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CONGRESSIONAL RECORD — SENATE

DRUG ADVERTISING

Mr. ROBERTS. Mr. President, I thank Chairman KENNEDY, Ranking Member ENZI and all of my colleagues for accepting my amendment to improve the drug advertisement provisions included in S. 1082, the Food and Drug Administration Revitalization Act.

My amendment, replaces the drug advertisement provisions in the underlying bill with what I believe is a more commonsense approach to dealing with prescription drug advertisements.

During the markup in the HELP Committee a few weeks ago, the chairman and Ranking Member ENZI committed to working with me to address my concerns on this issue. This amendment represents the result of our efforts to achieve an outcome that is acceptable to all of us.

I also want to thank Senators HARKIN, BURR, and COBBurn for their leadership on this issue and for cosponsoring my amendment.

Chairman KENNEDY and Ranking Member ENZI, I want to say that I truly appreciate the hard work you both have done in putting together this bill. I know you and your staff have put in many long months of work to get us to this point.

I specifically want to thank David Bowen of Chairman KENNEDY’s staff and Amy Muhlbeger of Senator ENZI’s staff for working so closely with me and my office on finding a resolution to the drug issue. David and Amy, I appreciate your commitment and professionalism in helping us to achieve this compromise.

While I strongly support the goals of this legislation to ensure drug safety and to renew some very important prescription drug and medical device programs, I have serious concerns with provisions in the underlying bill regarding drug advertising. I believe these provisions would infringe on our first amendment rights to free speech. I believe the ad would be false or misleading ads.

Of most concern to me is a provision in the underlying bill to give the Secretary the discretion to institute a 2-year ban on advertising for new drugs and related restrictions on drug advertising.

As a former editor and reporter for several newspapers, I feel that these provisions violate the first amendment and would do nothing to address concerns that have been expressed with drug advertising. Instead, we would have a situation where the Secretary would become the editor for all prescription drug advertisements and could ban drug advertising for up to 2 years.

This would certainly put us on a slippery slope to restricting advertisements in other industries, and I don’t think that is a responsible approach.

The freedom that is guaranteed to us under the first amendment demands the Secretary to assess civil monetary penalties—up to $150,000 for the first violation and $300,000 for subsequent violations—on drug companies that produce false or misleading ads.

This will ensure that patients will know truthful and accurate information about new prescription medications in a timely manner, rather than having to wait until 2 years after their arrival in the marketplace.

My amendment also allows the Secretary to require the disclosure of a serious risk or date of approval of the drug, or the advertisement itself if he or she believes the ad would be false or misleading without the disclosures.

My amendment requires that major statements about a drug’s side effects, contraindications and effectiveness in television or radio ads be presented in a clear and conspicuous manner so as not to mislead the public.

My amendment also does not change the current language in the underlying bill which allows the Secretary to review direct-to-consumer ads before a drug company disseminates these ads to the public.

This will allow the FDA to comment and provide constructive feedback to companies to ensure their ads are appropriate and not misleading. Many companies are already submitting their ads to the FDA for review.

Truthful and accurate prescription drug ads do provide a benefit to the public. Research has shown that people are more likely to go to the doctor, ask thoughtful questions and discuss sensitive health issues with their doctors and/or members of their families.

My amendment ensures these positive aspects of advertising will continue, but also gives the FDA the tools
they need to protect the public from false or misleading prescription drug ads.

The agreement that was accepted today is a fair compromise that addresses the concerns of all of the Members involved.

Again, I thank the chairman and Ranking Member Enzi for their efforts to work on this important issue, and I thank all of my colleagues for accepting my amendment.

I ask unanimous consent to add Senator Wein as a cosponsor of the Drug Safety Act.

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

DRUG IMPORTATION

Mr. DORGAN. Mr. President, if and when we pass the underlying bill, we will have advanced this country’s interests, I believe. But if we pass this bill by defeating the Cochran amendment, which effectively kills the underlying amendment on which we have now voted cloture last Thursday, dealing with the safe importation of FDA-approved drugs at a much lower price—if we kill the amendment to the Cochran amendment, we will have substantially diminished the opportunity to provide for drug safety. That is a fact.

The underlying bill doesn’t have in it what we have in the Dorgan-Snowe amendment, for which we have 33 cosponsors. We have pedigree requirements. We have serial requirements to be written on the pill bottles. We have anticoercing measures. We have addressed all of those issues in the amendment. None of those requirements exist today, and none of those will exist with the domestic drug supply or with imported drugs when this legislation passes.

The only way those provisions will exist is if we defeat the Cochran amendment and then pass the amendment that we have offered, allowing for the safe reimportation of prescription drugs, because we put the safety provisions in our amendment.

Mr. President, let me ask unanimous consent to show once again two bottles of Lipitor.

