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Senate

The Senate met at 10 a.m. and was called to order by the Honorable SHERROD BROWN, a Senator from the State of Ohio.

PRAYER

The Chaplain, Dr. Barry C. Black, offered the following prayer:

Let us pray.

O God, our rock, fortress, and deliverer, we trust You to strengthen us today.

Empower our Senators with humility to listen, wisdom to understand, courage to attempt, and power to obey. May they devote themselves to the honorable, the noble, and the good. Keep them from self-indulgence, mental lethargy, and negative expectations as You guide their hearts and minds in the knowledge of Your love. Purify their ambitions so that they may set their hearts only on that which pleases You. May they find even in problems opportunities to discover Your power.

We pray in Your great Name. Amen.

PLEDGE OF ALLEGIANCE

The Honorable SHERROD BROWN led the Pledge of Allegiance, as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

APPOINTMENT OF ACTING PRESIDENT PRO TEMPORE

The PRESIDING OFFICER. The clerk will please read a communication to the Senate from the President pro tempore (Mr. BYRD).

The assistant legislative clerk read the following letter:

U.S. SENATE,
PRESIDENT PRO TEMPORE,
Washington, DC, May 1, 2007.

To the Senate:

Under the provisions of rule I, paragraph 3, of the Standing Rules of the Senate, I hereby appoint the Honorable SHERROD BROWN, a Senator from the State of Ohio, to perform the duties of the Chair.

ROBERT C. BYRD,
President pro tempore.

Mr. BROWN thereupon assumed the chair as Acting President pro tempore.

RECOGNITION OF THE ACTING MAJORITY LEADER

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

ORDER OF PROCEDURE

Ms. STABENOW. Mr. President, I now ask unanimous consent that when the Senate resumes S. 1082 this morning, it be for debate only until 12:30 p.m., with no amendments in order during that time, with the time equally divided and controlled between the two leaders or their designees.

The ACTING PRESIDENT pro tempore. Is there objection?

Without objection, it is so ordered.

RESERVATION OF LEADER TIME

The ACTING PRESIDENT pro tempore. Under the previous order, the leadership time is reserved.

MORNING BUSINESS

The ACTING PRESIDENT pro tempore. Under the previous order, there will now be a period for the transaction of morning business for up to 60 minutes, with Senators permitted to speak for up to 10 minutes each, with the first half of the time under the control of the Republicans and the second half of the time under the control of the majority.

The Senator from Utah is recognized.

Mr. BENNETT. Mr. President, I ask unanimous consent that I be allowed to speak for up to 15 minutes.

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

PERFORMANCE OF THE MEDIA

Mr. BENNETT. Mr. President, my theme today has to do with our friends in the media, or the fourth estate as they like to call themselves. There are two items I wish to call to the attention of the Senate and anyone else who might be listening with respect to the performance of the media. The first one is highlighted in an editorial that appeared this morning in the Wall Street Journal entitled ''Frist's Vindication.''

All of us in this Chamber know Senator FRIST. We know him as a man of integrity, intelligence, and grace. He presided over the Senate as the majority leader for 4 years. He has a long history as a humanitarian, as a scientist, as a skilled doctor who pioneered procedures in the process of heart and lung transplants.

We also know him as the target of media attack for insider trading, and we know groups that are self-anointed as watchdogs of the public consciousness that picked that up and kept the drumbeat alive. Our friends in the media also kept the drumbeat alive saying, over and over again, Dr. Frist was a hypocrite, Dr. Frist engaged in insider trading, Dr. Frist used his position to enrich himself while he was here in the Senate.

Well, the Securities and Exchange Commission was sufficiently aroused by those attacks that they entered into an investigation of Dr. Frist's activities with respect to his stock. That investigation is now closed. I did not realize the investigation was closed because there has been no hue and cry whatsoever in the media. There has been no mention that came to my attention in the media, until I picked up this morning's Wall Street Journal and saw this editorial.

I would like to quote from it. Under the title ''Frist's Vindication'' and the subhead ''So much for that 'insider trading' smear,'' here is what it says:

When insider-trading allegations against former Senate Majority Leader Bill Frist

● This "bullet" symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor.

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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?

It goes on to describe the allegations against Dr. Frist. I shall not repeat them. Basically, it says he used his position in the Senate to get insider information and started selling his stock in HCA in advance of a drop in the stock that occurred because of earnings reports.

The editorial says:

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.

It goes on to discuss the groups that attacked him. Again quoting:

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.

The editorial indicates that while this absolution is a relief to Dr. Frist, ''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.'''

A great deal was made out of this. The editorial quotes American University professor James Thurber as saying that Dr. Frist ''came in like Jimmy Stewart and was leaving like Martha Stewart.'' That is a great line. That gets headlines. The press loves things of that kind.

Now that it is clear he behaved in an absolutely ethical way—documented everything he did, turned over all of his e-mails—and has been completely cleared, after 18 months of careful examination by the Securities and Exchange Commission, we hear nothing in the press, we hear nothing in the way of an apology from Public Citizen or Citizens for Responsibility and Ethics in Washington. Maybe ethics does not apply to them when it comes to apologizing for smears against legitimate and responsible public servants. Maybe we will now hear that Dr. Thurber has something else to say besides his quick quip about Dr. Frist being the same as Martha Stewart as she went to jail. But I doubt we will hear any of that. I doubt the press will even notice. I doubt there will be a sidebar anywhere.

I am grateful to the Wall Street Journal for pointing this out to us, and I appreciate the opportunity on the floor of the Senate to speak on behalf of a man whom I consider a friend, I think whom all of us consider a responsible Senator, a devoted leader. He deserves better at the hands of the press and those self-appointed leaders of ethics who are quick to criticize but slow to apologize.

Now, Mr. President, the next issue I would like to raise with respect to the media has to do with the hysteria over America's trade deficit with China. I have some charts I would like to put up to show some historical evidence with respect to this issue.

Let's talk about China and the trade deficit and the rise of China. This chart has two lines on it, one in red, which is American exports to China, and one in blue, which is American imports from China.

Let's go back to 1975, before people were all excited about China and how China was destroying us in the age of globalization, how China's cheap labor was taking all of our jobs, and we were flooded with Chinese imports. We notice on the chart there was a gap between American exports to China and American imports from China. No one felt that gap was ready to threaten and destroy the American economy. No one got excited about it. All right.

You go to 1990, and you find that neither line has moved up very much, but the gap remains virtually the same. Now, the Chinese economy started to take off and we started to buy things from them, and at the same time we started to sell things to them. Both lines started moving up. We saw, yes, imports from China were going up, but exports to China were going up. By 2002, 2003, both were up significantly over where they had been in 1975. But the gap remained roughly the same. All right.

Interestingly enough, as we get toward 2005 and so on, there are moments when the gap disappears, when our sales to China were greater than our imports from China. Why would that be? It would be because the improving Chinese economy now has enough money to buy American goods. They want to buy our airplanes. Boeing does well in China. The last time I was in China, I met with the manager of General Motors in China. General Motors was having a very bad year in the United States, but they were having a good year in China. They were making money in China. They were selling Buicks and other automobiles in China.

The red line started to move up, and, as I say, at one point they actually crossed the blue line. OK, the blue line opened up again, not as great as the gap back in 1975, but it began to open up. Once again, we saw the gap closed. Sales to China reached the same level as purchases from China. And then it opened up again. It appears if we want to project from this period on into the future that the pattern of our importing slightly more from China than we sell to China is likely to continue.

I doubt this historic demonstration of facts comports with the way the media is talking about China. They are telling us China is going to overtake us. They are telling us China is going to destroy us. They are telling us China is the nation of the future. We have heard in the media statements about the 20th century being the American century; the 21st century is going to be the Chinese century.

Well, let me put up another chart that I think will demonstrate that might be a little bit premature.

Let's look at the size of the two economies. The size of the economy is measured in gross domestic product. The gross domestic product of the United States in 2000 was $9.8 trillion. The gross domestic product in China in 2000 was $1.2 trillion. This is the beginning of the Chinese century? The Chinese are starting off pretty far behind in this race if they are going to turn the 21st century into the Chinese century. They are at $1.2 trillion and we are at $9.8 trillion. We have sprinted into what the media is calling the Chinese century now for the first 6 years.

Where are we? These statistics are for the first 5 years, the first 5 percent. In that period of time, our annual GDP growth has been 3.2 percent. The Chinese has been 10 percent. Those are the numbers that say they are going to overtake us. Ten percent is clearly better than 3 percent.

I would make this one footnote with respect to the 10 percent. I am a little suspect of these numbers because the Chinese released their annual figures on December 31 of the same year. We don't know our annual figures for months afterwards. Then, when more data comes in, we revise them upward or downward, based on additional information. Somehow they know on New Year's Eve exactly how they have done during the year. If they were a corporation required to report to the SEC, there would be some investigations about the possibility of ''cooking the books.'' I think they make the determination of where they want the number to be and then report it thusly, either too high or too low for whatever their political purposes might be.

So all right, let's take these numbers at their face value. These numbers mean from 2000 to 2005 the Chinese GDP grew from $1.2 trillion to $2.2 trillion, a $1 trillion increase. That is not a slouchy thing to do. That is clearly a tremendously impressive performance—almost doubling a $1 trillion increase. How about the United States. We are just limping along at 3 percent, 3.2 percent, but we went from $9.8 trillion to $12.4 trillion.

In other words, they went up $1 trillion, and we went up $3 trillion. How is that possible if they are growing another 10 percent, and we are only growing at 3 percent? It is because they are starting from a very low base. Those who say the 21st century will be the Chinese century and the Americans are through need to pay attention to what the real numbers are.

If we are going to have a game and we start out the game with one team having almost 10 times as many points as the other, and then add on to that on a percentage basis rather than an

absolute basis, we see in terms of the gap between the size of the American GDP and the Chinese GDP the gap is actually widening rather than shrinking. Yes, they can have a higher rate of growth, but their higher rate of growth is on a much lower base. Our growth on a higher base is unprecedented in world history.

My message today is we need to hold the media accountable as well as all of the others. We have had two examples I have highlighted this morning where the media has misled us: the first with respect to one of our respected and beloved colleagues, Dr. Frist, where he was smeared and then when he was vindicated, that fact was ignored. The second has to do with telling us where the world is going. For whatever reasons, there are those who are constantly panicked about China and its impact on the United States who need to pay attention to the reality of the numbers.

Mr. President, I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Texas is recognized.

IRAQ

Mr. CORNYN. Mr. President, today is an important yet a sad day for our Nation because it represents the 85th day that our fighting men and women in uniform have been waiting for emergency aid from the Congress. Yet they have been left waiting because of political gamesmanship and political theater in Washington, DC. The latest is reported in the Congressional Quarterly today, an article I have here in my hand—actually the date is April 30, 2007, 10:45 p.m., entitled: ''President's Veto Dependent on House Speaker's Signature.'' The report is that Congresswoman PELOSI wanted time to personally read the emergency supplemental bill and to sign it before sending it to Pennsylvania Avenue. I would have thought that Congresswoman PELOSI and Members of Congress would have read legislation before they voted on it, not afterwards.

Also, in today's edition of The Hill, there is a story that says:

> Congressional leaders today will put an exclamation point on their political showdown with President Bush on Iraq spending, staging a signing event to send their Iraq supplemental bill to the White House.

I don't think this is Congress's finest hour, and I think it is an embarrassment that when our troops are waiting on an emergency spending bill to provide them essential equipment, we are staging signing ceremonies and going through political kabuki theater just to demonstrate on the part of some their disagreement on the present strategy in Baghdad and in Iraq. I think it is inappropriate and irresponsible.

I know one of our colleagues here has talked about, for example, the MRAP vehicles, the so-called Mine Resistant Ambush Prevented V-shaped hull vehicles that are awaiting $3.1 billion in spending in this appropriations bill to get those to the Marines and Army in Iraq, something that has proven, in the hands of the Marines, to be very resistant to the improvised explosive devices. They save lives. That is one example, one concrete example of funding for equipment that is being held up because Congress continues to dither and play political games now 85 days after the President has requested this funding for our troops. The bill that will—after this so-called signing ceremony and after this reading of the bill after it has passed rather than before it was passed exercise—be sent to the President and he will veto it is simply unacceptable. Why? For two reasons.

First of all, because it imposes arbitrary timelines on our generals in Iraq, including GEN David Petraeus, who was confirmed unanimously by the Senate, who was here last week to explain the progress that is being made in places such as Al Anbar Province, west of Iraq, which has been controlled by al-Qaida for some time now, and we are finally starting to see some real, concrete improvements being made there. We are seeing the local sheiks offering troops to supplement Iraqi police officers and the Iraqi Army to fight al-Qaida—the same organization that killed 3,000 Americans on September 11—right in Iraq. That is good news.

We are beginning to see some real security measures going forward. So why we would have Congress tie the hands of General Petraeus and these successful efforts in Al Anbar Province, west of Baghdad, controlled by al-Qaida, and why Congress would want to tie the hands of our military leaders at a time when we are seeing some real improvement there is, frankly, beyond me. Why would we simply give up when we are beginning to see some light at the end of the tunnel?

Then, of course, there is the second matter of providing porkbarrel spending in order to secure the votes of some Members of the House for this bill that they would not support on the merits. It is completely demeaning to our troops and the nobility of their sacrifice, not to mention the sacrifice of the military families who wait anxiously hoping their loved one will return from the fight only to be told that Congress is causing unnecessary delays in this spending—85 days now—putting arbitrary timelines on the troops, making it harder for them to succeed, denying them the equipment necessary for their very safety, while Congress engages in more porkbarrel spending in order to secure a political consensus for this ill-considered piece of legislation.

The bill, on its way to the President after this kabuki theater, substitutes congressional mandates for the considered judgments of our military leaders. This bill assumes and forces the failure of a new strategy, which is only halfway implemented. The new Baghdad security plan to back up Iraqi forces in Baghdad to implement the clear hold-and-build strategy that GEN David Petraeus is the architect of as part of our counterinsurgency measures is only halfway deployed. Only half of the troops that are a part of this so-called surge are on the ground. While we are seeing some progress, we are also seeing some increased violence and, unfortunately, deaths as a result of meeting the enemy in places where previously they were safe and secure because we could not even go into places such as Sadar City, which was controlled by Moqtada al-Sadr, the radical Shiite cleric who has since left to go to Tehran. He has left the country because he is afraid of the American and Iraqi military forces joining together. He has instructed the Shiite militias, one of the major causes of death squads and violence and ethnic cleansing in Iraq, to lay down their arms. What is there not to like about that kind of progress? Yet Congress, thousands of miles away in the safety and comfort of the Senate Chamber and our offices, is undermining the good efforts that are going forward in Iraq.

While no one believes success is assured, we know, in the words of General Petraeus:

> The mission is hard, but it is not hopeless.

The only thing that would make it hopeless is if Congress continues to undermine General Petraeus and our troops who are in harm's way. It boggles my mind that we have that sort of mindset in Washington, DC because of some rabid, antiwar, left-leaning groups that insist we ought to simply tuck our tail and run. They haven't come up with an adequate explanation as to what they think would happen if we were to leave precipitously, as some of them suggest.

I happen to believe that notwithstanding the fact that Darfur, where 400,000 people at last count have died as a result of terrible violence there, would pale compared to the ethnic cleansing and the violence that would follow if America were to betray our Iraqi allies and would leave precipitously. It would also create a regional conflict where Sunni majority nations would come in and try to stave off the Shiites from Iran for helping them and trying to prevent them from killing the Sunni minority there.

The Democratic leadership has not helped the situation in Iraq with their recent pronouncements either. Democratic leadership in recent floor statements has suggested that if the President vetoes this bill, then he will be the one endangering the troops. They further stated they hope the President would realize that with his pen in hand he can honor soldiers, honor his country, and bring an end to this war.

To that I say baloney. That is sheer fantasy that by cutting and running, by neglecting our allies in Iraq, by neglecting the improvements we have been able to make, by recruiting tribal sheiks to help us in fighting al-Qaida,

that somehow, by giving up on that, we are going to bring an end to the violence and the death in Iraq. To the contrary, we would create a failed state where al-Qaida, the very same people who hit this country on September 11, 2001, could reorganize, train, and recruit, and export future terrorist attacks to the United States.

I am chilled by comments made a few months ago when I attended a ceremony where the Deputy Secretary of Defense spoke.

He asked rhetorically:

> Do you know why al-Qaida killed 3,000 people on September 11, 2001, in New York and Washington, DC?

Then he answered his own question. He said:

> Because they could not kill 30,000, because they could not kill 3 million.

His point is if they had the kind of biological, chemical, or nuclear weapons they are seeking, they would have killed thousands—perhaps hundreds of thousands more innocent Americans. And they will do that at will if they are provided that sort of weaponry.

So it is sheer naivete on the part of those who say all we need to do is leave and somehow these people will go away. They will not go away and they will visit us here again with deadly results.

With General Petraeus back from Iraq for the first time last week since he assumed command of U.S. forces, and the emergency supplemental, I hope, reaching the President later today, it is appropriate to reflect on the majority leader's statement, where he said we have ''lost the war.''

Two weeks ago, the Senate Armed Services Committee heard testimony from GEN Barry McCaffrey, a proven combat commander from the first gulf war, and a recognized expert on the tactical, operational, and strategic situation in Iraq. I will quote for a moment from his statement. He said:

> The consequences of failure in Iraq will be a disaster to the American people and our allies if we cannot achieve our objective to create a stable, law-based state at peace with its neighbors. . . . We have 150,000 U.S. troops battling in Iraq and 22,000 fighting bravely in Afghanistan.
>
> These are the finest, most courageous military men and women we have ever fielded in battle. Their commanders—who have almost without exception at company, battalion, and brigade level served multiple combat tours—are the most capable leaders that I have encountered in my many years of watching our Armed Forces with admiration.

He goes on to say:

> Our new leadership team in Iraq—our brilliant new commander, General David Petraeus, and the equally experienced Ambassador Ryan Crocker—are launched on a new approach to use political reconciliation, new methods and equipment to strengthen the Iraqi security forces and enhanced U.S. combat protective power to stabilize the situation. We must give them time and space.

That is exactly what we are trying to do, to provide the basic security General Petraeus said is necessary, but not sufficient, to solve the problem.

I submit our colleagues who have said General Petraeus said there is no military solution in Iraq are not listening to what he is saying, because what he has said is that improving our security situation is necessary but not sufficient. It is not a question of whether we are going to do the security part or the political reconciliation part. One must precede the other. It makes common sense that it is hard to sit down and work out your differences around a conference table in a political debate, or an attempt at reconciliation, if people are driving automobile-borne improvised explosive devices or people are walking into the Parliament in a suicide vest. So security must precede the political reconciliation that we all recognize is so absolutely important. That is what General Petraeus is saying. That is what we have to accomplish.

We have some hopeful signs in Iraq now, for the first time in a long time, as a result of this new strategy that is only about half way implemented. But if we are going to succeed, it won't be because our commanders have had their hands tied by arbitrary deadlines in Washington, DC. It won't be because of the political theater going on here 85 days after the President had requested the emergency spending included in this bill for necessary equipment for our troops.

The leadership should sign this legislation and get it to the President so he can veto it and we can get down to the serious business of providing for our troops.

I yield the floor.

The ACTING PRESIDENT pro tempore. The minority's time has expired.

The Senator from New Jersey is recognized.

IRAQ

Mr. MENENDEZ. Mr. President, 4 years ago today, President Bush landed on the U.S.S. *Abraham Lincoln* in his flight suit. The banner behind him proudly said, ''Mission accomplished.'' President Bush announced to the world, and to the American people, that ''major combat operations in Iraq have ended. In the battle of Iraq, the United States and our allies have prevailed.''

I can think of almost no greater act of hubris, arrogance, and denial than the declaration of mission accomplished in Iraq 4 years ago. It is truly stunning how false that statement was.

Four years ago today, President Bush declared mission accomplished. Yet, since that time, 3,000 U.S. troops have been killed in Iraq. Over 104 American troops died in April alone, making it the deadliest month since last December.

Four years ago today, President Bush declared mission accomplished. Yet we have now spent over $450 billion on the war in Iraq. This war is costing us almost 10 times what the Bush administration initially said it would.

Four years ago today, President Bush declared mission accomplished. Yet we have now been in Iraq for nearly 50 months, longer than the United States was in World War II.

Four years ago today, President Bush declared mission accomplished. Yet U.S. troop fatalities are up 33 percent since the President's escalation of the war in January.

Four years ago today, President Bush declared mission accomplished. Yet today, Iraqi civilian casualties are estimated to be in the tens or even hundreds of thousands. It is impossible to know how many have been killed in Iraq, but the United Nations estimates that 35,000 civilians have been killed.

Four years ago today, President Bush declared mission accomplished. Yet today oil production in Iraq is still 15 percent lower than it was before the war.

Four years ago today, President Bush declared mission accomplished. Yet Baghdad is only getting 6 hours of electricity a day, significantly less than before the war.

Four years ago today, President Bush declared mission accomplished. Yet the Special Inspector General for Iraq Reconstruction just put out a new report detailing how projects the administration declared a ''success'' are actually failing and no longer operating.

Frankly, it reminds me of all the other ways we were misled by this administration. Let us remember what this administration told us about this war. Let us remember the Iraq myths. Remember the unfound weapons of mass destruction; remember the missing mobile weapons labs; remember the yellowcake uranium in Africa; remember Saddam's nonexistent vast stockpiles of chemical weapons; remember when Secretary Rumsfeld told us that ''we know where the weapons of mass destruction are;'' remember the nonexistent link between al-Qaida and Saddam; remember the claims that Iraqi oil and other countries, not the United States taxpayer, would pay for the cost of reconstruction; remember when the administration told us the war would cost only between $50 billion and $60 billion; remember when Paul Wolfowitz said ''it seems outlandish'' to think we would need several hundred thousand troops in Iraq; and remember when President Bush told us on May 1, 2003, that ''major combat operations in Iraq have ended.''

This is the same administration that now comes to this Congress and says: Trust us. This is the same administration that says: Trust us, our new escalation plan will work. This is the same administration that tells this Congress and the American people to be patient, to give their ''new'' plan to escalate the war time to work.

Yet their new plan is more of the same. To quote one of the witnesses who testified before the Senate Foreign Relations Committee:

> This plan is just stay-the-course plus 20,000 troops.

That is what they thought then when the witness testified, but eventually it has been a lot more than 20,000 troops.

Well, the American people and this Congress have run out of patience. This administration has run out of credibility to ask for more time or another chance, when all we are largely doing is staying the course. Frankly, I find it insulting that this administration thinks this Congress would simply go along with their escalation plan without question.

Why should we support President Bush's escalation—a plan with benchmarks but no real consequences? As I have said time and time again, benchmarks without consequences are simply aspirations. We have seen countless misguided plans from this administration, but the Iraqis have never been held accountable.

We were told by the end of 2006 a provincial election law would be approved. But that benchmark has not been met. We were told that Iraqis would approve a law for de-Baathification. But that benchmark has not been met.

We were told that Iraqis would create a law to help restrain sectarian militias. But that benchmark, too, has not been met.

We were told the Iraqis would establish a law to regulate the oil industry and share revenues, which is one of the critical elements to be able to achieve reconciliation in Iraq, the sharing of the nation's national resources. But that benchmark has not been met.

We were told that, by March, the Iraqi Government was supposed to hold a referendum on constitutional amendments. But that benchmark has not been met.

Time and again, the Iraqi Government has fallen short; and time and again, this administration has looked the other way—basing their plans on the hope that the Iraqis will step up. Continuing this failed policy in Iraq based on the mere hope that things will improve is not good enough. The broken promises must stop.

It also seems to me the President is once again out of touch about our progress on the ground and his escalation plan. The President said last week:

> The direction of the fight is beginning to shift . . . and so far the operation is meeting expectations.

This is very much like ''mission accomplished.'' Yet, last Monday, an attack carried out by a suicide bomber near Baqubah killed 9 soldiers and wounded 20 others. The explosion was one of the deadliest single ground attacks on American forces since the start of the war.

Two weeks ago, five different bombs exploded in Baghdad, killing at least 171 people. These attacks mark the deadliest day in the capital city since the new security plan was implemented 2 months ago.

In fact, almost four coalition soldiers have been killed per day in the past month—the highest rate since January of 2005. As I pointed out before, over 100 soldiers were killed in April, including 9 killed over the weekend, 1 of only 6 times that more than 100 servicemembers were killed in 1 month since the start of the war.

Violence outside of Baghdad is on the rise, with more than twice the number of American troops killed in the past 5 months in Diyala Province than were killed all of last year.

In terms of civilians, over 1,500 Iraqis were killed between February 14 and April 12. That is almost 500 more people than were killed during the previous 2 months.

Frankly, I don't believe the President's escalation plan is working. So I say to the President: The era of blank checks is over and the time of congressional oversight has begun.

The President would largely want us to send him a blank check. We have spent 10 times more than we were told we would spend on this war, and there is no end in sight in terms of lives and national treasure. That is why this Senate and the House sent the President an Iraq spending bill with a responsible timeline for withdrawing our troops from Iraq. I believe the President is making a serious mistake with his plan to veto the bill.

Some on the other side of the aisle like to point out that the President is the Commander in Chief. I remind my friends the Constitution puts the Congress in charge of appropriating funds. The Constitution, in article I, section 8, provides what scholars call the power of the purse, and it says: ''The Congress''—the Congress—''shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States.'' Congress has the power and the right and the obligation to make sure we spend the taxpayers' money wisely.

In a recent editorial, Leon Panetta, a member of the Iraq Study Group, reminded us the President has stated the goal of our involvement is for Iraq to be able to ''govern itself, sustain itself, defend itself.''

In order for us to get to that point, we need to hold Iraqis accountable for meeting the benchmarks they helped set. The emergency supplemental bill that passed the House and the Senate does just that, by including a plan to redeploy U.S. forces in relation to progress made by the Iraqi Government in achieving security and diplomatic benchmarks.

Leon Panetta also said:

> The worst mistake now would be to provide money for the war without sending the Iraqis any message at all about their responsibility for reforms. Both the President and the Congress at the very least must make the Iraqi Government understand that future financial and military support is going to depend on Baghdad's making substantial progress toward the milestones Prime Minister Nuri al-Maliki has publicly committed to.

The Iraq supplemental sends a strong message to the Iraqis that it is their responsibility to take control of their own country and that our involvement in Iraq is not indefinite.

Vetoing the supplemental sends the message to the Iraqis that they do not have to take responsibility and that our troops will be in Iraq indefinitely. But staying in Iraq isn't in the national interest or national security of the United States.

Our troops are caught in the middle of a civil war they cannot solve. Keeping more troops there will only put them directly in the middle of an Iraqi fight. Keeping our troops there is trying to solve a political problem with a military solution. Staying in Iraq actually keeps the Iraqis from taking responsibility for their actions.

Frankly, what we hear from the other side doesn't make sense. They talk about victory, but what is the definition of ''victory''? Is that the victory we have heard is around the corner? They talk about benchmarks for the Iraqis, but they set no consequences.

Four years after the President declared ''mission accomplished,'' 4 years and over 3,000 Americans lives later, 4 years and over $450 billion later, 4 years with no new plan for Iraq, just more of the same, 4 years after the President declared ''mission accomplished,'' I ask: How many more lives must we lose and how much more money must we spend?

I close by asking: When will this administration finally understand that ''mission accomplished'' was a myth of their own imagination, born of delusion and denial, yet another terrible mistake in a series of tragic errors? When will we finally hear the words ''major combat in Iraq has ended'' and know they are true?

I yield the floor.

The PRESIDING OFFICER (Mr. WHITEHOUSE). The Senator from Ohio.

Mr. BROWN. Mr. President, 4 years ago today, as Senator MENENDEZ said, the President landed on an aircraft carrier, amid a flurry of pomp and circumstance, and declared, ''Mission accomplished.''

Since that day, much has happened. Since that day, 3,000 brave American soldiers and marines have died in Iraq. This war has gone on, since that day, longer than World War II. Since that day, the United Nations has estimated that 35,000 Iraqi civilians have been killed. Since that day, U.S. taxpayers have spent $450 billion on the war in Iraq.

To get an understanding of what $450 billion is, if we spent $500 every second of every minute of every hour of every day, it would take 29 years to spend the $450 billion we have spent in Iraq.

Now, 4 years later, our troops in Iraq are stuck in the middle of a civil war. Too many of our brave soldiers do not have the body armor they need, in spite of the imploring of so many of us to the administration to do what they need to do to protect our soldiers. Now thousands of Guard men and women face early and extended redeployment.

Four years later, the will of the people resonates in townhalls and in

churches, in back yards and in living rooms across this country. Their message is clear: Mr. President, redeploy our troops out of Iraq.

Up to now, however, the President has refused to hear the calls of millions of Americans. He has refused to listen to voters last fall who demanded a different course in Iraq. He has refused to listen to the Iraq Study Group, which recommended the redeployment of our troops out of Iraq. He has refused to listen to his own generals who have implored him, in many cases, to disengage from this civil war. He has refused to listen to Congress.

The supplemental on its way to the White House echoes what many of us in Congress and military families across this great country have been saying: We need a new direction for Iraq.

We take a backseat to no one in supporting the brave men and women fighting in Iraq. That is why so many of us have pushed this administration, pushed the civilian leadership in the Pentagon and in the White House to equip our soldiers with proper body armor.

We take a backseat to no one in supporting the families of our soldiers overseas. That is why so many of us in this Chamber have pushed to help these support groups that have formed all over the country for soldiers and helping them reintegrate back into their jobs, back with their families and their society when they return home from Iraq.

But more of the same is not a plan for our troops and will not end the war in Iraq. This war has made our country and our world less safe. Congress will continue to fight for our Nation's military by working to see that they have the resources and the support they need and the leadership they deserve.

This legislation fully funds and supports our troops, while establishing conditions that will bring our troops home. It provides desperately needed funding to the Veterans' Administration, something this administration and previous Republican Congresses have woefully underfunded. It provides desperately needed funding to the Veterans' Administration to help care for the hundreds of thousands of new veterans created by this war.

If the President will not take responsibility for his failures in his conduct of this war, then Congress will. If the President will not lead our troops home, then Congress will. We owe it to our soldiers, to our sailors, to our airmen, airwomen, and to our marines, and we owe it to their families.

Instead of threatening a veto, the President should listen to the military leaders, listen to the American people, and work with Congress to change the course in Iraq.

Vetoing this legislation would deny funding our military and our veterans desperately need: $99 billion in emergency Department of Defense spending, more than the President's budget; $3 billion for Mine Resistant Ambush Protected vehicles; $4.8 billion in military construction for BRAC, the Base Closing Commission; and the VA, which has been underfunded by $2 billion in the President's budget, under this bill would get $1.7 billion immediately, more than the President's VA proposal, and will do better in the next budget. It includes $100 million for VA mental health services.

It is absolutely outrageous that this Congress—the House and Senate—and this President send our men and women off to war, not equipping them with the right body armor, not giving them the Mine Resistant Ambush Protected vehicles we know how to build in this country, and then when they return home, not giving tens of thousands of soldiers and marines the health care they deserve.

In addition to what we do to restore that spending and take care of our veterans when they return home, this emergency legislation has over $1 billion for Katrina relief, $13 million for mine safety because of the increase in deaths in mines in places such as Pennsylvania and West Virginia, $625 million for the pandemic flu response, something we absolutely need to be prepared for, and $400 million for energy assistance for the low-income elderly.

Please, Mr. President, before you decide to veto this bill, read this legislation. Don't turn your back on millions of Americans, don't turn your back on your military advisers and the military experts, don't turn your back on our soldiers. Sign this legislation.

HONORING OUR ARMED FORCES

Mrs. BOXER. Mr. President, I rise today to speak about the issue of Iraq, to call on the President to sign the supplemental appropriations bill, the emergency bill that we will be sending him, and also to pay tribute to 43 young Americans who have been killed in Iraq from my State since January 30, 2007. This brings to 720 the number of soldiers who were either from California or based in California who have been killed while serving our country in Iraq. This represents 22 percent of all U.S. deaths in Iraq.

I ask unanimous consent to have printed in the RECORD their names, their ages, the circumstances of their death.

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

SGT Alejandro Carrillo, 22, died January 30, while conducting combat operations in Al Anbar Province, Iraq. Sergeant Carrillo was assigned to Combat Logistics Battalion 7, Combat Logistics Regiment 1, 1st Marine Logistics Group, I Marine Expeditionary Force, Twentynine Palms, CA. He was from Los Angeles, CA.

CPL Richard O. Quill III, 22, died February 1, from a nonhostile cause in Al Anbar Province, Iraq. Corporal Quill was assigned to 2nd Battalion, 4th Marine Regiment, 1st Marine Division, I Marine Expeditionary Force, Camp Pendleton, CA.

CWO Keith Yoakum, 41, died on February 2, in Taji, Iraq, when his helicopter crashed. Chief Warrant Officer Four Yoakum was assigned to A Company, 1st Battalion, 227th Aviation Regiment, 1st Cavalry Division, Fort Hood, TX. He was from Hemet, CA.

SGM Joseph J. Ellis, 40, died February 7, while conducting combat operations in Al Anbar Province, Iraq. Sergeant Major Ellis was assigned to Battalion Landing Team 2nd Battalion, 4th Marine Regiment, 15th Marine Expeditionary Unit, Special Operations Capable, I Marine Expeditionary Force, Camp Pendleton, CA.

SGT James R. Tijerina, 26, died February 7, when the helicopter he was flying in crashed while supporting combat operations in Al Anbar Province, Iraq. Sergeant Tijerina was assigned to Marine Medium Helicopter Squadron 364, Marine Aircraft Group 39, 3rd Marine Aircraft Wing, I Marine Expeditionary Force, Camp Pendleton, CA.

SGT Travis D. Pfister, 27, died February 7, when the helicopter he was flying in crashed while supporting combat operations in Al Anbar Province, Iraq. Sergeant Pfister was assigned to Marine Medium Helicopter Squadron 364, Marine Aircraft Group 39, 3rd Marine Aircraft Wing, I Marine Expeditionary Force, Camp Pendleton, CA.

CPT Jennifer J. Harris, 28, died February 7, when the helicopter she was flying in crashed while supporting combat operations in Al Anbar Province, Iraq. She was assigned to Marine Medium Helicopter Squadron 364, Marine Aircraft Group 39, 3rd Marine Aircraft Wing, I Marine Expeditionary Force, Camp Pendleton, CA.

1LT Jared M. Landaker, 25, died February 7, when the helicopter he was flying in crashed while supporting combat operations in Al Anbar Province, Iraq. First Lieutenant Landaker was assigned to Marine Medium Helicopter Squadron 364, Marine Aircraft Group 39, 3rd Marine Aircraft Wing, I Marine Expeditionary Force, Camp Pendleton, CA. He was from Big Bear City, CA.

SGT Robert B. Thrasher, 23, died on February 11, in Baghdad, Iraq, when his dismounted patrol received small arms fire. Sergeant Thrasher was assigned to D Company, 2nd Battalion, 12th Cavalry Regiment, 1st Cavalry Division, Fort Bliss, TX. He was from Folsom, CA.

PVT Clarence T. Spencer, 24, died February 4, in Balad, Iraq, of wounds suffered when his unit came in contact with the enemy using small arms fire in Baqubah, Iraq. Private Spencer was assigned to the 1st Battalion, 12th Cavalry Regiment, 3rd Brigade, 1st Cavalry Division, Fort Hood, TX. He was from San Diego, CA.

SP Dennis L. Sellen, Jr., 20, died on February 11, in Umm Qasr, Iraq, of noncombat related injuries. Specialist Sellen was assigned to Headquarters and Headquarters Company, 1st Battalion, 185th Infantry Regiment, Army National Guard, Fresno, CA. He was from Newhall, CA.

SP Ronnie G. Madore Jr., 34, died February 14, in Baqubah, Iraq, when an improvised explosive device detonated near his vehicle. Specialist Madore was assigned to the 1st Battalion, 12th Cavalry Regiment, 3rd Brigade, 1st Cavalry Division, Fort Hood, TX. He was from San Diego, CA.

SGT Carl L. Seigart, 32, died February 14, in Baqubah, Iraq, when an improvised explosive device detonated near his vehicle. Sergeant Seigart was assigned to the 1st Battalion, 12th Cavalry Regiment, 3rd Brigade, 1st Cavalry Division, Fort Hood, TX. He was from San Luis Obispo, CA.

LCpl Brian A. Escalante, 25, died February 17, while conducting combat operations in Al Anbar Province, Iraq. Lance Corporal Escalante was assigned to 3rd Battalion, 4th Marine Regiment, 1st Marine Division, I Marine Expeditionary Force, Twentynine Palms, CA.

SGT Clinton W. Ahlquist, 23, died February 20, while conducting combat operations in Al Anbar Province, Iraq. Sergeant Ahlquist was assigned to 2nd Battalion, 4th Marine Regiment, 1st Marine Division, I Marine Expeditionary Force, Camp Pendleton, CA.

LCpl Blake H. Howey, 20, died February 18, while conducting combat operations in Al Anbar Province, Iraq. Lance Corporal Howey was assigned to 2nd Battalion, 7th Marine Regiment, 1st Marine Division, I Marine Expeditionary Force, Twentynine Palms, CA. He was from Glendora, CA.

SP Louis G. Kim, 19, died on February 20, in Ar Ramadi, Iraq, when he received small arms fire. Specialist Kim was assigned to B Company, 1st Battalion, 26th Infantry Regiment, 1st Infantry Division, Schweinfurt, Germany. He was from West Covina, CA.

PFC Rowan D. Walter, 25, died February 23, of injuries suffered when an improvised explosive device detonated near his vehicle during combat operations in Ramadi, Iraq, on February 22. Private First Class Walter was assigned to the 1st Battalion, 9th Infantry Regiment, 2nd Brigade Combat Team, 2nd Infantry Division, Fort Carson, CO. He was from Winnetka, CA.

SGT Richard A. Soukenka, 30, died on February 27, in Baghdad, Iraq, when an improvised explosive device detonated near his military vehicle. Sergeant Soukenka was assigned to the 2nd Brigade Special Troops Battalion, 10th Mountain Division, Fort Drum, NY. He was from Oceanside, CA.

SSG Dustin M. Gould, 28, died March 2, while conducting combat operations in Al Anbar Province, Iraq. Staff Sergeant Gould was assigned to 7th Engineer Support Battalion, 1st Marine Logistics Group, I Marine Expeditionary Force, Camp Pendleton, CA.

Hospitalman Lucas W.A. Emch, 21, died March 2, when an improvised explosive device detonated in his vicinity while conducting combat operations in Al-Anbar Province, Iraq. Hospitalman Emch was a hospital corpsman assigned to 1st Marine Logistics Group, 1st Marine Expeditionary Force, Camp Pendleton, CA.

SP Christopher D. Young, 20, died March 2, in Safwan, Iraq, of wounds sustained when an improvised explosive device detonated near his vehicle. Specialist Young was assigned to Company C, 3rd Battalion, 160th Infantry Regiment, California Army National Guard, San Pedro, CA. He was from Los Angeles, CA.

LCpl Raul S. Bravo, 21, died March 3, while conducting combat operations in Al Anbar Province, Iraq. Lance Corporal Bravo was assigned to 3rd Battalion, 4th Marine Regiment, 1st Marine Division, I Marine Expeditionary Force, Twentynine Palms, CA.

SSG Christopher R. Webb, 28, died March 7, in Baghdad, