fact that there is unanimous agreement that it really works.

In the 5 years since this initiative was created, the fees collected under PDUFA have cut drug approval times in half. With its renewal as part of this bill, we can expect drug approval times to drop an additional 10 to 16 months.

In addition, by improving the certainty of product review process, this bill encourages U.S. companies to continue to develop and manufacture in the United States. This bill asks the FDA and industry to begin collaborating early in the approval process to prevent misunderstandings about agency expectations that ultimately could delay a needed product from reaching consumers.

This bill also establishes or expands upon several mechanisms to provide patients and other consumers with greater access to information and to lifesaving products.

For example, this bill will give individuals with lifethreatening illnesses greater access to information about ongoing clinical trials of drugs—information that may offer the only hope for those patients who have not benefited from treatments already on the market.

Based on a bill originally championed by Senators SNOWE and FEINSTEIN, I offered an amendment in committee, which I was pleased to see adopted, to expand an existing AIDS database to include clinical trials for all serious or lifethreatening diseases.

Individuals struggling with chronic and debilitating diseases should not be burdened with the daunting task of searching, without assistance, to locate studies of promising treatments. This database will provide one-stop-shopping to help those patients quickly and easily access vital information.

Mr. President, I am particularly pleased that this bill incorporates the Better Pharmaceuticals for Children Act, legislation originally introduced by our former colleague from Kansas, Senator Kassebaum, and now cosponsored by myself and Senator DEWINE.

This provision addresses the problem of the lack of information about how

drugs work on children, a problem that President Clinton recognized recently as a national crisis.

According to the American Academy of Pediatrics, only one-fifth of all drugs on the market have been tested for their safety and effectiveness in children. This legislation provides a fair and reasonable market incentive for drug companies to make the extra effort needed to test their products for use by children.

I was pleased to join Senator JEFFORDS as the first Democratic cosponsor of this bill. I would thank him again for the hard work and long hours that he and his staff have contributed.

I look forward to joining my colleagues in voting in favor of this legislation.

Let me join here, Mr. President, the chorus of praise for those who have been involved in putting this bill together. It has been a long journey and not always an easy one, but I think the final product is a good one. I commend the chairman of the committee, Senator JEFFORDS, and his staff, Jay Hawkins, Sean Donahue, Jeanne Ireland of my staff, for their hard work and dedication in seeing this process to its conclusion. We swept the Senate with an overwhelming vote of 98 to 2 on what I thought was a good bill. Our conferees worked very hard. I thank Senators KENNEDY, COATS, HARKIN, CRAIG, MIKULSKI, FRIST, and DEWINE for their successful efforts in this area as well.

This is a critically important piece of legislation that will expedite the process of getting needed medicines and devices to patients, without compromising safety or effectiveness. That was a desired goal of everybody here.

Let me, if I can, mention two or three provisions in the bill that I think are worthy of special note. One, of course, is a 5-year reauthorization of PDUFA, which is very, very important. I think it demonstrates the success of the PDUFA and how well it worked over 5 years.

Secondly, I also would like to commend our colleagues for accepting the several mechanisms to provide patients and consumers with greater access to information and to life-saving products. For example, this bill gives individuals with life-threatening illnesses greater access to information about ongoing clinical trials and drugs that could be very, very important to them and their families. By the way, Senator SNOWE and Senator FEINSTEIN deserve particular credit. It was originally their idea that we incorporated in the bill, the Better Pharmaceuticals for Children Act. Former Senator Kassebaum of Kansas originally authored that idea, Mr. President. Senator DEWINE and I included it in this bill. I think it has been improved upon in the conference. It is a very important provision that could make a huge difference for young children and their families who want to have reliable products that will become available to them.

So, Mr. President, let me conclude by again thanking all those who have been involved in this process. Passing this legislation can truly be considered one of the very fine achievements of this first session of this Congress. I look forward to its effectiveness with the American consumer.

