have been all the time, which is to engage in the legitimate kind of intervention on a diplomatic level and to put on the table all of the issues of the region in a way that proves the kind of sincerity and seriousness of purpose that raises the level of credibility of the discussion so people can trust that we, in fact, are going to be moving in a common direction, which is in their interests.

The reason Saudi Arabia is sending such public messages of discontent for the policies of this administration today is because, given what has happened, that is the way they have to play it in order to deal with their own politics of the region and their own politics of the street and their nation. It is our absence from a creative, diplomatic effort, it is our absence from a credible and legitimate diplomatic lift that has left no choice even to our friends than to begin to distance themselves from our country.

With this veto, the President will deny our troops the vehicles they need, for the time being; he will deny them the basic care they deserve, for the time being, because all of us know the Congress will come back and we will fund those things. But the most significant thing he will deny us is the kind of leadership and the kind of consensus the country deserves in order to move forward in our policy in Iraq.

We honor the lives lost in Iraq, not with words but with lives saved. We honor the lives lost in Iraq not with words and with the political partisanship here but with a policy that is right for them and for the region. We honor their sacrifice by creating a situation in the region where we protect America's and the region's interests at the same time and begin to recognize the degree to which our presence in Iraq is playing into the hands of the terrorists, is advancing the very cause we seek to fight, which is diminishing the ability of the United States to be able to leverage, not just the Middle East issues, but a host of other issues in the world.

I believe we need to change course, and it is only by changing course that we will honor their sacrifice, respect our interests, and bring our troops home with honor.

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

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

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

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

Mr. KENNEDY. I want to let our Members know about the substitute that has been included, that is before us now. It essentially clarifies the FDA's authority to place restrictions on drugs with safety problems; applies only to drugs like Thalidomide that could not otherwise be approved. We can understand why it is important that the FDA probably would not have approved Thalidomide, for all of the dangers it has, but it has now approved it to deal with some of the problems of leprosy. We want to make sure it is not going to be out there and be utilized in terms of expectant mothers. So we have worked this out. I thank Senator COBURN for his help on this issue.

We also make sure the FDA takes into account concerns of rural communities in setting safety policies. We have given enhanced authority to the FDA in terms of safety policies. We want to make sure in the implementation of those, particularly in rural areas, they are not going to be so restrictive as to limit the opportunities to get the necessary prescription drugs. I thank Senator HARKIN and Senator MURKOWSKI, who were enormously helpful in working through that issue.

This also adds a Web portal for FDA so consumers will have a single point of access, via the Internet, to drug safety information. I thank Senator GREGG for that. That will be very important for consumers who are concerned about the safety issues. All of those changes and alterations are very helpful and valuable in terms of the legislation itself.

I wish to speak for 3 minutes as in morning business and not under the time on the bill.

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

SUPPLEMENTAL APPROPRIATIONS

Mr. KENNEDY. Madam President, the President is going to be making up his mind on the issue of the supplemental and making a judgment in the next several hours. President Bush stubbornly clings to the false hope that success is just around the corner and that the mission will be accomplished. We have heard it all before. Ending the rule of Saddam Hussein was supposed to lessen violence and bring a new wave of democracy into the Middle East. It has not. Saddam Hussein's capture was supposed to quell the violence. It didn't. Free elections and the drafting of the constitution were supposed to be a breakthrough. They weren't. The surge was supposed to bring stability, essential to political reconciliation and economic reconstruction. It has not and it will not.

Only the Iraqi people can save Iraq and it is time for them to do so. American military force cannot solve the problems of the Iraqi people. It is time for the President to put the Iraqis on notice that our military will begin to withdraw. No one in the administration can honestly tell the American people we are making progress in Iraq. It is time the President listened to the Iraq Study Group, Congress, and the American people, and work with us to bring our troops home.

The President is wrong to veto the Iraq spending bill and reject its needed timeline for the orderly, responsible, and safe withdrawal of our forces from Iraq. He was wrong to lead us into the war, wrong to conduct it so poorly, and wrong to refuse to change course.

We cannot continue business as usual in Iraq. It is time for America to end its participation in the brutal civil war. The message from the American people couldn't be louder or clearer: Instead of defying the will of the American people, President Bush should listen to their plea and begin working with Congress to bring this tragic war to an end.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Madam President, I am going to make even briefer remarks than the Senator from Massachusetts did.

One of the questions I had been asked over the weekend was: Why hasn't the President already vetoed the supplemental appropriations bill? He promised he would veto the bill because it has all this extra spending in it, with directions on the war from people who really are not even involved in administering the war.

Of course, what I found out is the bill has not even been sent to the President yet. He cannot veto a bill until he receives a bill. So to chastise him for not having already vetoed the bill when there is a hold card keeping him from being able to veto the bill I think is unconscionable. Hanging on to that bill and not getting it there so the decisions can be made on it one way or the other just is not right. That is not the way to run the Senate. It is not the way to run the country. And it is not the President's fault if he does not have the bill to make the decision.

There can be a lot of debate on what that decision ought to be made and how to carry them out. I am certain the President will veto the bill; he has been very clear on that. There is a differing philosophy on how a war ought to be run. There are a lot of people throwing in the towel. It is kind of hard to win at anything if your opponent knows the point at which you are going to give up.

That is where we are in this battle, with the complete direction to give up, to throw in the towel, to say what has been done over there has not done any good, won't do any good, and to keep calling it a civil war. It is not a civil war. It is a religious war that is brewing. There is a tremendous difference. It is a religious war that involves the entire Middle East, not just Iraq. And in preparation, for what the other people in the Middle East have heard said on the Senate floor, armies are gearing up in Saudi Arabia and Syria and Israel and Iran, ready to move into the vacuum that would be caused by a U.S. departure.

That will not be the first time there has been a religious war in the world. If we do not step in, it would probably be the first time we had the chance to stop a religious war and did not help.

So we could leave, have a regional religious war, and then try to decide what we are going to do about that.

Religious wars are not easy things to solve. We have seen that with Kosovo with religious genocide. We got to see what happened in Kosovo. We helped out in Kosovo just as we are helping in Iraq.

So, Madam President, I hope we would actually debate the Food and Drug Administration bill, which is what we were set out to do this week. I hope people who have amendments would bring the amendments to the floor.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Madam President, as we know, the supplemental passed last Thursday. It is Tuesday today. So the comments I made were directed to the fact that the President has announced he is going to veto it. I just wanted to comment about that issue.

Although we differ on that issue, we are together in wanting to get the Senate to both debate and dispose of amendments. The afternoon is moving along. We had statements yesterday from Senator ENZI and myself on this legislation, spelling this out. We had an opportunity in our caucus today—I imagine the Senator did as well—to go through the details of the legislation. So we have addressed many of the concerns. But there are still some concerns that are out there, and this is an extremely important piece of legislation. So we are asking our colleagues to come to the floor to let us know their amendments, to see if we can work those out. If not, we would like to have the debate on those measures and let the Senate exercise its will. We are ready for those amendments, and we urge our colleagues to bring them to our attention at the earliest possible time.

The PRESIDING OFFICER (Ms. KLOBUCHAR). The Senator from Illinois.

Mr. DURBIN. Madam President, I ask unanimous consent to speak as in morning business before addressing the pending legislation.

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

Mr. DURBIN. Madam President, there have been comments on the floor about the fact that in just 2 hours the President of the United States will have an opportunity to sign or veto a bill which literally will affect the lives of 150,000 soldiers and their families, if not every American. It is a bill that was passed by the House and Senate, with bipartisan votes in both bodies, and sent to the President. It fully funds the troops in Iraq, giving them all the resources they need, and more, so they can execute this war and their duties in a safe manner.

But it also does something significant; it starts to change the mission in Iraq. We are in the fifth year of this war. We have lost 3,351 American lives. I respect very much the Senator from Wyoming. He tries to make a point that it is not a civil war. My understanding of a civil war is when people of the same nation are at war with one another.

That, sadly, is the reality of what is going on in Iraq today—Iraqis killing one another while Americans stand in the midst of the crossfire. Had the President of the United States come to this Congress in October of 2002 and suggested we send 150,000 soldiers into Iraq for the purpose of refereeing a civil war or a religious war that had its origins in 14 centuries of anger, had he said to us we must stay as long as 5 years and spend $500 billion and risk thousands of American lives, with no end in sight, what were the chances we would have passed that resolution? None. That is not what the President told us.

He told us Iraq was a threat to the United States of America with weapons of mass destruction, and nuclear weapons, that somehow they had been in concert with al-Qaida, that led to 9/11. None of those things turned out to be true—not one of them.

On that basis, we authorized the President to go to war, and he decided to take a preventive course of action—not preemptive but preventive course of action—and invade this country before they threatened the United States. That is what we are in today.

Within 2 hours, the President will pick up a pen and have a chance to start bringing this to an end. If he signs this bill we have sent to him, it will mean that American soldiers can start coming home and that, equally important, the Iraqis understand it is now their country, their war, and their future, that they have to put their lives on the line and not rely on the bravery of our soldiers to keep their country intact.

If the President vetoes this bill, exactly the opposite message goes to the Iraqis. Its message: Continue business as usual. Continue waiting out the political opposition, not resolving your differences, really allowing this religious or civil war to become even worse.

The month of April was the deadliest month for American soldiers this year. We continue to see thousands of Iraqis killed each month in this country. The President, though he is limited in support for this position, continues to argue that with just a few more American soldiers, a little longer period of time, some more money, everything is going to get better. Many of us are skeptical. The American people believe—and I concur with their belief—we do need a timetable to start bringing American troops home on a responsible, reasonable basis.

I hope the President will reconsider. I hope he will sign this bill. I hope the troops will be funded and the direction of this war will change.

Madam President, this bill is for the Food and Drug Administration's reauthorization. This is an agency which is often overlooked. Madam President, $1.7 billion a year in a Federal budget is not a huge amount of money. There are many other agencies with less responsibility and more resources. The Food and Drug Administration is responsible for really determining the safety of so many things American families take for granted: when you are buying food, when you are buying drugs, when you are buying over-the-counter medicines. Many of the appliances you buy really have to be tested to be safe by the Food and Drug Administration. We count on this small agency to do a very big job and a job that gets bigger by the year.

The bill that is before us is basically the law which authorizes the Food and Drug Administration to do its business. I am glad we brought it to the floor. I salute Senator ENZI on the Republican side and Senator KENNEDY on the Democratic side for their leadership.

The Food and Drug Administration is an essential guardian of the public's health and safety in America. In recent years, their reputation has been at risk because of incidents of drug safety problems and questions about their independence. The FDA has been faulted for neglecting its drug safety responsibilities and for failing to respond to concerns raised by its own drug safety specialists.

Experts have warned that the FDA does not have adequate authority to pull dangerous drugs off the market, mandate changes in drug labels, or sanction drug companies that do not monitor drug safety.

The most glaring example of a drug safety problem is the handling of Vioxx, a painkiller that was found to increase the risk of heart attack and stroke and was used by 20 million people across America. Merck was aware—the company that made Vioxx—that product raised the risk of cardiovascular problems, and they continued to market it, nevertheless, long before it stopped selling the drug in 2004. The episode has raised serious questions about FDA's ability to react quickly to signs of safety problems with drugs already on the market.

Listen to what one of FDA's own drug safety experts said in testimony before the Senate Finance Committee. I quote:

> I would argue that the FDA, as currently configured, is incapable of protecting America against another Vioxx. We are virtually defenseless.

That is quite a statement. It troubles me.

That concern of that individual does not stand alone. A survey of FDA scientists conducted last year by the Union of Concerned Scientists found the following: 47 percent of FDA scientists said their FDA office is less effective than it was 5 years ago; nearly 40 percent said the FDA is not acting effectively to protect public health; more than one-third of FDA scientists said FDA officials care more about approving new drugs and devices than ensuring they are safe; and 15 percent

said they personally have been inappropriately asked to exclude or alter information or conclusions for nonscientific reasons. That is a horrible comment on an agency with the responsibility of the Food and Drug Administration.

Our priority must be to take this reauthorization as an opportunity to change the FDA. The bill does that. It restores balance between timely approval of innovative drugs and safety and effectiveness.

Problems with drug safety in recent years highlight the limits of FDA's ability to monitor and respond to safety problems that arise after approval. Safety problems may not be detected prior to FDA approval because the clinical trials FDA relies upon often involve only a few thousand people.

This bill, S. 1082, responds to this problem by making postapproval monitoring of drugs a core responsibility of the FDA, strengthening and clarifying the tools it has to make their products safer. The bill requires active monitoring for drug safety problems through the use of Federal and private databases. It creates a system for approving drugs with a specific strategy for evaluating and mitigating their risks. It promotes greater transparency by disclosing information on clinical trials.

These and other provisions in this bipartisan bill will help to restore public confidence in the FDA. S. 1082 will help FDA fulfill its crucial and complex mission. I look forward to supporting it.

One of the things most people do not realize is the major responsibility the Food and Drug Administration has for the food we eat.

Now, let me tell you at the outset, I am not capable, having served on Capitol Hill for a few years, to describe to the people who follow this debate what we call the food safety system in America. Imagine, if you will, that we have 12 to 15 different Federal agencies responsible for food safety. Imagine 30 different laws and legal standards for food safety, 40 or 50 different committees on Capitol Hill with jurisdiction, hundreds, if not thousands, of lobbyists and special interest groups hovering over this whole scene. Add to that thousands of Government workers and bureaucrats who are protecting their turf, and we have a system that is virtually out of control—not just when it comes to drugs, as important as they are, but when it comes to the food we eat.

I thank Chairman KENNEDY and Senator ENZI and others for partnering with me on an amendment which I will offer as soon as I am given the green light by the chairman and the ranking member on the issue of food safety. I thank them for working with my staff for several months to come up with language to the deal with some serious challenges.

For too long, we have gone without updating the resources and authorities of the FDA in the area of food safety. I think our system has broken down. Now is the time for an appropriate amendment to close some of the gaps we have in our current system.

In the larger picture, I have been working on this issue for a long time. I said, over 10 years ago, we need a single food safety system.

I see Senator LIEBERMAN from Connecticut on the floor. His House colleague, Congresswoman ROSA DELAURO, herself a victim of food poisoning at an early age, has been my ally in this effort. We believe a single food safety system, based on science and not on politics, is the only answer. We need to do that and do it soon.

The amendment which I am going to offer does not reach that level. It does not achieve all of the goals we wanted to on a legal basis, but it moves us forward.

How important an issue is food safety? The Centers for Disease Control estimates that as many as 76 million people suffer from food poisoning each year. Thirty-two thousand Americans will be hospitalized each year for food poisoning; 5,000 will die. With emerging pathogens, an aging population, and an increasing volume of food imports, this situation isn't going to improve without decisive action.

I agree with Chairman KENNEDY and Senator ENZI that we should proceed with the broad issue of food safety within general order, and I appreciate their willingness to work with me. The amendment is not what I hoped for in creating a single food safety agency, but it is a step forward.

The most recent news, of course, is about pet food, but believe me, it hasn't been that long ago when we talked about salmonella-contaminated peanut butter and E. coli-contaminated spinach. If it seems as if these food crises are occurring more frequently, they are. We may have the safest food supply in the world, but the fact is, every parent, every family wants to have peace of mind that when they buy something at the grocery store, they can put it on the table, feed it to their family, and no one will get sick. There are questions that are being raised almost on a daily basis about whether we can have that confidence.

The issue that came up recently was on pet food. Batches of wheat gluten and rice protein concentrate contaminated with a chemical called melamine were imported from China by several shipping companies. We just learned over the last few days from stories printed in the press that melamine is regularly added to animal feed in China.

Why would they add a chemical called melamine to something they are going to feed to livestock? Well, it is a way to increase the value of the product. If there is more protein in the feed, then they can charge a higher price. When the food product is tested to see if there is protein, you look for the presence of nitrogen. The chemical, melamine, when added, tests for higher nitrogen levels, therefore they argue higher protein levels, therefore they argue they should be paid more. So it is an economic fraud. They have argued that this is a product that doesn't hurt people. We are not sure of that, but we do know that the animals that died as a result of contaminated pet food, some of them were found to have melamine in their system. It is a serious question as to whether it is toxic.

We know now that this pet food contamination has resulted in the deaths of more than 4,000 animals across America. This contaminated product came into America without inspection or without suspicion. The FDA did not have a memorandum of understanding with China or a certification that their standards for food safety were even close to those of the United States. The product made its way from the importer ChemNutra into various manufacturers of pet food. Menu Foods is a Canadian company. They make pet food under a dozen different labels. They learned on February 20 there was a problem. How did they know there was a problem? The cats and dogs told them. They stopped eating their food and they started getting sick.

So you own a company that has dozens of different pet food labels, and you notice that animals are getting sick. What is the responsible thing for a company to do at that time? Pull the product off the shelf and notify the Federal Government. They waited 3 weeks before they sent out a notification. By the time the Food and Drug Administration learned about this, there were millions of cans of pet food and other products under different labels spread all across America with this contaminated product. Three weeks they waited. Why? Because the law does not currently require them to report on a timely basis.

I asked the FDA last week: What is the penalty against Menu Foods for waiting 3 weeks? They said: Well, we are considering. We are talking to our counsel. We will get back to you. Months have passed. Nothing has happened. Menu Foods waited 3 weeks instead of reporting on a timely basis. By then, the product was all across America.

In the case of rice protein concentrate, there is less certainty. Importer Wilbur Ellis purchased product from the Binzhou Futian Company in China. It then distributed the product to a host of companies that produce pet food. These brands and labels have been recalled in a haphazard way over the past 3 weeks—again, delays in reporting. The FDA has even refused to name several companies for more than a week trying to get to the bottom of this investigation because the records process is so broken down at this agency.

One or more of the manufacturers sold some refuse pet food that it produced using contaminated product to hog farms in California and other States. These farms fed their hogs the

contaminated feed, some of which was sold to consumers and much more of it has been quarantined and is slated for destruction.

In addition, we just learned this week that 38 poultry farms in Indiana received contaminated feed. So the plot thickens, and the safety issue grows as we wonder if what was originally pet food is now being fed to livestock, and if humans consume the food what impact it will have.

There is a mystery importer involved as well from China that we have heard about but we can't identify yet. Supposedly this second importer purchased rice protein from the Chinese firm in question in larger quantities than the firm Wilbur Ellis.

In terms of the investigation in China, the FDA said: We want to send inspectors to China to see what they are sending to us. Well, first the Chinese said: We deny you the visas for your FDA inspectors. Imagine that. Millions of dollars worth of foodstuffs coming in from China, contaminated and poisoned, killing off pets, threatening human consumption, and when we say to the Chinese that we want to take a look at their production facilities, they denied us visas. I joined with Congresswoman DELAURO and sent a letter to the Chinese Embassy, and they reversed their position, offering the visas. We have to make it clear to China and every other country that if they want to do business with the United States, they will do it on our terms when it comes to health and safety. We will never allow them to compromise the safety and health of American citizens in the process.

The amendment I am going to offer—and I hope it will be accepted—does several things based on what we have learned over the last 6 weeks. First, during this recall, consumers, veterinarians, and retailers, among others, expressed concern about the scope of the recall, what products were included, or what not to feed to domestic animals. The FDA was slow, uneven, and inconsistent in sharing information on the recall. While there are mechanisms in place to proactively track human food-borne illnesses and then share information, no similar system exists for companion animals.

I visited the FDA pet food recall Web site the day before the March 12 Agriculture appropriations hearing and found a jumble of corporate press releases. It was virtually unintelligible. I said to the FDA: Can't you make this information clearer so consumers can have the information they need to purchase these products? They took it to heart and made the changes. That is good.

In addition, following the recall, the FDA checked the records of companies such as Banfield, the largest privately owned veterinary hospital chain in the United States. The records kept showed a statistically significant increase in the instances of renal failures of cats. A system in place to track these events might have caught something like melamine earlier. So the amendment creates an early warning and surveillance system for companion animals and directs the Secretary to work with professional organizations, veterinarians, and others to disseminate information.

While we are at it, the amendment would direct the FDA, in cases of both pet food and human food, to keep up-to-date, comprehensive, searchable recall lists on their Web site.

Second, the amendment closes the gap that FDA itself identified in an earlier draft framework posted on its Web site in December of 2006. The guidances and practices that govern the pet food industry are currently generated by the American Association of Feed Control Officers, known as AAFCO. The guidelines on best practices and ingredient lists are updated annually and implemented on a voluntary basis by manufacturers and State departments of agriculture. However, there is no requirement under the law for States to adopt these practices, and they don't have the force of Federal guidelines. Inspections are not coordinated State to State, and some States have different standards. While the FDA participates in the AAFCO process, it does not provide a list of ingredients and additives. AAFCO's list is more comprehensive than the FDA's. Our amendment would direct the FDA to work with AAFCO and other stakeholders to give these guidelines the force of law.

Third, the amendment closes a loophole that this contamination has exposed with regard to our imports of food. The source of the contamination we know of was wheat gluten and rice protein concentrate originating in China. Neither shipment was inspected by the FDA. If you have some peace of mind or belief that a Federal inspector is watching food as it comes into the United States, the odds are 99 to 1 you are wrong. Only about 1 or 1.5 percent of all the shipments of food products coming into the United States are actually inspected.

As imports have increased the number of inspectors have decreased. This is an indication of U.S. food imports by country. As you can see, there have been dramatic increases in these fiscal years showing that the amount of food coming into the United States is increasing in volume. The number of inspectors who watch for this food to protect our families and consumers across America just hasn't kept pace.

In 2003, the United States imported $45.6 billion worth of agricultural products—in 2003; today, $64 billion. Agricultural imports from China have almost doubled in that period of time, from $1.2 billion to $2.1 billion. Due to flat budgets and increasing responsibilities, the overall number of FDA inspectors looking at these shipments and at domestic food processors has actually decreased from 2003 to the present time; imports up, inspectors down.

Are we surprised at what has happened? The FDA doesn't have the resources or the authority to make sure what we are bringing in from overseas is safe. We need to tackle it in a larger bill.

What our amendment does is close the loophole by improving data collection and reporting. It creates an FDA database of food adulterants that would be filled by FDA inspectors as well as importers of food. The extra series of data points would better pick out trends and help FDA do a better risk-based inspection job. It also creates a system in which adulterations are reported quickly so as to prevent contamination from spreading. This would have helped in this most recent case, but because of delays in reporting it led to an expansion of recalled product into dozens of different companies and got perilously close to the human food chain. The data would then be used by the Secretary to issue import alerts, blocking similar risky products.

I have also pursued a separate track on the issue of resources for FDA by sending a letter to Chairman KOHL of Wisconsin and Senator BENNETT of Utah requesting additional resources for food inspection at the Food and Drug Administration. I hope my colleagues will join me in that effort.

Also, I am filing an amendment that would authorize a study on user fees for food producers. It is vital that we explore various revenue streams for the FDA in light of the shortage of resources they have for inspection.

The last two items in my amendment are a sense of the Senate and a clarification that companies are required to maintain records and make them accessible to the FDA as part of an investigation. This latter item would prevent delays that keep contaminations from being known as quickly as possible. In the case of recalled peanut butter this past winter, an FDA report showed that inspectors were denied documents when they were requested. The language would clarify that when the FDA makes the inspection, it will have access to those documents needed for purposes of safeguarding the food supply.

The sense-of-the-Senate language goes beyond this amendment and this bill, stating that it is vital to update resources, direction, and authorities of the FDA to better safeguard our food supply. The sense of the Senate directs the FDA to work with our trading partners to establish cooperative agreements.

Several weeks ago, Robert Brackett, Director of the FDA's food arm, said:

> These outbreaks point to a need to completely overhaul the way the agency does business.

I am thankful the sponsors of this legislation for the reauthorization of the Food and Drug Administration understand that expanding the scope of our debate on this bill to include food safety is overdue.

Mr. Brackett went on to say:

We have 60,000 to 80,000 facilities that we are responsible for in any given year. We have to get out of the 1950s paradigm.

Dr. Stephen Sundlof, Director of the Center for Veterinary Medicine of FDA, which has jurisdiction for pet food, implied as much when he was quoted last month as saying:

In this case, we're going to have to look at this after the dust settles and determine if there is something from a regulatory standpoint that we could have done differently to prevent this incident from occurring.

I couldn't agree more. This is a situation where we need one food safety agency, not driven by the politics of Washington but driven by science, to make sure the food fed to our children, the food fed to our pets, or any food served in America is as safe as possible. As we import more food with fewer inspectors, the risk increases.

I might add that we have looked at the pet food contamination and others from the aspect of greed and negligence. In the instance of China, they were adulterating their product with a chemical so that it was worth more in the marketplace. That is economic fraud. In the instance of spinach and peanut butter, we are dealing with negligence—negligence that results in a deadly product being sold across America. But we can't stop there, unfortunately. In the world we live in, with the vulnerabilities we have, food could also become a terrorist weapon. That may sound far-fetched to some, but when Governor Tommy Thompson left the Bush Cabinet, he said in parting that he found it hard to imagine why the terrorists had not attacked our food supply. He said he worried about it on a regular basis.

We have to have inspection standards in place that mitigate against greed and negligence and the possibility of someone intentionally contaminating our food supply, causing terrible suffering and death across America.

That is why this amendment is a step in the direction for a safer food supply. I sincerely hope my colleagues on both sides of the aisle will support my efforts.

I yield the floor.

The PRESIDING OFFICER. The Senator from Connecticut is recognized.

Mr. LIEBERMAN. Madam President, I ask unanimous consent that I be able to speak as in morning business.

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

SUPPLEMENTAL APPROPRIATIONS

Mr. LIEBERMAN. Madam President, I rise this afternoon to encourage President Bush to go ahead and veto the supplemental appropriations bill that Congress has sent him this afternoon because of the language in that bill on Iraq that I consider to be bad for our troops and dangerous for our country.

The legislation that Congress has passed, in my opinion, represents the worst of all worlds. As I have said before, if people feel the war in Iraq is lost, or if people feel it is not lost but not worth fighting for, then what they ought to do is act to end the war. This legislation would do no such thing. It would not end the war in Iraq. It will not require the withdrawal of all American troops from Iraq. It will not cut off funding for the war in Iraq.

On the contrary, what this legislation proposes to do is something far worse. It would handcuff our soldiers with an inflexible and arbitrary set of restrictions—restrictions that would take life-and-death decisions about how, when, and where our troops can fight away from those troops and their commanders. It would substitute the judgment of politicians in Washington for the judgment of our military commanders on the ground. That is wrong.

What is more, this legislation will impose on our soldiers in Iraq a binding deadline of October 1, 2007—5 months from today—to begin withdrawal. That withdrawal would be required to begin regardless of conditions on the ground, regardless of the recommendations of our military leaders, regardless of the opinions of our allies in the region—in short, regardless of reality—on October 1, 2007.

This is a deadline as arbitrary as it is inflexible. It is a deadline for defeat—defeat for America and a defeat for the hopes of the majority of the Iraqi people for a better, freer future.

I know we have heard from some supporters of this legislation that by ordering a withdrawal we will encourage the Iraqis to make political compromises. Where is the evidence of this?

According to the legislation this Congress has now sent to the President, the withdrawal must begin regardless of what the Iraqi Government does. Where, then, is the incentive for the Iraqis to reconcile? On the contrary, there is every reason to conclude this legislation will have exactly the opposite effect that its sponsors claim for it.

Listen to the latest National Intelligence Estimate on Iraq, which has been saluted by Members of this Chamber on both sides of the question of what to do now in Iraq. That latest National Intelligence Estimate predicted that a withdrawal of American troops in the months ahead would ''almost certainly lead to a significant increase in the scale and scope of sectarian violence, intensify Sunni resistance, and have adverse effects on national reconciliation.''

How do the supporters of this legislation explain that National Intelligence Estimate? For that matter, how do they justify this legislation, in light of what we all heard directly from GEN David Petraeus, the commander of our forces in Iraq, when we spoke with him and he spoke with us last week?

General Petraeus told us very clearly that we have achieved progress since our new strategy in Iraq—the so-called surge—began. Consider the situation in Anbar Province to the West of Baghdad, which has dramatically improved. That has been documented not by representatives of the administration or people who support the current policy but on the front pages of the New York Times and USA Today in the last few days.

At a moment when Sunnis in Anbar are finally helping us in targeting al-Qaida terrorists, this legislation would require us to abandon them.

Madam President, what message are we sending to our friends and our foes with this ill-advised legislation? We have heard from some that we need to abandon Iraq because it is not part of the war on terror. But here again, listen to General Petraeus, who is on the ground, one of the most outstanding generals of our military that I have met since I have been a Senator, confirmed unanimously by the Senate a short while ago. Here is what General Petraeus warned us:

Iraq is, in fact, the central front of al-Qaida's global campaign against us.

Let me repeat that. General Petraeus said:

Iraq is, in fact, the central front of al-Qaida's global campaign against us.

If we withdraw, as this legislation would require us to begin to do, al-Qaida wins—the same al-Qaida that attacked America on September 11, 2001, killing 3,000 innocents, the same al-Qaida that intends to attack us again, the same al-Qaida that has made very clear to us what its plans for domination and control of large sectors of the world are.

Madam President, the violence we are seeing in Iraq today, the suicide bombings in Baghdad, the chemical weapons attacks in Anbar Province, the targeted assassinations of Iraq's leaders—these are all primarily the work of al-Qaida. So the big question, then, for me—and I ask my colleagues to consider it—is whether we respond to al-Qaida's terrorism by pulling out, as it hopes we do, and as this legislation would require us to do—abandoning the future of Iraq, the Middle East, and ultimately our own American security, to the very people responsible for the terrible atrocities and suicide bombings we see in Iraq today.

The alternative to pulling out is standing up and fighting. That is what we are doing now in Iraq and doing with some success in Baghdad and Anbar Province. Rather than undermining General Petraeus and handing al-Qaida a victory, Congress should take swift and responsible action to get General Petraeus and our troops in the field the support they need to prevail.

The Iraq war is not lost. But if this supplemental became law, it would be lost and America would suffer the consequences of that defeat for generations.

President Bush, veto this bill.

I yield the floor, and 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. KENNEDY. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

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

Mr. KENNEDY. Madam President, we are still looking for amendments. It is true that there are probably four important areas where negotiations are going on with the principals in a bipartisan way, and progress is being made. It does seem to us that we ought to continue that progress. We will describe in greater detail those procedures tomorrow.

We are urging our colleagues who have amendments to get in touch with us. We know this is complex legislation, but it is enormously important, and we have a lot of business in the Senate. Our leaders have indicated that they wanted us to be ready to move ahead on amendments. Senator ENZI and I are quite prepared to do so.

I understand the Senator from Michigan, Ms. STABENOW, has an amendment she is going to speak to and offer later on. We will look forward to her presence.

We want to again underline the importance that if Members have amendments, notify us as soon as possible, so we can work on them and accept them if we can. We want to be able to conclude this legislation in a timely way in the not-too-distant future.

I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Madam President, I thank the Senator from Massachusetts for his comments. I'll make a slight addition to what he said. For some, it may not look as if there is a lot of progress being made, but I assure you there is a lot of progress being made. One of the secrets to our committee operation—which used to be one of the most contentious committees in the Senate, and now it works productively on issues such as this to get things done—is that we recognize if somebody brings an amendment to the floor and we have not heard about it before, it creates difficulty. When the amendment is filed, we don't have a real good process for amending an amendment. Technically, we can, but it requires a lot of time and votes. In the meantime, it polarizes people. Instead, we take a look at them, talk about them, and we use the body of knowledge we have gained from a lot of hearings on the issue to show where there could be inconsistencies and problems with the amendment. We get the problems ironed out so the amendment can have a logical chance for inclusion if it adds to what we are doing.

That is what is going on as we are speaking. The Kennedy staff and the Enzi staff, and those Senators with amendments are meeting together and working out difficulties. We will accept many of them. Some of them are already in the substitute bill we have. So a lot of progress has already been made on this bill. We want to get the remaining things cleared up. We would like to get it done tonight and tomorrow, if possible. I think we are getting a long way down the list now on problems that people had with it, and we are getting those cleared up in a way that I think both sides can agree on.

So that is why this is not quite as controversial as some people might expect or perhaps even want. I thank the Senator from Massachusetts, Mr. KENNEDY, for all his cooperation on this and the tremendous effort of all the staff. We need people to come down with amendments, particularly if they have something new that we have not heard about.

I yield the floor and 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. GREGG. Mr. President, I ask unanimous consent the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mr. SALAZAR). Without objection, it is so ordered.

Mr. GREGG. Mr. President, I rise to speak today on this FDA bill that has been brought forward by Chairman KENNEDY and Senator ENZI. I begin by thanking them for their cooperative, collegial, and inclusive approach over the last couple of weeks to get this bill in a form that makes it much more effective, accomplishing the goals we all have.

Senator KENNEDY and Senator ENZI for a long time have been great advocates of making sure we have a strong and effective FDA. Senator KENNEDY, of course, has been involved in this for many years and has played a huge role in the success of the FDA, which is, as we know, one of the extraordinarily successful agencies in the Federal Government. It gives the American people confidence, when they go into a grocery store and purchase food or when they go into a pharmacy and purchase a pharmaceutical product or have a prescription filled, that they are going to receive goods which are safe and effective and that they are not going to be at risk of harm as a result of adulteration, fraud, abuse, or misuse of those goods.

It is one of the most amazing successes of our Federal Government in the area of protecting consumers. It arose out of the early 1900 period when there were serious issues relative to food safety in this country, and has evolved into clearly one of the finest agencies, not only in our Government but in the world. It is respected around the world as the gold standard for protecting American citizens and citizens who use the products made by American companies.

This bill builds on that success. I congratulate the Senator from Massachusetts and the Senator from Wyoming for doing such a strong job of building on that success. This bill continues the effort to make sure we have a prompt but safe procedure for getting drugs approved in this country, something called PDUFA, which basically allows drug companies to pay a fairly significant portion of the cost of the approval of new drugs, which has expedited dramatically the rate of approval of new drugs. That means pharmaceuticals and biologics come to the market, which help people, which save lives, which basically makes life better. That is the good news.

In addition, there is, for devices, the MDUFMA proposals, which deal with devices, medical devices the way we deal with pharmaceuticals, setting up a fee system for the approval of medical devices. This is something, when I was chairman of this committee, I had the good fortune to be involved in developing. These two initiatives are the essence of how we maintain a vibrant drug and medical device approval process in this country. It is absolutely critical they be reauthorized, and this bill does it in an effective way.

In addition, the bill takes on a number of other issues which are timely and appropriate. The most significant, from my perspective, although there are a lot of significant ones here, is the issue of drug safety and how we make sure the drugs which do come to the market are safe. This involves not guesswork but finding out what the science is and what happens when people start using these drugs and medical devices. The concept behind that in this bill is that we should set up a regime that basically collects information from all sorts of different sources. There are literally thousands of different sources, but there are some very big ones that we develop information about the reactions people have when they take drugs. We have the tremendous database of the Medicare system, for example. We have the tremendous database of provider groups, such as the Kaiser Permanente fund out in California. These different provider groups have a huge amount of information on what is happening when somebody takes some form of medication. But what happens is that information, although it is collected, is not effectively screened and is not effectively evaluated.

What this bill does, essentially, is create a regime that allows us to more effectively, first, collect the data; second, when there are red flags popping up on that data that say there is a reaction here or reaction there or something occurs here that was not expected, that information becomes more visible under this regime and more available; and then, third, if it is clear there is something that is not going right here, that there is a series of aberrations nobody expected, then it sets up a process where we take that information out and we give it to selected groups of specialists in the academic and private world who have the ability to evaluate that information and tell us what is going on.

There are centers at MIT and I believe at Duke, for example, that do exactly this. The idea, of course, is to first collect the information effectively; second, make sure when those aberrations or red flags start to show up they are noted; and, third, when there is a certain critical mass of information that reflects something that may not be correct or is out of kilter, it makes sure we have that information evaluated in a very science-based, professional way by people who specialize in this and who have the ability to do it—something which FDA does not have the resources, necessarily, to do right now.

With that information in hand, with that science in hand, then you can make decisions. This bill creates a new regime for making those decisions—as to what a company must tell people or tell providers when they are using these different drugs and medications. But it will be a science-based decision, and that is the key here. All of this will key off of science that is hard and that is effectively reviewed and evaluated in order to come to the conclusion that certain actions must be taken in how you distribute this medication and how you communicate what the implications of this medication are. So this new safety and surveillance regime, which is known as mining the information, and then pulling it together and taking advantage of it, validating it and integrating it—this new regime is at the essence of the safety concerns which are involved in this bill.

It is very positive. It opens a new world of review in the area of pharmaceuticals and medicines, a postmarket review process which will be based on science and which will be very healthy to the system as a whole. I congratulate and thank both Senator KENNEDY and Senator ENZI for evolving this process in this bill.

In addition, there is the pediatric language in this bill. There is the BSE program, which is the program which basically rewards companies that are willing to go out and do extra research to see how a drug might affect a child. Historically, drugs will be brought to the market and you would never know—because all the clinical exams have been done on adults—how they would affect children. Some of these drugs, obviously, if given to a child, could have a significant negative impact and, if given in the wrong doses, might have an extraordinarily adverse effect. Some could actually be very positive if given in the right dosage. So it became a guessing game as to when these pharmaceuticals, when these medications, were good for children, in many instances. As a result, doctors and prescribers simply didn't know whether to make them available, in many instances, to children.

This BSE pharmaceutical procedure said essentially, We will give you, the producer of this pharmaceutical, of this medication—we will give you an extra 6 months of exclusivity in exchange for your testing this and making sure it will work effectively, or finding out if it will not work effectively, on children. The practical effect of that, of giving that incentive, has been that hundreds of new drugs have been made available to children which were not available before. This has had a very positive impact on children and the ability of children to get pharmaceuticals.

With the BSE program, we also developed a program called the Pediatric Research Equity Act, which essentially takes the opposite approach from the BSE program. It creates a mandate where, in certain instances, certain medications have to be tested on children. They have to go through a process of seeing if they will work for children. The two together basically work in tandem and the idea is they will feed off of each other, and you will create an atmosphere out there where the two different approaches—one basically being a carrot and the other being a stick—will lead to better medications being available for children.

It has worked amazingly well. The key to this, of course, is to keep these two in tandem. In order to accomplish that, they both, in my opinion—and fortunately in the opinion of the chairman and the ranking member of the committee now, at least—have to be on the same wavelength. They have to be dealt with the same way relative to things such as their sunsets, when they get reviewed and when they don't get reviewed, because if you were to have one sunsetted at a different time than the other or one sunset and the other not sunset, you wouldn't get an effective review of the two together, and they both work, as I said, together.

This bill makes sure they are treated the same way in that area, and that is a major step in the right direction toward making sure children get proper pediatric care. There is still going to be an issue tomorrow, I understand, on exclusivity, which is going to be brought up by another Senator; that is, the length of the exclusivity that is necessary in order to get pharmaceutical companies to pursue proper research on children is an issue. But I happen to think what we have now has been shown to work, and why fix something that is not broken, in my opinion. So I believe we should stay with what we have for the 6-month exclusivity period.

In addition, there are a number of other issues floating around this bill. This bill, obviously being a major health care bill, attracts a lot of other concerns. One of them that I have filed as an amendment—but I don't intend to bring it up unless we move into the issue of reimportation, which may be brought up on the floor—is the question of safety of Internet pharmacies. I believe very strongly, when somebody goes on line and purchases a pharmaceutical product over the Internet—which is happening more and more often as people become more comfortable with dealing with the Internet on a variety of different levels, but certainly senior citizens as people age into their senior citizenship years who had been dealing with the Internet for quite a few years and are comfortable with it—I believe it is critical we have in place a system which allows people, when they look at the site on the Internet, to know whether that Internet pharmacy is selling the product they say they are selling and whether the product they say they are selling has received FDA approval.

The problem we have here is a lot of these pharmacies will represent that they are selling some sort of pharmaceutical good and it turns out that product is, in many cases, adulterated or inappropriately made, in which case people end up getting a pharmaceutical product which is bad for them. In some cases it can actually lead to death. So it is critical that we have a way so when somebody goes on the Internet and looks at a site on the Internet, they know that Internet pharmacy they are looking at is legitimate and the products they sell are legitimate and have been through the FDA approval process.

In order to accomplish that, we need to set up a whole new regime, basically, and we need to pay for it. This amendment which I have put in accomplishes that. It essentially gives the FDA the authority to review pharmacy sites on line, to meet with the people who have set up those sites, to make sure to set up a certification process where they are guaranteed the sites are meeting the conditions of selling pharmaceutical products or medications which have met the FDA approval, and then to put sort of a Good Housekeeping seal on that site, which is tamperproof, which says this site has FDA-approved products. It would be a huge step forward in safety for American citizens using Internet pharmacies.

It is complicated, though, in its enforcement. It is simple to state but complicated to enforce because it means the FDA needs the resources to deal with these sites and also to deal directly with these pharmaceutical Internet sales places which may be somewhere other than the United States. Second, you have to have in the United States a point at which you can deal with the site if something goes wrong, a responsible representative on the ground in the United States who has the economic wherewithal to basically bond the site, for all intents and purposes.

Setting up that type of regime will be expensive. The language of this amendment puts in place a fee system which allows that to be paid for so we can be assured that the FDA has the resources necessary to review these sites and accomplish this goal of making sure these Internet pharmacy sites are safe for Americans to use. I think this would be a tremendous step forward in safety for all Americans, especially as we move toward a much more

Internet-oriented purchasing process in this country.

Another issue which is going to be discussed here, and which I understand from the chairman may be held over for conference or come into play in some area, is a crucial issue of follow-on biologics or similar biologics.

We know we can produce a generic pharmaceutical and do it with a fair amount of predictability. We know that if a generic company brings on a pharmaceutical product which has run its course, it has proper patent coverage, that that generic is going to be safe and effective and be essentially the same thing as the pharmaceutical because they are chemical compounds.

In the biologics area, this is not the case because you are dealing with a much more complex process of producing the biological medication. It is a fermentation process, it involves proteins, it involves mutation of proteins, which depends to a great extent on a huge number of factors which are very uniquely identified with the way that that vat of medication was evolved through the process.

Anyone who has been to one of these facilities can see how complex it is to maintain consistency, even within the facility that is producing the medication. If you stepped out of that facility and tried to reproduce that medication, the complexities would even be more difficult to replicate.

It is critical that as we move into this biologic area, we understand we are not dealing with generic pharmaceuticals. You know, when you put the title ''generic pharmaceuticals'' on something that is sort of a motherhood term, that is a good idea. It is a good idea if it works. But if you put the generic title on biologics, you are probably going to mislead a lot of people and, in the process, potentially produce medicines which can be extremely harmful or could not accomplish the purposes.

So as we move down this road of looking at biologics and how we give the opportunity to produce similar biologics to people after the patent life has run, we have to be very careful that we don't oversimplify the exercise in the name of getting something, as ''motherhoodish'' as generics; rather, we have to make sure we put in place a process which allows those biologics, when they are produced as similar biologics, to have been properly reviewed to be sure they accomplish what they claim they are going to accomplish.

This means that almost in every instance of an individual biologic, you are going to have to have clinical trials for the similar biologic. There are going to be very rare instances where you can actually bring to the market something that doesn't go through clinical trials in this area, in my opinion, and you have to be very sure that you demonstrate safety and effectiveness of the similar product before you step into this arena of awarding the authority to go ahead and sell that product in the market generally.

You will also need very aggressive postmarket surveillance in this area because you do not know, in many instances—you hope you know, but you do not necessarily know—how individuals will react to taking this type of medication, which is developed as a similar medication, as versus the basic medication which is trying to be replicated.

This area of biologics is a complex one. It should not be rushed into. I know there is a great desire to step forward and say: We have a huge victory for the American people, we can now have generic biologics. But if we rush into this exercise and create a process with approval which does not adequately account for the significantly, the exponentially more complex process of bringing online a biologic when compared to a chemical pharmaceutical, then we will not have done our job as policy people but will simply have given ourselves a good press release and in the end probably have given ourselves a very dangerous process relevant to protecting the American people in the area of biologics.

As we move down this road of generics, I do hope we will move in a way that understands there is a significant difference in pharmaceuticals and that those differences are going to require a much more detailed and a much more complex approval process than we presently have in moving in the generic pharmaceutical area.

Those are some of the concerns I have relative to other issues that might be brought up in this bill. But I do again wish to congratulate the Senator from Wyoming, I wish to congratulate the chairman from Massachusetts for once again bringing to the floor a very strong piece of legislation, which will significantly improve the capacity of the FDA to continue its extraordinary record of protecting the American people relevant to food and drug safety.

I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Mr. President, I wish to thank the Senator from New Hampshire, Mr. GREGG, for the tremendous effort he put into this bill. He spent years on the committee. He became chairman of the committee. He used those years with the institutional memory and the experience with a great deal of diligence and creativity which he has always used on that committee to provide us with fuller explanations and wording for several of the provisions that are in this bill.

I thank him for helping us to perfect those and the diligence he always has on all of the issues we bring up in the committee. I also appreciate the work he has done on Internet safety. This is not something he just developed now. He has been working on it for at least 3 years that I am aware, to make that as safe a system as possible if we ever have to put it into place.

I am hoping we will not have to have that full debate at this time and appreciate his submitting it in case we need to have that debate.

I also appreciate the explanation he gave on the follow-on biologics. It is a hard thing for people on the committee who have been through a number of hearings to understand. I am sure the public as a whole has an even greater difficulty with it. But it is a whole new phase of medications. By the name, ''biologics,'' it is alive. That makes it a lot more complicated than a set of chemicals that are ground up and put together in a particular order. Even with the chemicals that are ground up and put together in a particular order, if they aren't done quite right, they would not dissolve and people do not get any benefit from them. That is why we are doing the bill. Then we will be working on biologic similars to see if there is some way that that can be done effectively and safely. I thank the Senator for his comments and his tremendous work.

I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I would add a note of thanks to the Senator as well. We are strongly committed to information technology, the use of information technology eventually. We have that on our list. We passed it unanimously through this body a couple of years ago, but the House didn't act and we are going to act further.

But what we are talking about in the database, which the Senator from New Hampshire talked about, is using the information technology and database in terms of the postmarketing or approval surveillance. This makes a great deal of sense. That is a key aspect of safety in the legislation. The Senator from New Hampshire is very interested in shaping that.

The second is to make sure we are going to bring the latest information on drug safety to the consumers; that is more scattered at the present time than it should be.

We have accepted the recommendation of Senator GREGG to include one what they call portal in the Internet to make sure that that information will be collected and available to the consumers on safety, which is a useful addition. So these are important. I thank him for his strong support for this legislation. This is very helpful.

Now we are beginning to see, we have got broad support on our side and on both sides of the aisle for this legislation. We are working hard to clear up some of the—still a few of the outstanding items, but we are moving ahead. We want to indicate to our colleagues again that we want to try and respond to many of their amendments, but we want to do it in a timely way. We were in here yesterday afternoon with the presentation. We welcomed suggestions during the course of the evening last night, and we have done so during the course of the day. We are moving along we hope that anyone who

has any other further amendments would be in close touch with us because we are giving every opportunity to our colleagues to make any recommendations they have or would like to move along to conclusion at a reasonably swift time.

I yield the floor.

The PRESIDING OFFICER. The Senator from Louisiana.

AMENDMENT NO. 1004

Ms. LANDRIEU. Taking that advice to heart, Mr. President, I call up amendment No. 1004.

I would like to speak about that amendment now.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Louisiana [Ms. LANDRIEU] proposes an amendment numbered 1004.

The amendment is as follows:

(Purpose: To require the Food and Drug Administration to permit the sale of baby turtles as pets so long as the seller uses proven methods to effectively treat salmonella)

At the end of the bill, add the following:

TITLE ____—DOMESTIC PET TURTLE MARKET ACCESS

SEC. ___. SHORT TITLE.

This title may be cited as the ''Domestic Pet Turtle Market Access Act of 2007''.

SEC. ___. FINDINGS.

Congress makes the following findings:

(1) Pet turtles less than 10.2 centimeters in diameter have been banned for sale in the United States by the Food and Drug Administration since 1975 due to health concerns.

(2) The Food and Drug Administration does not ban the sale of iguanas or other lizards, snakes, frogs, or other amphibians or reptiles that are sold as pets in the United States that also carry salmonella bacteria. The Food and Drug Administration also does not require that these animals be treated for salmonella bacteria before being sold as pets.

(3) The technology to treat turtles for salmonella, and make them safe for sale, has greatly advanced since 1975. Treatments exist that can nearly eradicate salmonella from turtles, and individuals are more aware of the causes of salmonella, how to treat salmonella poisoning, and the seriousness associated with salmonella poisoning.

(4) University research has shown that these turtles can be treated in such a way that they can be raised, shipped, and distributed without having a recolonization of salmonella.

(5) University research has also shown that pet owners can be equipped with a treatment regiment that allows the turtle to be maintained safe from salmonella.

(6) The Food and Drug Administration should allow the sale of turtles less than 10.2 centimeters in diameter as pets as long as the sellers are required to use proven methods to treat these turtles for salmonella.

SEC. ___. SALE OF BABY TURTLES.

Notwithstanding any other provision of law, the Food and Drug Administration shall not restrict the sale by a turtle farmer, or wholesaler commercial retail seller of a turtle that is less than 10.2 centimeters in diameter as a pet if—

(1) the State or territory in which such farmer is located has developed a regulatory process by which pet turtle farmers are required to have a State license to breed, hatch, propagate, raise, grow, receive, ship, transport, export, or sell pet turtles or pet turtle eggs;

(2) such State or territory requires certification of sanitization that is signed by a veterinarian who is licensed in the State or territory, and approved by the State or territory agency in charge of regulating the sale of pet turtles;

(3) the certification of sanitization requires each turtle to be sanitized or treated for diseases, including salmonella, and is dependant upon using the Siebeling method, or other such proven method, which uses an antibiotic to make the turtle salmonella-free; and

(4) the turtle farmer or commercial retail seller includes, with the sale of such a turtle, a disclosure to the buyer that includes—

(A) information regarding—

(i) the possibility that salmonella can recolonize in turtles;

(ii) the dangers, including possible severe illness or death, especially for at-risk people who may be susceptible to salmonella poisoning, such as children, pregnant women, and others who may have weak immune systems, that could result if the turtle is not properly handled and safely maintained;

(iii) the proper handling of the turtle, including an explanation of proper hygiene such as handwashing after handling a turtle; and

(iv) the proven methods of treatment that, if properly applied, keep the turtle safe from salmonella;

(B) a detailed explanation of how to properly treat the turtle to keep it safe from salmonella, using the proven methods of treatment referred to under subparagraph (A), and how the buyer can continue to purchase the tools, treatments, or any other required item to continually treat the turtle; and

(C) a statement that buyers of pet turtles should not abandon the turtle or abandon it outside, as the turtle may become an invasive species to the local community, but should instead return them to a commercial retail pet seller or other organization that would accept turtles no longer wanted as pets.

(b) FDA REVIEW OF STATE PROTECTIONS.—

The Food and Drug Administration may, after providing an opportunity for the affected State to respond, restrict the sale of a turtle only if the Secretary of Health and Human Services determines, that the actual implementation State health protections described in subsection (a) are insufficient to protect consumers against infectious diseases acquired from such turtles at the time of sale.

The PRESIDING OFFICER. The Senator from Louisiana is recognized.

Ms. LANDRIEU. This amendment, I will discuss briefly at this time, and then according to the leaders on how they would like to go ahead and proceed with these amendments, it can be voted on at another time.