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

Mr. DORGAN. This is a prescription drug made in Ireland. It is made in Ireland. It is called Lipitor. It is for the reduction of cholesterol. It lowers your cholesterol—the same pill, put in the same bottle, made by the same company, made in the same FDA-approved plant. It has only one difference—one only. That is, this one costs twice as much. Why? Because this one was sent to Canada and this was sent to the United States. The U.S. consumer is told: Congratulations, you get to pay twice as much for the prescription drug.

But that is not unusual. It is happening all the time.

Let’s talk about counterfeiting. This is a $20 bill. This is a new $20 bill, you know, the ones we brag about, the ones the mint has press conferences about. We have all kinds of technology in this $20 bill to prevent and prohibit counterfeiter from reproducing this $20 bill.

We can build a technology in a $20 bill to prevent counterfeiting, but we can’t do it for medicine? Are you kidding me? What we have provided in this amendment is a series of steps: complete pedigree, serial numbers, RFID technology and anticoercing measures for the $20 bill but not for a bottle of medicine? Don’t believe it.

We are going to vote at 4 o’clock. The question is going to be: Will the pharmaceutical industry have their way once again, as they have so often?

Let me make a point that is important. The Cochran amendment is already law. It was passed in 2003—in 2003. It already exists in law. The result is the Secretary of Health and Human Services can implement because I can’t certify there is no risk. The fact is the Secretary can’t certify there is no risk with any new drug. He couldn’t certify there is no risk with spinach coming from Mexico and strawberries coming from any other country. He couldn’t certify there is no risk with any food product being imported. They can’t certify there is no risk with the domestic drug supply. In fact, the domestic drug supply, without our amendment, will be dramatically less safe because you will not have the protections we put in this amendment.

The pharmaceutical industry has never wanted them, and the underlying bill doesn’t include them. It doesn’t include the anticoercing provisions. It doesn’t include the pedigree, the serial requirement on the individual bottles to track back. It does not include that. That is a fact.

So don’t vote for the Cochran amendment. We don’t want to allow Americans to import FDA-approved, lower priced drugs. The question is this: Should the American people be paying the highest prices in the world for prescription drugs? The answer is, no; it is not fair.

Why should that be the case, that we should pay the highest prices in the world? So we have put together a piece of legislation—bipartisan, people on both sides of the aisle, 33 cosponsors. Then when we’re told, well, it is unsafe to do this. It is not.

That is nonsense. It is not unsafe. Europe has done it for 20 years. Europe can do it, but we can’t do it? It gives consumers the opportunity to take advantage of the global marketplace. We are talking about FDA-approved drugs, made in FDA-approved plants, sold all over the world with one difference—price. The American consumers are told they have to pay the highest price. Dr. David Kessler is the expert on medicines. He was FDA Commissioner for 8 years, the head of the Food and Drug Administration. The Dorgan-Snowe bill provides a sound framework for assuring that imported drugs are safe and effective.”

Safe and effective. End of story, in my judgment. I understand the pharmaceutical industry does not want this. I understand that. They want to keep prices. Yes, controls in America, not Government price controls but price controls by the pharmaceutical industry.

It is the only industrialized country in the world that I am aware of that does not have prices set for the pharmaceutical industry. Price it as you wish. It doesn’t matter. You just price it as you wish.

Well, what they have done—I had a hearing. Here is what they told me. They price at the level they price prescription drugs in this country because they can. Because they can. That might sound OK for the bottom line, but what does it mean for the person walking into the grocery store tonight in a small town in the Midwest who does not have much money and has to add the drug to the back of the store—I better go buy the prescription drugs the doctor says I need first to find out how much money I have left for groceries?

It goes on all the time. Many of us believe that Republicans and Democrats, we ought to at least open the global marketplace for consumers to be able to pursue those FDA-approved drugs, made in FDA-approved plants, at lower prices, the prices at which they are produced virtually every other country in the world. This is unfair to the American consumer. That is the point.

Interestingly, there was a long description of counterfeit drugs in the New York Times this weekend. None of that would be available to report, in my judgment, because it would not have happened if we had had the provisions, the safety provisions we have in the Dorgan-Snowe amendment.

The fact is, you would not have danger in the drug supply because you would have much more money going to the FDA for the purpose of making certain the drug supply is safe. I am not just talking about the imported drugs, I am talking about a drug supply sold in this country, produced here and sold here. The lack of serial numbers, the lack of a pedigree, the lack of effective anticounterfeiting technology, the lack of resources to go after RFID technology, all of that is lacking in the underlying bill.

It is not in the bill. The only way it is going to get there is if we are willing to defeat the Cochran amendment and to pass the amendment I have offered along with many of my colleagues. This is not a new issue. We have come to this issue on many occasions in the past. Each and every time the pharmaceutical industry has been able to trump us with votes on the floor of the Senate or the House. I hope—first I wish second I hope, and finally I expect—that one of these amendments will be able to prevail. One of these days we may be able to win this debate. Maybe it is today at 4 o’clock. I hope so.