

it is not made so by simply certifying with respect to drug importation. As I said, twice before we have been through this—in 2000, and of course in the Medicare Modernization Act of 2003 under the prescription drug benefit for the Part D Program.

Many who are in the Senate today supported a certification requirement in good faith, recognizing that the Secretary of Health and Human Services would certify the safety upon reviewing and evaluating circumstances, but that has not occurred. Most would not think such a certification would block Americans from legally importing medications. That is because for years we have seen our constituents—and certainly those from my State of Maine—using Canadian pharmacies, and both the safety and savings were indisputable. Yet certification did not arrive.

As a result, the former Secretary of Health and Human Services, Secretary Shalala, declined to make the certification with respect to the MEDS Act, and we know she did so because of three specific flaws in the law, each of which this legislation addresses.

After the passage of the Medicare Modernization Act, which included the prescription drug program, we saw that former Secretary Thompson could not certify importation. The fact is, it is patently unfair to ask the Secretary to make such a certification, especially as to safety. That is because you must give the Secretary the resources and the authority to implement measures to make prescription drugs and their distribution as safe as possible.

So it comes as no surprise that given no standards, no authority, and no resources, we have failed to see a Secretary provide certification over the last 7 years. Secretary Thompson understood this well. He said it simply:

The law is this: In order to import drugs from any country, and especially Canada, I have to certify that all those drugs are safe. That is an impossible thing. If Congress wants to import drugs, they should take that provision out.

The certification of savings is no less of a red herring. In fact, it has become a persistent roadblock every time we have passed certification to allow drug importation by the Secretary of Health and Human Services. Without a doubt, Americans would not purchase imported medications if substantial savings were not being realized. Indeed, the Congressional Budget Office has told us the countries from which we would import under this bill pay 35 to 55 percent less for brand prescription drugs and that we can realize a drug savings alone of \$50 billion over 10 years. It should be patently obvious the savings part of certifying importation is a nonissue.

In fact, the Congressional Budget Office has confirmed those savings again, estimating that in addition to consumer savings, the Federal Government would save \$10.6 billion—including the Medicare and Medicaid Pro-

grams that would achieve indisputable savings. Every cent of that savings, the CBO estimates, will be lost if the Cochran amendment is adopted because, as we all know, there would be no legal importation.

The savings are clear. Yet the advocates of certification continue to insist certification is critical—particularly regarding safety. Yet what is needed is not a certification requirement, which simply is a stamp on the status quo, but real action to assure the safety of prescription drugs.

By way of analogy, I would like to know where we would be if we applied this simple certification approach to other areas. Consider air travel. Americans embark on thousands of flights every day, but the travel of millions is not dependent on certifying the status quo. We rely on regulation and oversight of the aircraft that fly and their maintenance—of the individuals who crew, service, and direct those aircraft—of every critical aspect of aviation. If we were waiting for the FAA and its international partners to simply say flying is safe rather than acting to make it safe, we simply wouldn't have commercial air travel.

I note that last week, as the Senate discussed problems with both the drug and food safety, I did not hear my colleagues suggest FDA certify that imported food is safe. We, instead, spoke about measures to make it so. That points to what this amendment is about—not ensuring safety but blocking fair access to imports for Americans.

The fact is, Americans simply cannot see why it is that they cannot be provided a safe and effective system, which is exactly what the Dorgan-Snowe amendment does and what this legislation has been drafted to accomplish year in and year out. We have taken every conceivable concern regarding safety and incorporated it in this legislation.

As you can see on this chart, we incorporate 31 provisions. Compare that to the Medicare Modernization Act, which included the Part D prescription drug program for seniors, that included only six safety-related provisions. We included 31 different provisions. That is crucial to understanding that this sets up a system that will allow FDA inspectors to approve registered prescription drugs imported from other countries—in fact, countries that meet or exceed our standards. Compare that, for example, to the fact that the FDA approves manufacturing facilities in other countries that actually have lower standards than our country does. We allow medications to be manufactured in other countries with lower standards than what we have. Yet we are now saying we will not allow importations of medications from countries that meet or exceed our standards.

At a time in which American consumers are paying 35 to 55 percent more for drugs than foreign con-

sumers—in fact, paying the highest prices in the world—this amounts to \$99 billion more than the foreign consumers. That is what Americans pay today. Some would say: Oh, that affects research and development. Well, no, not exactly. In fact, the pharmaceutical industry spends about 10 percent of that \$99 billion. So about \$10 billion in research and development more than they do in Europe. So we are not seeing the increase in prices that Americans pay being channeled into more research and development. It simply is not the case.

What this does say is that American consumers are paying more than anyone else in the world. Not only are they paying more for their drugs, but American taxpayers are underwriting the research and development, as we have seen obviously with the National Institutes of Health. The taxpayer understands how important it is that the Federal Government remain on the vanguard of research and development of life-threatening medications, and not only are they paying for the research and development that benefits foreign consumers, who are paying 35 to 55 percent less, but they are also paying the highest prices in the world.

That is why this legislation allowing for drug importation is so essential. We have addressed every safety concern. We create a regime for tracking the shipments, creating a pedigree, creating a history with FDA approval—inspected and registered. So I would urge the Members of the Senate to defeat this certification amendment and to support the Dorgan-Snowe amendment. I think we have achieved a milestone moment in the Senate, where we have finally recognized and acknowledged that the day has come to allow Americans to take advantage of more competitive prices than have been available to them before.

I yield the floor.

ORDER OF PROCEDURE

Mr. KENNEDY. Mr. President, we will speak as in morning business for 10 minutes and if the Chair would let me know when I have a minute left.

Mr. DORGAN. Mr. President, reserving the right to object, and I certainly would not object, but I want to understand the time. We have a vote at 4 o'clock, I believe, which is already ordered. Would the President tell me what the time is between the two parties, how it is divided and who controls time at this point?

The PRESIDING OFFICER. The time for morning business has been equally divided until 4 o'clock. The Republicans have no time remaining, and the majority has 33 minutes.

Mr. DORGAN. Senator KENNEDY is asking for 10 minutes in morning business?

The PRESIDING OFFICER. Senators are permitted to speak for 10 minutes.

Mr. DORGAN. Might I ask to follow Senator KENNEDY in morning business for 10 minutes?

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.