Mr. President, sometimes we offer amendments that affect large industries and millions and millions of people in large industries. Sometimes they are smaller industries but very important industries that we have to stand for as well.

One of them is a small, relatively small industry in my State. That is the industry of turtle farmers who grow and produce and trade and sell turtles to be used in a variety of different ways. One of the ways is by selling them for pets. In 1975, the FDA banned the sale of small turtles for pets domestically but allowed those sales to continue internationally.

So there is a group of farmers, turtle farmers, in Louisiana particularly, but I am sure there are others around the country, who have maintained their business by selling overseas. Recently, because of the competition and development of overseas markets, they are getting very constricted in what they can sell because they have now gotten competition from the countries in which most of these sales occur.

There has been a great deal of pressure to try to reopen the domestic market. That is what this amendment will do. It will open a domestic market again because the science has caught up with the regulations. We now have developed a vaccine, universally-tested and proven, that can keep those small turtles nearly free of salmonella, and with the right licensing procedures this amendment calls for and the right information that is required when these turtles are sold for pets, either to a wholesaler or retailer or to a family who might purchase them, I believe the safeguards are in place, as the science and technology have caught up with the problem.

There are many wonderful aspects about technology. Sometimes we can think our way through a problem. That is basically what has been done over the last 35 years. I am proud of the role that LSU, Louisiana State University, has played in developing these treatments. I am proud the industry survived through a very difficult time and proud they are now proposing very strict rules and regulations.

I might add that when this ban went into place for this particular reptile, there was no such ban for other reptiles that also can carry salmonella, which are still continuing to be sold on the domestic market. So on behalf of this industry, which is small but important, mainly in Louisiana, and I am certain there are turtle farmers in many places, I offer this amendment to repeal this 1975 ban in light of the new technology and new opportunities that are out there to give protection to our general public.

That is the essence of the amendment. I would like to set it aside now and speak to it at a later time when votes are scheduled.

Mr. KENNEDY. Mr. President, I thank the Senator.

We are reviewing the proposal. I understand the State of Louisiana has had a very strong regulatory process in terms of safety, which has been recognized and commended for some period of time.

Ms. LANDRIEU. Mr. President, the Senator is correct, because I understand, as I am learning more about this industry, it is more robust in the State of Louisiana than elsewhere. So I think our legislature has put the appropriate restrictions, licensing, information, as well as keeping the research going, that could develop the appropriate ways to treat these reptiles so we can maintain an industry, allow people to make a living, and keep our population safe as well.

Mr. KENNEDY. Mr. President, I thank the Senator. We are reviewing the proposal. We will work very closely with the Senator, and we will be back in touch making a recommendation, working with her. We thank the Senator very much.

Ms. LANDRIEU. Mr. President, I thank the Senator from Massachusetts.

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

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. HATCH. Mr. President, I rise in support of S. 1082, the Food and Drug Administration Revitalization Act.

This legislation addresses many critical issues, including the need for provide proper incentives and support for the development and review of pharmaceuticals and medical devices, including products for children, and the need for heightened efforts to assure the safety of medications.

As we debate this legislation, let us remember we all have the same goals in mind.

We want Americans to benefit from life-saving, life-enhancing drug and device products.

We want Americans to have access to drugs that are safe and effective.

We want Americans to have all the relevant safety information available on their drugs.

And, indeed, we want Americans to know that the Food and Drug Administration, the agency responsible for ensuring drug and device safety, has the resources to do its job.

That is what this bill is all about protecting Americans and giving the FDA the tools to do its job.

The legislation before us reauthorizes both the Prescription Drug User Fee Act, better known as PDUFA, and the Medical Device User Modernization Fee Act, better known as MDUFMA.

It is of critical importance that both programs be authorized by the end of the fiscal year. This legislation embodies the agreements reached by both industries and the FDA, along with refinements added by the Congress.

Let me make clear that I am supportive of these reauthorizations. It is fair to say that I had reservations about PDUFA when it was enacted in 1992, questioning the wisdom of whether an industry should be required to support a governmental function. To a certain extent, I still have those reservations. That being said, it has become abundantly clear that there are not the resources in the Agriculture Appropriations bill to support these review functions absent a user fee, and thus I recognize their necessity.

With regard to MDUFMA, I have been particularly concerned about the impact that user fees could have on small medical device manufacturers, many of which are located in Utah. Indeed, I am proud that there are over 100 medical device companies in Utah, companies that represent the best in American innovation. They are true world leaders in their industry.

The changes made in the last reauthorization at my request, along with the new structure of the user fee in FDARA and the improved trigger provision satisfy me that the manufacturers are being fairly treated by the user fee program in this bill. And, indeed, this is a serious concern.

In February of 2006, the Lewin Group prepared a report for the FDA entitled ''Medical Device Industry Perspectives on MDUFMA. That report revealed that senior industry experts felt FDA is generally doing an excellent job in premarket regulation of medical devices and that the industry was generally supportive of the purpose and goals of MDUFMA. However, key among the findings was the fact that the industry perceived little or no evidence of attaining the main intent of the program or in realizing a favorable return on investment from user fees. In fact, whenever I return to Utah to meet with medical device executives, I hear the same concern. And it is a concern I share.

Indicative of that concern is the astounding fact that 70 percent of responding device manufacturers perceived that MDUFMA goals have not resulted in meaningful improvements in either the predictability or timeliness of reviews. In fact, when I reviewed the device approval times, I understood those concerns. For some classes of devices, FDA had made great progress. For others not. This was disturbing to me, since we would all hope that progress would have been made across the board.

It is my hope with the new fee structure embodied in S. 1082, we will make better progress in achieving the approval time goals. I am pleased that Chairman KENNEDY and Senator ENZI included provisions at my request which make certain the fees for smaller companies are affordable.

Let me turn to the issue of direct-to-consumer advertising, or DTC. This is an issue on which our colleague, the senior Senator from Kansas, Mr. PAT ROBERTS, has shown great leadership, both in the HELP Committee, and here in the Senate Chamber. Senator ROBERTS has led the charge to eliminate the 2-year moratorium on prescription advertising for newly approved drugs. He has expressed constitutional concerns about such a moratorium. I share those concerns. He is right to bring this up.

In general, I believe we should be guided by a very simple rule. Advertising about products the FDA regulates should be truthful and not misleading.

I do understand the arguments that some in this body make with respect to pharmaceutical advertising. Some nights, when I watch television, those ads do become tiresome. But I could say that about a lot of ads.

Some have argued we need to be particularly careful about what pharmaceutical advertising is allowed, because we have limited knowledge about drugs, especially when they come on the market.

Those who make such arguments fail to recognize that FDARA will guarantee that consumers have access to greater clinical and safety information about medications because it gives the FDA more authority to review and react to drug safety data. User fees created by S. 1082 will bolster the FDA office responsible for reviewing drug advertisements.

The FDA has told my office and others that drug manufacturers cooperate fully with the FDA when a concern is raised about an advertisement. That would be my preference for how these ads should be handled.

I am hopeful we will be able to address this issue and I am encouraged by recent discussions involving the Senator from Kansas and others members of the Senate HELP Committee.

The bill's drug safety provisions are probably its most important component. Indeed, shortly after the Institute of Medicine issued its report on this issue, we all began to see a floor of letters in support of efforts to improve the drug safety program.

Members of the HELP Committee undertook serious discussions on how to address the problems that have been identified, and the result is this legislation developed by Senator ENZI and Chairman KENNEDY. The Enzi-Kennedy bill has benefited from the guidance of our colleagues, former Chairman GREGG and Senator BURR, who have pointed out the necessity for more flexibility in determining when a risk evaluation mitigation plan—or REMS—is needed. Senator COBURN added greatly to the discussion by raising issues relating to the access of our constituents in rural areas to needed pharmaceuticals.

I believe the product of these discussions strikes the appropriate balance. It requires, for example, that determining whether the FDA should further assess the safety of a drug should be based on scientific evidence. To me, that is probably the most integral part of this bill—when concerns are raised about drugs, these concerns must be based on scientific evidence and not on innuendos or hearsay. This approach allows proper evaluation of relevant information and gives the FDA greater authority to warn consumers when there are problems.

In addition, the drug safety title strengthens the FDA's existing authority to monitor drugs once they have been approved by making it clear that evaluation must occur before and after approval. One of the most important components of this legislation is that more drug safety information will be made more available to the public. I believe that is an important victory for the American consumer.

I also want to take a few minutes to talk about the pediatric testing and research provisions included in this bill.

I have supported both the Best Pharmaceuticals for Children Act and the Pediatric Research Improvement Act. In fact, I have supported these efforts since our former colleague from Ohio, Senator MIKE DEWINE, brought the need for additional pediatric testing of prescription drugs to our attention during consideration of the FDA Modernization Act of 1997. He fought long and hard to encourage drug companies to conduct clinical trials on pediatric uses of their drugs. His efforts paid off and this program has been extremely successful.

My good friend and colleague from Connecticut, subcommittee Chairman CHRIS DODD, has also shown great leadership on this issue when FDAMA was being considered in 1997. He held a hearing on this issue earlier this year with his ranking Republican member, Senator LAMAR ALEXANDER. That hearing was very insightful and I believe that many of us are trying to do the right thing as we reauthorize both programs.

I urge my colleagues not to lose sight of the purpose of these two programs as we make decisions on this part of the bill. We want good, solid information about the safest way to prescribe drugs for children. And by giving companies market exclusivity to conduct clinical trials, we will know the safest dosage levels for children. So let us not lose sight of the original propose of these programs—to help children have the safest dosages for prescriptions. I am hopeful that we will be able to work out our differences on these provisions on these very important issues.

Food safety is another issue that is on nearly everyone's mind these days. When I was a kid, we were always told to eat our spinach so we could grow muscles like Popeye. Peanut butter is almost a staple for most Americans. And yet these ordinary, common foods have harmed rather than helped. Pets are getting sick and we have discovered that their food has been contaminated. Something needs to be done.

I have worked with Senators KENNEDY, ENZI, DURBIN and ALLARD to figure out a constructive approach to these important issues. I think that we have made a lot of progress and I look forward continuing those discussions as the bill progresses toward enactment.

One factor that is not discussed enough is the need to appropriate more funding for inspectors and inspector training, especially abroad. I can recall over a decade though when Jim Phillips, a former investigator for the FDA, brought to our attention the woefully lacking FDA resources for foreign inspections. We were shocked then, and unfortunately, we are shocked now.

Today, only one percent of imported food is inspected. I believe this issue needs to be carefully reviewed by Congress so people no longer have to worry about whether food for them or their pets is safe.

I offered and withdrew an amendment during the HELP Committee consideration of this bill that would address another important issue. My amendment had several provisions which encouraged innovation and development of safe antibiotics, required the FDA to convene a meeting to determine how the Orphan Drug Act should be applied to antibiotics, and reauthorized the grant programs for the Orphan Drug Act. Finally, my amendment provided for a 5-year exclusivity for enantiomers of previously approved racemic drugs if and only if, one, they are approved for new therapeutic uses and, two, a completely new data set has been created for approval of this enantiomer. It is my expectation that our current discussions on these provisions will lead toward their adoption later in the week.

I also want to point out that there have been many discussions on ways to ensure that citizens' petitions do not unfairly delay generic drug approvals. I believe this is a problem, although I do not believe it is of a magnitude as some would suggest. I do not oppose making changes to ensure that any abuses in this area are stopped, as long as FDA still has the ability to do the appropriate scientific and legal review of abbreviated new drug approval applications in the timeframe it desires.

Let me turn now to one provision which is not in the bill: language authorizing a pathway for the Food and Drug Administration to approve copies of biologics. This is commonly referred to as the ''biosimilars,'' ''biogenerics,'' or ''follow-on biologics'' legislation. Senator GREGG spoke so well about this subject just a few minutes ago.

While language on this issue is not included in the bill we consider today, I want to make perfectly clear that it is my intention to work toward development of an acceptable compromise that can be included in the final version of FDARA and signed into law. It is my hope Senators will refrain from offering any amendments on this issue until we have time to develop consensus. And I do believe consensus can be developed without delay. It is my intention to do so.

As my colleagues are aware, I am the Hatch of Hatch-Waxman. I have a serious interest in making certain the law Chairman WAXMAN and I developed in 1984, the Drug Price Competition and Patent Term Restoration Act, is used as the basis for development of legislation to provide an abbreviated pathway for approval of follow-on biological products. In so doing, we must make certain we include the appropriate incentives for development of those products. Indeed, that is my high priority.

By any estimate, the Hatch-Waxman law has done consumers tremendous good by fostering today's modern generic drug industry. It has saved patients literally billions of dollars. Similarly, using it as a basis for development of a pathway for follow-on biologics will help consumers with access to the innovative, life-affirming biologic products. But in so doing, we must be mindful of the fact that we need to encourage and nurture the innovation that provides the biologics that the generic companies seek to copy. This is a tremendously complicated task, but it is one worth doing.

In 1984, when Chairman WAXMAN and I undertook a series of negotiations that led to approval of the Drug Price Competition and Patent Term Restoration Act, it was a very different time.

There were no cell phones, no DVDs, almost no one had a personal computer, and a stamp cost 20 cents

It was a much less complicated time. Generic drugs were a small, struggling industry, with no discernible footprint in the pharmaceutical world. The innovators had yet to respond to their first paragraph IV certification. In 1984, brands versus generics largely an American endeavor. Today, the pharmaceutical market—both innovator and generic—is an international marker—for research, development and marketing.

Biological products were not an issue in 1984. Today, they are becoming an increasingly larger part of pharmaceutical spending.

It is my strong belief that we can learn from this experience and build another solid law that will help consumers—both by supporting the incentive to discover and develop new biologics, and by fostering a climate that will lead to lower prices. This is a classic win-win situation.

And why is that so important?

A February report by the Center for Medicare and Medicaid Services paints the picture very well: America's health care spending in the next 10 years will double to $4.1 trillion. Or, to look at it another way, that is 20 cents out of every dollar spent. We spend about $7,500 per capita on health care in the U.S. Yet in 2016, that will rise to an astounding $12,800 per person. Greater spending for pharmaceuticals is expected to fuel much of the increase, the report's authors concluded.

And there it is in a nutshell. The good news and the bad news.

Not much worries Congress more than the costs of medical care—both from the perspective of a balanced budget, and from the view of our constituents' pocketbooks.

In many ways, it is an embarrassment of riches.

We have exciting new therapies to treat our medical ills—new drugs, new devices, stem cell treatments. Their potential to improve human health and well-being is almost limitless.

And yet the cost of those treatments, the impact they have on the budget, at times seems equally limitless. In fact, in 2005, prescription drug spending was estimated at $214 billion, a healthy amount by anyone's measure. That same year, spending on biologics was estimated at $32 billion.

Since biologicals are generally more expensive products, ways to reduce their costs interest policymakers and

other stakeholders in expenditure of the health care dollar, foremost among them employers, insurers, pharmacy benefits managers, and of course, the government.

Comes now the generic drug industry, which has been proven to provide alternative, safe and effective therapies in a much more cost beneficial manner. We look to them to be part of the solution to this problem. And they, in turn, look to us to help them be part of that solution.

It is no secret that several senators have been meeting to develop a bill that would establish a pathway for biosimilar products to be approved by the Food and Drug Administration. We had hoped to have it ready for inclusion in FDARA, but it was not, despite the talks of the four Senators. I am referring to Health, Education, Labor, and Pensions Committee Chairman TED KENNEDY, the committee's ranking Republican, MIKE ENZI, Senator HILLARY CLINTON, and me. All members of the HELP Committee, we have worked to develop consensus on what legislation would include.

Senator KENNEDY and I began these talks several months ago. He is committed to developing a bill on a priority basis. Our staffs literally have been working night and day.

Our work has been aided immeasurably by the leadership of Chairman WAXMAN, and in the Senate, Senator CHUCK SCHUMER and Senator CLINTON, who have introduced the companion to the Waxman bill. Their legislation, the Access to Life-Saving Medicine Act, H.R. 1038/S. 623, provides a solid starting point for discussions. It is an important work that has added immeasurably to the congressional dialogue.

It is my hope that our discussions will also be informed by the work of Representatives JAY INSLEE, GENE GREEN and TAMMY BALDWIN, who recently introduced the Patient Protection and Innovative Biologic Medicines Act of 2007, H.R. 1956, and by the views of the many, many stakeholders in this legislative effort.

The time to develop a pathway for approval of biosimilar products is long past overdue. It should be our priority, and it should be our high priority, to get it done this year. But, we should get it done right. Our deliberations must be based on science. The original balance of the law must be maintained, but we must also recognize the emerging realities of this new world.

And what are those realities? First, biotechnology products are not drugs; they are very complicated molecules that are not easily reproduced. An inadvertent change in the structure of that molecule can lead to very devastating consequences.

Second, today, it is unlikely that any follow-on company will be able to produce an exact copy of a biotech molecule, a generic biologic if you will, at least at first.

Third, because science advances, and because American researchers are very good at advancing science—stem cell research is one example that comes readily to mind—we must hold open the possibility that one day there will be true biogenerics.

And we must also develop a pathway so that biosimilar products can be approved without a full biologics license application, a time-consuming and expensive process.

But whatever policy we develop, it must be based on soundness of science, rather than the practicalities of politics.

Fourth, we must take into account the unique nature of today's industry. This is so much more than an exercise between big Pharma and the generics, or even between big bio and the generics.

