

Mr. LIVINGSTON. I just wanted to assure the gentleman that it is my intention that not only our joint leaderships, but that the gentleman and I and the respective subcommittee chairmen from both the majority and the ranking minority members have full opportunity to review all proposals before they hit the floor and that the staff has adequate time to read it and make sure that mistakes are not made.

The fact is that the committees are working, and especially, I think, the Committee on Appropriations in this instance is working as expeditiously and efficiently as is absolutely possible under rather uncertain conditions, and I am proud of the job we are doing. I am just not able to give the gentleman any guarantees about the ultimate schedule.

Mr. ROGERS. Mr. Speaker, will the gentleman yield?

Mr. OBEY. Again, further reserving the right to object, Mr. Speaker, I yield to the gentleman.

Mr. ROGERS. Mr. Speaker, the gentleman from Wisconsin and the chairman of the committee is correct. Just on the Commerce-State-Justice bill it will take 12 or 13 hours of staff time just to read through, to proofread, that one bill.

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So we need a lot of lead time. We have been trying to pre-read the portions that are more or less agreed to. But even in spite of that, it is going to take that long a period of time, just to read on the one bill.

Mr. OBEY. Mr. Speaker, continuing my reservation, let me simply make this point, I think we have terrific staff on the Committee on Appropriations. But as good as they are, they are likely to make some significant mistakes if they are reading out these bills when they have been strung out through night after night with virtually no rest.

It seems to me that if there is not a reasonable expectation that we can finish, that we ought to recognize that so that Members can get some sleep. My observation is that this place usually works better and the Members get along better with each other when their tails are not dragging, and everybody's are, as far as I can see right now, and certainly the staff.

Mr. Speaker, we are not going to get any more information, but what we have been told so far is that the fast-track legislation is going to come up sometime tonight, that we may or may not be moving ahead with other appropriation bills, and, if we do move ahead with them, they may or may not be in an omnibus form, and we do not really have any idea at this point how long it is going to take to read out these bills or to bring them to the Congress in a form which is safe for Members to vote on.

Under those circumstances, I would simply say I am dubious that a one-day CR is going to solve anything.

Mr. Speaker, I withdraw my reservation of objection.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

The text of House Joint Resolution 104 is as follows:

H.J. RES. 104

Resolved by the Senate and House of Representatives of the United States of America in Congress assembled, That section 106(3) of Public Law 105-46 is further amended by striking "November 9, 1997" and inserting in lieu thereof "November 10, 1997", and each provision amended by sections 122 and 123 of such public law shall be applied as if "November 10, 1997" was substituted for "October 23, 1997".

The SPEAKER pro tempore (Mr. PETRI). Without objection, the joint resolution is considered and passed.

There was no objection.

A motion to reconsider was laid on the table.

CONFERENCE REPORT ON S. 830, FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997

Mr. BLILEY. Mr. Speaker, I move to suspend the rules and agree to the conference report on the Senate 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.

(For conference report and statement, see prior proceedings of the House of today.)

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Virginia [Mr. BLILEY] and the gentleman from Michigan [Mr. DINGELL] each will control 20 minutes.

The Chair recognizes the gentleman from Virginia [Mr. BLILEY].

GENERAL LEAVE

Mr. BLILEY. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous remarks on the conference report on S. 830.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Virginia?

There was no objection.

Mr. BLILEY. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, today we stand on the verge of medical advances that will revolutionize the quality of health care in America, and today we make the promise of better medicines and treatments a reality for millions of Americans. The bipartisan conference agreement reached earlier this afternoon to modernize the FDA is a victory for American patients.

After almost 3 years of work by the Committee on Commerce, we have delivered a piece of legislation that will do more to help patients than any legislation passed in decades. When we first discussed the need to modernize the FDA in 1995, we knew that outdated rules were slowing down the vital work of the agency and that patients

were the ones who were suffering. Vital new medicines and medical devices were not getting to the patients who needed them quickly enough.

As I said back then, it is not right that American patients are having to go overseas to get the care they need to stay alive. Congress had to act. Our FDA reform team conducted the most extensive legislative outreach in recent memory. Literally thousands of hours were devoted to reaching out to all corners of the country. Our goal then was to achieve a balanced legislation, legislation that the President would be eager to sign.

Today we have fulfilled our objectives. This agreement will result in a better and more efficient FDA. It will enhance the safety of the medicines we take and the medical devices we use and the foods we feed our children. Medicines will be approved faster, medical devices will get to people sooner, and those with life-threatening diseases will have access to the best experimental new drugs that science can provide. That is important, because when you are sick, when you are suffering, every minute counts.

Some of my colleagues deserve special praise and thanks. Their work on this issue has been tireless, and the credit for this legislation belongs to them. The members of our FDA reform team, the chairman of our Subcommittee on Health and Environment, the gentleman from Florida [Mr. BILIRAKIS], along with the gentleman from Pennsylvania [Mr. GREENWOOD], the gentleman from North Carolina [Mr. BURR], the gentleman from Texas [Mr. BARTON], and the gentleman from Kentucky [Mr. WHITFIELD].

I also want to reach across the aisle to thank our friends, the gentlewoman from California [Ms. ESHOO], the gentleman from New York [Mr. TOWNS], and the gentleman from Texas [Mr. HALL], and all our ranking members, the gentleman from Michigan [Mr. DINGELL] and the gentleman from Ohio [Mr. BROWN], for their invaluable contributions to this effort. And to our colleagues over in the Senate, Senators JEFFORDS and KENNEDY.

I also want to thank my committee staff, Howard Cohen, Eric Berger, and Roger Currie, as well as the personal staffs of the FDA reform team, Patti DeLoache with the gentleman from Florida [Mr. BILIRAKIS], Mora Guarducci with the gentleman from Pennsylvania [Mr. GREENWOOD], Alyson Neuman with the gentleman from North Carolina [Mr. BURR], Beth Hall with the gentleman from Texas [Mr. BARTON], Pete Bizzozero with the gentleman from Wisconsin [Mr. KLUG], and Tim Taylor with the gentleman from Kentucky [Mr. WHITFIELD].

I would also like to extend my gratitude to the able and hard-working legislative counsels who helped craft this measure: David Meade, Pete Goodloe, and Liz Aldridge.

Finally, I would like to express my sincere gratitude for the hard work and dedication of minority counsel Kay Holcombe. She is leaving us at the end of this session, and, believe me, she will be greatly missed, not just by the gentleman from Michigan [Mr. DINGELL] but by this chairman as well.

They should all be proud of a job very well done. The American people thank them, and so do I.

Mr. Speaker, I reserve the balance of my time.

Mr. DINGELL. Mr. Speaker, I yield myself 4 minutes.

(Mr. DINGELL asked and was given permission to revise and extend his remarks.)

Mr. DINGELL. Mr. Speaker, from the beginning, our goal in reforming Food and Drug has been to benefit patients and people. We can talk about a lot of things, but when we get right down to it, the question is keeping people safe, seeing to it that foods, drugs, cosmetics, devices and other things which are regulated by Food and Drug which are absolutely essential to the life of people are safe and that they come quickly to market.

The bill does a number of things. First, it reauthorizes the Prescription Drug User Fee Act. This is a program that has given FDA the resources needed to approve drugs in a way that none of us would have anticipated 10 years ago. Today, new drugs are reviewed by FDA in a year or less. Drugs essential for people with serious and life-threatening illnesses are reviewed in 6 months or less. This is enormous progress.

The bill authorizes a clinical trials data bank that would be established through the National Library of Medicine at NIH. Patients with serious illnesses will be able to get critical information about experimental therapies being tested in clinical trials.

The bill codifies a number of procedures that FDA developed over the years to expand access to experimental drugs and medical devices to people with serious illnesses and emergency situations through so-called expanded access protocols.

Market incentives are included in this bill to encourage companies to produce pediatric studies of drugs, so that the labeling of these products will be useful to pediatricians. Today, most of these drugs prescribed for children have no proper pediatric label. The bill remedies this situation. I expect the FDA will use this new authority carefully to avoid detrimental impact on the availability of generic drugs.

The medical device provisions of the legislation have been the most controversial and difficult. I am pleased that the conference report includes provisions based on a careful consideration of two goals: Expediting the availability of new, sophisticated products; and protecting patients from medical devices that are either unsafe or not effective.

The bill gives the FDA the ability to streamline its evaluation of medical

devices, but without compromising its ability to make absolutely sure that the products are safe, that they work the way they are supposed to be, and are labeled properly.

I am also pleased the conference report retains two significant provisions from the House bill. One makes certain FDA will not be forced to approve a product the agency knows the manufacturer cannot make according to good manufacturing practices. The second ensures that FDA can evaluate all aspects of a new medical device, not just the ones that the manufacturer chooses to include in the label.

I am concerned, Mr. Speaker, that while we are busy reforming the Food and Drug Administration, we put a number of burdens on the agency and that the potential to interfere with the review and approval of new products is real. I am also concerned that the speed which is required may have an element of risk for the consuming public for patients and for people involved in health care.

Mr. Speaker, I want to commend and thank my good friend and colleague, the gentleman from Virginia [Mr. BLILEY], for his excellent work on this important legislation and for his leadership in what has been a truly bipartisan effort.

In addition, the work of the subcommittee chairman, the gentleman from Florida [Mr. BILIRAKIS], was essential to the success of the effort, as were the labors of the gentlewoman from California [Ms. ESHOO], the gentleman from Texas [Mr. BARTON], the gentleman from California [Mr. WAXMAN], the gentleman from Ohio [Mr. BROWN], the gentleman from Pennsylvania [Mr. KLINK], the gentleman from North Carolina [Mr. BURR], the gentleman from Pennsylvania [Mr. GREENWOOD], and the gentleman from Kentucky [Mr. WHITFIELD].

Our Senate colleagues, Senators JEFFORDS, KENNEDY, and COATS worked very hard.

The staff of the committee, Howard Cohen, Eric Berger, Roger Currie, and the staff of the conferees, Kevin Brennan, Paul Kim, Emmett O'Keefe, Pattie DeLoache, Alyson Neuman, Beth Hall, Mora Guarducci, and Tim Taylor were valuable and important in the accomplishments of this legislation, as were the tireless efforts of David Meade and Peter Goodloe of House Legislative Counsel and Elizabeth Aldrich of Senate Legislative Counsel.

I want to refer to the work done by my dear friend and our valuable staff member, Kay Holcombe, who will be leaving us at the end of this year. Simply put, without her labors, we would not have achieved the consensus FDA bill that we have before us today. It took a great deal of effort on her part, her unquestioned integrity, her considerable intelligence, her extensive expertise, and her legislative tenacity to help us get to the point where we are.

The legislation is a fitting capstone to the labors of all who have partici-

pated, but especially to Kay's distinguished career in public service and her 4 years with the staff of the Democratic part of the committee. Her retirement is a loss to all.

This is a fine piece of legislation. I urge my colleagues to support it.

Mr. BLILEY. Mr. Speaker, I yield 5 minutes to the gentleman from Florida [Mr. BILIRAKIS], the very able chairman of the Subcommittee on Health and Environment of the Committee on Commerce.

Mr. BILIRAKIS. Mr. Speaker, I thank the gentleman for yielding me time.

Mr. Speaker, I rise, of course, in support of the conference report. As chairman of the subcommittee of jurisdiction, I believe the conference report represents our best effort in many years to improve the health and safety of all Americans.

In short, this comprehensive law will chart a new course in public protection, allowing the Government to fulfill its obligation to protect the public health without undue delay, while ensuring that we preserve the economic incentives inherent in our free market system. Although it has taken many months, indeed, many years of hard work, this legislation represents a bipartisan effort to work through our political differences and resolve contentious issues.

Over the last 3 years, Mr. Speaker, the Committee on Commerce and my Subcommittee on Health and Environment in particular have produced a number of landmark bills which have enjoyed support from both sides of the aisle.

Last year, for example, the Subcommittee on Health and Environment produced the innovative Food Quality Protection Act and legislation to substantially improve the operation of the Safe Drinking Water Act. In addition, my subcommittee crafted a health insurance portability act to make basic reforms to the health insurance system and worked on the Balanced Budget Act of 1997 to include the new children's health care program and important reforms to the Medicare and Medicaid programs.

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We also reauthorized the Ryan White Act, thus authorizing Federal dollars to States for HIV education, prevention and health service programs. I am very proud of these important accomplishments, particularly because they were done in a bipartisan way.

The foundation of the present FDA bill was developed during the last Congress, and from the beginning, our effort has been an open process, open to anyone interested in FDA reform. Our committee conducted 17 separate formal hearings on FDA reform and FDA-related issues. This represents 72 hours, 44 minutes, and 2,094 pages of testimony.

There are many who deserve credit for bringing this legislation to the

floor today, several Committee on Commerce members in particular: The gentleman from Pennsylvania [Mr. GREENWOOD]; the gentleman from North Carolina [Mr. BURR]; the gentleman from Texas [Mr. BARTON]; the gentleman from Wisconsin [Mr. KLUG]; the gentleman from Kentucky [Mr. WHITFIELD]; the gentleman from Ohio [Mr. BROWN]; the gentlewoman from California [Ms. ESHOO]; the gentleman from California [Mr. WAXMAN]; the gentleman from Pennsylvania [Mr. KLINK]; the gentleman from Texas [Mr. HALL]; the gentleman from New York [Mr. TOWNS], along with our personal staffs who have dedicated many long hours to this bill. However, it was the leadership and direction, of course, of the gentleman from Virginia [Mr. BLILEY], our full committee chairman, and the gentleman from Michigan [Mr. DINGELL], our ranking minority member, which enabled us to bring the consensus bill before the House today. At the beginning of this Congress the chairman of the full committee made it clear that he wanted action to FDA legislation and his determination to see this through has been a guiding force in our deliberations.

In addition, the cooperation of both HHS Secretary Donna Shalala and Acting FDA Commissioner Dr. Michael Friedman during this process enabled us to achieve our ultimate goal of creating thoughtful and practical FDA reform legislation which will be signed into law, I trust, by the President this year.

Finally, I want to acknowledge and thank the most important people, the committee staff on both sides of the aisle, for their dedication and hard work in crafting this important legislation, especially Howard Cohen, Kay Holcombe, who is leaving us, and, boy, are we going to miss her; Rodger Currie, Eric Berger, David Meade, Pete Goodloe and Pattie DeLoache of my personal staff.

I am proud of this legislation, Mr. Speaker. It will reduce the overregulation of research-based businesses while greatly improving the lives of millions of Americans. I believe we have done our work and done it well. I urge my colleagues to support this conference.

Mr. DINGELL. Mr. Speaker, I yield 3 minutes to the distinguished gentleman from Ohio [Mr. BROWN].

Mr. BROWN of Ohio. Mr. Speaker, today the House considers the conference report on the reform of the Food and Drug Administration. The debate on FDA reform progressed from irrational and unfounded accusations about FDA's regulation of medical products to much more rational discussions about how to modify this agency's regulatory policies and procedures in a way that will ease unnecessary regulation without reducing essential protections of public health.

I want to commend the gentleman from Virginia [Mr. BLILEY] and the gentleman from Michigan [Mr. DINGELL], the ranking member, and the

gentleman from Florida [Mr. BILIRAKIS], chairman of the subcommittee, for their diligence in holding the House conferees together on issues that this body believed in. I want to commend the tireless work of our staffs, particularly Kay Holcombe and Howard Cohen.

This was not an easy task, particularly in light of the tremendous differences of opinion about what constitutes "unnecessary regulation." To make the system more accessible to consumers, it was necessary to draw a line between creating reasonable public processes and overburdening the FDA with administrative duties that take time away from the most important functions of getting safe and effective new products to market as quickly as possible.

Many argue that FDA reform is essential, because new and improved products were not reaching American consumers quickly enough. The facts simply did not bear this out. The FDA's Center for Devices literally overhauled its operations and dramatically improved its review time for new products. We reached a compromise where critics of this process and the medical device industry can be comfortable.

Perhaps the most important provision included in this legislation is the reauthorization of the Prescription Drug User Fee program. This program has provided the resources that FDA needed to make it the world leader in the review and approval of new drugs. If there were one single reason for Congress to pass this bill today, drug user fees is that reason.

Some of us may not be completely satisfied with the reforms of FDA regulation of generic drugs. I believe, however, that the debate led to some very much needed improvements. While these products are not the so-called miracle drugs we read about in headlines, generic drugs are critically important, because they provide options for physicians and for patients that often are less expensive than brand name products. Generic drugs literally save billions of dollars in health care costs, much of those savings occurring to the Federal Government through Medicaid, Veterans and Department of Defense facilities. In addition, savings in drug costs are important especially for senior citizens who obviously purchase the largest percentage of prescription drugs.

Mr. Speaker, I was especially pleased that a number of issues raised by Democratic members of the subcommittee, chaired by the gentleman from Florida [Mr. BILIRAKIS], were addressed in this legislation. I appreciate the willingness of the bill's sponsors, the gentleman from Virginia [Mr. BLILEY] and the gentleman from Florida [Mr. BILIRAKIS], to engage in these negotiations, and they were able to hold the House position during this conference.

Mr. Speaker, FDA is a remarkably effective agency. I have never been per-

sueded that massive changes in law were needed to correct some dreadful problem lurking under the surface.

I ask my colleagues to pass the conference report.

Mr. BLILEY. Mr. Speaker, I yield 2 minutes to the gentleman from North Carolina [Mr. BURR].

Mr. BURR of North Carolina. Mr. Speaker, I thank the gentleman for yielding me this time.

Mr. Speaker, today we take a historic step towards the future of health care in America. Today we will vote on the conference report for the Food and Drug Administration modernization legislation, originally H.R. 1411 in the House, and now S. 830.

FDA modernization is not radical, it is responsible. It is not senseless, it is safe. For thousands of patients and their families, the FDA has become a cold, inhuman and indifferent bureaucracy with a lagging drug and medical approval process and a culture of unresponsiveness and disconnect. The FDA has become an obstacle in some American families in the hope for new treatments. The FDA, regulating 25 cents of every dollar in the U.S. economy, affects every American family.

This legislation will prepare the agency for technology and medical breakthroughs for the 21st century. This legislation provides hope from the corner store pharmacist who wants to provide the best medication possible to his customers, to the hospital passionately fighting against an outbreak of an antibiotic-resistant bacteria strain, to the rural doctor who desperately seeks medication to treat patients, to the terminally ill cancer patient who has no medical option left in the struggle against a devastating disease.

This legislation in fact puts a human face on the Food and Drug Administration. By infusing common business sense into the daily operation of FDA, we will enable the agency to approve safe drugs more efficiently and to reduce skyrocketing costs of research and development that is bogged down in bureaucratic red tape.

I want to thank the gentleman from Virginia [Mr. BLILEY], the chairman of the committee, Chairman JEFFORDS in the Senate, the gentleman from Florida [Mr. BILIRAKIS], the gentleman from Michigan [Mr. DINGELL], the FDA Reform Task Force, the committee staff, my staff and the Senate staff who literally spent hundreds of hours working on this very important legislation that I believe deserves the support of our entire House membership.

Today we celebrate hope and life. This legislation would not be possible without hundreds of patients who brought their personal stories to Washington. Unfortunately, many of those patients did not live to see this day.

Mr. DINGELL. Mr. Speaker, I yield 3 minutes to the distinguished gentlewoman from California [Ms. ESHOO].

Ms. ESHOO. Mr. Speaker, I thank the gentleman from Michigan [Mr. DINGELL] for yielding me this time.

This evening I rise in strong support of the conference report, and I urge my colleagues to support it as well. Let me start out by acknowledging the leadership, and without the leadership of the gentleman from Virginia [Mr. BLILEY], our committee chairman, the gentleman from Florida [Mr. BILIRAKIS], our subcommittee chairman, and certainly the gentleman from Michigan [Mr. DINGELL], our ranking member, and the gentleman from Ohio [Mr. BROWN] of the subcommittee, and all of the Members from my side of the aisle as well as the majority, we would not come to this moment.

Like all conference reports, it represents a compromise. Nonetheless, the agreement is entirely consistent with the bill which passed the House by a voice vote last month. That is highly unusual for a bill of such substance and such importance to come to the floor and be passed by a voice vote. I am proud of the role that I was able to play in this.

The FDA, I believe, will be a better agency because of this legislation. Drugs and medical devices will get to patients sooner without any reduction in the safety and the effectiveness of these products.

I am particularly pleased that a compromise was reached among the conferees on a provision allowing for accredited third parties to review medical devices, and that the House held its position with regard to the labeling of devices. Had the House not insisted on this language, this conference report would have been vetoed, and all of our hard work would have been lost.

I hope, Mr. Speaker, that my colleagues appreciate the tremendous bipartisan, bicameral support that went into bringing this conference report to the House today. The list of people to thank is far too long to mention here, but there is one, because I think if there were a subset title to this bill, it would be the Kay Holcombe Act of 1997. The tributes that have been paid to her are well-deserved and she should receive the gratitude and the applause of the American people, because they are the ones that we really went to the table for, and were it not for her professionalism, her patience, her hard work, we would not have arrived at this moment.

I salute everyone that was a part of this, and if there is anyone on either side of the aisle that thinks that there are not unending opportunities to seize in the Congress, they are wrong. I found one with my colleagues, and one of them seated on the other side of the aisle, JOE BARTON, my partner on the medical device bill, many thought that with the two of us being partners that it could not be done. It was done, we come to this moment, and I urge my colleagues to support the conference report. It is good for the American people, and we are proud of the effort.

Mr. BLILEY. Mr. Speaker, I yield 2 minutes to the gentleman from Texas [Mr. BARTON].

(Mr. BARTON of Texas asked and was given permission to revise and extend his remarks.)

Mr. BARTON of Texas. Mr. Speaker, I thank the gentleman from Virginia for yielding me this time.

Mr. Speaker, most of us go through life being blessed with good health for ourselves and our loved ones, but as Members of Congress, we have all been literally begged by parents of sick children and our very ill adult patients themselves to try to help them work through the regulatory nightmare that is the current FDA review process.

When the bill before us becomes law, that nightmare will be no more. Instead of confrontation, we will have consultation and cooperation between the FDA, patient groups, researchers, and manufacturers. Instead of needless bureaucracy, we will have streamlined procedures for bringing the most comprehensive new medical devices and drugs to market as soon as is safely possible.