APPROPRIATIONS TRIGGER

Mr. BUMPERS. Mr. President, on September 23 of this year, my colleague, Senator COCHRAN, chairman of the Appropriations Subcommittee on Agriculture, Rural Development, and Related Agencies, rose on the floor of the Senate to express objection to a provision of the FDA reform bill that would direct the appropriations subcommittee to provide established levels for salaries and expenses of the Food and Drug Administration through fiscal year 2002. If the appropriations bills did not meet those levels, referred to as trigger, the FDA would not be able to collect or use receipts authorized by the Prescription Drug User Fee Act [PDUFA]. The effect of the provision Senator COCHRAN found so troublesome would have been to place a budgetary gun to the head of the appropriations subcommittee under threat of PDUFA fees not being collected and the Nation's drug approval process placed at risk. As ranking member of the appropriations subcommittee, I shared Senator COCHRAN's concerns, but honestly hoped that the problem he highlighted would be corrected before we were faced with final passage of the conference report on FDA reform. While the conference report before us today does provide some relief in fiscal years 2001 and 2002 from the earlier Senate language, I am still disappointed that more progress was not achieved to inject a greater dose of realism into the expectations of the FDA authorization committees of the House and Senate.

I do not mean to detract from the very important work of the FDA nor to minimize the need to push ahead aggressively with drug approvals. I equally appreciate the concerns of the prescription drug industry, which will be responsible for paying the PDUFA fees, that their considerable contributions will be used to supplement, not supplant, the drug approval process. However, an unfortunate charade has been employed to suggest the language now contained in FDA reform is going to protect, in fact guarantee, increases in the level of Federal funds appropriated for FDA drug approvals. I must point out to my colleagues that the language before us does nothing to assure that very goal and I feel compelled to highlight the provision's failing.

FDA reform would require the appropriations bills for fiscal years 1999 through 2002 to provide levels for the FDA salaries and expenses account at levels no lower than the fiscal year 1997 level adjusted by the lesser of inflation based on the consumer price index or changes in growth of national domestic discretionary spending. The FDA sala-

ries and expenses account contains funding for all activities of FDA, including drug approvals, subject to an appropriation other than amounts for buildings and facilities. The FDA reform legislation contains no requirement that FDA allocate any portion of the salaries and expenses account for drug approvals. Therefore, while our appropriations subcommittee may comply with the full letter of FDA reform requirement, that act alone would provide no assurance to the drug industry that the FDA appropriation would be used as they expect. FDA certainly has other pressing budgetary demands such as the need to account for the rental space arrearage for which the General Services Administration is threatening action against FDA, and continued work on tobacco issues. FDA will also need increased attention in the area of food safety which continuing headlines, such as that appearing in the Washington Post this weekend about the more than 700 people made ill by contaminated food in southern Maryland, will no doubt place greater workload on the agency. An arbitrary appropriation trigger will produce no magic bullet aimed solely at the problem of drug approval backlogs.

Mr. President, I might have a little more understanding for the concerns of the drug industry if there was any merit to their claim that the appropriations subcommittee would not hold faith with their requests. Over the past 10 years, our subcommittee has increased new budget authority for FDA salaries and expenses from \$456,004,000 to \$857,501,000. In fact, I would like the RECORD to reflect the amounts provided in that account on a year-to-year basis since fiscal year 1988 to the present, and I ask unanimous consent the year and amounts be printed in the RECORD.

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

Fiscal year 1988—\$456,004,000.
 Fiscal year 1989—\$487,344,000.
 Fiscal year 1990—\$574,171,000.
 Fiscal year 1991—\$656,519,000.
 Fiscal year 1992—\$725,962,000.
 Fiscal year 1993—\$746,035,000.
 Fiscal year 1994—\$813,339,000.
 Fiscal year 1995—\$819,971,000.
 Fiscal year 1996—\$819,971,000.
 Fiscal year 1997—\$819,971,000.
 Fiscal year 1998—\$857,501,000.

Mr. BUMPERS. I have included this history of funding to show how the amount of appropriations for FDA salaries and expenses has increased every single year since fiscal year 1988 except for the period between fiscal year 1995 and fiscal year 1997 when the level was held at a freeze. I also want to note that the 3-year period connecting fiscal year 1995 and fiscal year 1997 was a period in which the 602(b) allocation to our subcommittee fell by 11 percent. I hope my colleagues see in this history a commitment by our subcommittee to recognize the importance of FDA's activities. Further, I hope my colleagues see that even during a time when near-

ly all other programs under our jurisdiction had to take significant reductions, FDA was held harmless. I believe this history reflects well on the commitment and good faith of our subcommittee.

An obvious result of the provision contained in FDA reform will be continuing further reductions in other programs under the jurisdiction of our subcommittee. Those programs will again have to suffer unless, in the unlikely event, we receive substantial increases in our future 602(b) allocations. There are many, many other programs for which our subcommittee is responsible that are important to people and communities all across the Nation. Our bill provides funding for all activities at the U.S. Department of Agriculture—except the Forest Service—and the Commodity Futures Trading Commission. At USDA alone, there are hundreds of programs essential to rural and urban America that will be harmed, again, if our subcommittee is expected to provide FDA, and FDA only, with inflation increases through fiscal year 2002. USDA programs have already been radically cut by our subcommittee over the past several years while, as noted above, FDA was provided substantial increases or, at least, held constant.

I understand a few other proposals were suggested, and rejected, during consideration of the FDA reform legislation. One proposal was to hold FDA to a freeze, something which we have shown we have done historically. Another proposal would have specifically protected the FDA activities for drug approvals. That approach would have better addressed the concerns I outlined above. I understand this proposal to protect FDA drug approvals was rejected due to objections from nondrug related industries concerned that FDA resources might be transferred from their own specific priority areas to drug approvals. Ironically, that is the same concern I have heard from groups fearful about what the provision in FDA reform will do to USDA and CFTC programs.

Mr. President, at times I feel there is an outright assault on the appropriations process. Too many times in recent years we have seen requirements imposed on the Appropriations Committee by other legislative and procedural vehicles that continuously impairs our ability to respond to agency needs and responsibilities to our states and the American people. Based on administration projections, the trigger mechanism contained in FDA reform would force the appropriations subcommittee to increase the FDA salaries and expense account from the current \$857 to \$876 million in fiscal year 2002. According to the President's 1998 budget, the projected request for FDA salaries and expenses for fiscal year 2002 is only \$691 million. This is a difference of nearly \$200 million, an

amount worthy of deliberate consideration by the appropriations subcommittee. Additionally, the FDA reform provision does not account for the possibility of a tobacco settlement that might replace current appropriations expenditures, consolidation of food safety functions in some agency other than FDA, or other potential changes that would affect, and possibly reduce, the budgetary requirements of FDA. Even though the provision does attach the trigger to the lesser of the consumer price index or changes in the growth of national domestic discretionary spending, there is no guarantee that any increase in overall domestic discretionary totals will be reflected in the 602(b) allocation for our subcommittee.

For the coming year, I can assure my colleagues that I will work with Senator COCHRAN and others to assess the requests of all agencies and departments that will come before our subcommittee. I strongly believe that we have been fair in our setting of priorities and that we will continue to consider the merits of all requests in order to balance the fiscal demands and resources in a manner consistent with our abilities, good judgment, and the recommendations of all Senators.

Ms. MOSELEY-BRAUN. Mr. President, I support S. 830, the conference report for the Food and Drug Administration Modernization and Accountability Act of 1997, and commend the conferees for quickly reaching agreement on compromises that will ultimately improve the FDA and improve the public's access to cutting edge medical technology.

I am also pleased that we are going to pass this important legislation before adjourning for the year. The American people will be much better off as a result of our actions here today. S. 830 is a perfect example of Congress enacting public policy that Americans both want and need.

There is no disagreement as to the caliber of the Food and Drug Administration. FDA is one of the finest regulatory agencies in the Nation and the world. However, the length of time and amount of paperwork required for FDA approval of new products may still be excessive. For many companies, particularly small and startup businesses, the FDA application process is a formidable time consuming obstacle. These barriers exist despite the recent agency improvements to their review process. In some cases, the length and complexity of the process can force companies to launch their products abroad rather than here in America. This is a troubling prospect, particularly given the increasingly competitiveness of global markets.

The FDA, like all other entities, must evolve and adapt to the changing global landscape. Traditional methods of product review are no longer efficient. Industrialized and emerging nations now participate in multilateral trade agreements aimed to reduce

trade barriers. While the U.S. continues as the world's premiere economy, our market dominance is dwindling. A recent Washington Post article indicated that our Nation was far more dominant economically following World War II, when the U.S. economy accounted for more than 25 percent of the world's output, than it is today. Evolving global markets hold untapped potential for product manufacturers. The ability to lucratively launch products abroad will bring pressure on the FDA to harmonize its regulatory policies with other international safety and performance standards. The traditional policies that have made the U.S. the "gold standard" in public health protection threaten to undermine our competitiveness. In order to maintain its status as the gold standard, the FDA must implement policies that encourage the launching of new products in this country, as opposed to Europe, and ensures that the United States maintains its technical and scientific leadership in health disciplines.

Mr. President, S. 830 strikes a delicate balance between protecting the public health, fostering global trade under multilateral agreements, ensuring swift access to new health technology for Americans, and strengthening the U.S. technical and scientific leadership.

The conference agreement reauthorizes the Prescription Drug User Fee Act (PDUFA) for an additional 5 years. PDUFA has been one of the most successful pieces of governmental reform legislation. During the 5 years since we first passed PDUFA, the average approval time for pharmaceutical products has dropped over 40 percent. The pharmaceutical and biologics industries overwhelming support reauthorization of PDUFA because they have seen tangible results from their fee payments. The American public also supports reauthorization of PDUFA because they have received access to innovative treatments in a more timely manner.

S. 830 also makes considerable progress in expediting patients' access to important new therapies and potentially life saving experimental treatments. I have long held that access to alternative medical treatments is an essential part of health care freedom of choice. Under the conference agreement, patients with fatal illnesses will no longer be denied access to potentially life-saving treatments. I am sure that each of my colleagues can recount tales of constituents who have encountered considerable bureaucratic red-tape in their efforts to access a non-FDA approved but potentially life-saving treatment. Although I have great respect for the role that the agency and its employees play in protecting consumers from unsafe and ineffective products, there is a problem when informed Americans cannot get access to desired therapies. S. 830 makes some much needed reforms to enhance that access.

Mr. President, the conference agreement includes reasonable compromises on provisions concerning medical device labeling, dissemination of information concerning drug off-label use, and regulation of device manufacturing. Ensuring that unapproved medical devices not get onto the market that clearly have a different use than the labeling indicates is a vitally important task. This issue alone was responsible for delaying approval of the Senate version of the FDA Modernization Act. I am pleased that the conferees reached an agreement to give FDA the necessary regulatory authority but not subject manufacturers to the whims of various application reviewers. FDA will be given the necessary authority to prevent fraudulent labeling as a means of achieving product approval.

Similarly, S. 830 strikes an appropriate balance between protecting the public interests and allowing manufacturers to share important off-label use information with providers. It would have been a grave mistake to either prevent the distribution of off-label use information or not allow the FDA to play a vital role in ensuring the adequacy of information being distributed by manufacturers. I know that a lot of work went into the compromise reached regarding off-label usage information and the agreement greatly benefits the American public.

Mr. President, I would also like to congratulate patients groups for their steadfast pursuit of this reform. During this year, I have met with countless numbers of my constituents who will immediately have better access to medical treatment as a result of this conference agreement. Each time we met, their message was loud and clear—pass FDA reform now. This is a resounding message that I cannot ignore.

S. 830 builds on the reforms that the FDA has already put into place over the past 5 years. The agency has taken a number of steps to streamline administrative functions and work better with industry and consumers to facilitate the availability of cutting edge medical technology. The success that FDA has achieved in reducing the time to review new drugs and get potentially life-saving therapies on the market is laudable. However, more improvements are needed and S. 830 moves another step in the right direction.

My support for S. 830 is not a complete endorsement of the bill. There are a number of important provisions absent from this legislation. I am particularly concerned that the bill does not adequately address food safety, which will certainly emerge as a major public health issue. Most of the recent criticism of the FDA has focused on the biologics and medical technology areas. Regulation of imported food products will probably be the pressing issue of the next millennium. As more imported agricultural products find their way to American tables, there

will be more pressure upon FDA to act to prevent tainted products from getting to the market. The recent problems with tainted meat and poultry highlight this need for greater focus on food safety. Hopefully, Congress can revisit the shortcomings in food safety standards next year.