Indeed, there are about 1,400 biotech companies in the United States. How many of them are profitable? Astoundingly, only 20.

Many of these companies are small, with revenues of under a million dollars per year. Many do not even have a product on the market.

We must examine closely the issue of who will be making biosimilars? Will it be the Barr Labs and Tevas of the world? Undoubtedly.

But it may also be generic subsidiaries of innovator companies.

It is also very likely to be companies in India and China. As we have seen with the recent concerns over pet food, inspecting foreign manufacturing plants has historically been a problem for the resource-constrained Food and Drug Administration.

Fifth, we must use the framework of Hatch-Waxman where we can, but we must recognize there may be ways to improve it.

There are obvious differences between regulating a pathway for biosimilars and for copies of chemical drugs. For example, as I mentioned, today's science will probably not allow identical copies of today's biologics. So, the concept of bioequivalence cannot be imported into this debate. Instead, we must work carefully to define biosimilarity.

Another difference today is the fact that process patents are much more integrally tied to the manufacture of biologics. Current law does not require listing of process patents in the orange book.

Waxman-Hatch is inherently a litigious process. But its framework—the patent holder or drug manufacturer—v. the generic—does not easily translate to a system in which multiple patent holders may exist, including, for example, major universities and research centers.

Sixth, the incentives for development of biotech products must be maintained, enhanced where it advances public policy. But at the same time, we cannot seed a new generation of roadblocks that preclude biosimilar entry. This is the nub of the key, crucial balance.

Seventh, the role of the FDA must be carefully evaluated. We must empower the agency to evaluate pure, safe and potent copies of biotech products, but we must all recognize that there must be a bright line that separates a safe copy from a new product which should be subject to a full biologic license application.

We need to free the agency and provide it with the flexibility to evaluate the adequacy of a biosimilar submission based on good science, but we must also recognize that, as Commissioner von Eschenbach has said, there may be some products which cannot be copied safely with today's science.

Eighth, we must make certain the resources are there for the FDA to do the job right. I must note that negotiations between the agency and the pharmaceutical industry on the Prescription Drug User Fee Act reauthorization, or PDUFA, took over one year. Every indication I have is that review of a biosimilar application is very likely to be more complex and time consuming than that for a new biologics license application.

There must be authority for a fee to be collected that reflects this complex workload. If we do not provide adequate resources to the FDA, then review of new products could suffer at the expense of cheaper copies as reviewers become siphoned off from new products to the biosimilars. We should not design a system in which this occurs.

And I must digress at this point to underscore that the FDA is already cash-strapped and that situation simply must be corrected. The dire FDA resources issue appears to have manifested iself in such recent revelations as to the inadequacy of food inspections for some of the most ubiquitous products in American life, including pet food and peanut butter.

Federal policymakers must take this into account when legislating, and the Food and Drug Administration Revitalization Act is a good place to start.

Enacting follow-on biologics legislation is a top priority for me. I want us to finalize a bill on a priority basis, and it is my hope it can be included in the final version of FDARA that emerges from the conference committee.

Before I close, I want to talk about one other issue that is often debated when FDA-related legislation is considered on the floor: importation of prescription drugs. This morning, I listened to our colleague, the Senator from North Dakota, Mr. DORGAN, talk about his legislation which allows prescription drugs from other countries to be imported into the United States from other countries. My colleague refers to this as drug reimportation which I believe gives people the false impression that these drugs are originally manufactured in the United States, exported to another country and then imported back to the United States. I just want to clarify that is not typically the case.

In addition, I saw the Senator from North Dakota hold up two bottles of

Lipitor and say that there is no difference between a drug manufactured in Ireland and a drug manufactured in the United States. He suggested that the pills may be different colors but the bottles are the same and the medicine in the bottle is the same.

That may be true for the two bottles of drugs that he had on the Senate floor. But how could we be assured that is always the case? Can we always guarantee that pills in a bottle labeled from Ireland are actually manufactured in Ireland? I don't think so.

This issue is the crux of the problem—unless the FDA has approved these medications, we have no way of knowing what is actually in the bottle. In fact, when I served as chairman of the Senate Judiciary Committee, I held a hearing on drug importation and this issue was raised by one of the members of the committee. At that July 14, 2004, hearing, one Senator specifically asked about a prescription drug bottle labeled as being from Canada. William Hubbard, the Associate Commissioner for Policy and Planning for the FDA, told her that even though the label said the bottle was from Canada, the FDA had no idea where that bottle had originated.

In fact, at that hearing, Mr. Hubbard said:

> Although some purchasers of drugs from foreign sources may receive genuine product, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are outdated and have been diverted to unscrupulous resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. Furthermore, in the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, the consumer may have little or no recourse either because the operator of the pharmacy often is not known, or the physical location of the seller is unknown or beyond the consumer's reach. FDA has only limited ability to take action against these foreign operators.

On a related issue, I would like to share Mr. Hubbard's insights on the safety of drugs that have been imported from other countries.

> FDA remains concerned about the public health implications of unapproved prescription drugs from entities seeking to profit by getting around U.S. legal standards for drug safety and effectiveness. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage, warnings and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent degradation, and there is no assurance that these products were manufactured under current good manufacturing practice (cGMP) standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life-threatening. More commonly, if the drugs are subpotent or ineffective, they may suffer complications from the illnesses that their prescriptions were intended to treat, without ever knowing the true cause.

Mr. President, this was a sobering hearing and I urge my colleagues, especially those who support the importation of prescription drugs into this country, to take the time to review the testimony from the July 14, 2004, hearing. We had many witnesses who provided valuable insights on this issue.

To address Senator DORGAN's other point regarding the cost of prescription drugs, I want to make one thing perfectly clear—I want Americans to have access to affordable drugs, but I also want these drugs to be safe and effective. As one of the authors of Hatch-Waxman, I understand the problem of pharmaceutical costs, and I have a record of working to find solutions. But bringing potentially unsafe medicines, medicines uncertified by the FDA, into the United States is not a solution.

In conclusion, I ask my colleagues who are skeptical about this bill to reserve judgment and listen carefully to the debate. While I supported this bill when it was considered by the Senate HELP Committee 2 weeks ago, I honestly believe that members of the HELP Committee have worked hard together to make the reported bill even better. So I urge my colleagues to take the time to review the bill because there are a lot of good provisions in it.

I would like to take this opportunity to recognize the hard work of the staffs of both our committee chairman, Senator KENNEDY, and our ranking minority member, Senator ENZI. I would specifically like to thank Amy Muhlberg and David Dorsey for their dedication and hard work on this issue—they have been working on drug safety legislation for over 2 years and I want both of them to know how much all of us appreciate their efforts. I also want to recognize Shana Christrup and David Bowen for their leadership in helping their bosses get this bill to the floor under very difficult time constraints. All of the HELP Committee members' staff have worked long hours and many weekend hours and I just want you to know how much I appreciate all of you.

Mr. President, I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from West Virginia is recognized.

IRAQ

Mr. BYRD. Mr. President, 4 years ago, I stood in this very spot and warned against an ill-advised invasion of Iraq. Today, the situation in Iraq has spiraled out of control, into a bloody, deadly, sectarian civil war. Yet the President and his team continue to hold fast to their ''stay the course'' nonsense. While they do, thousands of brave young Americans place their lives in jeopardy every day. That reality is one this Nation and the world did not have to experience. It is a tragic reality, brought on by a war of choice and an occupation that has yielded neither stability nor reconciliation.

Four years ago today, the President landed on the deck of the USS *Abraham Lincoln* to declare, ''Mission accomplished.'' Four years ago—it feels like an age. For thousands of our soldiers and their families, and likely for the Iraqi people, it feels like a lifetime. How wrong our President was then, and how wrong our President continues to be today.

Ralph Waldo Emerson said:

> A foolish consistency is the hobgoblin of little minds, adored by little statesmen and philosophers and divines.

No matter how many times the President wishes it were so, peace in Iraq will not be found at the barrel of an American gun. No matter how hard the President hopes that it will happen, sectarian violence will not be quelled with U.S. forces occupying the Iraqi nation. Cross your fingers, pull out your lucky rabbit's foot, even nail a horseshoe over the Oval Office door, but hoping for luck will never change the deadly dynamic in Iraq.

Peace demands an Iraqi-led political solution to transcend the ethnic and sectarian divisions that are splitting the country apart—a political effort which, to date, the Iraqi Government has been unable or unwilling to take on. Our legislation could have spurred that progress, but President Bush has defiantly said no. This White House clings to its ''foolish consistency.''

When he took office as President more than 6 years ago, George W. Bush issued a call for renewed responsibility in government. Where are the echoes of that call today? What is responsible about clinging to this failed course in Iraq and refusing to consider a new path? What is responsible about the President continuing to foster and manipulate the fears of the American people?

Faced with the tragic consequences of its misjudgments in Iraq, the Bush administration is paralyzed, unwilling to acknowledge, much less remedy, its catastrophic blunders. President Bush has gone so far as to say that the way out of Iraq will be decided by future Presidents.

What an outrageous abdication of responsibility. It is unacceptable to pass this buck to future leaders while our brave troops fight and die today in the crosshairs of this Iraqi civil war. The time to begin rectifying this dreadful blunder is now, not in 2 years, not with the next President but now.

With the supplemental bill, Congress responded to the call of the American people. We offered a new beginning in reconstruction and stability for Iraq. Our proposal could have generated political reconciliation and economic security in Iraq. Our bipartisan plan shifted the responsibility for the Iraqi nation's long-term success to the Iraqi

people themselves. But plainly Congress offered a plan that could have meant a brighter future for Iraq, a future controlled by the Iraqi people themselves with continued support from the United States. But the President has flatly rejected that plan. It is a sad day for our Nation and for the world.

Before the war began, I urged the President to think through the consequences. There was no doubt as to the military outcome of the war between the United States and Iraq. Our military might was certainly unquestioned. I was very concerned about the repercussions that would follow this certain military victory. Tragically, the repercussions I feared all have come to pass. Oh, how I wish, yes, how I wish that I had been wrong.

Once again, I urge the President to think through the consequences of his choices, the consequences of his rejection of this new plan for Iraq, the consequences of clinging to false hopes, for that is what this veto does. This veto endorses the falsehoods that took us to war. It cements failed policy in place. This veto ensures that hundreds, maybe thousands, more will die in Iraq without any true plan for peace. It forces our military to continue to pursue a mission impossible, creating democracy at the point of a gun.

I am sorry this day has come to pass. I am so sorry the horrors of this deadly and mishandled occupation have become the stuff of political gamesmanship. There is ample blame to go around for that fact.

I have seen clashes between the legislative and executive branches. I have seen Presidents make mistakes in the past. Everyone, yes everyone, makes mistakes. I certainly have made mistakes, but I have never seen such arrogance in a White House that seals its eyes and ears and blindly sends so many people to their doom. I pray for our troops, for our President—yes, I do—and I pray for our country, yes, for our country, and for the people of Iraq.

President Bush has chosen to hold hostage $100 billion for our troops to his, President Bush's, policies, his failed policies. But his choice, his choice, is not the last word. Congress will get to work on a new version of the supplemental appropriations conference report. We, with the Lord's will, will not delay, but we also will not stop our efforts to stand for what is right and to craft policies that reflect the true strength of America: humility, modesty, honesty.

We will continue to press for a strong, intelligent foreign policy that does not rely on military might alone. And we will not stop in our efforts to bring peace to Iraq and our troops home from war, so help me God.

I yield the floor.

The PRESIDING OFFICER (Mr. MENENDEZ). The Senator from North Dakota is recognized.

Mr. DORGAN. Mr. President, what is the pending business?

The PRESIDING OFFICER. S. 1082 is before the Senate. The Landrieu amendment is currently pending.

Mr. DORGAN. Mr. President, I ask unanimous consent that the Landrieu amendment be set aside and that I may be able to offer an amendment.

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

AMENDMENT NO. 990

Mr. DORGAN. I have amendment No. 990 at the desk. I ask for its consideration.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from North Dakota [Mr. DORGAN], for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL, proposes an amendment number 990.

Mr. DORGAN. Mr. President, I ask unanimous consent that the reading of the amendment be dispensed with.

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

(The amendment is printed in today's RECORD under ''Text of Amendments.'')

Mr. DORGAN. I offer this amendment on behalf of myself and Senator SNOWE and other cosponsors, including Senator STABENOW, Senator GRASSLEY, Senator MCCAIN, Senator PRYOR, Senator SANDERS, Senator WHITEHOUSE, and Senator MCCASKILL.

This amendment comes from a piece of legislation we have previously introduced dealing with the reimportation of prescription drugs, FDA-approved, lower priced prescription drugs that are sold in other parts of the world for much lower prices than they are priced in the United States. There are 33 cosponsors on the bill as it was introduced in the Senate. It seems clear to me that the best approach to advancing this legislation is to offer it as an amendment to the legislation that reauthorizes the Food and Drug Administration. Inasmuch as this subject deals with the FDA, it would provide funding for the FDA, guidelines for the FDA on reimportation of drugs. I am not going to speak at length today. I spoke earlier today. I intend to come back tomorrow morning to speak at some greater length.

I know my colleagues, Senator SNOWE and Senator GRASSLEY and Senator STABENOW and Senator SANDERS—I have talked to him—I know others will wish to come and speak as well. But suffice it to say, we have a situation in this country today in which the U.S. consumer is charged the highest prices in the world for prescription drugs. That is just a fact. Today I held up two pill bottles on the floor of the Senate, identical bottles that contained the same prescription drug medicine made in Ireland. It was called Lipitor, for controlling cholesterol. The tablets were made in a manufacturing plant, FDA-approved plant in Ireland. The two bottles I held up today were different only in that one was sent to Canada and one was sent to the United States.

The one sent to the United States was priced nearly double the price of the medicine sent to Canada. But that is not unusual. The same thing would be true with respect to medicine that was sold in Germany or Italy or France or Spain or England. They all pay much lower prices for the same prescription drug, the identical drug made in the identical plant—FDA-approved, sold all around the world, except the U.S. consumer is given the privilege of paying the highest prices in the world, in some cases 80 or 90 percent higher, in some cases 120 percent higher than others pay for the identical prescription drug.

Our point with this amendment simply is that if the global economy is going to work, why doesn't it work for everybody? How about the little guy who is buying prescription drugs and is paying the highest prices in the world.

We have put together a piece of legislation with very significant safety precautions so that there are no safety issues at all. I mentioned today that Europe does this routinely. They have a parallel trading system in Europe. They have had it for a couple of decades. If you are in Germany and want to buy a prescription drug from France, no problem. If you are in Italy and want to buy it from Germany, no problem.

They have a parallel trading system that allows the consumers to access the best prices. It is only the American consumer that is disadvantaged by a sweetheart deal that allows the prescription drug industry to engage their own price controls, which means that we pay the highest prices in the world.

We have offered an amendment. We have 33 cosponsors on the underlying legislation. The amendment I offer on behalf of myself and Senator SNOWE, bipartisan legislation, as I indicated—Senators GRASSLEY and MCCAIN, STABENOW, PRYOR, SANDERS, WHITEHOUSE, MCCASKILL.

This is a good amendment. It is good public policy. I know the prescription drug industry, the pharmaceutical industry doesn't like it. I understand that. I do not come here with a grievance against that industry. I just do not like their pricing policy. I do not like the fact that they say to the American people: You pay the highest prices in the world.

That is not fair. It ought to change. Our amendment is aiming to change it.

Mr. President, I will speak at greater length on the subject tomorrow.

I yield the floor.

The PRESIDING OFFICER. The Senator from Utah is recognized.

Mr. HATCH. As usual, my dear friend from North Dakota is articulate, and he deserves to be listened to, but I disagree with him.

The Dorgan amendment allows individuals to import a qualifying drug, and this will pose an overwhelming set of resource burdens for the FDA, Customs, and other agencies, especially

the FDA. It would, as I have mentioned before, create very significant safety concerns.

This amendment establishes a complicated system for the regulation of imported drugs. Now this system that he suggests is so vast, it would take and require a lot of money, more than all of the proposed fees could support.

Where would an already strapped Federal agency such as FDA get these additional dollars? So far we have not given it to them. There have been estimates that these dollars would amount to so much that there is no way that we could give them enough money.

This amendment allows foreign-imported products to be approved for distribution in the United States even when they may not be bioequivalent to the FDA-approved products. Now the reason I cite that is because the letter from the FDA, this letter was sent to the Honorable BYRON L. DORGAN, Senator DORGAN. This letter was sent April 10, 2007.

I ask unanimous consent that this letter be printed at the conclusion of my remarks.

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

(See exhibit 1.)

Mr. HATCH. In that letter, just to mention a couple of things, the Acting Deputy Commissioner for Policy, Randall W. Lutter, Ph.D.—let me just mention a couple of sentences.

He said:

Nevertheless, the Agency continues to have concerns with enacting such a sweeping importation program and fears that intermediaries would likely swallow the bulk of cost-savings, preventing the American consumers from enjoying much, if any, practical benefit from such a program.

On safety concerns, he said:

We have safety concerns related to both the identification of unsafe or non-complaint drug products and about the substitutability for domestic products.

On identifying unsafe/noncompliant drug products, he said:

The section of the bill that would allow individuals to import a qualifying drug from a registered exporter would likely pose an overwhelming resource burden for the Agency and create significant safety concerns.