In the medical device section of the bill that the gentlewoman from California [Ms. ESHOO] and I cosponsored together in the House, we have a very practical third-party review process, we have a dispute resolution procedure that will allow researchers and manufacturers to work out their differences with the FDA reviewers; we have a reclassification of the existing device section that will let a lot of devices that are now class 3 be class 1 or class 2. Very importantly, we have an expanded and reformed use for humanitarian medical devices that will bring some of these experimental devices as quickly as possible to the market.

I must thank the gentlewoman from California [Ms. ESHOO], who has just been a one-man band in trying to force compromise and get me to back down when I really did not want to. She has done excellent in that. The staff level, in addition to the other staffers, I would like to thank Bill Bates of the office of the gentlewoman from California [Ms. ESHOO], Alan Slobodkin of the committee oversight staff, and Beth Hall of my staff, who have all done yeoman's work.

This is not a perfect bill, but it is a great start. I am going to use the oversight chairmanship to oversee implementation, and I hope that we pass this unanimously this evening. It is good for the American public.

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Mr. DINGELL. Mr. Speaker, I yield 3 minutes to the gentleman from California [Mr. WAXMAN].

Mr. WAXMAN. Mr. Speaker, my congratulations to the gentleman from Virginia, Chairman BLILEY, and the gentleman from Florida, Mr. BILIRAKIS, and our Democratic leaders, the gentleman from Michigan, Mr. DINGELL, and the gentleman from Ohio, Mr. SHERROD BROWN, for producing the Food and Drug Administration Modernization Act, which marks the successful end of a long 3-year process. I

do not agree with some of the provisions in this bill, and I certainly would have written it differently, but I do support it today.

I have no difficulty in supporting this legislation in large part because Chairman BLILEY developed a process where all Members could participate, their views could be heard, and compromises could be reached. That kind of leadership is harder than some might think, because there is always pressure to be partisan and to get what one side and only one side wants. But if we are going to ever pass legislation into law, we have to recognize that it needs to be done on a bipartisan basis, and we have to have a process where we try to find common ground.

I want to express my appreciation to our chairman for his leadership. I do have some reservations about the scope of many of the provisions in this legislation, particularly when it comes to the off-label promotion of drug and devices and third-party review of devices. But I want to point out that these are experimental provisions with sunsets which will allow us to critically reexamine their public health consequences.

I applaud very strongly the reauthorization of the Prescription Drug User Fee Act, which I was proud to have authored. It has been very successful and has allowed the FDA to speed the approval of drugs.

There are a number of other provisions that we ought to take note of because they will directly benefit many patients. The requirement that drug companies report on their fulfillment of postmarketing studies fills an important gap in ensuring that critical information is reaching patients. The clinical data base will create new opportunities for patients to have greater access to comprehensive information about experimental therapies for serious and life-threatening diseases. It is my expectation that companies will work with the FDA in this enterprise in the same cooperative spirit in which it is enacted.

The pediatric drug provision complements the FDA's recent regulations, and provides targeted incentives to improve the quality of health care for infants and children. Although I had reservations regarding the need to provide additional market exclusivity following the proposal of the regulations, there may still be limited situations in which this provision will encourage new clinical research to establish the safety and effectiveness of drugs for children.

The provision requiring notice of discontinuance of the manufacture of life-saving drugs will ensure that patients receive time to find alternatives to medicines which will no longer be available. Instead of having to make medically sensitive decisions in haste, they will have 6 month's notice of a company's decision which could have tremendous implications for their health. Only a company with "good

cause" will be permitted to end distribution or manufacture of its drug with less than 6 months notice, and in that event, the FDA will be able to determine the accuracy of this claim through records and documentation.

The preemption of state laws regarding over-the-counter drugs and cosmetics has been resolved in an important compromise, under which the FDA is granted new enforcement authority over OTC drugs, the states are not preempted with respect to cosmetic safety, and preemption of cosmetic packaging and labeling only occurs where the FDA has taken action on specific and narrow questions. Most importantly, this provision does nothing to affect California's Proposition 65, an innovative state initiative that has helped reduce Californians' exposure to toxic hazards.

This bill is a far cry from the proposals first floated three years ago which ran roughshod over consumer protections, supplanted our own product approvals with those of other countries, and weakened crucial statutory guarantees of safety, effectiveness and quality. The reason for this striking difference was the persistent skepticism of American consumers, who understood that it is the FDA which ensures that our food is safe and our medicines are safe and effective.

This was made clear by the Patients' Coalition, which represents a hundred patient and consumer organizations and hundreds of thousands of patients. For three years, the Coalition has vigorously opposed extreme and controversial proposals for FDA deregulation. Today, this bill will receive bipartisan support because of the Coalition's unremitting vigilance and hard work in defeating efforts to weaken public health protections through FDA "reforms."

Given the extraordinary success of PDUFA, it makes sense for Congress to apply user fees to other areas of FDA jurisdiction, including medical devices. Enacting such fees, modeled on authorized, additive user fees under PDUFA and not upon the unauthorized "sham" fees frequently proposed by OMB, would bring similar efficiencies to the device approval process.

Regrettably, this legislation does not do so. Instead, it enacts substantial new burdens on the FDA and, in particular, the Center for Devices and Radiological Health. I am deeply concerned that unrealistic deadlines and dozens of new mandates will slow the tremendous progress that has been made in speeding device approvals. It remains to be seen whether we will inadvertently divert limited staff, time and resources from the FDA's most important business—ensuring that our food supply is the safest in the world and that drugs and devices are safe and effective.

I want to recognize the important work of the staffs on both sides of the aisle in developing this legislation. Without them it would have been im-

possible for us. I want to compliment as well those in the Senate who played such an active role, and all of my colleagues who have played an important role, in developing this legislation.

I especially want to recognize the dedication and hard work of Kay Holcombe, our Commerce Committee staff, and the work of Howard Cohen, Eric Berger and Rodger Currie, the Majority committee staff, on this legislation. I would also emphasize the tireless work by the professionals at the FDA, including Bill Schultz, Peggy Dotzell and Diane Thompson, and the representatives of the Patients Coalition, Scott Sanders, Michael Langen, Maura Kealey and Tim Westmoreland.

I complement Chairman BLILEY and Congressman DINGELL of the Commerce Committee, and Chairman JEFFORDS and Senator KENNEDY of the Senate Labor and Human Resources Committee, for their hard work and join my colleagues in supporting this important legislation.

Mr. BLILEY. Mr. Speaker, I yield myself 15 seconds.

Mr. Speaker, I just want to thank the very kind and generous remarks of the gentleman from California [Mr. WAXMAN]. I hope that not too many of my people down in Richmond were watching. It might have an adverse affect on me in the next election. But again, I thank him very much, and I have enjoyed working with him.

Mr. Speaker, I yield 3 minutes to the gentleman from Pennsylvania [Mr. GREENWOOD], whose work played a great part in bringing this legislation to us this evening.

Mr. GREENWOOD. I thank the chairman for yielding, Mr. Speaker, and I thank him also for the opportunity to chair this task force.

When Chairman BLILEY asked me to chair the task force on the FDA reform, I did not know a whole lot about the FDA, not more than most people did, but I learned an awful lot. One of the things that I learned is that we are approaching what I think will be a golden age of medicine. We are making such incredible breakthroughs right now in biotechnology and genetic engineering, in pharmacology, in the development of high-tech medical devices, that I believe that we are going to give the next generation in the next century, as well as many of us, opportunities to defeat diseases that have plagued mankind for a very long time, and be able to relieve people from their suffering from these diseases.

