They have to defend their own country. He said: Well, pretty soon they will be able to do it. Clearly, they are not doing it. Clearly, the Iraqis are turning on each other. What is our military to do?

As Thomas Friedman said,

Our troops are protecting everyone, and yet they are everyone's target.

They are protecting the Sunnis from the Shia. When they are protecting the Shia, the Sunnis get them. That is an irresponsible policy. So what we need to do is, to speak out loud and to this President,

I ask all the American people to keep on speaking out, to ask the President in these next couple of hours to sign this bill. We can finally change course. We have been in Iraq longer than World War II. We can’t afford this conflict, and that doesn’t mean you cut and run. Anyone who says that is what we are saying is wrong. Read the bill. We redeploy out of Iraq, we stay in the region to go after al-Qaida and to train the Iraqi forces.

We can’t afford this anymore. Mr. President: Sign the bill. I yield the floor.

Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. DORGAN. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

POLICE CHASES

Mr. DORGAN. Mr. President, I would like to talk about a decision by the Supreme Court yesterday that greatly troubles me. Some many years ago, I received a call at 10:31 in the evening that my mother had been killed in a car accident. She was killed in a car accident as a result of a high-speed police chase. My mother was driving home from visiting a friend in the hospital, going 25 or 30 miles an hour on a street in Bismarck, ND. A drunk, on Main Street in Bismarck, ND, was spinning his wheels on his pickup truck, and the police then decided to apprehend him. The drunk driver took flight. Witnesses said he was going 80 to 100 miles an hour on the city streets. Regrettably, he ended in a tragic crash that took the life of my mother.

I have spent many years here in Congress talking about this issue of police chases and training for law enforcement officials, about guidelines—when to chase, when not to chase. I have been joined by a good number of people around this country who have lost loved ones, innocent loved ones who were killed as a result of high-speed police chases. One who came to mind was a former member of law enforcement whose son was killed. Someone with a taillight that was out was to be apprehended by the police, and he took flight and the police chased at very high speeds. The family member of this law enforcement official was killed as a result.

In the middle of working on this, over the years, a county sheriff called me one day. He heard me speak about it. He said: You know, just last week we had a man who was a drunk driver in our community who had two little children in the backseat. The sheriff’s department attempted to apprehend that drunk driver off at a high rate of speed. The sheriff’s office decided to discontinue the chase immediately. They got a license number. They discontinued the chase. Three hours later, they arrested the man. He said: It could have turned out differently. We could have chased that man at 80 to 100 miles an hour, and the end of that chase could have resulted in the death of those children in the backseat of that car. But we didn’t do that because we had guidelines and we had training.

The Supreme Court yesterday issued a ruling, regrettably, that I believe will result in more deaths in this country, deaths of innocent bystanders, as a result of high-speed police chases. I think the ruling is a horrible ruling.

Incidentally, the Supreme Court, apparently for the first time in history, put a video on their Web site so people could see this which was the subject of the decision in the case they were considering. Let me suggest to the Supreme Court that perhaps they could put some other videos on their Web site. I know high-speed police chases have become a form of television entertainment all too often, but they all too often end in disaster and end with innocent people losing their lives. There are other videos they could perhaps put on their Web site, if the Supreme Court were interested. Among those videos might be the resulting crashes of high-speed police chases in the middle of our cities, at 80 and 100 miles an hour, where innocent bystanders ended up losing their lives.

I understand why the police chase when there is a felony, a bank robbery, a serious crime. I understand that. What I don’t understand is this: why chases ensue in these communities because of a broken taillight or a person going 5 miles an hour over the speed limit and a chase ensues. Yes, the responsibility is in the person fleeing the police. Yes, that is the case, I understand that. But that does not give rise, in my judgment, to reason to endanger people on the city streets with chases at 60, 80, or 100 miles an hour. That is not justified.

Law enforcement needs guidelines. They need training to understand what the consequences are to chase, when not to chase. Regrettably, I believe the Supreme Court ruling yesterday will result in more high-speed police chases and more deaths of innocent Americans. That is a profound disaster. I understand why the police chase when there is a breaking of the law. I understand why the police chase when there is a legitimate reason to do so. But we have seen the results of these high-speed chases.

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is closed.

PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

The PRESIDING OFFICER. Under the previous order, the Senate will resume consideration of S. 1082, which the clerk will report.

The legislative clerk read as follows:

A bill to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

The PRESIDING OFFICER. The time until 12:30 is to be evenly divided between the majority leader and Republican leader and to be used for debate only.

The Senator from North Dakota is recognized.

Mr. DORGAN. Mr. President, I ask unanimous consent that Senator BOXER from California be recognized for 15 minutes, obviously as the next Democratic speaker following my presentation.

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

Mr. DORGAN. Mr. President, I have come to the floor to talk about the underlying bill that is being considered, a piece of legislation to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions and so on. It may be that there will be an agreement by which I and some others will offer legislation or an amendment to deal with the issue of prescription drug prices will do that at another time and not on this bill. If that is the case, I am fine with that. I understand there are discussions underway now. I would be perfectly amenable to not offering an amendment on this legislation and instead having an opportunity to offer it at a different time. That amendment is about the reimportation of prescription drugs.

Let me talk just a little about this issue. This is an issue which is getting a gray beard these days because it has been around so long with so many promises to be able to take it up here in the Congress. We have 33 cosponsors on a piece of legislation that would try to break the back of the pricing monopoly that exists with the pharmaceutical industry for prescription drugs in our country. The fact is, the American consumers are charged the highest prices for prescription drugs anywhere in the world. The highest prices for prescription drugs are charged to the American consumer. It is not right. It is not fair. It ought to stop. We do have price controls on prescription drugs in our country; they are just controlled by the pharmaceutical industry. That is why we have the highest prices in the world.

Mr. President, I ask unanimous consent to show a couple of bottles of medicine.
The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. DORGAN. Mr. President, these two bottles of medicine are Lipitor. Lipitor is a very common prescription drug used by many Americans to reduce cholesterol. As you can see, this drug, Lipitor, is made in Ireland, as a matter of fact, and then imported into this country by the pharmaceutical industry. From Ireland it is sent many places, but in this case the bottle in my left hand was sent to Canada, and the bottle in my right hand was sent to the United States. Same bottle, same pill, slightly different color on the front of it. It is an FDA-approved medicine produced in an FDA-approved plant in Ireland and then sent to Canada and the United States.