Just reading at random:

S.242 would establish a complicated system for the regulation of imported drugs. This complex system is so vast that it would be enormously resource-intensive, likely much greater than the proposed registration fees and inspection fees could support.

On a lack of substitutability, he said:

The proposed bill provides a mechanism for foreign imported products to be approved for distribution in the U.S. even though these products may not be bioequivalent to the FDA-approved product.

This letter is a serious letter. I don't think we should ignore letters such as these in our zeal to resolve problems. I believe the distinguished Senator from North Dakota is very well intentioned. I have a tremendous regard for him and for his ability to explain things on the floor of the Senate.

I also ask unanimous consent to have printed in the RECORD excerpts of the testimony before the Senate Judiciary Committee on July 14, 2004, entitled ''Examining the Implications of Drug Importation,'' of Mr. William Hubbard, Associate Commissioner for Policy and Planning of the U.S. FDA.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

TESTIMONY: UNITED STATES SENATE COMMITTEE ON THE JUDICIARY

EXAMINING THE IMPLICATIONS OF DRUG IMPORTATION, JULY 14, 2004

Mr. William Hubbard, Associate Commissioner for Policy and Planning, U.S. Food and Drug Administration

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Mr. William K. Hubbard, Associate Commissioner for Policy and Planning at the U.S. Food and Drug Administration (FDA or the Agency). With me is John M. Taylor, Associate Commissioner for Regulatory Affairs at FDA. We appreciate having this opportunity to discuss with you the issues relating to the importation of prescription drugs into the United States and the use of the Internet to facilitate the sale of these drugs.

At FDA, our statutory responsibility is to assure the American public that the drug supply is safe, secure, and reliable. For more than 60 years, the Federal Food, Drug, and Cosmetic (FD&C) Act has ensured that Americans can be confident that, when they use an FDA-approved drug, the medicine will be safe and effective and will work as intended in treating their illness and preventing complications. In carrying out this responsibility, FDA is working to do all we can under the law to make medicines accessible and help doctors and patients to use them as effectively as possible, through such steps as expanding access to generic medicines, reducing the time and cost of showing that new medicines are safe and effective, and providing up-to-date information for health professionals and patients to obtain the benefits and avoid the risks associated with powerful medicines. That is the primary mission of the thousands of dedicated staff, including leading health care experts, doctors, economists and scientists who work tirelessly at FDA in public service for the American people. FDA remains strongly concerned about counterfeit, and/or illegally imported pharmaceuticals whose safety (and effectiveness cannot be assured because they are distributed outside the legal structure and regulatory resources provided by Congress.

IMPORTATION OF PRESCRIPTION DRUGS

Sixty-five years ago, Congress responded to widespread instances of unsafe drugs by directing FDA to implement a system for assuring that Americans have a drug supply they can trust will not harm them. Over forty years ago, Congress required that legal drugs be proven to be effective as well, because modern medicines—when they are produced, distributed, prescribed, and used properly—should not only be safe but effective in the treatment of disease. More recently, in 1988, Congress enacted the Prescription Drug Marketing Act (PDMA) to establish additional safeguards to prevent substandard, ineffective, or counterfeit drugs from entering the U.S. Under PDMA, it is illegal for anyone other than the drug's original manufacturer to re-import a prescription drug into the U.S. that was manufactured in the U.S. This law was enacted with strong bipartisan support because of high-profile cases of unsafe and ineffective drugs entering the U.S. in large volumes. In one instance, over 2 million unapproved and potentially unsafe and ineffective Ovulen–21 ''birth control'' tablets from Panama were distributed into the U.S. as ''American goods returned.'' In another case, a counterfeit version of Ceclor, a widely used antibiotic at the time, found its way into the U.S. drug distribution from a foreign source. Over the years, FDA has employed PDMA and other authorities to build a drug safety infrastructure to ensure that Americans enjoy the highest-quality drug supply in the world.

Unfortunately, the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. This is evident in the recent significant increase in efforts to introduce counterfeit drugs into the U.S. market. FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990s. Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well-funded and elaborately organized networks. At the same time, inadequately regulated foreign Internet sites have also become portals for unsafe and illegal drugs. For example, FDA recently worked with domestic and international authorities to shut down a website that was advertising ''FDA-approved'' and safe ''European'' birth control pills and other drugs, but was actually responsible for importing ineffective, counterfeit drugs. Evidence strongly suggests that the volume of these foreign drug importations is increasing steadily, presenting an increasingly difficult challenge for Agency field personnel at ports-of-entry, mail facilities, and international courier hubs, and our laboratory analysts and border and law enforcement partners.

FDA is doing its best to use its limited resources and international authorities to stop the increasing flow of violative drugs into this country, but the task is daunting. FDA's Office of Regulatory Affairs has inspectors working in the field who perform investigations pertaining to imported prescription drugs, a job that is not limited to inspections at ports-of-entry. Each day, however, thousands of individual packages containing prescription drugs are imported illegally into the U.S., simply because the sheer volume has grown to exceed the capability of FDA field personnel to properly process.

SAFETY CONCERNS RELATING TO IMPORTATION

FDA remains concerned about the public health implications of unapproved prescription drugs from entities seeking to profit by getting around U.S. legal standards for drug safety and effectiveness. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage, warnings and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent degradation, and there is no assurance that these products were manufactured under current good manufacturing practice (cGMP) standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse

events, some of which can be life-threatening. More commonly, if the drugs are subpotent or ineffective, they may suffer complications from the illnesses that their prescriptions were intended to treat, without ever knowing the true cause.

Patients also are at greater risk because there is no certainty about what they are getting when they purchase some of these drugs. Although some purchasers of drugs from foreign sources may receive genuine product, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are outdated and have been diverted to unscrupulous resellers, or dangerous subpotent or super-potent products that were improperly manufactured. Furthermore, in the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, the consumer may have little or no recourse either because the operator of the pharmacy often is not known, or the physical location of the seller is unknown or beyond the consumer's reach. FDA has only limited ability to take action against these foreign operators.

The Agency has responded to the challenge of importation by employing a risk-based enforcement strategy to target our existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. However, this system, as it works today, is already overwhelmed by the number of incoming packages, and this presents a significant ongoing challenge for the Agency.

Recent spot examinations of mail shipments of foreign drugs to U.S. consumers revealed that these shipments often contain dangerous or unapproved drugs that pose potentially serious safety problems. In 2003, inspectors found that the majority of the packages examined in these ''blitzes'' contained illegal drugs. Last summer, FDA and the U.S. Customs and Border Protection agency (CBP) conducted blitz examinations on mail shipments at the Miami and New York (JFK Airport) mail facilities in July, and the San Francisco and Carson, California, mail facilities in August. In each location, the agencies examined packages shipped by international mail over a 3–day time span. Of the 1,153 shipments examined, the overwhelming majority (1,019 packages, or 88 percent) contained unapproved drugs. The drugs arrived from many countries. For example, 16 percent entered the U.S. from Canada; 14 percent were from India 14 percent came from Thailand, and 8 percent were shipped from the Philippines.

Mr. HATCH. These are serious statements by serious people. I don't think we should ignore them. It is one thing to argue that you don't like the pharmaceutical companies, and many don't. It is another thing to argue that these drugs that are going to be imported or reimported are absolute identical copies of what they represent. I would pay attention to what these people are saying.

I also ask unanimous consent to print in the RECORD the statement of a Customs officer who came and testified on the 14th.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

U.S. SENATOR ORRIN G. HATCH (R–UT) HOLDS HEARING ON DRUG IMPORTATION

Mr. HATCH. Ms. Durant.

Ms. Durant. Mr. Chairman, members of the committee, thank you for this opportunity to testify.

I'm Elizabeth Durant, director of trade compliance and facilitation in the Office of Field Operations at the Bureau of Customs and Border Protection.

Today I'd like to discuss with you CBP's efforts to address the ever-increasing trend of personal and bulk importation of pharmaceutical products and controlled substances into the United States.

Although the main focus of the CBP has shifted to protecting the United States from terrorist attacks, we also enforce over 400 requirements for more than 40 other federal agencies at U.S. borders. These include the laws that prohibit the importation of illegal or unapproved pharmaceuticals that fall under the jurisdiction of the Food and Drug Administration, as well as those controlled substances that are under the jurisdiction of the Drug Enforcement Administration.

The issue of U.S. consumers buying prescription drugs from foreign sources has become a significant concern. A growing number of Americans obtain their medications from foreign locations. However, the safety of drugs purchased from these sources cannot be insured. Drugs produced outside the United States may be counterfeit. Counterfeiting can apply to both brand name and generic drugs where the identity of the source is deliberately and fraudulently mislabeled in a way that suggests that it is the authentic approved product.

The CBP is concerned with three avenues that pharmaceuticals are imported: Those that are purchased through the Internet and shipped through our international mail express courier facilities; those carried into the States by individuals transiting our land borders; and bulk shipments of adulterated or counterfeit pharmaceuticals. During the course of the past year we have taken several steps to address each of these areas.

Millions of packages come through the mail and express courier facilities every year. Thousands of packages, particularly in the mail, are found to contain illegal and approved pharmaceuticals. We also estimate that 10 million people cross the land border annually carrying unapproved products.

Additionally, we have found bulk pharmaceutical shipments that were attempted to be imported through the mail potentially indicating that these products could be making their way to pharmacy shelves.

In order to address what is clearly a growing threat to this public health, CBP has been working cooperatively with the DEA, the FDA, our own U.S. Immigration and Customs Enforcement, ONDCP and the Department of Justice attorneys in an interagency working group directed at addressing issues related to the importation of prescription drugs and miscellaneous pharmaceuticals.

The working group has conducted regular meetings since January 2004 and has achieved several key accomplishments since its inception, including conducting a joint interagency enforcement operation known as Operation Safety Cap, which was designed to look at passenger importations of pharmaceuticals from Mexico.

Operation Safety Cap was an interagency plan to enforce laws related to the importation of prescription drugs at the border. Both FDA and ICE participated in the enforcement operation. The plan began with a public outreach, followed by an enforcement effort at the Ports of Andrade, Yuma, Tecate, San Luis and Calexico. The purpose was to evaluate compliance with laws related to the importation of prescription drugs.

During the course of the operation there were several troubling instances of returning U.S. residents receiving different medications than the ones they thought they were being prescribed.

In one instance there was no active ingredient in the unmarked, undeclared bottle that was brought into the U.S. The overall seizure detention rate was nearly 7 percent of the number of individuals inspected, which was significant enough to warrant additional enforcement efforts at our land borders.

Based on an operation nicknamed ''Operation Safeguard'' that we have carried out over the last couple of years, we have found the volume of pharmaceuticals shipped through international mail to be enormous. We have also found a significant number of these products do not contain an active pharmaceutical ingredient, but merely contain substances such as starch or sugar.

Other problems include expired materials, unapproved products, improper use instructions and products made in facilities not under proper regulation. The vast majority of the pharmaceuticals that enter the United States via the mail do so in a manner that according to FDA violates present FDA and other requirements.

It is clear that the importation of pharmaceuticals and controlled substances remains an overwhelming problem for CBP. We are working with the FDA, the DEA, ICE and other regulatory agencies to develop a more practical and workable approach to solve this huge problem.

I want to thank you and the members of the committee for considering Customs and Border Protection in your review of the importation of pharmaceuticals and controlled substances. This is an issue that speaks directly to our mission. We will continue to make every effort possible to work with the Congress and our fellow inspection agencies to address the health and safety concerns of the American people.

Thank you, Mr. Chairman, I look forward to responding to any questions today.

Mr. HATCH. It was a startling statement. I know at least one Democratic Senator, who takes matters very seriously and who was for importation or reimportation of drugs, was shocked at some of the testimony because she did not believe things could be as bad as they represented and was kind of shocked that they made a pretty darn good case that these matters are much more serious than some are taking them.

I don't have anything more to say at this time, but I hope we will think this through before we saddle the American people with something that can be disastrous in their lives. I am familiar with how some of these drugs that people think are good drugs that come into this country are adulterated. Some are made with contaminated water, do not have any efficacy in them at all. Yet they look identical to what our U.S. manufacturers are making or what other qualified manufacturers are doing. We can't ignore these things. I think even if we could give FDA all the money—and it would amount to trillions of dollars, certainly hundreds of billions of dollars but I think trillions of dollars—to handle this, there is still no way FDA can take care of all the problems that would come up.

We have a pretty good system here. I have to admit, I wish we could get drug prices down. As the author of the Hatch-Waxman Act, we worked hard to get the generic business into action. At the time we did Hatch-Waxman, generics were no more than 17 or 18

percent of the total marketplace. Today they are over 50 percent. Hatch-Waxman is the reason they are there. In every case, every year we have saved at least $10 billion for the consumers. What many in this body seem to ignore is that it costs these innovator companies upwards of $1 billion to create one of these drugs. Most of them go through at least 6,000 failed experiments before they arrive at one of these drugs. We can't ignore that fact. The only way they can recoup that money is within the few years that are left of their patent life.

This is the only industry I know of—there may be others, but I can't think of any—where if you create a widget, you have 20 years of patent life, market exclusivity. In this industry, a lot of that is eaten up by the FDA process. It means that the innovator companies have very few years in which to recoup that billion dollars, upwards of a billion dollars. A few years ago, it was $800 million, which was astounding to me. Now it is approaching a billion; in some cases, maybe even more.

It is one thing to throttle the pharmaceutical companies in the interest of politics. It is another thing to ignore reality and ignore what happens here.

One reason for Hatch-Waxman was because one side wanted all drug price competition. They wanted 100 percent generics if they could get them. The problem is, there would not be any generics if you don't have the innovator companies doing the innovative drugs.

Mr. DORGAN. Will the Senator yield for a question?

Mr. HATCH. Sure.

Mr. DORGAN. My friend from Utah did not mean to suggest those of us who are offering this amendment on a bipartisan basis are doing so for the purpose of politics, as he said. My expectation is, he would think this would be a serious and thoughtful amendment that he disagrees strongly with, but I hope he would not suggest the motive is politics. CBO has suggested this bill will save $50 billion for the American consumer, $5 billion of which is for the Federal Government. This is a serious issue and a thoughtful issue. One might disagree, but I hope that one would not ascribe motives of politics to those of us on a bipartisan basis who are offering this amendment.

Mr. HATCH. I have heard some who I believe are using it politically in the Congress. But I would never ascribe that type of attitude to the distinguished Senator from North Dakota. I believe he is very sincere. I believe he is truly trying to represent the consumers in the best possible way. I just believe he is ignoring some of these comments and statements made under oath before committees of the Senate that fly in the face of what is being said here. I would like to see drug prices reduced. There is no question about it. I worked hard to get them reduced. That is what Hatch-Waxman is all about. But there are two sides to that. One was drug price competition, to make sure we could get drugs in generic form immediately, once they come off patent, which we did. The other, of course, is the patent term restoration so that we could give innovator companies some restoration of patent life or market exclusivity so they could recoup the moneys, the extraordinary costs that are involved.

When I say I have heard some in the Congress who I think have exploited this for political purposes, I would never say that about my friend from North Dakota. I don't particularly want to disparage anybody else, but I can say this: There have been some who have used this issue politically, and there is no doubt about it. I believe the Senator from North Dakota is articulate and means what he says and is doing so for the right reasons. Having said that, I don't think we should ignore the testimony of these top people in the administration who say this could be a disaster for the American consuming public. I don't think you can ignore those comments. I am suggesting that I hope people will read these comments, and I will put more into the record before we are through with this debate. We are all interested in getting drug prices down. There is no question about it. I don't think there is anybody in this Congress who has done more to bring drug prices down than I have, through Hatch-Waxman and my friend HENRY WAXMAN over in the House and others who supported that bill. There is no question about it. I am as interested as anybody in making sure the consumer public is not ripped off.

On the other hand, these innovative drugs cost a lot of money to develop. When we get into follow-on biologics, it apparently costs even more for these large-molecule drugs that may not be readily duplicated. In fact, under current science, they are not readily duplicated. I am very concerned about this whole issue. I am very concerned about making sure that the record shows that we have brought out how serious this issue is and how serious the consequences are if people are wrong, if they happen to get this type of legislation through.

Let me add one other thing. I would suggest to my friend from North Dakota that the President has already said that if this language is in this bill, he is going to veto it. I believe that veto would be sustained. I think it should be sustained. It is one thing to come out and argue for something such as this, but I would hope that he will withdraw his amendment because I would hate to see a bill as important to our country as this drug safety bill, a bill that has brought together Democrats and Republicans from the left to the right, a bill that would help to save as many lives as this bill will do, a bill that will help bring to the forefront the FDA in a way that it should be brought, a bill that has the MDUFA and PDUFA moneys in, a bill that has children's programs in, I would hate to see this bill vetoed, but I would not blame the President one bit if he vetoes it based upon the testimony of scientists who have testified before our committees.

Frankly, I would think he would be right if he vetoed it. But be that as it may, I am only one Senator, and I think most people know I am very sincere in this area. I work very hard in these areas. I have a record of accomplishment in these areas. I just want to make sure that our consuming public has every protection they possibly can. Unfortunately, it costs a lot of money to give them that protection. I wish there was some way we could bring those prices down.

