of Americans across this country and obviously not just children. But most importantly, I think that this legislation will go a long way toward changing the culture at the Food and Drug Administration. It is a move away from scare tactics and toward sounds science on food policy, away from redtape and toward sound science and speedy approval on new medical devices. Perhaps most importantly, it is a move away from bureaucracy, and finally toward compassion.

Congratulations to my colleagues who have worked on this bill for so long and so hard for the past 3 years, the gentleman from Virginia [Mr. BLILEY] and the gentleman from Michigan [Mr. DINGELL], the gentleman from Florida [Mr. BILIRAKIS] and the gentleman from California [Mr. WAXMAN], the gentleman from Texas [Mr. BARTON], the gentleman from North Carolina [Mr. BURR], and the gentleman from Pennsylvania [Mr. GREENWOOD]. Our fight has gone back a long way, back to the early days of 1994.

And thanks to the professional staff on both sides who have worked so hard for the last 3 years as well. But most of all, congratulations to my three young friends. For Cody and Amber and Kristin and millions of Americans suffering from diseases across the country, this bill is for them.

Mr. SMITH of New Jersey. Mr. Speaker, I am pleased that today the House has finally taken long-overdue action to reauthorize the Prescription Drug User Fee Act (H.R. 1411).

In 1992, Congress enacted the Prescription Drug User Fee Act (P.L. 102–571) to authorize the Food and Drug Administration [FDA] to collect user fees from pharmaceutical companies to pay for more timely reviews of new, breakthrough drugs. It has been estimated that over $300 million in user fees have been collected under Public Law 102–571 to help finance safety and efficacy trials at the FDA. All of these user fees have been returned directly to the FDA, which used the money to expand its staff and cut review times for new drugs, thereby ensuring that patients ultimately benefit from the program.

H.R. 1411 also institutes a number of important reforms to the FDA to reduce drug review times and provide more information to patients and physicians in a timely manner. The net effect of this legislation will be to save and improve the lives of sick and injured persons across our nation.

But despite these much needed reforms to the FDA, there is much work that remains to be done. Specifically, I am concerned, like many Americans, about the FDA's plans to accelerate the elimination of metered dose inhalers [MDI's] that contain chlorofluorocarbons [CFC's].

As many of you know, on March 6, 1997, the FDA proposed a plan to phase-out the use of CFC's and MDI's, which are used by asthma and cystic fibrosis patients to breathe.

While I agree it is important to institute a transition strategy that will eventually eliminate CFC use, the advance notice of proposed rulemaking [ANPR] published by FDA on March 6 is deeply flawed and should be scrapped in favor of a plan that put patients—not international bureaucrats—first.

And it is Congress which must ensure that the interests of patients are in fact upheld throughout the formation of our country's MDI transition strategy. To that end, my colleague and friend from Florida, Mr. CLIFF STEARNS, and I have introduced legislation, H.R. 2221, that will temporarily suspend the FDA's ANPR until a new proposal can be crafted. It is our intention to offer our legislation as an amendment to H.R. 1411 had we been afforded an opportunity to do so.

Mr. Speaker, our legislation is necessary because the FDA's plan has numerous problems, including the fact that under the plan patients will have significantly fewer choices in asthma medications, which will leave some patients deprived of the medicines that need to breathe.

Specifically, FDA has classified most MDI-delivered respiratory medications into two therapeutic classes. One therapeutic class has five moieties, or drug types which are delivered to the lungs by the MDI, and other has seven moieties. A moiety refers to the drug's active ingredient, and for each moiety there are usually multiple generic versions produced and marketed.

According to the FDA proposal once two moieties are available in a non-CFC MDI form, all other drugs, including generics, in that therapeutic class will be banned. Thus, if you are a patient that relies on a moiety that is banned by the FDA policy, and the two non-CFC MDI's that remain on the market are unsatisfactory or unusable, your very life could be placed at risk.

As Congress continues to assess and debate the best way to craft a CFC transition strategy for metered dose inhalers, I would like to highlight the case of Tommy Farese, a 9-year-old boy from Spring Lake, NJ, who wrote to the FDA in April to oppose their plan. Tommy told the FDA that as someone who depends on Intal, Vanceril, and Provental every day to breathe, he does not want these medications taken away from him.

Under the FDA plan, the entire therapeutic class of drugs Tommy—and other like him—use to survive could be banned when two different non-CFC MDI moieties are marketed. However, if the first two non-CFC MDIs approved by FDA in a therapeutic class do not include the moieties for Intal and Vanceril, Tommy would lose access to the drugs he needs to physically breathe. Mr. Speaker, as the father of two daughters with asthma, I find any plan that could lead to such an outcome completely unacceptable.