The difference? No difference—same plastic in the bottle, same medicine inside—except the price. The Canadian pays $1.83 per tablet, and the American pays $33.57—96 percent more. Let me say that the price difference, same medicine, same bottle, same price, made in the same plant, FDA approved. Difference? The American consumer is told: Guess what, we have a special deal for you, you get to pay 96 percent more for the medicine.

Is this unusual? No, it is not. I sat on a hay bale one day at a farm with an old codger. He was in his eighties. This is in North Dakota. He said: You know, my wife has been fighting breast cancer, and she has been on this now for 3 years. We have gone to Canada. We had to go to Canada to get the medicine, to buy Tamoxifen, and the reason we had to drive to Canada every 3 months or so to get the medicine is we save 80 percent by buying it in Canada. We cannot afford the price in the United States. We can't afford the price to have my wife fight this breast cancer.

The question is, Is it just Canada? No, not at all, but let me at least describe the difference with the United States and Canada. I could put up the chart with Italy, Spain, Germany, France, England—I could put up this chart with virtually every country because the U.S. consumer pays the highest prices in the world.

Lipitor, I just described it; Plavix, we pay 46 percent more; Prevacid we pay 97 percent more; Zocor, 31 percent more; Nexium, 55 percent; Zoloft, 52 percent more. The list goes on and on, as you might imagine.

We have a position that receives a lot of benefit from miracle drugs. There are prescription drugs that allow you to manage your disease without having to go to an acute care bed in a hospital. It is a wonderful thing. A substantial portion of the research to develop those drugs is done in the National Institutes of Health, paid for by us. We turn that research over to the pharmaceutical industry, they produce medicine from it, and then they sell us the medicine.

Another body of research is done by the prescription drug industry themselves. They spend a lot of money on that. They also spend a lot of money on advertising and promotion. Now, anyone who was standing in front of a mirror this morning brushing their teeth, shaving, perhaps getting ready for work and had their television on, one of those little television sets, if they happened to be changed in an ad—what was doing that probably saw a television commercial. It said this: You should go ask your doctor whether the purple pill is right for you. It didn’t necessarily tell you what the purple pill was for; it only said that your doctor has done purple, so ask your doctor to see if you should have the purple pill.

It also makes you want to run out and say: Hey, what is this purple pill? Maybe I should have some of those purple pills, without knowing what they are for. It goes on all day, every day, advertising directly to consumers for medicines that can only be prescribed by a doctor for a prescription saying: Go talk to your doctor. Wouldn't you like to know, Mr. United States? We have an unbelievable amount of promotion and advertising with respect to prescription drugs. That is another issue. I believe there is only one other industrialized country that allows that; that is New Zealand. That is another issue for another time.

The issue is pricing. I have described what is happening with respect to pricing. This is Canada, but I can describe it for other countries as well. The prescription drug manufacturer, the wholesaler, the pharmacy, the manufacturer, the wholesaler, the retailer.

Before we move on, I want to say this: We have had a quote from Dr. McClelland, the former head of the FDA, virtually identical chain of custody from Canada as opposed to the United States between the pharmaceutical manufacturer, the wholesaler, and the retailer.

So is the chain of custody in Canada safe with respect to prescription drugs being sold to Canadian consumers? The answer is yes. So why would you not be able to establish a regime, just as they have in the United Kingdom? They have a fair number of friends in this Chamber who would want to help them derail this legislation and continue to be able to charge the highest prices to the American consumer.

Lipitor comes from Dublin, Ireland. Nexium comes from France. Of course, these are all imported by the pharmaceutical manufacturers themselves. Any one of these—Vytorin, Singapore, Lescol, Poland—comes from Osaka, Japan. All of these are made in other countries, brought back to this country, and, by the way, sold in every other country in most cases for a lower price than when they travel back to this country by the manufacturer.

The legislation we have introduced is very simple. It gives the American consumer the opportunity to take advantage of lower prices for an FDA-approved drug. This is not new. If you are in Europe and you are living in France and want to buy a prescription from Spain, or living in Italy and find a prescription drug priced lower in France through a parallel trading system, you can easily do that.

To my knowledge, we have testimony from one of the people involved. To my knowledge, there have been no issues of safety at all. They have done it for 20 years. Are those who oppose this saying, well, the Europeans are smarter than we are, they can do it but we can't? I don’t understand that. That is not the case. I don’t understand that.
This is a very simple case. We propose an amendment that would allow drug reimportation and would make it safe. That is the fact.

We understand that the pharmaceutical industry does not like it. That is a fact, too. I understand why they don’t like it.

Suppose I were running a pharmaceutical company and had the ability to price however I wanted to price inside the United States, one of the most important markets in the world, perhaps the most important market in the world, and I would have no competition from lower prices because I was able to keep that out. I understand why they would like to keep that working for them, but it does not work for the American people. It is not fair for the American people; it just isn’t.

That is why we have put together a bipartisan piece of legislation, the Doran-Snowe bill, that is supported by Republicans and Democrats, which now has 30 cosponsors. It is one that should pass in the Senate. The House has already passed a similar piece of legislation in the last session. I believe, finally, given a fair opportunity—and I believe we will be given that fair opportunity—is on this bill or perhaps with some consent to do it on another bill, I believe we will get this done.

This is important. There are some things that do not surprise us. There are things that are not very surprising, as it were, that are very important. One of the things that is perhaps the most important is the right to have the right to affordable prescription drugs. One of the things that I believe is one of the most important is the right to affordable drugs. I believe we will get this done.

I understand the pharmaceutical industry is pulling out all of the stops. They have a full court press, trying to find as many Members of the Senate as they can who will stand up for their current pricing strategy. And they will find a few, no question about that. I think there are some Members of the Congress who like the pricing strategy. The problem with the pharmaceutical industry is the pricing strategy, the pricing strategy which says to the American people: You pay the highest prices in the world, and there is nothing we will let you do that can alter that. That is wrong. That is why I and others come to the floor of the Senate to say let’s fix this. Not later, let’s fix this now.

Mr. President.

The PRESIDING OFFICER. The Senator from California is recognized.

Mrs. BOXER. Mr. President, I thank my colleague, Senator DORGAN, for all his hard work on this issue of affordable prescription drugs. He has been such a consistent voice. I stand with him on that. I thank him.

