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

Mr. GREEN. Mr. Speaker, this morning we are considering a bill that I never believed would be debated under suspension rules. In fact, I thought my chances of winning the lottery in Texas were much better than the FDA reform bill being on the suspension calendar.

This bill has had a long and contentious history on the Committee on Commerce. It was not always clear that a compromise bill could be reached. This bill is a step forward for reform. I believe both sides of the aisle should support it, and we have heard this morning they do.

One of the areas that caused the most concern for me was the approval process for medical devices, particularly third party review. I am pleased that the gentlewoman from California [Ms. ESHOO] and the gentleman from Texas [Mr. BARTON] have come together and worked out a compromise that would utilize the expertise of outside reviewers, prevent conflicts of interest, and involve the FDA in the certification of reviewers. Even with the use of outside reviewers, the bill still gives the FDA discretion to accept or deny the recommendations of outside reviewers.

This reform, combined with other portions of the bill, will help medical device companies know what is required of them during the FDA review, and gives them a sense of certainty that their application will be handled within a certain period of time. At the same time, it recognizes the FDA's role at the center of the medical device and drug review process and reassures the American people they will be accountable for the safety and efficacy of drugs and devices.

Mr. BLILEY. Mr. Speaker, I yield such time as he may consume to the gentleman from Florida [Mr. FOLEY].

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

Mr. FOLEY. Mr. Speaker, I rise in support of the bill, and will include concerns which were not addressed in the bill which would allow the FDA and EPA to ban products used by asthmatics that are medically necessary.

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

Mr. GANSKE. Mr. Speaker, I rise in strong support of H.R. 1411.

E. coli bacteria results in between 10,000 and 20,000 illnesses a year. While proper cooking can kill *E. coli*, it deprives us of something that many of us really like, a nice juicy rare hamburger. Pasteurizing red meat with low-dose irradiation kills bacteria without harming the food. The process has already been approved by FDA for spices, poultry, pork. Why not hamburger?

For more than 3 years the Food and Drug Administration has been sitting on a petition to allow the use of low-dose irradiation for red meat. It is time

that they passed. H.R. 1411 includes an amendment I offered to make the FDA complete its review within 60 days. Mr. Speaker, we need to have safer meat. Low-dose irradiation would provide that. A vote for this bill will make all of us a hamburger helper.

Mr. DINGELL. Mr. Speaker, I yield myself 1 minute for the purposes of a colloquy, and I yield to the distinguished gentleman from Rhode Island [Mr. KENNEDY].

Mr. KENNEDY of Rhode Island. Mr. Speaker, I would like to thank my colleague from Michigan for yielding to me.

Thirty million Americans rely on CFC propelled metered-dose inhalers. These are the inhalers for asthmatics. Over 30 million Americans rely on them. Yet in March 1997, the FDA proposed a policy that would ban these metered-dose inhalers for asthmatics all across the country, while the FDA did not take into account what alternatives would be available to millions of children in this country.

I want to thank the ranking member of the committee and the chairman for recognizing the need to modify this FDA policy, and look forward to working with them to see that appropriate amendments are made to the FDA law so that metered-dose inhalers are not banned for children in this country.

Mr. DINGELL. Mr. Speaker, the committee considered this matter. We regard it as important and we will pursue it further.

Mr. BLILEY. Mr. Speaker, I reserve the balance of my time to close.

Mr. DINGELL. Mr. Speaker, I yield 2 minutes to the gentleman from Florida [Mr. DEUTSCH].

Mr. DEUTSCH. Mr. Speaker, this is what this process is supposed to be about, making legislation to make the people's lives in the United States a little bit better. I believe very strongly that that is what this legislation will do.

I think just for a second though we should remind ourselves that this was not an easy process and it was a long process. I think the work in particular of the gentleman from Michigan [Mr. DINGELL] and other leadership on the Democratic side and the Democratic Members really have brought us toward this point in time. Just 12 months ago, 24 months ago, the FDA legislation that was in front of us was a much more radical, in fact, a radical and really threatening piece of legislation to the American people.

In terms of the prescription drug area, we have made some dramatic strides. I believe there is still one area in the conference committee. I know that the Members, the gentleman from North Carolina [Mr. BURR] in particular, as well as the gentleman from Florida [Mr. BILIRAKIS], will be working on. That is the issue of exclusivity for new antibiotic drugs. The bill limits its exclusivity to new antibiotics and that exclusivity would not apply to any drug for which an NDA is already pending. I am also pleased that we have a commitment to continue working on

eliminating exclusivity to antibiotics in which there is not a pending I&D, which is the final stage of clinical investigation.

This Congress has made very significant strides in promoting the use of generic drugs in the United States of America as a cost containment and a health issue for all Americans. In an attempt to both balance the need for innovation in terms of resistant strain antibiotics, while at the same time balancing the need for generics and the purpose for generics that this Congress has stated very strongly on many occasions over the last years, I think it is important that any additional exclusivity that we grant in terms of antibiotics, which would be the first time that there would be exclusivity for antibiotic drugs, that it be limited in scope very narrowly to the challenge that we face in terms of resistant strains. I know we have made some moves in that direction, and hopefully as we enter the conference report we can continue that as much as possible within the specifics.

Mr. DINGELL. Mr. Speaker, I yield myself 1 minute for purposes of closure.

I simply want to read the language of the administration on this. It says:

The administration applauds the House for its efforts to produce a bipartisan FDA reform bill and appreciates the responsiveness to concerns that have been raised. Because of the importance of obtaining a 5-year extension of the Prescription Drug User Fee Act, [PDUFA], the administration has no objection to the House passage of H.R. 1411.

I urge my colleagues to recognize that this is a compromise. This is a good compromise. It represents a bill which makes progress, which serves the public interest, which helps the manufacturers but which also protects the consumer with exquisite care. It is an excellent bill. I urge my colleagues to vote for it.

Mr. BLILEY. Mr. Speaker, I would like to say, it has been said before in the debate but I want to thank the staff, particularly Howard Cohen, Eric Berger, Roger Carey, and Alan Hill and Kay Holcombe.

With that, Mr. Speaker, I yield the balance of my time to the gentleman from Wisconsin [Mr. KLUG].

Mr. KLUG. Mr. Speaker, I thank the gentleman. I have watched a number of young friends in my district grow a head taller as we have worked on this bill for the past 3 years. And while they have outgrown last year's school clothes, unfortunately they cannot outgrow their diseases. Amber still has juvenile diabetes. Cody still has epilepsy. And Kristin still has asthma. Today's bill will go a long way toward easing their suffering by setting up special testing for new drugs aimed at children and expediting new uses for drugs also aimed at treating children's diseases.

This bill is going to go a long way towards easing the suffering of millions

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