But central to this promise is the role of the Food and Drug Administration. The Food and Drug Administration exists for the very critical job of making certain that all of these miracle cures, all of these devices and drugs, are both safe and effective.

The problem we discovered is that the agency had become bureaucratic, and the law that governs it had become antiquated and was not keeping up with this modern age of miracle cures. We set about the role of seeing if we

could make the FDA work more efficiently, bring these cures to those who are suffering more rapidly, while still maintaining the golden standard of safety and efficacy.

I also learned of some very human situations. I learned that I had a constituent whose name is Shelbie Oppenheimer. She is a hero to me. She is a 30-year-old woman who at the age of 28 was running a day care center and discovered that she had ALS, Lou Gehrig's disease. It is a progressive, fatal neuromuscular disorder that attacks nerve cells and pathways in the brain and spinal cord.

There is no cure for it, but there is a new medication that can delay the onset of the disease and slow its progress. My constituent, Shelbie Oppenheimer, and her husband, Jeff Oppenheimer, desperately want her to have access to this medication. Mr. Speaker, it is my hope that this legislation gives Shelbie Oppenheimer the extra time and the extra hope that this new medication will provide her.

I would like, Mr. Speaker, to dedicate this bill to Shelbie Oppenheimer and to all of the other Shelbie Oppenheimers around the country who are waiting for the Congress to reengineer the FDA so that it can approve these new miracle cures for them more rapidly.

I am also pleased that the legislation that I had introduced separately, the better pharmaceuticals for children bill, has been incorporated into this reform package, so we can bring the miracles of modern medicine not only to adults, but to the children who up until this time were not the subject of trials.

I would like to thank all of my colleagues and the chairman, the gentleman from North Carolina [Mr. BURR], the gentleman from Texas [Mr. BARTON], the gentleman from Wisconsin [Mr. KLUG], and the gentleman from Kentucky [Mr. WHITFIELD], for their assistance, and certainly echo the comments of those who have praised our very, very able staff.

Mr. DINGELL. Mr. Speaker, I yield 3 minutes to the distinguished gentleman from New Jersey [Mr. PALLONE].

Mr. PALLONE. Mr. Speaker, the conference report before us has been the product of hard work, tough negotiations, and true bipartisanship. The result is a well-crafted bill that will reauthorize the Prescription Drug User Fee Act, and enact common-sense Food and Drug Administration reform.

I want to congratulate the chairman and the ranking member and the professional staff of the committee on both sides of the aisle, particularly Kay Holcombe, for their work on this very successful piece of legislation.

Pursuant to the bill, patients will have access to safe new drugs, treatment, and equipment faster than before; businesses will be able to save their customers money without sacrificing safety; and the FDA will be able to focus more time and money on regulating medical treatments instead

of pushing paper. I think it is a win for everyone.

Mr. Speaker, I just wanted to mention a few provisions of the bill that I am particularly concerned with, concerning the drug provisions. I am particularly pleased with the inclusion of a bipartisan amendment that would provide for notification when a company terminates a product which could cause severe harm to a patient because of its discontinuance.

To allay industry concerns, I ask that there would be included in the bill a good cause waiver that allows the FDA to waive the time requirement. I understand that the provision has been slightly modified in conference in that companies have to certify to the FDA that these good cause waiver requirements are met. This provision still represents good citizenship by the sole-manufacturers of medical products, and I believe that the conference report compromise is a good one.

In addition, two amendments concerning mercury were incorporated into this bill. One of them requires the FDA to restudy the impact of a form of organic mercury in nasal sprays on the brain, and the second provision provides for a study that would examine the sale of mercury as a drug or for other home use. These are both good government provisions. I appreciate the work of the committee for including them in the conference report.

On the device side, I wanted to congratulate the gentlewoman from California [Ms. ESHOO] and the gentleman from Texas [Mr. BARTON] for their ability to find common ground with the FDA and the industry on many issues. While third-party review may not be the panacea, freeing up the FDA's limited resources to review and approve high-risk devices is the next best thing, especially without greater resources being devoted to the FDA directly.

Finally, I am very pleased that language was included, the House language, to ensure that this legislation does not hinder the FDA's authority to reduce teen smoking. We are going to be dealing with the issue of teen smoking and tobacco in general in the committee. I know we are going to start having hearings on it next week. I think it was important and sound policy that this provision be included.

I just want to urge adoption of this conference report. I know that the committee and the staff and all have worked very hard on this. I think it is a very successful bill that will be passed into law and signed by the President.

Mr. BLILEY. Mr. Speaker, I yield 1 minute to the gentleman from Florida [Mr. STEARNS], a member of the committee.

(Mr. STEARNS asked and was given permission to revise and extend his remarks.)

Mr. STEARNS. Mr. Speaker, I am here to support the FDA reform bill, and to compliment the chairman and ranking member, and, of course, the

subcommittee chairman, the gentleman from Florida [Mr. BILIRAKIS], who is a colleague. But I am disappointed that this legislation lacks a provision preventing the FDA from going forward with its proposed plan to ban certain metered-dose inhalers.

I have introduced legislation, and myself and other colleagues have worked hard to try and lobby the conference. We were not successful. The FDA is proposing to ban metered-dose inhalers containing chlorofluorocarbons sooner than America agreed to in the Montreal Protocol. I am going to reach out to both sides to see if we can pass a standing piece of legislation, because CFC damage is there, it hurts the ozone layer, but, frankly, we need to phase it out and not move abruptly.

The Federal Government allows the use of CFCs for bear repellent and wasp and hornet sprays, yet the FDA wants to take away medicines for metered-dose inhalers because they have CFCs. Are killing bugs and chasing away bears really more important than the health of our children? I do not think so. Next session, Mr. Speaker, let us keep the FDA from banning these inhalers until safe and effective alternatives are developed.

Mr. DINGELL. Mr. Speaker, I yield 2 minutes to the distinguished gentleman from Rhode Island [Mr. KENNEDY].

(Mr. KENNEDY of Rhode Island asked and was given permission to revise and extend his remarks.)

Mr. KENNEDY of Rhode Island. Mr. Speaker, I thank my colleagues who have been speaking out on this issue, most notably the gentleman from Florida, Mr. CLIFF STEARNS, who just spoke. Asthma kills roughly 5,000 people every year. There are over 30 million Americans who depend on those metered-dose inhalers, such as the one I have in my pocket, in order to relieve themselves of the terror of being gripped with asthma.

What the FDA has proposed is they have proposed phasing out these metered-dose inhalers because of their CFC content. CFC content in metered-dose inhalers contributes less than 1 percent of the chlorofluorocarbons in the atmosphere, yet the FDA would like us to believe that by banning these inhalers, we will get about complying with the Montreal Protocol and achieving a reduction in chlorofluorocarbons.

As my colleague, the gentleman from Florida, Mr. CLIFF STEARNS, said, this is all while the EPA has yet to ban refrigeration and air conditioning, which contributes 58,000 tons of CFC's, things such as solvent applications, red pepper bear repellent, lubricant coatings, and foam blown with CFC's used in coaxial cables.

The point I am going to make is we are going after less than 1 percent of the CFC's in the atmosphere by banning these metered-dose inhalers when we have not taken into full account the public health impact on asthmatics all across the country who depend on

these metered-dose inhalers in order to relieve them from their asthma.

I can tell the Members, I have four different inhalers. I think there is only one of them that has a non-CFC component. We should not be rushing to ban these inhalers without fully testing and evaluating the impact of those non-CFC inhalers, so we do not adversely impact the public health of our people.

I want to thank the gentleman from Michigan [Mr. DINGELL] and the gentleman from Virginia, Chairman BLILEY, for agreeing to a bill that will address this issue in the upcoming year.