(The further remarks of Mrs. BOXER are printed in today’s RECORD under Morning Business.)

The PRESIDING OFFICER (Ms. KLOBUCHAR). The Senator from Wyoming is recognized.

Mr. ENZI. Madam President, this morning there have been a couple of topics brought up. The bill before us, of course, is the bill of the Food and Drug Administration, several important parts of the Food and Drug Administration, and a new section on drug safety to give the Food and Drug Administration a few more tools for their tool box. So I will start to that topic instead of addressing the one more recently brought up. I have some very strong feelings on that and some very strong opinions on how America ought to be involved in the war and what the consequences are of us pulling out. However, I want to stick to the topic of the day, which is our pharmaceutical supply.

Most Americans who turn to imported drugs do so because of the cost. We need to answer a lot of questions before we open our borders to imported drugs to be sure we don’t endanger consumers or jeopardize research or jeopardize the pharmaceutical supply. If you grind them up, they have exactly the same chemicals in them, but one of the things we found out from some of these drugs is that the treatment they have is different. One would appear to come from Canada, but it might very well come through Canada from Saudi Arabia, have exactly the same packaging, labeling, colors, seals, even the same look of a pill. But one of the things we found out from some of these drugs that have come from other countries through Canada is that they don’t work. If you grind them up, they have exactly the same chemicals in them, but it isn’t just the chemicals that do it. It is the way the drugs are packaged. If you provide no miracles for those who can’t afford them. I don’t think there is anybody in this Chamber who couldn’t agree more with that statement, but I am sure they would agree that a counterfeit or tainted drug is unsafe at any price.

As we consider the issue of drug importation, the safety of our citizens must be our primary concern. As ranking member of the committee charged with oversight of the health, it is certainly mine. You will find the focus of the bill that is before us to be on safety. I think everything in the bill leads to safety. I don’t want to come up with a counternutation that might put people at risk.

As we consider the issue of drug importation, the safety of our citizens must be our primary concern. As ranking member of the committee charged with oversight of the health, it is certainly mine. You will find the focus of the bill that is before us to be on safety. I think everything in the bill leads to safety. I don’t want to come up with a counternutation that might put people at risk.

I am reminded we are going to have a little bit of debate on the safety of our food supply—we talked about that a little bit last night—because there is a crisis with pet food, in particular, but even some potential for human consumption, partly because of the pet food, partly because of some other possibilities. There are some kids dying in the United States because they have melamine in their food. This is a product that is added to food to increase the appearance of protein. If you add that to grains or other things, you can get a higher protein count, and usually the protein count relates to the price you get. The more protein, the higher the price.

I was talking to the Senator from Colorado, Mr. ALLARD, who is a veterinarian, and he was pointing out this morning that if you take a fingernail, it is 100 percent protein. If you take a fingernail, it is 100 percent protein. If you grind it into the liver, that is 100 percent protein. One of the differences is if you grind liver up and you put it in food, it is digestible. If you grind a fingernail up and put it in food, it isn’t digestible at all. So you are not getting any protein out of it. So kids have died in China who thought they were getting sufficient food, and they weren’t. The cause of death was starvation. One of the countries that could be getting drugs to the United States would be China. If you grind a fingernail up and put it in your food, do you think they would hesitate a minute to fool with our prescription drug supply? It worries me a lot. There is a lot of risk that is involved in this. The first bottle that came from North Dakota held up two bottles. The second bottles were identical. One was cheaper in Canada than the other bottle in the United States. In a minute, I will go into how that price difference happens. I could hold up two bottles that would look exactly the same. One would come from China, but it might very well come through Canada from Saudi Arabia, have exactly the same packaging, labeling, colors, seals, even the same look of a pill. But one of the things we found out from some of these drugs that have come from other countries through Canada is that they don’t work. If you grind them up, they have exactly the same chemicals in them, but it isn’t just the chemicals that do it. It is the way the drugs are packaged. If you provide no miracles for those who can’t afford them. I don’t think there is anybody in this Chamber who couldn’t agree more with that statement, but I am sure they would agree that a counterfeit or tainted drug is unsafe at any price.

The Food and Drug Administration is charged with watching our borders and the things that come in to see if the drugs that come into this country are legitimate. There are warehouses full of drugs they have found that are not legitimate. So it is a matter of safety, and we are concentrating on the safety portion of this bill. So I am hoping we will save the drug importation question for a separate debate of its own.

We know each one of us takes a risk every time we take a drug, but Americans who buy prescription drugs in Canada and other countries or purchase drugs from Internet pharmacies
that operate outside the United States are taking an even greater risk by obtain-
ing their prescription medicine from pharmacies and Internet sites that do not always meet the high standards we require here at home. Here is where we have a problem with counterfeit and substandard drugs in the United States. Concern about the quickly growing counterfeit market is not lim-
ited to the United States. In Europe, dangerous counterfeit drugs are already a problem, and the problem is growing as the European Union ex-

pands. In addition, we have little knowledge of the extent of counter-
feiting in Asian markets such as India, Pakistan, and China, other than that it may be the best.

Now, prior to legalizing an untested, drug importation project on a large scale across our Nation, we must con-
sider any new vulnerabilities in our drug distribution system, especially since those vulnerabilities could be massive in size. I know we all share the same goals. We want to ensure that drugs are safe, effective, and will not compromise the integrity of our Na-\ntion’s prescription drug supply or our world pharmaceutical research, and we want it to be at the lowest pos-
sible cost. Similar to many Americans, I am concerned about the high and ris-
ing cost of prescription drugs. How-

ever, I doubt the importation of drugs from other countries will solve the problem all by itself. We better be cer-
tain about exactly what we are doing and how we are going to do it. We have had some hearings on that. We have also gotten some phone calls from the Canadian Minister in charge of the pro-
gram who has said: Do you realize that if America suddenly started buying its drugs from Canada, we would have to prohibit Americans from doing it. We are a small country. We could not take the advantage others might be able to get because we do have price fixing.