Having said that, back in the early 1990s, I helped put through this body the FDA Revitalization Act. Among the purposes of that act was to create a unitary campus for FDA rather than have over 30 different locations in the greater metropolitan area around the District of Columbia, to have a central campus, state-of-the-art equipment, the highest technology we can, with an incentive to bring the very best scientific minds we can into FDA. We all know the White Oak complex is being built now. It didn't start until about 5 or 6 years ago. It is going to take another 10 years and probably cost a lot more than it would have had we done what that bill said we could do immediately. It was only an authorizing bill. The appropriators did not appropriate the funds to develop that campus. But we have to find a way of helping FDA. The sooner we get that campus and they have all of the integral online services and equipment and top-of-the-line approaches that they can bring to bear, we should be able to bring drug prices down through that. But we are a long way from the completion of White Oak, as we stand here today.

Frankly, at least we are doing it. At least we are going somewhere. I wish to attribute some of that to the distinguished Senator from Maryland, BARBARA MIKULSKI, and others in the House who have worked very hard to make sure that the FDA revitalization approach finally comes to fruition.

One of the biggest problems we have in Government today is to get top scientists at FDA. We can't pay them commensurate with scientists at the major pharmaceuticals or even the major generic companies. In fact, they can start at three times or more what we pay at FDA. So we have a very difficult time continuously getting top scientists to come and work at FDA. That is a big problem. It is a blessing that we do have some of the best scientists in the world working there who are willing to sacrifice to do what they consider to be the important work of the Food and Drug Administration. This bill will help the Food and Drug Administration to do a better job, to go forward with more backing from the Congress and, in the end, benefit all of us who benefit so much from the work of the Food and Drug Administration.

I yield the floor.

EXHIBIT 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

Rockville, MD, April 10, 2007.

Hon. BYRON L. DORGAN,

Chairman, Subcommittee on Interstate Commerce, Trade and Tourism, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, DC.

DEAR SENATOR DORGAN: Thank you for the opportunity to testify at the March 7, 2007, hearing entitled, ''Policy Implications of Pharmaceutical Importation for U.S. Consumers,'' before the Senate Subcommittee on Interstate Commerce, Trade, and Tourism. The Food and Drug Administration (FDA or the Agency) is responding to address the March 9, 2007, correspondence you sent in follow-up to that hearing.

Your correspondence included statements made by former FDA Commissioner, David Kessler, at an April 19, 2005, hearing entitled, ''Examining S. 334, to amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs,'' held by the Senate Committee on Health, Education, Labor, and Pensions. Dr. Kessler's statements focused on the issues of safety, resources, supply chain security, and standards for approval of foreign versions of FDA-approved drugs. You asked that I explain my views on the ''Pharmaceutical Market Access and Drug Safety Act'' in the context of these issues. The bulk of this response details our views about these issues.

I would like to start, however, by commending you for your efforts to address American consumers' concerns regarding access to affordable prescription medications. Nevertheless, the Agency continues to have concerns with enacting such a sweeping importation program and fears that intermediaries would likely swallow the bulk of cost-savings, preventing American consumers from enjoying much, if any, practical benefit from such a program. We expect such a result might lead consumers to continue to look for substantial savings on their prescription medications by seeking products outside the legalized importation system, just as some do now. We continue to observe that many consumers buy drugs from foreign Internet sources even though generic versions of those products are approved by FDA and such products are generally cheaper in the United States than abroad.

We note that legalizing commercial importation may have unintended effects on protection of intellectual property and may reduce incentives for research and development, as noted in the 2004 report issued by the Health and Human Services' (HHS) Task Force Report on Drug Importation.

SAFETY CONCERNS

We have safety concerns related to both the identification of unsafe and or non-compliant drug products and about the substitutability of foreign products for domestic products.

Identifying unsafe/non-compliant drug products

The section of the bill that would allow individuals to import a qualifying drug from a registered exporter would likely pose an overwhelming resource burden for the Agency and create significant safety concerns. Under such a program, the anticipated high volume of products would make it extremely difficult for FDA and U.S. Customs and Border Protection officials to examine adequately all of the personally imported drug products to ensure that they comply. In fact, the HHS Task Force estimated that it would have cost $3 billion annually to examine and process each of the 10 million packages that entered the U.S. in 2003. Even if a lower level of examination were considered adequate, the costs to FDA would still be very high.

Despite its registration and inspection fee provisions, the bill likely provides inadequate resources to conduct such examination on a routine basis. Resources are limited to 2.5 percent of the total price of qualifying drugs imported by registered exporters, an amount likely to be a small fraction of the cost of inspecting packages at international mail facilities. This is a particular concern because, once personal importation is given the appearance of legality, consumers may be less vigilant in scrutinizing the drug shipments they receive from abroad.

S. 242 would establish a complicated system for the regulation of imported drugs. This complex system is so vast that it would be enormously resource-intensive, likely much greater than the proposed registration fees and inspection fees could support. The bill and its associated fees also do not appear to account for the costs of the increased volume of packages likely to inundate the U.S., or address the accompanying and likely substantial enforcement work that will arise as a result of legalized importation as more unscrupulous vendors set up shop to circumvent the new U.S. system.

Lack of substitutability

The proposed bill provides a mechanism for foreign imported products to be approved for distribution in the U.S. even though these products may not be bioequivalent to the FDA-approved product. This mechanism seems to by-pass the existing drug approval process for drug products that are not bioequivalent to an FDA-approved product, which is through the submission of a new drug application (NDA) that is thoroughly reviewed for safety and efficacy. Ultimately, the bill appears to establish for imported drugs an alternative to FDA's existing generic drugs program.

The bill would allow non-bioequivalent products to be sold in the U.S. as approved ''variations'' of the innovator product under the existing NDA, which would create confusion for doctors and pharmacists in prescribing or dispensing, respectively. Dr. Todd Cecil of the U.S. Pharmacopeia testified at the April 2005 Senate HELP hearing regarding pharmaceutical equivalence and bioequivalence and his concerns with this bill. In addition, doctors cannot anticipate which version of a drug product their patients will receive, and pharmacists may not know which version of a drug the doctor intended to prescribe. The possibility of confusion is significant and poses a real public health concern as this increases the chance of error in prescribing and/or dispensing of medications. In addition, the domestic and foreign versions of prescription drugs may become commingled in the drug supply chain. It is unclear whether a patient will be able to specify if he wants the foreign version or the original FDA-approved version when he gets his prescription filled at the pharmacy or receives medication at a hospital or other medical treatment facility.

INADEQUATE RESOURCES

It is uncertain whether the anticipated fee revenues will be realized because the market response to legalization of importation cannot be accurately predicted. This uncertainty could pose problems for FDA's program, because large costs of starting and developing a program to regulate imports will have to be incurred even if the volume of legalized imports is initially low. Although the bill does assume certain sales volumes in the first several years for purposes of collecting inspection fees, with only a few registered importers and exporters participating initially, the high pro rata share of fees may actually discourage participation and make it difficult for FDA to collect fees at the designated levels. Even once a program is developed, the bill is not likely to provide the necessary funds to continue an adequate regulatory program if inspection fees are low because imports do not reach the anticipated levels.

SUPPLY CHAIN SECURITY

We are proud of FDA's efforts with supply chain stakeholders and states to maintain a safe and secure drug supply in the U.S. that is premised on a closed, tightly regulated system. The type of drug importation program in the bill would increase the number of foreign entities FDA would have to monitor and regulate. It can be difficult for FDA enforcement to reach foreign entities violating our laws and regulations. This bill would open the door to more entities outside our domestic legal framework. We also have grave concerns for consumers who may be harmed from products from these foreign sources. The bill does not take into account protecting the rights of the consumer if they are injured after using one of these products.

As we all agree, counterfeit drugs must be kept out of the U.S. drug supply chain. FDA is currently using its resources and authorities as efficiently as possible to secure the drug supply chain and protect American consumers from counterfeit and diverted drugs. Opening the U.S. drug distribution system to foreign markets would provide more opportunity for counterfeit drugs to enter our currently closed system and would significantly complicate FDA's efforts to investigate irregularities in the drug supply chain.

Conducting foreign investigations and prosecutions is inherently costly and difficult and often is complicated by language barriers and issues of extraterritorial jurisdiction and extradition. We are concerned that the bill does not provide sufficient enforcement tools and penalties to deter foreign entities from introducing counterfeit or otherwise substandard drugs into the U.S. drug supply chain.

APPROVAL OF FOREIGN VERSIONS

We believe the bill creates complicated application and inspection requirements for imported ''foreign'' versions of FDA-approved products. These requirements would be difficult to implement, as each foreign country has its own regulatory scheme and requirements for the information necessary to approve a drug product. FDA would essentially have to review foreign information in a foreign format, all in less time than is required for review of traditional NDAs. In addition, the bill would require imported ''foreign'' versions of a drug bear the labeling associated with the original FDA-approved product. This practice would essentially legalize the misbranding of these products, and raises concerns for FDA not only in the approval context but also in the counterfeits context. It is difficult enough for FDA and other federal enforcement agencies to detect counterfeit drug products and packaging; creating a mechanism that would allow persons to label foreign drugs with reproductions of FDA-approved labeling would make it even harder to distinguish between ''legal'' foreign products and counterfeits.

U.S. consumers currently have a number of options available to them when looking for affordable medications within the closed U.S. drug distribution system. Many essential drugs have a generic alternative and some even have many generics, which are generally less expensive than the brand product. We continue to find that many consumers currently buying foreign products are actually trying to purchase, or are unknowingly receiving, a foreign product that

often is more expensive than the U.S. product. In addition, the consumers are at risk when receiving foreign drug products, as there are documented cases where the wrong medication was received (the haloperidol case mentioned in my testimony). Many pharmaceutical companies and Pharmaceutical Research and Manufacturers Association of America offer discounts and sometimes even free medications for consumers who cannot afford them. Medicare Part D has also helped some seniors cut their prescription costs. Consumers should not feel restricted to higher priced innovator (brand) products.

Consumers must also understand that if a medication is costly, they should discuss other treatment options with their doctor and pharmacist, as most often there are lower-cost alternatives available. We will continue to strive to make more affordable medicines available to consumers, but we remain concerned about the implications of legalizing drug importation as one of those options.

In conclusion, I would like to reiterate concerns about the economic implications of prescription drug importation, as stated in the 2004 HHS Task Force Report on Drug Importation. Even if all the safety concerns could be allayed, these concerns would remain: that savings to U.S. consumers would be small as a percent of total drug spending; that implementing such a program would incur significant costs; and that legalized importation would likely adversely affect the future development of new drugs for American consumers. In 2004, the HHS Task Force Report noted that generic drugs account for most prescription drugs used in the U.S. and that these are usually less expensive in the U.S. than abroad. We thus have a well-functioning system of intellectual property rights that balances the short-term interests of consumers with the long-term research incentives.

Thank you for the opportunity to address some of our concerns with S. 242.

Sincerely,

RANDALL W. LUTTER,
Acting Deputy Commissioner for Policy.

The ACTING PRESIDENT pro tempore. The Republican leader is recognized.

Mr. MCCONNELL. Mr. President, I ask unanimous consent to proceed as in morning business.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

EXONERATION OF SENATOR FRIST

Mr. MCCONNELL. Mr. President, a great injustice has come to an end. I rise to recognize the clearing of a good man's name.

Former Senator Bill Frist, with whom I and my Republican colleagues had the honor of serving for 12 years in the Senate, was cleared last week of every allegation of wrongdoing related to his ownership and sale of stock while serving as majority leader.

I rise because, with the exception of an editorial in this morning's Wall Street Journal, the clearing of this good and honorable man's name has gone largely unreported.

It is a sad fact of political life in America that the mere allegation of wrongdoing—the mere allegation of wrongdoing—has the power to tarnish someone's name and dog them for years. But worse still is the silence that so often greets the vindication of the accused.

I remember the rush to judgment that followed the allegations. I remember the memo Democrats sent out attacking Bill on ethical grounds. The authors were later forced to apologize, but the piece had its intended effect.

Republicans knew then—and everyone now knows—those allegations were absolutely false. But the damage, of course, was already done. As the Journal writers put it today:

Despite flimsy evidence, the media storm cast a shadow over [Frist's] office . . . [and] the Nashville heart surgeon chose . . . to take a sabbatical from public life.—

[And] Dr. Frist now joins a long line of public servants to be smeared on page one and [then] exonerated next to the classifieds, only to wonder if anyone noticed.

Well, his friends noticed. Still, it is hard not to lament the damage these reckless claims have caused—caused for Bill, his family, and potentially our political system.

The Founders envisioned a nation in which citizen legislators would be willing to leave the plow and the workbench to serve.

Bill embodied this ideal by leaving his profession and the comforts of private life for a career of public service. He graced this body with his intelligence, his thoughtfulness, and his vision.

We can only hope that future citizen legislators, and judges, are not deterred from entering and elevating politics because of the threat of similar treatment.

A great American statesman once said:

Reputation is like fine china and glass—easy to crack, but hard to mend.

We hope a political culture that allowed the abuse of Bill Frist's good name for political gain does not deter others from choosing the same path that he chose—and so honorably followed.

Mr. President, I ask unanimous consent that the editorial entitled ''Frist's Vindication'' from today's Wall Street Journal be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

[From the Wall Street Journal, May 1, 2007]

FRIST'S VINDICATION

When insider-trading allegations against former Senate Majority Leader Bill Frist surfaced back in 2005, they were splashed on the pages of major newspapers from coast to coast. Now that Dr. Frist has been vindicated, the silence is instructive. Is anybody out there?

Senator Frist was alleged to have received an insider tip and then sold shares in a hospital company run by members of his family. The Securities and Exchange Commission and Justice Department investigated for 18 months, and last week the SEC announced that it had closed its probe without taking action—that is, the doctor was cleared. Thanks in part to his meticulous email archives, Dr. Frist was able to show that he had begun the process of selling his HCA stock in April of 2005, months before he was alleged to have received the inside whispers.

The controversy surrounding his involvement in health care was a perennial bugaboo for Dr. Frist. For years he was harassed by such liberal lobbies as Public Citizen, and Citizens for Responsibility and Ethics in Washington, which alleged conflicts of interest. These groups objected even to those stocks he held in the blind trust he had created to avoid the appearance of a conflict of interest. Yet when he sold those stocks, with a possible eye on higher office, he was pilloried for doing what the ethicists had asked him to do all along.

Today, even this muted absolution is surely a relief to Dr. Frist. Yet it's impossible to undo the damage to his political career. Despite flimsy evidence, the media storm cast a shadow over his office, derailing any thought of a Presidential bid this year. The Nashville heart surgeon chose instead to ''take a sabbatical from public life.''

Democrats naturally cared less about the actual facts than about pinning another scandal on Congressional Republicans in the run-up to the fall elections. But what about others who thought it clever or funny or perhaps mandatory to get their share of media attention by confusing accusation with proof of wrongdoing?

American University Professor James Thurber got his name in the paper for quipping that Senator Frist ''came in like Jimmy Stewart and was leaving like Martha Stewart.'' What a card. As for the press corps, it ran off in a braying stampede in pursuit of the theme dujour, which was Abramoff-DeLay-GOP corruption. The accusations against Dr. Frist fit that template, so there was no need for the herd of independent minds to inspect the evidence and make distinctions. A Washington Post editorial from the day now looks especially embarrassing—and unfair.

As a medical professional with strong Tennessee roots, Bill Frist was the kind of person we'd hope would occasionally choose to participate in politics, as opposed to the permanent political class that now dominates Congress. That his previous engagement in the real world, even carefully and transparently managed, made him an unfair target of political attacks shows why so few people of accomplishment run for office. These are the kind of people that the goo-goo Naderites and their media acolytes end up driving from public life.

Dr. Frist now joins a long line of public servants to be smeared on page one and exonerated next to the classifieds, only to wonder if anyone noticed. As former U.S. Secretary of Labor Ray Donovan asked after his legal ordeal, ''Which office do I go to to get my reputation back?''

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

The ACTING PRESIDENT pro tempore. The assistant majority leader is recognized.

IRAQ SUPPLEMENTAL

Mr. DURBIN. Mr. President, about 1 hour ago, the President of the United States vetoed the supplemental appropriations bill for the war in Iraq. It was a bill that we have worked on in Congress since its arrival in the middle of February. It was the subject of lengthy deliberations. There were long debates on the floor of the House and Senate. There was a lot of compromise that led to the final work product and a bipartisan vote which sent it to the President.

There were people who were skeptical as to whether the Senate and the House

of Representatives could rise to this challenge. In a nation that is so divided on so many political issues, in a nation where the war in Iraq is the biggest issue by far, there were serious doubts as to whether this Congress, with scant majorities of Democrats in both the House and the Senate, could produce a bill for President Bush to consider.

Congress rose to that occasion. With the leadership of Speaker PELOSI and the leadership of our majority leader, Harry Reid of Nevada, we produced a bill which attracted not only the overwhelming support of the Democratic caucus but also the support of Republican Senators who joined us in passing this bill.

It was our hope that our work product would be considered seriously by the President. It was sent to him this afternoon. A few hours after receiving it, the President vetoed it and announced his veto in a public press conference.

I am disappointed. The President had a chance to sign a bill that would have funded the troops in this war. More importantly, it was a bill he could have signed which could have changed the course of this war—something that is long overdue.

I listened in my office as the President gave his veto message to the American people. It was short, direct but, in many ways inadequate when you consider the awesome responsibility we face in Congress and in the White House.