Mr. BLILEY. Mr. Speaker, I yield 1 minute to the gentleman from Kentucky [Mr. WHITFIELD].

(Mr. WHITFIELD asked and was given permission to revise and extend his remarks.)

Mr. WHITFIELD. Mr. Speaker, I thank the gentleman for yielding time to me. I want to give special thanks to the gentleman from Virginia [Mr. BLILEY] and the gentleman from Michigan [Mr. DINGELL] for the leadership they have provided. I rise in strong support of this conference report of FDA reform legislation as it relates to medical devices, prescription drugs, and food.

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The food provisions of the final version of this bill reflect closely the hard work of the House in addressing the need for fine-tuning the Nutrition Labeling and Education Act of 1990. Clearly, much more needs to be done before we can assert that our Nation's food laws have been completely reformed. However, this is a responsible down payment of food reform that we can expect to benefit public health.

I want to commend those Members and staff on both sides of the aisle who worked so diligently as we were successful in passing this legislation overwhelmingly. I would urge all Members of the House to support this conference report.

Mr. BLILEY. Mr. Speaker, I yield 1 minute to the gentleman from Pennsylvania [Mr. FOX].

Mr. FOX of Pennsylvania. Mr. Speaker, the gentleman from Virginia [Mr. BLILEY], the chairman, and the gentleman from Michigan [Mr. DINGELL], the ranking member, should be very proud of this legislation.

FDA reform is certainly one of the most important pieces of legislation to pass in this session. I know from testimony in my own home county, Montgomery, Pennsylvania, we had hearings regarding the fact that many people waiting for a cure, a vaccine, whether they have ALS, or cancer, or AIDS or epilepsy, up until now, it took \$5 million and 15 years for many of our drug companies to get approval from FDA.

This legislation will hasten the available market for miracle cures going from lab to the patient without bureaucratic delay. It will speed up that

approval time. Independent agencies will be able to do the testing. This will be a lifesaving procedure because of this legislation's adoption.

I also want to thank the gentleman from Florida [Mr. BILIRAKIS], the gentleman from North Carolina [Mr. BURR], the gentleman from Pennsylvania [Mr. GREENWOOD], and the gentleman from Texas [Mr. BARTON] for all of their leadership on this issue, because Americans, in a bipartisan fashion, want to have the drugs that are available for them to live longer and to live better. And the same applies, of course, to medical devices and biologics. I appreciate the support of every Member of this entire House to support this FDA reform.

Mr. BLILEY. Mr. Speaker, I yield 1 minute to the gentleman from California [Mr. BILBRAY], a member of the committee.

Mr. BILBRAY. Mr. Speaker, I have the privilege of representing the 49th District of the State of California, San Diego, which has one of the largest concentrations of pharmaceutical companies in the world, but also has more biotech industries in the area than anywhere else in the world, including a combination of Britain and Japan combined.

Mr. Speaker, I like this bill, and I think my constituents will appreciate this bill, not because of those industries, but because of what it does for consumers.

The fact is, Mr. Speaker, there are two ways of hurting a patient. One is to give them inappropriate treatment. But the other, and sadly all too common way of hurting a patient, is not to provide appropriate treatment and to deny that appropriate treatment to people who are ill.

One of the problems we have had in the past is that there have been medication and treatment that have been denied the American consumer that have been available all over the world. This bill is a progressive, well balanced bill that will finally now improve the situation to allow the American consumer to have what they need desperately: safe, effective drugs, as soon as possible. I appreciate the support for the bill.

Mr. DINGELL. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, I think we are witnessing an extraordinary event in this Congress and, indeed, almost in any Congress. In the closing days of the session, with the usual tensions and mischief that exist, we are finding great enthusiasm on a very fine piece of legislation which started out rather under a dark star and which, through some remarkable cooperation, has come to the point where we have not only agreement but firm agreement on a good bill, something which is going to help manufacturers, help the economy, to help the consumers and patients. It is going to help the medical profession, it is going to make Americans safer, and it is going to see to it that good

drugs, safe and efficacious, come more quickly to the marketplace.

It is also going to see to it that the other responsibilities of the Food and Drug Administration are conducted in a more efficient and speedy fashion. It shows what real bipartisanship can do when Members of Congress on both sides of the aisle get together and when there can be the kind of cooperation and goodwill there was in the conduct of this particular negotiation.

The result is a fine piece of legislation, one which will benefit the country, one which will benefit the industry, one which will make for better government, and one which will do something else, and that is to protect the consumer and see to it that we get to the American people the best drugs in the fastest and safest and the most assured fashion. I urge my colleagues to support the bill.

I want to commend my colleague, the gentleman from Virginia [Mr. BLILEY], for his fine leadership in this matter. And I want to express my personal thanks and that of the Members on this side of the aisle to Kay Holcombe for the superb job that she has done in preparing this piece of legislation for consideration today. I also am grateful to Secretary Shalala, Dr. Friedman, and the excellent FDA staff for their assistance.

Mr. Speaker, I yield back the balance of my time.

Mr. BLILEY. Mr. Speaker, I thank the gentleman from Michigan [Mr. DINGELL] for his kind words. Without his help, we would not be here.

Mr. Speaker, I yield the balance of our time to the gentleman from Iowa [Mr. GANSKE].

Mr. GANSKE. Mr. Speaker, my congratulations to all who have been involved with this bill.

As a physician, I am very proud to be in favor of this bill. This bill will help bring new and better drugs and medical devices to the market. It will also help older drugs be better used. There are many off-label uses of older drugs that are beneficial to our constituents, like aspirin to prevent heart attacks; 80 to 90 percent of cancer treatment is off-label. In fact, for some diseases, off-label treatment is a standard of care.

Section 7 of H.R. 1411 improves to help public health by increasing the amount of accurate, balanced, scientific information that is available to physicians and other health care professionals. This has been an important compromise between the administration, the FDA, and a bipartisan Congress.

Secretary Shalala said the language that we have agreed to will give the FDA the opportunity to review new information in advance of its dissemination to ensure that it is accurate and balanced. This provision is supported by the AMA, the American Cancer Society, the National Multiple Sclerosis Society, and many other groups who know that greater dissemination of scientific information means better care for patients.

Please vote for this bill.

Mr. WHITFIELD. Mr. Speaker, thanks are owed to several Members for their leading role in the development of the food provisions of this bill. Special thanks must be given to Chairman BLILEY, ranking minority member DINGELL, as well as Messrs. TOWNS, HALL, GANKSE, and of course, the author of the food reform legislation in the last Congress, Mr. KLUG. Praise is also due to the exceptional work of committee counsel, Eric Berger, as well as James Derderian and to staff of members of the committee including Tim Taylor of my staff, Brenda Pillors, Grace Warren, and Jon Traub. Special note should be made of the work of Kay Holcombe, who has served the Commerce Committee and Public Health as a whole with extraordinary professionalism of many years.

The food provision of the final version of this bill reflects closely the hard work of the House in addressing the need for fine tuning of The Nutrition Labeling and Education Act of 1990 [NLEA]. Clearly, much more needs to be done before we can assert that our Nation's food law has been reformed. However, this is a responsible down payment of food reform that we may reasonably expect to benefit public health.

A compelling problem that is addressed by this legislation is the Food and Drug Administration blocking truthful, nonmisleading information from American consumers. As a matter of public health, this has prevented, either by prohibition or excessive delay, consumers from receiving important information about the nutritional content or health benefits of various foods. This problem also takes the form of an abridgement of the first amendment rights of persons who seek to make truthful, nonmisleading statements about a food. FDA has an absolute duty to act within statutory time frames for action on petitions for claims. The failure to do so would constitute a violation of first amendment rights of petitioners. Particularly given the vulnerability of petitioners to retaliation from the FDA, the courts are urged to be expansive in issues of standing in suits regarding failure by the agency to take timely action.