We talk about negotiated prices and we talk about that in the context of Medicare drugs. Congress passed and the President implemented Medicare Part D that actually came in consider-
ably lower in cost for drugs for Amer-

ican seniors than what we or the Gov-
ernment Accountability Office had ever anticipated—dramatically lower. Why? Because of competition. How does one negotiate drug prices? Well, the way Canada did it was they said: If there are five drugs that treat heart problems, we make a bid for one drug against another drug. If there are five heart drugs, they all don’t do the same thing. Some doctors would pre-
scribe one and others would prescribe another. But if you are going to nego-
tiate prices, you make the five bid against each other and you pick one or two, and you tell the rest of them they can’t sell their drugs there, that the Government will not have any part of it. This eliminates choices.

Then there is another little caveat that some of the countries add to that which says: If you don’t come in with a low enough price, we are going to give your patent away and you would not get anything for it. We have some real patent issues if we are going to have people investing in the research to get new drugs potentially approved, and we should take a little look at the process that you have to go through to get a drug approved. It is about a $1 billion project to get a drug approved. They don’t do that because they are wanting to drug to drugs; they are doing it because they expect there will be some profit on the other end of selling the drug. Otherwise they wouldn’t go through all that research, all the trouble, all the clinical trials, and then turn it over to people for free.

They give away quite a few drugs, but that is to people who can’t afford them. There is a lot to the fact that we have more pharmaceutical companies developing more drugs than anywhere else. I am pleased that through our committee we fund the clinical trials happening right now on various cancer drugs. That is just in the area of cancer: 650 drugs in the pipeline. That is a lot of billions of dollars being spent for us.

Every once in awhile somebody men-
tions the high cost of insurance. That is something else our committee is working on. I think we have some po-
tential for making some good changes there. But I think I always remind people of is I could get 1980 insurance prices if they would settle for 1980 treatments. Then they start to realize how many things that have been in-
vented since 1980 that make a dif-
f erence in our life and in our longevity. I don’t know of anybody who wants to settle for pre-1980 treatments, but they are cheaper.

In any importation discussion, it is critical we limit imported drugs only to those that have been approved by the FDA. We have to understand how small differences between drugs can mean big differences in patient health. We are talking about a drug safety bill on the Senate floor this week. We all acknowledge that there are drug safety problems that must be addressed. It makes no sense to open up our borders when we don’t have things quite right here at home. Imagine trying to handle the world’s drug safety when we are having some prob-
lems to begin with in the United States. Furthermore, we should not tell companies with whom we must do business how much they have to sell and at what price they have to sell it. Those are mandates I strongly believe will ultimately limit consumer access to drugs.

So I look forward to a spirited discus-

sion. I think it will answer some of my questions about the legislation and will help us all on the best di-
rection we can take from here. There are possibilities for solutions on drug importation. I hope it will be a sepa-
rate discussion from how the Food and Drug Administration administers the

safety of pharmaceuticals and medical devices and particularly when they concern children. We actually forced the pharmaceutical companies and the medical device companies to pay to have their products tested and re-
viewed. That is what a big portion of this bill is about, how they will pay for having the products tested and re-
viewed.

That needs to be reauthorized before September, or it expires. That would mean a lot of additional costs on the taxpayer if we don’t do those two parts.

There is also a portion on that which deals with pharmaceuticals for chil-
dren. It is important that tests be done with the pharmaceuticals to be sure that they can be done quickly as possible. What dosage they are safe for children. There is a portion of the bill which gives in-
centives to companies that will go to that extra length to see which of the drugs can be used for children as well. There is another potential for a fas-
cinating discussion over the next cou-
ples of days.

I compliment the Members who have been working on that. Many are on the HELP Committee and have been look-
ing into this with as much depth and detail as I have seen on any bill we have ever done. I have also seen as much cooperation between both sides of the aisle as I have seen on any bill we have done—working together to find a way to take care of the concerns and make sure we are improving the safety but also making it possible for people to get the pharmaceuticals and the drugs as quickly as possible. It doesn’t do any good to have a miracle drug and not be able to get it on the market. It doesn’t help to have a mir-
acle drug with some problems and, be-
cause FDA doesn’t have the tools to change some of those problems, they have to pull it off the market and take it away from some people who really rely on that drug. That is what this bill does essentially.

I think in the substitute, or man-
gers’ amendment, that will be coming out, many of the difficulties people have will have been worked out. People are working on them as we speak. That is why the managers’ amendment has not been laid down. It has been vetted with all Members who are interested and working on this, and there has been incredible cooperation. I hope people will continue to work with us.

I do not want anybody to think this bill is a complete answer to safety. It doesn’t cover some topics. That is be-
cause we are still working on some top-
ics that are not developed to a point yet where they can be done. One is this drug importation. It is being looked at, hearings are being held, we are try-
ning to find out some way prices can be lowered in the United States.

Another problem is biosimilars. There is a whole new area of drugs that has come out because the genome has
been unlocked and proteins can be de-
veloped which can be used as medica-
tion which will solve some of those ge-
etic problems. Those are called bio-
logics. There are people who would like
them to become generics right away be-
because that would bring the cost down.
Again, we want to make sure we have a
bill that takes care of the safety of the
biosimilars, to be sure they truly are
similar and will have the same ef-
fect. The Europeans have been working
on that for a while. We have looked at
their models and a number of Sen-
ators—again from both sides of the
aisle—have been working on that prob-
lem. Senator CLINTON and Senator
HATCH have been very involved in that,
providing guidance from both sides of
the aisle. We appreciate their efforts
on it. I do not expect that to be a part
of this bill.

There are a number of tobacco issues,
and our committee has a lot of concern
on that. There are some bills which
would provide a different way of doing
that—maybe put the regulation of to-
bacco under the jurisdiction of the
FDA. I hope that will not be a part of
this bill. That is not ready yet, either.
We have a lot of parts that are ready,
and particularly the user fees need to
be done before a deadline that is com-
ing up.

I really appreciate the cooperation
we are having in making sure we can
meet the deadline and have an FDA
that is even more responsive and has
more tools in the toolbox to make sure
the drugs out there are safe and
that there is a system for making sure
safety is maintained and if there is a
problem, that it can be corrected with
some of the new tools in the toolbox.
I thank everybody for their coopera-
tion and patience.
I yield the floor.

Mr. CRAIG. Mr. President, I ask
unanimous consent that I may speak
for 10 minutes as in morning business.

Mr. CRAIG. Mr. President, I am on
the floor, as others have been today, to
speak to an issue that I think is appro-
priate for this day and time. I say so
for a variety of reasons but most im-
portantly because May 1.

I have put it this way, because I
think it sets the context in which I
would like to speak for a few moments.

Mayday, Mayday, Mayday—do you
hear me calling? Do you hear the frus-
tration of the American consumer
today who goes to the gas pump and
pays record-high gas prices? I saw
prices in my State of Idaho today
verging on an all-time high—$3.32, $3.35,
depending how far you are from the
head of the pipeline.

Mayday, Mayday, Mayday. The year
1923 is when that term first came into
use by Frederick “Big John” Mockford
in an airport in London, speaking in
the French term. What he was saying
was: Help me, help me, help me.

I do believe that is what the Amer-
ican consumer is saying today—help
me. And to the Congress of the United
States and to this Senate, that sound
ought to bring us through this Cham-
berr and certainly through the halls
and the committee rooms that deal
with national energy policy.

We are where we are today for ab-
sence of policy and for some policy
that has driven us to less production
and becoming increasingly more reli-
ant upon someone else to produce our
energy for us. It is in that context of a
Mayday appeal that I speak for a few
moments during this noon hour.
Here is what the chart shows us very
clearly. From 1890 to 2030, these are
the trend lines. In 1950, we crossed a
unique point when we began to see our
demand outstrip our supply, and this now—
well over 50 percent of our consumption—is
being picked up by other countries in
the region. In those circumstances, it
would be less friendly to us than we
would like.

What is happening on May Day—this
May Day—to a major supplier to the
south of us, a guy by the name of Hugo
Chavez in Venezuela is privatizing today
oil fields where our companies produce. He
is bringing them into his control, into his
form of petronationalism, and he is saying
the priority for Venezuelan oil today is
not going to be to the United States, it is
going to be Cuba, Bolivia, Nica-
ragua, and Haiti. He is going to become
their supplier first. He is also going to
leave the World Bank and create the
Bank of the South. He is one of our
major suppliers, and he is less than
friendly.

Shouldn’t we be speaking out on May
Day, as he speaks out toward energy
independence, toward a greater sense of
our own responsibility toward our own
consumer? What is Fidel saying today?
He didn’t mail a letter, apparently,
but he sent a letter. He is talking
about biofuels and saying that America
is shifting toward biofuels and they are
going to consume all of the food supply
of the hemisphere to produce energy. I
find that a bit of a uniqueness. Obvi-
ously, while he produces some oil, he
ships it off to have it refined, and Hugo
Chavez and he are deciding that Ven-
zuela will be the largest supplier.

There are a few of us in Congress who
read those lines—sense of emergency, that cry for the “help me”
that I think the American consumer is
speaking out to today. Our committees
are working their will at this moment
to add to the National Energy Policy
Act of 2005, which will continue to push
the renaissance of energy production
in this country in all forms, not just for
hydrocarbons but electricity and other
forms, in a way that will increasingly
make us independent and self-reliant.

Our Senator BYRON DORGAN and I intro-
duced the Safe Energy Act of 2007 a
month or so ago, which strikes at the
heart of the combination of efforts that
will move us further down the road to-
ward accomplishing self-help, self-reli-
ance, and energy independence. In that
act, we said conservation would be a
part of it, as it should be. I, for the
first time, stepped out and said that I
would accept mandatory CAFE stand-
ards on a growth rate of 4 percent a
year and bring them into greater senses of efficiency and lead us
toward greater levels of conservation.
That was title I of the SAFE Act which
we think the Commerce Committee
will mark up in the next week.

We spoke to innovation in the advance
of biofuels and the importance of doing that and that we
really ought to strive toward the 30 bil-
lion gallons, which our President spoke
to in the State of the Union, by 2020—
15 of that being picked up by corn
but more importantly, now, 15 billion
gallons being picked up by cellulosic
energy—and advancing that as rapidly as
we can and getting the loan guarantees
out and the grants that will take it out
of the lab and cause it to be a standup
commercial refinery using straw, corn
stover, and all of those types of things
which are the production that we think
ought to go on in the cellulosic area.
That is title II of the bill. We think
that will be marked up tomorrow in
the Energy Committee.

But the one that hasn’t yet been
marked up and the one I wish to spend
a little time on today is the area of
continued production of hydrocarbons
in the Outer Continental Shelf. I have
called this in the past the “no zone”
speech. Let me combine that with May-
day. While we are saying no, our con-
sumers are saying: Help me, help me,
because I am spending more of my dis-
cretionary income on consumables and
in the form of energy at a rate and
level I never had to before. It is caus-
ing the American economy to shift signifi-
cantly.

Here are a variety of things we have
done over the years that have shaped
the Outer Continental Shelf capability.
These areas which are pointed out on
this map are known reserves of oil.
Yet, because of attitudes at the State
level, environmental concerns and frus-
trations, much of that production or
the ability to explore within those
fields has simply been taken off limits.
They became the “no zone.” even after
technology clearly proved that you can
go into these waters, produce there
safely, protect the ecosystems in-
volved, and reward the American con-
sumer by less dependence upon foreign
oil and reserves.

This area here, this small area, was a
sale and an area we were able to put
through just in the beginning of this
year. This, of course, is the area in
the gulf that is being heavily drilled
today. These are the off-limits areas.

I came to the floor some time ago
and asked what is going on in Cuba,
and asked that that was an unaccord-
ting thing and we ought to do something
about it. So in the legislation we are
talking about, for greater flexibility
and opportunity in the Outer Continental Shelf, what we are really talking about in the SAFE Act—that last title yet to be introduced—that really balances conservation with new biofuels and increased production in this area. There is the new Cuban basin. It is an area that is off limits to our producers, and Cuba is now moving to produce it. They are going to do so by reaching out to other countries—other than ours because we have a prohibition on our companies doing business there—and they are looking at the French, Spaniards, the Chinese, and others to come and drill.

Here is my frustration: While we are saying no, all around our coastlines, just a few miles off our coastline, the Cubans have let leases for the purpose of drilling.

I was in Cuba a few years ago visiting with their Interior Minister, and he said: We want your companies here. Why? Because you have the best technology. You are environmentally proven. You place this valuable ecosystem at less risk. That we know. But our policy today denies us that.

I am embarrassed to see that last Chinese, and others to come and drill.

Here is my frustration: While we are saying no, all around our coastlines, just a few miles off our coastline, the Cubans have let leases for the purpose of drilling.