Nonetheless, S. 830 is a good start down the road of FDA reform. This conference agreement is better than the bill passed by either the House or Senate and considerably better than the bill developed last year. I am happy to have a conference agreement that I can support and that I truly believe moves the country in the right direction. S. 830 is good for patients, good for the industry, and good for the Nation's global competitiveness. I hope that my colleagues will join me in supporting this important legislation.

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

The PRESIDING OFFICER. The Senator has 5 minutes 48 seconds.

Mr. KENNEDY. I yield myself 5 minutes.

Mr. President, I just want to review once again, very briefly, the principal provisions in the legislation which I think are enormously constructive and positive.

First of all, building on the PDUFA record, this provision that we have enacted expands the existing program by setting additional performance targets. It puts special emphasis on expanding early cooperation and FDA and the industry, which will reduce the development time, so that the drug development process, not just the regulatory review process, can be expedited. That is very important.

There are many other positive achievements in the legislation. I am particularly gratified, as I mentioned earlier, with the broader use of the fast-track approval. The streamlined accessibility procedure now available primarily to patients with cancer or AIDS will also be available for drug treatments for patients with any other life-threatening diseases. This bill also provides for expanded access to drugs still under investigation for patients who have no other alternatives. The compromise combines protections for patients with expanded access to new investigational therapies, without exposing patients to unreasonable risks.

The bill includes a new program to provide access for patients to information about clinical trials for serious or life-threatening diseases.

It provides incentives for research on pediatric applications of approved drugs and for development of new antibiotic to deal with emerging, drug-resistant strains of diseases.

It requires companies to give patients advance notification of discontinuance of important products. And in that connection, I am disappointed that we were not able to address the issue of assuring that asthma patients and others will not be put at risk by any abrupt discontinuance of

inhalers containing CFC's. I have been informed by FDA that no notice of proposed rulemaking will be issued before this summer, which will give Congress plenty of time to return to this question, if necessary.

The bill includes many measures that will reduce unnecessary regulatory burdens and appropriately clarify its authority.

These provisions, as well as others, are extremely constructive and will be enormously helpful to the American consumer.

Mr. President, I would like to mention some of the staff who have been a crucial part of this whole process. Those members of our staff on the Labor Committee: Nick Littlefield, David Nexon, Diane Robertson, Debbie Kochevar, Pearl O'Rourke, Jim Manley, Leslie Kux, and Carrie Coberly.

Bonnie Hogue with Senator REED, Sabrina Corlette and Peter Reinecke with Senator HARKIN, Jeanne Ireland with Senator DODD, Deborah Walker with Senator BINGAMAN, Anne Grady with Senator MURRAY, Linda DeGoutis with Senator WELLSTONE, Lynne Lawrence with Senator MIKULSKI, and Anne Marie Murphy with Senator DURBIN.

With the Republicans are the following staff:

Jay Hawkins, Sean Donohue, and Mark Powden, with Senator JEFFORDS; Vince Ventimiglia with Senator COATS; Kimberly Spaulding with Senator GREGG; Sue Ramthun with Senator FRIST; and Saira Sultan with Senator DEWINE.

Also, the House staff were instrumental in the success of this conference:

Kay Holcombe, as Senator HATCH has indicated, worked with us when she worked with Senator HATCH on the committee years ago and was very constructive during this process. Howard Cohen, Rodger Currie and Eric Berger also with the Commerce Committee, and Paul Kim on Congressman WAXMAN's staff.

And I thank the FDA staff: Bill Schultz, Peggy Dotzel, and Diane Thompson.

I thank them all very much for all of their help and their involvement.

PRIVILEGE OF THE FLOOR

Finally, I ask unanimous consent that Tom Perez, a Justice Department detainee on the Judiciary Committee, be given floor privileges for the remainder of the session.

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

Mr. KENNEDY. Mr. President, how much time remains?

The PRESIDING OFFICER. One minute forty-five seconds.

Mr. KENNEDY. Mr. President, we again thank our colleagues and friends and look forward to the passage of this legislation.

If there are no other comments, I would be prepared to yield the remainder of our time.

Mr. JEFFORDS. Mr. President, I yield the remainder of my time.

The PRESIDING OFFICER. The question is on agreeing to the conference report.

The conference report was agreed to.

Mr. KENNEDY. Mr. President, I move to reconsider the vote by which the conference report was agreed to.