The President referred to our timetable to start bringing American troops home as a date for failure. It is ironic the President would make that statement on the fourth anniversary of his appearance on the USS *Lincoln* aircraft carrier under a banner announcing, 4 years ago, that our mission was accomplished. For the President to announce success and failure, accomplishment and lack of accomplishment, leaves something to be desired after that experience 4 years ago.

I am particularly troubled as well by the President's notion of what this bill was all about. You see, he said, at one point, for us to set a timetable to bring American troops home would—in the President's words—''demoralize the Iraqi people.'' Those were his words.

Mr. President, excuse me, but I am not as interested in building up the morale of the Iraqi people as I am in inspiring the leaders of the nation to stand up and lead. For too long now, with the protection of the U.S. troops, this Iraqi Government has failed to make even basic progress in taking control of their country. They have failed to address the key political issues that would lead to stability.

So the President is arguing that if we continue to send 150,000 or more American soldiers to risk their lives, it will build up the morale of the Iraqi people to seek nationhood, stability, and peace. So we expect American soldiers to stand in this crossfire of a bitter religious and civil war, hoping that the Iraqi people will be inspired enough to ask their Government for leadership?

Mr. President, 3,351 American soldiers have fought and died in Iraq, as I stand here today. Mr. President, 3,351 American lives should be enough to inspire the Iraqi people and their Government. How many more American lives will it take for that inspiration the President is looking for?

I am troubled by this notion that unless we will sacrifice our treasure and the lives of our brave soldiers, the Iraqis cannot rise to the occasion and lead themselves out of this morass.

I also listened to the President when he characterized the money that we added in Congress to his budget request. He called it—and I will quote—''billions in nonemergency spending that has nothing to do with fighting the war on terror.''

I wonder if the President's staff put the bill in front of him for him to take a close look at, in the few hours he had it before vetoing the bill.

Is the President arguing to the American people that providing $2 billion more in equipment to keep our troops safe in Iraq has nothing to do with fighting the war on terror?

Is the President arguing that the $1 billion in our supplemental appropriations bill—the $1 billion to replenish National Guard equipment destroyed and lost in the war in Iraq—that $1 billion has nothing to do with the war on terror?

Is the President arguing that the $2 billion in this bill for military hospitals—such as Walter Reed, so we do not relegate our fallen soldiers and those who were injured to a flophouse motel across Georgia Avenue from Walter Reed Hospital—is he arguing that the $2 billion that is in the bill for military hospitals has nothing to do with the war on terror?

Perhaps the President is not aware of the fact there was $2 billion in this bill for veterans hospitals all across America, for those who have come home with post-traumatic stress disorder, traumatic brain injury, and amputations who need the services of the VA hospitals. Is the President arguing that money for VA hospitals has ''nothing to do with the war on terror''? That is what he said. That is an exact quote.

This bill has add-ons that relate to real emergencies in America. I have outlined a few related directly to the war on terror, directly to our troops, directly to our national security.

There is money, as well, for the base closing commission, which it is my understanding the President wanted included. There is money, as well, for Hurricane Katrina. Here we are, a year and a half after that terrible tragedy, still trying to put New Orleans back on its feet and rebuild Louisiana and Mississippi and areas affected by Katrina and Rita. Yes, there is money in the bill for those emergency purposes.

For the President to dismiss this as billions in nonemergency spending suggests his staff did not do their job, they did not spell out to the President what was in that bill before he vetoed it.

Well, the President knows—and he said as much—we do not have the votes to override his veto. That is a reality. It takes 67 votes in the Senate. We have been able to rally 51 or 52 votes on a good day to question the President's policies in Iraq. Two or three Republican Senators have stood by our side on the Democratic side of the aisle. Few others have been willing to do so. So the thought of reaching 67 votes is probably a bridge too far. I think we know that reality.

But this much I will say: Congress cannot override the President's veto, but the President cannot override the reality of Iraq. The reality of Iraq is this: We are in the fifth year of a war. We have seen 3,351 American lives sacrificed, 25,000 or more injured, 7,000 or 8,000 seriously injured with traumatic brain injury and amputations.

Americans have sacrificed from their hard work and earnings $500 billion for this war and for rebuilding Iraq. That is the reality of Iraq today.

The reality is, this last month of April was the deadliest month this year for American soldiers. The reality is, this President has no plan to exit that country and bring our troops home. That is the reality. We may not be able to override this veto, but the President cannot override those realities.

Now it is time for the American people to understand what happens next.

We will fund these troops. We have made that promise, and we will keep it. They will not be bargaining chips in our policy debate in Washington. But we will continue, through this bill and through other legislation this year, to continue to put the issue of the Iraq war in front of the President, in front of the American people. They expect nothing less.

For those who are frustrated by the President's veto today, I join them in that frustration. But I join them, as well, in believing that as the American people speak out on this issue, the likelihood that Republicans will cross this aisle and join us increases.

The time will come—I am not sure when but I hope soon—that tipping point will be reached where the Republicans finally say to their President: Enough. We cannot ignore the reality of this war and what it has done to America. Then they will join us. Then this will truly become a bipartisan effort. Then we will be able to override vetoes and pass legislation that will make a meaningful change in the policy of this war.

I encourage those across America seeking a new direction in Iraq, do not be discouraged by this veto. There will be another day. There will be another bill. There will be another chance for us to change this policy. We need to keep our forces together—the forces for change in Iraq on the Democratic side and on the Republican side. We cannot allow the President's veto pen to be the

last word on this war in Iraq. We have to stand together, and we have to work together.

The President comes up with rosy reports on what is happening in Iraq. But we know the reality. Sectarian deaths are down, he said. Well, I guess they are down slightly, a small percentage, of those innocent civilians killed last month. There were fewer this month. I guess that is progress. But those who are there say the violence is subsiding while the surge is underway, and they are afraid it will return. I am, too.

We need to pass a bill for the troops, and sometime soon. We will work hard to try to find a way with the President. He has invited the leadership of the Senate and the House to meet with him tomorrow in the White House. I have been to those meetings before. There have been little results to point to for the time we have met and the dialog we have exchanged. But I go tomorrow with the hope that things will be different. I hope this President, after his moment in the sun with this veto, will now understand that we face the grim reality of Iraq, and the reality that we have no exit plan. This failed policy in Iraq must come to an end. We will continue to fight, with this democratic Congress, to make a change in that policy. We will stand by our soldiers, but we will not stand by a failed policy. I am encouraged by the fact that so many of my colleagues are ready to continue this fight, and I encourage the American people: Don't give up. Don't lose heart. This democracy works when you work with us to bring the will of the people to the law of the land.

Mr. President, I yield the floor.

The ACTING PRESIDENT pro tempore. The senior Senator from New York is recognized.

IRAQ SUPPLEMENTAL

Mr. SCHUMER. Mr. President, tonight is a sad night for America, but what the President's veto indicated was not that Democrats don't want to support the troops—we do—but that he does not want a change in direction, a change in mission, a change in course. It indicates the President is still in his bunker thinking everything is going fine in Iraq, and it clearly isn't.

The bottom line is very simple: We can do two things at once. We can support the troops and at the same time we can change our mission. The bottom line is simple, and that is that the present policies have failed. Everyone except a handful of supporters of the President, and the President and the Vice President themselves, know that, but unfortunately they stubbornly cling to staying on the same course, to the detriment of about everybody else in this country and the world.

The bottom line is very simple: that President Bush, when he asked Americans to go to war, never talked about policing a civil war, and yet that is the largest part of our efforts in Iraq. We on this side of the aisle hope to change that direction so that we are fighting terrorism and directing counterterrorism and not simply policing a civil war.

The next few weeks will be momentous in our history. Frankly, when these few weeks began, the President, with his bully pulpit, his harsh rhetoric, his idea that he was trying to persuade people we didn't support the troops, many thought he would win the fight—the fight here in this Chamber and in the minds of public opinion. But that hasn't happened at all. In fact, the American people are so disgruntled by this war in Iraq, that the old name-calling, the old kneecapping, the old attempts to instill fear in people who disagreed with him don't work for this President anymore. He has only one choice. That choice is a simple one, which is to change the course of the war in Iraq. It is inevitable. It will happen. It will happen sooner or it will happen later, but it must happen because failed policies can never continue on and on and on.

They have asked us to have faith in the surge. If it won't work with 150,000 troops, it won't work with 180,000 troops, and it won't work because the Government in Iraq does not have the support of the people, is unable to accomplish any goals, is unable to bring Sunnis, Shiites, and Kurds together. It doesn't matter how many troops we have there; the bottom line is simple. Our President is in the twilight days of his administration, and he has only two choices. One is to do what his predecessor Ronald Reagan did: See that things have gone off course and seek a correction. Ronald Reagan did that in 1986, and by 1988 the wall came down and Ronald Reagan had restored the faith of the American people. Why this President can't see the necessity to do the same when his policies, if anything, are in far worse shape than those of President Reagan, speaks either to an inability to sense what is going on or a stubbornness despite the facts. We can't tolerate that.

We here tonight make a pledge to the American people. We will continue this struggle to change our direction in Iraq. We will not run away from fighting terrorism. We believe it every bit as fervently as anybody else, but we will also not run away from fighting terrorism smartly, which is what we are not doing here.

So we will continue to try to reach a compromise with this President, to try to figure out a way we can both support the troops and change the course of the war in Iraq in maybe a different way, but we will not give up on our mission. The American people demand no less and we will not disappoint them.

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

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

The ACTING PRESIDENT pro tempore. The majority leader is recognized.

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

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

SENATOR FRIST'S VINDICATION

Mr. REID. Mr. President, I had the good fortune of working with Senator Bill Frist for 4 years as a leader. He was a leader. There were times he and I had some political disagreements, and that is an understatement, but on a personal basis we had no misunderstandings. He was in public service for the right reason. He was a very fine, outstanding, nationally recognized transplant surgeon. He comes from a good family. He and I had many discussions, personal in nature. He was always available to anyone in the Senate. When there were any medical problems involved, he was always there to give advice and counsel. I went to him on many occasions about situations involving my friends and he would lay things out for me and head me in the right direction.

Senator Frist had a situation arise front page in many of the newspapers, problems with the Securities and Exchange Commission. Senator Frist comes from a family that has done well. They have been involved in health care for many years. He and I had conversations about this and he said at the time it was unfair. He had to spend a lot of money hiring lawyers and accountants and consultants.

This matter was closed yesterday, but the closing of this in the newspapers and on the news was certainly not the top story, not at the top of the newspaper. It was buried some place in the back. At no time during my conversations with Senator Frist or in my dealings with Senator Frist did I ever have any doubt about his integrity.

His wife Karen and my wife are good friends. They worked together on a number of activities that Senate spouses work on. They had to do things because Senator Frist and I were the two leaders of the Senate and they did them together based on our relationship.

I extend to Senator Frist my congratulations on getting this put behind him. I want the RECORD to be spread with the fact that I know this was a difficult time for him on occasion, but never at any time did I doubt his integrity, his honesty. I will long remember Senator Frist and I appreciate my dealings with him over these many years.

CLOTURE MOTION

Mr. REID. Mr. President, I send a cloture motion to the desk.

The ACTING PRESIDENT pro tempore. The cloture motion having been presented under rule XXII, the Chair directs the clerk to read the motion.

The legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule

XXII of the Standing Rules of the Senate, hereby move to bring to a close debate on the Dorgan amendment No. 990 to S. 1082, the FDA Revitalization bill.

Byron L. Dorgan, Dick Durbin, Claire McCaskill, John Kerry, Ted Kennedy, Amy Klobuchar, Sherrod Brown, Ken Salazar, Mark Pryor, Daniel K. Inouye, Chuck Schumer, Harry Reid, Ron Wyden, Dianne Feinstein, Carl Levin, Blanche L. Lincoln.

Mr. REID. Mr. President, this is a cloture motion on Senator DORGAN's longstanding endeavor to allow Americans to go to other countries for the importation of cheaper drugs. We know people are going to Canada now from around the country who live on the border, and it works pretty well. But if you are someone who lives in Nevada, you certainly need these drugs as well as someone living in Minnesota, and it makes it much more difficult. Nevadans go to Mexico a lot of times for cheaper drugs. It is unfortunate.

Senator DORGAN is right. He has worked on this very hard for a number of years. This is an effort to bring this matter to a close. I hope the Senate votes to invoke cloture so we can have a vote on this amendment. It is important. I am confident it will pass if cloture is invoked. It is something that has been needed for such a long time to help in one way to lower the cost of medicine for the American public.

MORNING BUSINESS

Mr. REID. Mr. President, I ask unanimous consent there now be a period of morning business with Senators allowed to speak therein for a period of up to 10 minutes each.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

HONORING STEVEN SCHWARZ

Mr. REID. Mr. President, last week I attended a ceremony in the Capitol Rotunda to commemorate the 2007 Holocaust Days of Remembrance.

Fred Zeidman and Joel Geiderman, Chairman and Vice Chairman of the U.S. Holocaust Memorial Council, spoke eloquently about the horror and courage, the unspeakable tragedy and unimaginable heroism that even 62 years later we cannot begin to comprehend.

Sara Bloomfield, Director of the U.S. Holocaust Memorial Museum, as well as my colleague, Senator JOE LIEBERMAN, added their own powerful words.

I was privileged to sit beside Steven Schwarz. As we sat together, Steven listened silently, tears streaming down his face. Afterward, he told me his story.

Born in Poland, Steven lost both parents and a brother in the Holocaust. Forged with sheer willpower and blessings from God, he, his late wife Tina, and his brother Henryk managed to survive by hiding out in Poland. In 1953, they came to the United States and were welcomed with open arms. In the years that followed, Steven and his brother rose to become prominent and successful businessmen, overcoming great suffering to live the American dream.

Steven Schwarz embodies the grace and fortitude of all those who wrested triumph from despair. I am honored to have shared that day of remembrance with him and pleased to now pay tribute to his life story in the RECORD of the U.S. Congress as a powerful and poignant example of the unbreakable human spirit.

AAA SCHOOL SAFETY PATROLLERS

Mr. REID. Mr. President, I wish to recognize several young people who were recently selected by the American Automobile Association to receive special awards for their work as school safety patrollers.

More than 560,000 students in 52,000 schools across the country participate in AAA's School Safety Patrol Program. These young people have taken on the important responsibility of making the streets around their schools safer for their classmates. Though their responsibilities are often routine, the patrollers on occasion must place themselves in harm's way in order to save lives. It is my honor today to recognize two students who were selected to receive the AAA Lifesaver Award for their selfless and heroic actions in fulfilling their duties as patrollers.

Taylor Pitzer and Caleb Jarrell participate in the AAA School Safety Patrol Program at Southdale Elementary in Kettering, OH. On November 8, 2006, Taylor and Caleb pulled a younger child to safety when a speeding van ran the red light at the intersection they were patrolling. The younger child was watching carefully for the ''walk'' signal. When the light changed, she began crossing the street and did not notice the oncoming vehicle approaching the intersection. Responding to an adult guard's ''hold back'' indication, Taylor and Caleb reacted quickly by locking arms so the child could not cross the street, which allowed the van to speed by without incident or injury to the child.

I would also like to thank AAA for making the school safety program possible. This program has helped save many lives over the years and has made our schools safer for our students, though, as the story of the Life Saver Award recipients demonstrate, the streets around our schools are not safe enough. That is why I worked to create the national Safe Routes to School Program, which was adopted as part of the Federal transportation bill on July 29, 2005. Funds for this program can help communities construct new bike lanes, pathways, and sidewalks, as well as launch Safe Routes education and promotion campaigns in elementary and middle schools.

I am pleased to commend this important program today before the Senate. I know I speak for every member of the Senate in expressing our gratitude for their valuable work in our communities.

NORTHERN NEVADA CENTER FOR INDEPENDENT LIVING

Mr. REID. Mr. President, I wish to honor the Northern Nevada Center for Independent Living, NNCIL. I am honored to congratulate this organization for their 25 years of dedicated service to the people of northern Nevada.

NNCIL has helped disabled citizens in Nevada in all aspects of their lives. They have empowered disabled citizens to become more independent and have given disabled people a stronger voice in matters that directly affect their lives. With the skills taught by NNCIL, disabled people who were benefactors of this program are now participating fully in the community by volunteering in the center and in other service agencies across Nevada.

NNCIL has helped disabled citizens thrive socially as well. The center has instituted ''recreation night'' that has helped disabled people form peer support groups. They have incorporated game night and movie night into their organization to build communities throughout Nevada.

The efforts of NNCIL have garnered broad respect and support from the community as a whole. NNCIL has incorporated multiple programs to educate the public concerning issues concerning disabled citizens. They have encouraged Nevada residents to get involved in their communities, and the citizens of northern Nevada have responded by volunteering in a home-modification program that has helped install ramps, handrails, and other improvements to make life easier for disabled people.

I would like to commend NNCIL for their many years of dedicated service to the people of Nevada. They have been an important part of improving the lives of disabled members of our community, and I wish them continued success.

RECOGNIZING NEVADA'S 45TH ANNUAL RENO JAZZ FESTIVAL

Mr. REID. Mr. President, I wish to recognize the 45th annual Reno Jazz Festival. Hosted by the University of Nevada, Reno, the Festival has grown into one of the largest of its kind in the United States, with over 10,000 people attending last year's event.

The competition portions are one the highlights of the festival. Musical groups and individuals from junior highs, high schools, and colleges from throughout the country are invited to participate. The festival winner and other highly acclaimed musical groups will perform at the festival's showcase on its concluding day.