I was in Cuba a few years ago visiting with their Interior Minister, and he said: We want your companies here. Why? Because you have the best technology. You are environmentally proven. You place this valuable ecosystem at less risk. That we know. But our policy today denies us that.

I am embarrassed to see that last Chinese, and others to come and drill.

There is an interesting little anomaly that happened—and I praise the new Secretary of the Interior for doing what he did—and that was opening, right off the coast of Virginia, an opportunity to seek natural gas and to see if are out there, which I think will drive increased production.

So today I come to the floor on May Day saying: Mayday, America, Mayday, because Americans as they go to the gas pump are saying: Help us, help me; change the way this is happening. America, we have a great opportunity to move ourselves toward energy independence, less dependence on those unstable areas of the world where we now seek our oil, over 50 percent of our best technology, the carbon oil base. Shame on us. That is bad policy, and we have the power to change it if we have the will to change it. The will comes from the ability to build a complete portfolio of conservation, new technologies, and current production in areas where we know our reserves are, by building them up during this period of transition as our country moves to new technologies.

This is a great opportunity. The only reason we are not doing it is because of resistance right here in the Congress of the United States, in part, put on by pressure from some special interests. But my guess is that if we listen closely to the American consumer today, they would agree that the SAFE Act and all titles of the SAFE Act ought to become public policy and that America clearly ought to be articulating a policy of greater energy independence so that we can say, ‘We heard you call out for help, and we are answering that call. Mayday, America, Mayday.’

I yield the floor to the Honorable Mrs. Hutchison.

Mrs. HUTCHISON. Mr. President, I am pleased to follow the Senator from Idaho who is talking about an issue that is so important for our country. It is a wake-up call. Amazingly it is on May Day. I think that is the appropriate moniker for what we are facing in this country because of what is happening in Venezuela.

Mr. President, I wish to talk about what I see happening in Venezuela and what I think America should be doing to make sure we maintain the capability to control our national security and our economic security.

Today President Hugo Chavez is completing his latest and most ominous scheme out of the Fidel Castro playbook. He is nationalizing multibillion-dollar, heavy oilfields in the Orinoco Belt. This energy-rich region southeast of Caracas has so much energy potential that some experts claim it could give the country more oil reserves than Saudi Arabia.

By seizing the Orinoco Belt, President Chavez is consolidating his political power and increasing his ability to manipulate global oil markets.

This nation now accounts for 14 percent of America’s oil imports, and Mr. Chavez has promised to use his “strong socialistic petroleum policy” to “nationalize our oil, punish off the U.S. empire,” even if that means colluding with some of the most nefarious regimes on Earth.

Similar to Fidel Castro, who partnered with the Soviet Union during the Cold War in making common cause with America’s enemies, including the world’s largest state sponsor of terrorism, the Government of Iran.

Earlier this year, he met with Iranian President Mahmoud Ahmadinejad and made plans for a $2 billion joint fund, part of which will be used as a “mechanism for liberation” against American allies.

President Chavez hopes that the profits from the Orinoco Belt will fund his coffers for other foreign adventures. But by asserting government control over this coveted region, he is actually killing the golden goose that feeds his coffers to anyone who has followed the career of his Cuban mentor, Fidel Castro. While Chavez has turned what was once the third richest nation in Latin America into one of the poorest nations in the world, a real-life prison for 11 million people who rely on remittances from abroad to avoid starvation and collapse.

If President Chavez continues to adopt the Castro economic model, the greatest victims will be the Venezuelan people, but America will also suffer. That is because the deterioration of Venezuela’s oil industry could spark a surge in oil prices for American consumers, and we all know that prices have already jumped in the last 30 days. A doubling of oil prices would generate about $170 billion in taxes that are owed, and that means people are laid off.

So what should our response be? America must reenact its efforts to adopt a comprehensive plan for America’s energy independence, including more exploration for oil and gas at home. It should be a comprehensive plan that includes conservation, renewable energy, new research for new forms of energy that we have not yet explored, and it should include more exploration and drilling for our own resources which we can be assured of controlling.

I wrote an editorial in one of the December issues of the Houston Chronicle that I think we should follow. The Outer Continental Shelf of the United States, the Gulf of Mexico, Alaska and the Virginia shores and other shores on the Pacific and Atlantic sides.

Using the comprehensive energy legislation we passed last year, I was very pleased to see the announcement yesterday by the Department of the Interior that we would, in fact, increase production of the natural resources in the country. The Secretary, Dirk Kempthorne, who was once a member of this body, announced that there would be 21 lease sales in eight planning areas which could produce 10 billion barrels of oil and 45 trillion cubic feet of natural gas over 40 years. That would generate about $370 billion in today’s dollars.

The potential for this amount of oil exploration alone is equivalent to 20 years’ worth of what we import from Saudi Arabia or Venezuela.

They are doing exactly what Congress has authorized them to do—looking in the Outer Continental Shelf. Even the Commonwealth of Virginia is...
positive about this move because there are now incentives for States to allow production in the waters they control. This is one part of what we must do as part of a comprehensive approach to energy independence.

We also need to increase research into alternative fuels, such as solar and wind power. In March, I introduced legislation called the CREST Act, which provides a comprehensive, coordinated national research effort that would spur the development of renewable energy for the marketplace. The oceans and the Gulf of Mexico have potential for energy production and electricity production. Just as we have seen wind energy become a factor on land, it can also be a factor in our bodies of water.

The PRESIDING OFFICER. The clerk will call the roll.

Mr. SCHUMER. Mr. President, I ask unanimous consent the order for the quorum call be rescinded.

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

Mr. SCHUMER. Mr. President, I understand the Senate has been scheduled to recess at 12:30. First, I thank the Presiding Officer for waiting for me here. As always he is gracious and kind.

I now ask unanimous consent that I be permitted to speak for 5 minutes and that following my statement, the Senate stand in recess under the previous order.

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

EMERGENCY SUPPLEMENTAL APPROPRIATIONS

Mr. SCHUMER. Mr. President, I rise today to join so many of my colleagues in the Senate—understanding there are people in the military and so many of the American people in urgent the President to sign the emergency spending bill that relates to Iraq when it reaches his desk. Despite what the President keeps repeating, we can do both—we can fund the troops and change the mission in Iraq. The emergency spending bill we will send to the President shortly gives our troops all the money they need and even more than the President requested, and it changes our mission in Iraq from policing a civil war to focusing on counterterrorism.