Specifically, the conferees have brought forth a bill that addresses these issues by providing a maximum review time for final action on petitions for claims, including a requirement that the Secretary report on any instances where final action is not taken within the 540 day review period so that the committees of jurisdiction may be promptly informed of a breakdown in the regulatory scheme. Also, special streamlined review mechanisms are provided for health or content claims that are based on the conclusions of authoritative scientific bodies, such as the National Academy of Sciences. The Secretary is granted authority to make proposed rules effective immediately as an exceptional tool to assure that the FDA's duty to pre-approve claims can be met without delay that undermines the regulatory scheme or threatens the first amendment right of petitioners. Unnecessary requirements regarding referral statements that accompany certain nutrient content claims have been eliminated under the bill. And, in a matter where both food safety and first amendment rights have been jeopardized by heavy handed regulatory requirements, an important provision of the bill addresses the labeling of foods treated by irradiation.

To implement the irradiation amendment, FDA is to expeditiously conduct a rulemaking to revise its current irradiation disclosure requirement. The current requirements of the rule, a "Treated with Radiation" or "Treated by Irradiation" statement, accompanied by the international radura symbol, make clear that the process has been used. However, it is equally clear that this requirement has had the perverse effect of discouraging many consumers from purchasing food that has been made safer by this process. The conferees are concerned that the current disclosure requirement may be perceived as a warning and that it may raise common but inappropriate anxieties about radiation technologies. FDA should use the new rulemaking to assure that disclosures are only required as necessary to inform consumers of a material fact regarding the food. FDA's 1986 preamble to its final rule regarding irradiation disclosure well explained the general rule regarding disclosure of material facts and how that rule relates to food that has been irradiated:

In this case, the standard for misbranding under sections 403(a) and 201(n) of the act is whether the changes brought about by the safe use of irradiation are material facts in light of the representations made, including the failure to reveal material facts, about such foods. Irradiation may not change the food visually so that in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed.

The Agency recognizes, however, that the irradiation of one ingredient in a multiple ingredient food is a different situation, because such a food has obviously been processed. Consumers would not expect it to look, smell, or taste the same as fresh or unprocessed food, or have the same holding qualities. Therefore, FDA advises that the retail labeling requirement applies only to food that has been irradiated when that food has been sold as such (first generation food), not to food that contains an irradiated ingredient (second generation food) but that has not itself been irradiated.

Thus, FDA determined that disclosure is required to convey to consumers the material fact that the food is not fresh or unprocessed. Given the fresh appearance of food treated by irradiation, FDA determined that the omission of such a disclosure would cause a false or misleading presentation of the food. FDA has authority in this regard only to prevent false or misleading presentation of the food. FDA would exceed its authority if it were to prohibit a truthful, nonmisleading presentation of the food. In any situations where FDA determines that an irradiation disclosure remains necessary, it is obliged to achieve that objective in a minimally burdensome manner. Disclosure statements may only be required where presentation of the food would be false or misleading absent a disclosure statement. Statements different from the current disclosure requirement would suffice if they inform consumers of the material fact that is basis for the disclosure requirement. FDA is obliged to permit disclosure of the material fact through any statements that are not false or misleading. Moreover, the conferees expect FDA to take pains to assure that where disclosure is appropriately required, such required statements not give rise to consumer confusion that could inhibit use of this pathogen reducing technology. It would be unacceptable for FDA to justify a disclosure requirement that may

cause consumer confusion with the excuse that the confusion may be corrected by a proper consumer education program. On its face, such an approach creates burdens that inhibit the use of this technology and, as a consequence, food safety.

The conferees strongly support the consumer right to know. The act contemplates that right being addressed through a vast array of truthful, nonmisleading voluntary label statements, as well as required disclosure of material facts that are not obvious in the presentation of a food. With respect to food that has been irradiated, this legislation does not limit FDA's existing authority to require disclosure nor does it forbid use of the international radura symbol as one of the means of making such a disclosure. The conferees expect FDA to continue to require necessary disclosures to prevent consumers from being misled about any material fact about a food.

Also in the area of labeling, I am disappointed to note that the Senate conferees would not accept the elimination of antiquated and bizarre provisions of the Food, Drug and Cosmetic Act that apply only to margarine. It is a sad measure of our food regulatory system when industries seek competitive advantage over one another through the imposition and maintenance of absurdly burdensome requirements such as these.

I am pleased to report that the conferees have agreed to direction for FDA to take final action within 60 days on the petition to permit the irradiation of beef. This petition has been pending in FDA for over 3 years, despite the requirement that FDA act on such petitions within 6 months. Also, the bill includes reforms in the review of food labeling packaging materials that should assist FDA in expediting appropriate approval of both these materials and, through greater efficiency of operation, all food additive petitions.

I urge my colleagues to vote for the conference report so that we may make this down payment on food law reform.

Mr. TOWNS. Mr. Chairman, I join my colleagues in applauding the scheduling of the conference report on S. 830, legislation to reform the Food and Drug Administration, prior to our adjournment of the 1st session of the 105th Congress. This bill is the culmination of 2 years of hard bipartisan work by the Commerce Committee to modernize procedures that the Food and Drug Administration uses to approve drugs, devices and food products. Once again, Mr. Chairman, the Commerce Committee under the able leadership of our chairman, Mr. BLILEY, and our ranking member, Mr. DINGELL, have demonstrated that we have the ability to develop comprehensive legislative responses to critical public policy questions. I also want to especially acknowledge the efforts of our subcommittee chairman, Mr. BILIRAKIS and our ranking subcommittee member, Mr. BROWN, for the willingness to guide the deliberations on this bill in a bipartisan fashion.

Without the modernizing steps that have been incorporated in this legislation today, the FDA would continue to be seen as a barrier to new innovative therapies and products. The bill before us today represents a careful balance between a new, streamlined process and consumer protections against harmful products. These innovations in the way the FDA will do business from now on makes the approval of drugs and devices a more predictable process.

Finally, Mr. Chairman, I am most pleased about the provisions in this bill which relate to food products. I had the wonderful experience of working closely on these issues in a bipartisan fashion with the gentleman from Kentucky [Mr. WHITFIELD], the gentleman from Wisconsin [Mr. KLUG], the gentleman from Pennsylvania [Mr. GREENWOOD], and the gentleman from Texas [Mr. HALL]. While some argued that food reforms were too controversial to include in this bill, my colleagues and I never stopped believing that we could craft reasonable and meaningful food reforms that would be acceptable to the industry, FDA, and consumers alike. With the able assistance of our committee counsels on both sides of the aisle, Eric Berger and Kay Holcombe, the measure incorporated in S. 830 accomplish this goal. The food issues in this bill build on the success of the Nutrition Labeling and Education Act and they represent a modest downpayment on more significant food law reforms, including the question of national uniformity.

Mr. Chairman, I join my colleagues from the Commerce Committee in urging the immediate passage of this legislation.

Mr. RAMSTAD. Mr. Speaker, I rise in strong support of the Conference Report on comprehensive legislation to reform the Food and Drug Administration [FDA]. And I thank Chairman BLILEY and the others who worked so hard to bring this important Conference Report to the floor for passage before Congress adjourns for the year.

