Mr. ROBERTS. Mr. President, reserving the right to object, if that is where we are.

Mr. KENNEDY. Mr. President, could I have the attention of Members. I understand the good Senator from Kansas wanted to make a brief statement about the terrible tragedies that have affected his State, and I see my friend from Vermont is here, so if he were to take 10 minutes, we would still have 10 minutes.

Mr. SANDERS. Ten minutes would be fine.

Mr. KENNEDY. I am wondering if Senator SANDERS would be willing to take 6 minutes and let Senator ROBERTS have 4 to talk about the tragedies in his State. He mentioned this earlier to me, and I didn't think we would have this time dilemma. Would that be acceptable?

Mr. SANDERS. Yes.

Mr. ROBERTS. I could not hear the amount of time I might be permitted.

Mr. KENNEDY. We have the whole 30 minutes, but the Senator from Vermont has said that, of his 10 minutes, he would be glad to yield to you 4 minutes, and then he will take 6 minutes. Would that be agreeable?

Mr. ROBERTS. If I could plead with the Senator for 5 minutes?

Mr. SANDERS. Yes.

Mr. ROBERTS. I thank the Senator from Vermont.

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

Mr. KENNEDY. Mr. President, I will yield 1 minute of my time to Senator SANDERS.

Mr. SANDERS. I thank the Senator.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

DRUG SAFETY

Mr. KENNEDY. Mr. President, hopefully during this afternoon we will have a chance to move irrevocably toward bringing the FDA into the 21st century, in terms of safety and security for American families. We do that with our primary focus making sure that in this time of the life sciences, the extraordinary breakthroughs we are seeing every single day, that the Food and Drug Administration is going to bring those new opportunities to American families but do it safely and do it efficaciously and do it in a way which is going to ensure that every family in America is going to have safe prescription drugs and safe products over which the FDA has jurisdiction.

I thank my friend from Wyoming for all his good work. We are going to have a series of three votes, and then we may very well set a pathway, hopefully, toward a successful conclusion of this legislation. He and I are both eager to see this legislation in the conference to work out, with the House of Representatives, the points of difference with the House. We are also eager to work out the extremely important area of the follow-on biologics. It is an enormously important area of public health, and it is going to demand a great deal of time and careful attention to make sure we get that issue correct.

It is important to not fail the American people but to see progress made in addressing this issue. The only way we can do it is make sure we get legislation that is going to pass the Senate, pass the House of Representatives, and move into conference. We are strongly committed to doing that.

I commend our colleagues for all their good work and assistance. We had a rigorous markup in our committee for several hours. There were a number of different amendments. We have addressed the issue of food safety with the Durbin amendment. This issue has been on the front pages all over this country and all over the world, particularly with regard to pet food as well as food safety generally. This legislation will go a long way toward giving assurances to American families that all of our food products are going to be safe and secure.

There are other provisions such as developing a nonprofit foundation so we can draw from the private sector and the public sector to make sure that agency is going to have the best of new techniques and new modalities, and to try to make sure the products that are before the Agency are going to be safe and secure and available as fast as possible. There will be a new emphasis in terms of science and also, as my friend from Wyoming points out, a toolbox that will be available to the FDA in order to ensure that we can get drugs more rapidly to the consumer but make sure they will be safer for American families, using the best of new technology, information technology, to make sure they are going to be more safe.

I am enormously appreciative of the work of my friend from North Dakota, Senator DORGAN, on the issue of cost and price. Part of this is making sure we are going to have drugs that will be safe, but we also want to make them accessible and available. I commend him and all those who have been a part of this process. This is certainly an aspect of the prescription drug issue that we should constantly address.

I thank Senator ROBERTS and Senator HARKIN for working with Senator ENZI and me on the important issue of DTC, direct-to-consumer advertising. We have accomplished our common goal of a constitutionally sound, effective, workable way to make sure that DTC ads provide accurate information to patients about the drugs they are taking. This amendment strikes the moratorium on DTC ads that had given rise to Constitutional concerns, and I think we have a very solid resolution. I wish to thank Senators STABENOW, BROWN, LOTT, THUNE, COBURN and HATCH for reaching agreement on the difficult issue of citizens petitions. Their amendment prohibits the abuse of the citizens petition process, a process that led to unwarranted delays in the approval process of FDA drugs, while making certain the FDA can review issues that have merit. The list also includes a novel proposal from Senator BROWNBACK and Senator BROWN to encourage the development of new therapies for neglected diseases. Under this innovative and thoughtful proposal, companies that have developed new treatments or vaccines for tropical diseases will receive a credit entitling them to a priority review at FDA for a product of their choosing. The proposal will not raise costs to consumers nor will it change safety standards. It is a very solid, imaginative, and creative approach. I commend Senator HATCH for his amendment on antibiotics, as well Senators BROWN, BURR, STABENOW and others for contributing important proposals to this amendment.

The amendment strikes the right balance between innovation and access, and closes a loophole that eliminated the incentives to bring old but never approved antibiotics to market.

If there were more time, I would describe other amendments on the list, but I simply wish to thank all our colleagues. This issue is a matter of enormous importance and incredible consequence to the safety and security of the American consumer. This legislation brings the FDA into the 21st century. I commend my friend and colleague Senator ENZI for all his work. Most of all, I want to thank our staffs. They have been tireless, over this past week, on a variety of different amendments and prior to that time as we worked our way to the floor of the Senate.

This is a very comprehensive bill. It is enormously important. We believe it will help in providing greater safety for American families, greater innovativeness in terms of breakthrough drugs and in terms of food safety, and greater opportunities for the FDA to have the best science there is.

Mr. President, whatever remaining time that I have, I yield it to the Senator from Vermont.

I yield the floor.

Mr. DORGAN. Mr. President, I will allow the Senator from Kansas, if he would prefer, to proceed for his 5 minutes, asking that I be recognized for 10 minutes following his presentation.

Mr. ROBERTS. Mr. President, I thank the distinguished Senator. I thank the distinguished Senator from Vermont for allowing me to speak.

DISASTER IN GREENSBURG, KANSAS

Mr. ROBERTS. My colleagues, last Friday evening the town of Greensburg, KS, was literally wiped off the map by an enormous, mile-and-a-half, level 5 tornado. As a result of this and storms associated with the system, 12 Kansans are confirmed dead—and I fear that number may still rise—and all of the 1,500 residents of Greensburg have been displaced.

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