It has been 4 long years since President Bush landed on the USS Abraham Lincoln and prematurely announced “mission accomplished” in Iraq. Today, 4 years later, there is one thing on which the American people, bipartisan majorities in both Houses of Congress, military experts, and the Iraq Study Group all agree: We clearly have not accomplished our mission in Iraq, and the only way to succeed is to change our current course of action.

It seems only the President and his small band of advisers think we have accomplished our mission in Iraq. Only they think we are ready, and only they think the President has the willpower to do it.

Only President Bush seems to think the only way to support our troops is for the Congress to be a rubberstamp to his policies. That is not what the American people want, and that is not what America is about. The American people want a change in mission. They want a new direction, not more of the same failed policies. That is why, if the President really supports our brave men and women fighting in Afghanistan and Iraq, he will sign the legislation that we will send to him very soon.

The bill provides reasonable and meaningful guidelines to protect our troops by ensuring that all units that are sent overseas are ready, trained, and equipped to fight. It will require the Department of Defense to adhere to its own guidelines to ensure that every unit that is deployed is “fully mission capable” for the task at hand.

Why would the President want to send our troops into Afghanistan and Iraq, into fierce battles against the Taliban and the Sunni insurgency without the training and equipment needed to get the job done and to come home safely? But, if the President vetoes this bill, he will not be so required.

More important, this legislation shows both the United States and the government of Iraq that the United States and Iraq have changed the failing strategy in Iraq. It has been clear all along that this administration has failed to plan for the war. They gave no thought what it would take to accomplish this mission. There was no planning for the day after.

When you think about this, it is infuriating: to think that just showing strength alone would solve the whole problem. That kind of careless, narrow thinking has led us to where we are now.

This administration and its President seem to be lost in Iraq. They can only do more of the same. We put in more troops to support a government that every day gets weaker and weaker, that seems to be crumbling from both the Shiite and Sunni side. Why are we putting more troops in Iraq to defend a government that nobody seems to like and in whom nobody seems to have much faith? The escalation is not working.

As a policy, a mission in Iraq has devolved so that most of what we do is patrol, police, and stand in the middle of a civil war. The Sunnis and the Shiites have hated each other for centuries. Their enmity goes way back. They will continue to hate each other, to not work with each other, to fight with each other long after we have gone, whether we stay 3 months or 3 years. Yet most of the time our troops, our brave men and women, are simply caught in the middle of a civil war, and we have not even chosen a side. We are just in the middle, and they are just in the middle—trying to defend themselves in the middle of a civil war when they should be fighting each other, and we are unable to bring the two sides together. It is a debacle.

That is why the Congress is demanding that the President change the current mission in Iraq. As we all know, including General Petraeus, the solution to violence in Iraq is ultimately political and not military, and that is why Congress has imposed tough benchmarks on the Government of Iraq. We cannot afford to send more military troops without doing something to change this weak, almost feckless Government. Our original purpose in Iraq was to fight terrorism. I believe we must continue to fight terrorism. I know that from what happened to my city, my beloved city, and the friends I lost and think of every day.

This legislation says let’s go back to that original purpose, counterterrorism, as well as force protection and training the Iraqis, and fighting a civil war. U.S. forces will protect U.S. facilities and citizens, including members of the U.S. Armed Forces engaged in targeted counterterrorism missions to prevent anything that happens in Iraq from hurting us at home and continue to train and equip Iraqi security forces, although I must say that has not worked out very well thus far.

I believe these benchmarks are reasonable and achievable with renewed political will from this administration and from the Government in Iraq. The benchmarks were not just pulled out of the air. They were suggested by the bipartisan, highly qualified, highly knowledgeable, highly experienced Baker-Hamilton commission. But more important, they signify the changes in strategy that must be implemented to correct the administration’s failing strategy in Iraq.

The President Bush’s war, but he has failed time and time again to make the difficult leadership decisions that are needed to protect our troops in Iraq. If he vetoes this bill, as he has threatened to do on many occasions, our brave men and women will continue to fight a brutal war with no forward look strategy, no long-term plan, little regional support, and little chance of establishing a stable, representative government in Iraq. Every day it becomes more clear the President never had a plan for Iraq.

So we have a mission. It is a sacred and important mission. We must change the mission in Iraq away from
policing a civil war and toward counterterrorism, which requires fewer troops and gets many more of them out of harm's way. That is what our bill does. It is what the American people want. It is what the facts on the ground demand.

I urge the President to strongly reconsider this threat to veto this legislation. If he does, he will be making a terrible mistake, one that all of us and maybe even he will come to regret. I urge the President to sign the supplement because it gives our troops and veterans the resources they need. It honors the sacrifices of those serving in Iraq with a change in mission that is long overdue, and it is my hope that one day we will all be able to say that we have accomplished our mission in Iraq. But until we change our mission and put in place a winning strategy, that day will continue to elude us.

I yield the floor.

The PRESIDING OFFICER. Under the previous order, the Senate will stand in recess.

RECESS

The PRESIDING OFFICER. Under the previous order, the Senate will stand in recess until the hour of 2:15 p.m.

Thereupon, the Senate, at 12:36 p.m., recessed until 2:15 p.m. and reassembled when called to order by the Presiding Officer (Mr. CARPER).

PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007—Continued

The PRESIDING OFFICER. The Senator from Oklahoma is recognized.

Mr. INHOFE. Mr. President, on the bill under consideration at the present time, it is my intention to—and I have already placed at the desk two amendments, 987 and 988.

Briefly, what is the order right now? The PRESIDING OFFICER. The Senator is recognized. The Senator has as much time as he may consume.

Mr. INHOFE. Today I have submitted amendments to S. 1082 requiring parental consent for intrusive physical exams administered under the Head Start Program. Young children attending Head Start Programs should not be subjected to these intrusive types of physical exams. We had an incident in my town of Tulsa, OK, where we felt that their rights, children’s rights, were violated. They were subjected to different types of intrusive examinations. I will be bringing this up at an appropriate time.

Secondly, briefly, as I see the manager of the bill is here, we will be introducing an amendment No. 986, having to do with protecting children from parents being coerced into administering a controlled substance or psychotropic drug in order to attend school.