Mr. JEFFORDS. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. JEFFORDS. Mr. President, I would like to take a moment to thank the staff who have worked to make this bill possible. In the office of Senate Legislative Counsel, Robin Bates, Elizabeth Aldridge, and Bill Baird worked tirelessly to produce countless bill drafts and amendments. I would also like to commend House Legislative Counsels David Meade and Pete Goodloe for their work on the conference report.

The staff at CRS, especially Donna Vogt, and at GAO, including Bernice Steinhardt deserve thanks for their willingness to provide essential information and documents on extremely short notice.

The staff to the members of the committee contributed greatly to the success of this bill. Vince Ventimiglia with Senator COATS' staff worked closely with mine in a true partnership on all aspects of S. 830.

In addition, Kimberly Spaulding with Senator GREGG, Sue Ramthun with Senator FRIST, Saira Sultan with Senator DEWINE, and Kate Lambrew-Hull with Senator HUTCHINSON all played important roles in fashioning compromises on key provisions of this conference report, as did Dave Larson and Barry Daylin.

Similarly, three staffers for members of the minority on the committee played pivotal roles throughout the process—from the premarkup stage through the development of this conference report. Their assistance was critical to making this bill a bipartisan success.

Lynne Lawrence with Senator MIKULSKI deserves special mention in recognition of her hard work both in the last Congress and in this one on FDA reform. Following passage of this conference report, Lynne will be leaving Capitol Hill. I am extremely pleased that she will be leaving on a high note, and we all wish her the best with future pursuits. Jeanne Ireland with Senator DODD and Linda Degutis, a fellow with Senator WELLSTONE also provided invaluable assistance throughout the process.

Finally, I thank, of course, the Labor and Human Resources Committee majority and minority staffs. On the minority staff, I would like to thank Nick Littlefield and David Nexon and two minority fellows Diane Robertson and Debbie Kochever.

On my own staff, I would like to thank the majority staff director Mark Powden, Jay Hawkins, and majority fellow Sean Donohue. All have devoted substantial portions of their time over the past 10 months to this effort.

Jay Hawkins, in particular, has been key to making this conference report a reality. His tireless efforts, his unfailing good humor, and his patience have allowed this process to maintain steady forward progress to a highly successful outcome.

The round-the-clock work, particularly over the past few days, of all the staff involved in the conference is greatly appreciated.

Mr. President, I could not be happier with this moment and at this time will happily leave the floor.

Mr. HARKIN addressed the Chair.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. TORRICELLI. Mr. President, will the Senator from Iowa yield?

Mr. HARKIN. I yield without losing my right to the floor for a unanimous-consent request.

Mr. TORRICELLI. Mr. President, I ask unanimous-consent that at the conclusion of the remarks of the Senator from Iowa, I be able to address the Senate for 20 minutes.

The PRESIDING OFFICER. The Senator should be aware that under a previous order the Senator from Massachusetts is to be recognized after the Senator from Iowa.

Mr. TORRICELLI. Then I will amend my unanimous-consent request that after those Senators are recognized under the unanimous-consent request that I be a able to address the Senate for 20 minutes.

Mr. JEFFORDS. Reserving the right to object, I make a point of order that a quorum is not present.

Mr. HARKIN. Mr. President, I have the floor, I believe, and I yielded only to the Senator for the purpose of a question.

The PRESIDING OFFICER. The Senator from Iowa is recognized, and he has the floor.

The unanimous-consent request from the Senator from New Jersey is on the floor. Without objection, it is so ordered.

Mr. JEFFORDS. I object. I make a point of order that a quorum is not present.

Mr. HARKIN. Mr. President, I believe I have the floor. I only yielded for the purpose of a unanimous-consent request.

The PRESIDING OFFICER. The Senator from Iowa has the floor.

Mr. HARKIN. Mr. President, I will reclaim the floor in my own right and let these Senators work it out if they want to come back.

The PRESIDING OFFICER. The Senator from Iowa has the floor and is recognized for 20 minutes. He may proceed.

Mr. HARKIN. Thank you, Mr. President.

FAST-TRACK LEGISLATION

Mr. HARKIN. I want to speak a little about the fast-track bill that is before us and which is scheduled to be voted on in the House tonight.