Not surprisingly, the FDA's plan has generated a firestorm of opposition from patients, respiratory therapists, and physicians: nearly 10,000 letters in opposition have been received to date by the FDA. Those expressing their concerns about the FDA plan include: Dr. C. Everett Koop, Mothers of Asthmatics, the Joint Council of Allergy, Asthma and Immunology [JCAAI], the Cystic Fibrosis Foundation, the American Medical Association, and the American Association of Respiratory Therapists.

In my view, any plan to remove safe and effective medications from the marketplace needs to place the interests of children like Tommy Farese first and foremost. Sadly, the FDA plans fails in this regard. Indeed, the FDA plan presumes that CFC-free inhalers serve all patient subpopulations—such as children and the elderly—equally well, despite the fact that children have special needs. Therefore, I call upon all Members to support H.R. 2221 and stop the FDA from implementing this terribly flawed and environmentally marginal proposal.

Mr. PAUL. Mr. Speaker, today, out of nowhere, comes the stealth Prescription Drug User Fee Re-authorization and Drug Regulatory Modernization Act of 1997. Regrettably, but unlike certain militarily procured aircraft, a little rain will not make this bill disintegrate.

According to its proponents, this FDA-strengthening bill was more than 3 years in the making—a so-called compromise between industry and the administration, we are told. Yet, despite the 177 pages attempting to reform an administrative agency and its rulemaking direction, the leadership did not see fit to announce floor consideration of this bill in the Weekly Whip Notice, yesterday's Shipping Post's ''Tuesday's Forecast'' section or any other commonly accepted medium as near as I can discern. More curiously, in my attempts to draw some attention to the broadsweeping nature of the bill on the House floor and the process by which it had come up for consideration, I am told by the bill's proponents that ''there is no time available to speak regarding the bill.'' Instead, C–SPAN viewers will be treated to a love-in during which each of the bill's drafters and advocates commend one another for the fine job of corporatism and internationalism they are about to bestow upon the American citizenry and in such a critical aspect of their lives; that is, their health.

When a 177-page bill comes to the floor under suspension with practically nothing more than an hours notice, one must always question what freedom-depriving regulation is about to be forced upon the citizens. Below is a sneak preview of the latest regulatory loss of individual liberty and State sovereignty.

So-called harmonization language contained in the bill requires the Secretary, through bilateral and multilateral agreements, to ''harmonize regulation * * * and seek appropriate reciprocal arrangements'' with foreign regulatory agencies. Vocal opponents of this harmonization language convincingly argue this internationalizing of what is already an unconstitutional usurpation of States rights, is very likely to greatly limit the availability of food supplements by requiring prescriptions for dispensation as is the case in certain parts of Europe. Perhaps with such harmonization, we will not only have a Federal war on drugs, but a Federal war on riboflavin, folic acid, and bee pollen. At last, an American alfalfa czar.

Food supplement availability may be the least of concerns amongst those who still revere states' rights and acknowledge the continued existence of the tenth amendment. Section 28 of H.R. 1411, as available on the Internet, entitled ''National Uniformity,'' ''prohibits states and subdivisions from regulating food, drugs, or cosmetics * * *'' The bill permits the FDA to set national standards for cosmetics but permits States to issue warning labels and take defective products off the shelves.

To the dismay of medical privacy advocates, the bill authorizes the FDA to mandate the tracking of medical patients who use certain medical devices for up to 36 months as well as conduct post-market surveillance of these patients.

The bill limits the speech of manufacturers who would claim health benefits on their product labels without the approval of a scientific

agency of the Federal Government. The bill responsibly makes provisions for such Scientific Advisory Panels in section 6. According to the bill, these panels are to be made up of ''persons who are qualified by training and experience * * * and who, to the extent feasible, possess skill in the use of, or experience in, the development, manufacture, or utilization of * * * drugs or biological products.'' Here we have yet another chapter in the book of corporatism detailing the means by which one politically connected private concern gains a competitive advantage or Government privilege at the expense of some less-politically-connected entity or the consumer via some Federal Government, regulatory framework.

A bill effecting a major reformation of the Food and Drug Administration with such serious implications for individual liberties and for States' ability to effectuate their constitutionally-ordained police powers, warrants something more than the ''stealth'' procedure by which this regulatory ''bomb'' has been brought to the house floor. This bill apparently will be passed without a real opportunity for responsible debate or even a recorded vote. At a minimum, an opportunity to speak or inquire regarding the bill's provisions on the house floor and/or the opportunity to amend the bill to improve or remove offensive language, should have been provided within the legislative process. Unfortunately, this was not the case. For these reasons, I oppose H.R. 1411.

Mr. TOWNS. Mr. Speaker, I join my colleagues in applauding the scheduling of this measure today. H.R. 1411, the Prescription Drug User Fee Reauthorization and Drug Regulatory Modernization Act of 1997 is the culmination of 2 years of hard work by the Commerce Committee to modernize procedures that the Food and Drug Administration uses to approve drugs, devices, and food products.