Mr. President, I yield the floor, and I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The PRESIDING OFFICER. The Senator from Oklahoma is recognized.

Mr. INHOFE. Mr. President, I ask unanimous consent that my amendments, No. 986 and No. 987, with the intention to rescind, when a substitute is made in a few minutes.

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

Mr. INHOFE. Mr. President, I ask unanimous consent to withdraw my amendments, No. 988 and No. 987, with the intention to rescind, when a substitute is made in a few minutes.

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

Mr. INHOFE. Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. REED. Mr. President, I believe the Food and Drug Administration Revitalization Act before us today raises crises, the FDA needs intermediary authority. The bill clarifies, and in some cases fortifies, the FDA’s authority. The FDA Revitalization Act is an opportunity to improve our current system of drug approval and drug monitoring and assure drug safety. Moreover, as the population ages and science inevitably advances, more and more drugs will come to market, presenting potentially groundbreaking health benefits to the public, but simultaneously increasing the need for sophisticated mechanisms for monitoring and assuring drug safety.

The FDA Revitalization Act is an opportunity to improve our current system of drug approval and drug monitoring, but it also adeptly anticipates changes in the future of prescription drugs and consumer safety brought about by advances in science and an ever expanding market for prescription drugs.

The primary mechanism this bill uses to strengthen drug safety is to strengthen and rearticulate the FDA’s authority. The bill clarifies, and in some cases fortifies, the FDA’s authority with regard to drug safety. Currently, if the FDA detects a problem or a potential problem with a drug post-approval, they have few options beyond what is often referred to as the “nuclear option.” That is, pulling a drug from the market. While the FDA’s authority to pull a drug from the marketplace is a powerful tool, it is a blunt instrument. Problems spiraling into major public health crises, the FDA needs intermediary authority. The FDA’s reluctance to pull a drug, potentially a drug upon which millions of Americans depend to manage an illness, unless it is overwhelmingly certain that the action is necessary, is understandable. However, prescription drug users suffer as a result of the “nuclear option.” It offers a forceful, but ultimately limited, response. Pulling a drug from the market potentially delays action and places individuals at major health risks in the interim. On the flip side, pulling a drug prematurely may needlessly deny patients the medications they need for their health needs.

This bill offers what I believe is a good solution to this paradox; one that considers input from patients, rights organizations, industry representatives, and the FDA, but ultimately places patients at the top of the list.

The risk evaluation and mitigation, REMS, system, the primary tool in the drug safety title of this bill, bolsters the FDA’s intermediary authority to oversee the manufacture, monitor, and provide important information regarding their products. By so doing, the FDA can actively require drug companies to provide information about the medications millions of Americans are taking and not just passively request drug companies to comply.

Most importantly, the REMS system focuses the FDA’s efforts and resources on postmarket surveillance. Increased drug user fees would be used to review REMS as well as for general drug safety surveillance. User fee revenue will increase by $50 million to fund drug safety activities, of which $30 million is authorized for the routine drug surveillance once they are marketed. Many of us would like to eliminate the need for these paid user fees, but this arrangement, agreed on by industry and the FDA, offers the best workable solution in this strained budget environment.

Another important objective of the FDA Revitalization Act is to improve the integrity of the agency and to enhance transparency on its actions. I am pleased that this bill improves the public’s access to information about clinical trials and, more importantly, the results of those trials. The bill enhances patient enrollment in trials by requiring late phase II, III and phase IV clinical trials on drugs are registered in a publicly available database. This will improve the public’s knowledge of important and potentially life saving clinical studies. The bill also creates a publicly available database of the results of those trials. This means, for instance, that a parent who wishes to understand why a much-talked about treatment for juvenile diabetes failed to advance past a clinical trial stage can track the progress of a potential problem from spiraling into major public health crises, the FDA needs intermediary authority. The FDA’s reluctance to pull a drug, potentially a drug upon which millions of Americans depend to manage an illness, unless it is overwhelmingly certain that the action is necessary, is understandable. However, prescription drug users suffer as a result of the “nuclear option.” It offers a forceful, but ultimately limited, response. Pulling a drug from the market potentially delays action and places individuals at major health risks in the interim. On the flip side, pulling a drug prematurely may needlessly deny patients the medications they need for their health needs. This bill offers what I believe is a good solution to this paradox; one that considers input from patients, rights organizations, industry representatives, and the FDA, but ultimately places patients at the top of the list.

The risk evaluation and mitigation, REMS, system, the primary tool in the drug safety title of this bill, bolsters the FDA’s intermediary authority to oversee the manufacture, monitor, and provide important information regarding their products. By so doing, the FDA can actively require drug companies to provide information about the medications millions of Americans are taking and not just passively request drug companies to comply.

Most importantly, the REMS system focuses the FDA’s efforts and resources on postmarket surveillance. Increased drug user fees would be used to review REMS as well as for general drug safety surveillance. User fee revenue will increase by $50 million to fund drug safety activities, of which $30 million is authorized for the routine drug surveillance once they are marketed. Many of us would like to eliminate the need for these paid user fees, but this arrangement, agreed on by industry and the FDA, offers the best workable solution in this strained budget environment.

Another important objective of the FDA Revitalization Act is to improve the integrity of the agency and to enhance transparency on its actions. I am pleased that this bill improves the public’s access to information about clinical trials and, more importantly, the results of those trials. The bill enhances patient enrollment in trials by requiring late phase II, III and phase IV clinical trials on drugs are registered in a publicly available database. This will improve the public’s knowledge of important and potentially life saving clinical studies. The bill also creates a publicly available database of the results of those trials. This means, for instance, that a parent who wishes to understand why a much-talked about treatment for juvenile diabetes failed to advance past a clinical trial stage can track the progress of a potential problem from spiraling into major public health crises, the FDA needs intermediary authority. The FDA’s reluctance to pull a drug, potentially a drug upon which millions of Americans depend to manage an illness, unless it is overwhelmingly certain that the action is necessary, is understandable. However, prescription drug users suffer as a result of the “nuclear option.” It offers a forceful, but ultimately limited, response. Pulling a drug from the market potentially delays action and places individuals at major health risks in the interim. On the flip side, pulling a drug prematurely may needlessly deny patients the medications they need for their health needs. This bill offers what I believe is a good solution to this paradox; one that considers input from patients, rights organizations, industry representatives, and the FDA, but ultimately places patients at the top of the list.