I doing so, I reread the President's speech on September 10 that he gave on fast track. He gave it at the White House, I believe in the East Room.

I found some interesting remarks in the President's speech. He talked about change. He said, "As we have done throughout our history, we have taken our Nation and led the world to the edge of a new era and a new economy."

He is absolutely right.

He talked about the economy, and how we are the largest producer of automobiles, agricultural exports, semiconductors, steel, and other items.

Then, closer to the end of the speech, the President said, "As we continue to expand our economy here at home by expanding our leadership in the global economy, I believe that we have an obligation to support and encourage core labor standards and environmental protections abroad."

He further said in his speech—this is the President's speech on September 10—"Our goal must be to persuade other countries to build on the prosperity that comes with trade and lift their standards up. As we move forward, we must press countries to provide the labor standards to which all workers are entitled," et cetera.

The President said in his speech that we are part of a new world economy. I would say, yes, Mr. President, we are also part of a new world community—a new world community the likes of which we have never seen because of the rapid dissemination of information, the globalization of communication, the instantaneous transmission of images and voice, transmittal of information around the globe. People living in the remotest villages of Africa, China, or Asia now know what is happening in other parts of the world. No longer is it kept from them. Increasingly the people on this planet are going to demand their human rights, their fundamental basic human rights, their individual freedoms. That is what Tiananmen Square was all about.

Yes, Mr. President, you were right. You were right, Mr. President, to say to President Jiang of China that China was on the wrong side of history at Tiananmen Square. You were right, Mr. President. But, Mr. President, to the extent that we have a trade bill before us that limits your authority to negotiate under fast track regarding exploitative child labor, that weakens the provisions dealing with child labor, then you, Mr. President, and this country are on the wrong side of history.

Those may sound like strong words, but as I have read the President's speech, and as I read the fast-track bill before us, one can only come to one conclusion. This legislation takes us in the wrong direction. It severely limits the ability of the President and our trade negotiators to address the issue of exploitative child labor in trade negotiations. That is right. This bill limits the President's authority. The 1988 bill didn't. I will explain this.

In this bill, child labor is included in a category of issues under the heading

"Regulatory Negotiations." Under this heading in the bill, negotiations under fast track on child labor may only cover—I will read it—"the lowering of, or derogation from, existing * * * standards."

That is all. The language does not allow negotiations aimed at getting a country to agree to raise its child labor standards, no matter how weak or non-existent they may be.

Furthermore, the negotiations may only address cases where the other country's lowering of, or derogation from, its child labor standards is—and I will read it directly from the bill—"for the purpose of attracting investment or inhibiting United States exports."

I want to make sure my colleagues understand that.

First of all, the President may only negotiate regarding the lowering of, or derogation from, existing labor standards. He can't negotiate on strengthening them. And he may only negotiate regarding the situation where the lowering of, or derogation from, standards is done for the purpose of attracting investment or inhibiting U.S. exports.

What about the case where a country lowers or fails to enforce its child labor standards for the purpose of producing goods at lower cost so it can ship them to the United States? That situation is not mentioned in this language, so the President does not have authority to negotiate on that basis according to the terms of the bill. Allowing the use of exploitative child labor to hold the price of goods down is unfair competition, plain and simple, but a country could do that.

Exploitative child labor in foreign countries unfairly puts competing firms and workers at a disadvantage in the United States and in other countries that do not allow it. Yet, the language in this bill does not indicate that President would have the authority to address that kind of unfair competition against U.S. companies and workers in negotiations and agreements under fast track. As long as the other country is not lowering or derogating from its standards for the purpose of attracting investment or inhibiting U.S. exports, our negotiators cannot negotiate to end this unfair competition.

The bottom line is that this bill limits the President's authority to seek agreements that would curtail exploitative child labor.

It is important to clarify this point. I think people will say "HARKIN, what are you talking about? How could it limit the President's authority?"

Well, let us examine that question.

Under this bill, the President actually has less authority to negotiate regarding child labor, and submit an agreement to Congress under fast-track procedures, than he had in the most recent fast-track legislation, which was contained in the Omnibus Trade and Competitiveness Act of 1988—the last bill laying out fast-track procedures that we voted on and which this Senator voted for.