Reforming the FDA's approval process has been a major goal of mine since I first came to Congress in 1991. In fact, in an effort to educate House members about the need for reform for medical devices, Representative Tim Valentine and I founded the bipartisan House Medical Technology Caucus, which I now chair with Representative ANNA ESHOO.

As we all know, it now takes 15 years and \$350 million to get the average new drug from the laboratory to the patient. The average time for the FDA to approve a medical device has increased from 415 days in 1990 to 773 in 1995—even though the FDA is currently required by law to take no longer than 180 days to approve new devices.

This is precisely why I became an original cosponsor of the medical device section of this reform package. The medical device provisions will save lives, improve health and create jobs in the United States by getting medical devices to market faster.

I also strongly support the sections in the bill to reauthorize the Prescription Drug User Fee Act [PDUFA] and reform the approval process for pharmaceuticals and animal drugs.

Mr. Speaker, these reforms passed today will force the FDA to get its act together so life-saving devices and drugs will get to people who need them as expeditiously and safely as possible.

The health care consumers, medical device and pharmaceutical companies of America deserve nothing less!

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Virginia [Mr. BLILEY] that the House suspend the rules and agree to the conference report on S. 830.

The question was taken; and (two-thirds having voted in favor thereof)

the rules were suspended and the conference report was agreed to.

A motion to reconsider was laid on the table.

SENSE OF HOUSE IN SUPPORT OF FREE AND FAIR REFERENDUM ON SELF-DETERMINATION FOR PEOPLE OF WESTERN SAHARA

Mr. ROYCE. Mr. Speaker, I move to suspend the rules and agree to the resolution (H. Res. 245) expressing the sense of the House of Representatives in support of a free and fair referendum on self-determination for the people of Western Sahara, as amended.

The Clerk read as follows:

H. RES. 245

Whereas United Nations Secretary General Kofi Annan appointed former United States Secretary of State James Baker III as his Personal Envoy for Western Sahara to end the prevailing referendum stalemate;

Whereas talks between the Kingdom of Morocco and the Front for the Liberation of Saguia el Hamra and Rio de Oro (also known as the Polisario Front) mediated by Mr. Baker have achieved agreement on ways to end the referendum stalemate;

Whereas the end of the stalemate over the Western Sahara referendum would allow for the release of civilian political prisoners and prisoners of war held by Morocco and the Polisario Front; and

Whereas the United States supports the holding of a free, fair, and transparent referendum on self-determination for the people of Western Sahara: Now, therefore, be it

Resolved, That the House of Representatives—

(1) expresses its full support to former United States Secretary of State James Baker III in his mission as Personal Envoy of the United Nations Secretary General for the Western Sahara;

(2) expresses its support for a referendum on self-determination for the people of Western Sahara that should meet the following criteria:

(A) free, fair, and transparent and held in the presence of international and domestic observers and international media without administrative or military pressure or interference;

(B) only genuine Sahrawis, as identified in the method agreed to by both sides, will take part in the referendum voting; and

(C) the result, once certified by the United Nations, is accepted by both sides;

(3) encourages the release of civilian political prisoners and prisoners of war held by Morocco and the Polisario Front at the earliest possible date; and

(4) requests the administration to fully support former United States Secretary of State James Baker III in his mission of organizing a free, fair, and transparent referendum on self-determination for the people of Western Sahara without military or administrative constraints.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from California [Mr. ROYCE] and the gentleman from California [Mr. MENENDEZ] each will control 20 minutes.

The Chair recognizes the gentleman from California [Mr. ROYCE].

GENERAL LEAVE

Mr. ROYCE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to

revise and extend their remarks on this measure.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. ROYCE. Mr. Speaker, I yield myself such time as I may consume.

This resolution expresses the support of the House of Representatives for the so-far successful negotiations between the Kingdom of Morocco and the Polisario Front, who have made the tough decision to peacefully work out their differences on the conduct of a referendum on self-determination for Western Sahara. The negotiations have been guided by former Secretary of State James Baker, now serving as the Special Envoy of the U.N. Secretary General for Western Sahara.

Secretary Baker's diplomacy have broken a 6-year stalemate on referendum negotiations. While no date has been set for balloting, we appear to be closer to fair and free referendum for Western Sahara than at any time in the last two decades. This conflict, which has often seemed intractable, has not received the attention it deserves. This is now changing with Secretary Baker's engagement, as well as with the attention that Congress is now paying to this issue.

This resolution not only praises the efforts of Secretary Baker but it puts the House on record as supporting a free, fair, and transparent referendum. At this sensitive point in the process, such a nonpartisan expression of support is valuable. Mr. Baker said in a Washington news conference last week that this resolution provides a much needed boost to a referendum process he referred to as the "last opportunity for peace" in Western Sahara.

Years of fighting between Morocco, the Polisario Front, and Mauritania have claimed thousands of lives and created hundreds of thousands of refugees. The equitable ending of this conflict is important to the United States. Morocco is a longstanding American ally, and continued turmoil in the region is contrary to United States interests.

The breakthrough achieved by Secretary Baker is important. That is why we need to take proper notice of it. It is time to show all parties that the United States is watching and cares. I urge my colleagues to support this balanced resolution as a sign of congressional support for the significant advance that has taken place toward resolving this longstanding conflict.

Mr. Speaker, I reserve the balance of my time.

Mr. MENENDEZ. Mr. Speaker, I yield myself such time as I may consume.

(Mr. MENENDEZ asked and was given permission to revise and extend his remarks.)

Mr. MENENDEZ. Mr. Speaker, I rise in strong support of House Resolution 245, expressing the sense of the House in support of a free and fair referendum on self-determination for the people of Western Sahara.

Mr. Speaker, I think we owe a great deal of gratitude to former Secretary of State James Baker for his service as Special Envoy. Clearly, it was his intervention which brought an end to the referendum impasse and which has allowed for an opportunity for peace in the region.

For too long, the situation in the Western Sahara has been left unresolved, and for too long it has caused tension in the region and within the African continent. It is crucial at this juncture that the U.S. Government and the Congress put their weight behind the plan negotiated by former Secretary Baker. There is only a small window of opportunity to implement the agreement, which itself remains quite fragile. If we bypass this opportunity by our inattention or if we allow either side to renege on the commitments made in Houston, we will be responsible for foregoing an opportunity for long-term peace in the region. That is not a cost we can afford, and it is a small price to pay for peace and democracy.

The Houston plan has at long last found a resolution which is acceptable to both the Moroccan Government and the Polisario Front. The referendum, which will be held next December, will grant the Sahrawi people their long-awaited right to self-determination, the same right enjoyed by free people throughout the world.

Sahrawi President Abdelaziz has given his word that he will stand by and respect the people's decision regardless of the outcome as long as the referendum is free and fair and allows only Sahrawis to vote. The Sahrawi people have been left in limbo due to political considerations rather than any really legal dispute.

In 1975, the International Court of Justice declared that there is no establishment of any legal ties of territorial sovereignty between the territory of Western Sahara and the Kingdom of Morocco. Now the Sahrawi people will have the opportunity to decide for themselves their political future, be it independence or incorporation into Morocco. It is their choice.

I want to thank the gentleman from California [Mr. ROYCE] for his leadership in bringing the resolution before the House and for sponsoring it. I am proud to be an original cosponsor. And I also want to again congratulate former Secretary Baker for his tremendous efforts. He has been and we expect will continue to be crucial to the success of this ultimate endeavor.

Mr. Speaker, I reserve the balance of my time.

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Mr. ROYCE. Mr. Speaker, I yield 2 minutes to the gentleman from New York [Mr. GILMAN], the distinguished chairman of the Committee on International Relations.

(Mr. GILMAN asked and was given permission to revise and extend his remarks.)