

What we have experienced in Greensburg is unlike any other event in recent Kansas history. The hospital is gone. The schools are gone. Every church is gone. Virtually every business in the community is gone, including all of Main Street. Estimates are that fully 95 percent of the structures in the town are damaged and destroyed.

But this is not all. Even as cleanup is starting, more storms continue to pound our State. Flooding and strong storms continue to compound the problem.

Too often, while government does not communicate and work well as partners in times of need and emergency, sometimes we could double that for Congress. However, this weekend my fellow Kansas Congressman and the Governor of Kansas and I all toured the devastated town of Greensburg. We were accompanied by our State's top-notch emergency officials. I spoke extensively with all levels of FEMA, in an effort to make sure they had everything they needed to move into place, and I talked to President Bush to give him a personal update from a McDonald's in Pratt, KS. Let me tell you, there is nothing quite like speaking to the President of the United States from a phonebooth in a local McDonald's to let the surrounding residents know their Government does mean business.

The President has been very supportive. We have been notified by the White House that he will be making a trip to Kansas to personally view the damage and visit with the people of Greensburg. The credit for this not only falls on Federal shoulders but those of our National Guard, all of the first responders, Red Cross, and many volunteers who, along with President Bush and the FEMA team and our State officials, are now working 24/7 to make it possible for the residents of Greensburg to rebuild and return home.

I stood here this winter, following a blizzard that buried much of western Kansas, and proclaimed the resiliency of Kansans, our willingness to help each other and our sheer determination when faced with great odds. That determination is being tested again, but I have no doubt in the coming days and weeks and months that the story of Greensburg will progress from one of horrible tragedy to one of optimism and hope for the future as we help one another rebuild, one brick at a time. It may be possible, indeed likely, that as we move forward, we may need additional emergency assistance or legislation from Congress to assist the residents of the town that no longer exists. I put our Senate leadership and all our colleagues on notice today that we will likely be coming to you with any requests for assistance to rebuild this Kansas community.

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 of this bill 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 COBURN 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 Muhlberg of Senator ENZI's staff for working so closely with me and my office on finding a resolution on the drug advertising 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.

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 that we carefully consider any proposal that would impose a ban or other limitation on speech. The first amendment says, "Congress shall make no law . . .

abridging the freedom of speech" For more than three decades, this protection has been extended to speech in the form of advertising, or commercial speech.

The U.S. Supreme Court has set down an explicit four-part test—known as the Central Hudson test—to determine if a speech restriction violates the first amendment.

I believe the advertising provisions in the underlying bill fail the key parts of that test and my view is supported by constitutional experts, including the American Civil Liberties Union—ACLU, the Washington Legal Foundation and several other constitutional experts.

However, I understand that there are strong concerns with drug advertising. I agree that we have a legitimate interest in ensuring these advertisements are not false or misleading. This is why my amendment takes a reasonable and commonsense approach to deal with drug advertisements.

My amendment stresses the importance of assuring that advertising is accurate and balanced and recognizes that companies should be held accountable if their ads are false or misleading.

My amendment strikes the 2-year moratorium on advertising in the underlying bill and instead allows 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 in the advertisement 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 as a result of DTC ads.

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 WEBB 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 adding 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 that by agreeing 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 anticounterfeiting 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—only one. 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 counterfeiters 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 anticounterfeiting measures. We can do it for a \$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 says it can't be implemented 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 or 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 anticounterfeiting 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 and then tell people you 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 we are told, well, it is unsafe to do this. It is unsafe.

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 this, in my judgment. 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 control prices. Yes, we have price 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 says to the drug 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 decide—the pharmacy is at 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, 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 sold in 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 days we 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.