

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.