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. This legislation will also provide patients with greater access to information about new investigational treatments. Additionally, we established reasonable national uniformity standards for OTC drugs and cosmetics. These standards offer a excellent beginning for future discussions about national uniformity for food products, discussions which I hope will begin next year with hearings on this issue.

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], 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 Holcomb, the measures you see before today accomplished 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. The bill promises to provide important public health benefits to consumers by enabling FDA to act quickly on petitions for new health and nutrient content claims and by removing impediments to critical food technologies like irradiation.

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

Mr. FRELINGHUYSEN. Mr. Speaker, I rise today in support of H.R. 1411, a package of three bills reforming the Food and Drug Administration.

Clearly, the modernization and streamlining of the FDA are important goals which have commanded considerable thought, time, and energy from Members of Congress, the Agency, and other interested parties. I am pleased that we are acting today on this important legislation, and I look forward to swift passage and enactment.

Mr. Speaker, I come from New Jersey. And I am proud to say that my home State is considered the Nation's medicine chest. New Jersey is home to some of the world's most innovative pharmaceutical companies, including Johnson & Johnson, Merck, American Home Products, Schering Plough, Warner-Lambert, Novartis, Hoffman-La Roche, and Bristol-Myers Squibb, just to name some of them. More than 40,000 pharmaceutical company employees are working in my State, leading the way in discovering, researching, developing, and marketing life-saving new drugs. I am proud to represent these individuals and businesses.

While the bill will benefit these individuals, by reauthorizing the Prescription Drug User Fee Act [PDUFA] and streamlining and modernizing the Agency, I am supporting H.R. 1411 today because it benefits a larger group: America's patients. All Americans who are in desperate need of new therapies for Alzheimer's, Parkinson's disease, cancer, AIDS, and all other maladies for which no adequate drug treatment exists today. Furthermore, our work benefits the world in every country where there is sickness and suffering.

There is so much in this bipartisan bill that is designed to help patients. There is the reauthorization of PDUFA, the enactment of which has meant more to expediting approval of life-saving new therapies than anything else. Last year, the FDA approved 53 new drugs and 9 new biologics. Since enactment of PDUFA, FDA has approved more than 125 new molecular entities—totally new medicines—all of which have brought relief and benefit to patients.

H.R. 1411 also provides for expedited approval of life-saving new medicines and access to unapproved therapies for the most critically ill among us. The bill allows manufacturers to disseminate information about unapproved uses of approved drugs, while ensuring that the information is balanced and encourages additional research on already-approved products.

The package also facilitates the development, clearance, and use of devices to maintain and improve public health and quality of life.

Finally, H.R. 1411 maintains the Agency's high standards of efficacy and consumer safety.

Mr. Speaker, when we enact this legislation, we will be giving the hope of better health and longer lives to millions of Americans and people around the world. That is good news for New Jersey and good news for America. I urge support of this legislation.

Mr. STEARNS. Mr. Speaker, I rise in support of H.R. 1411. First, I would like to thank Chairman BLILEY and Chairman BILIRAKIS and the staff for getting us to this point. It has been a long and at times very difficult process and you are to be commended for your leadership.

I would also like to give special thanks to my colleagues, Representatives RICHARD BURR, JOE BARTON, and ED WHITFIELD for all their hard work on these three bills.

Legislative proposals to reform the FDA to speed up the approval process for new drugs and medical devices and to improve the regulation and labeling of food is long overdue. Today's vote is historic and I am pleased to see that we have finally gotten to this point.

The problems associated with FDA's regulation of products and related issues are already known in the biomedical industry. Several key issues are: how regulation affects patient access to new drugs, how it impedes new drugs and biotechnology products from being brought to market, and how regulatory delays are forcing drug and medical device companies overseas.

If we are to continue to compete in this global economy, we must streamline the current FDA approval process. Because European review of new medical technologies is more efficient and timely than the FDA, these companies are increasingly moving out of the United States. Start-up biotech companies, also unable to meet the capital demands due to the lengthy and uncertain FDA process, have lost thousands of jobs through both direct exports and opportunity costs.

While our position has slipped in recent years, the United States is still the world's leader in the development and production of medical technology. However, the sad fact is that the United States is beginning to lose ground in health technology to foreign competitors. Unless we provide relief for this industry and curb FDA's burdensome over regulation and countless delays in the approval process, we will continue to see a steady erosion in an industry in which we have always been recognized as a world leader.

It is very gratifying to be a part of this process and I want to applaud the Commerce Committee's desire to make these necessary changes contained in the legislation before us today. We have an opportunity to reverse the trends which have our companies going outside the United States to conduct initial development of new products. When this occurs, not only do we lose jobs, but we also lose U.S.-produced technologies.

One question that we might ask is: What are we doing in comparison to the rest of the world. For instance, it might be useful to have a list of these products and whether they have been approved in tier one countries and for how long. Perhaps there should be some type of annual report that provides us with that type of data. If the FDA objects to this, I think it might be advisable to ask what we can do to make sure that the FDA makes such information available in the future.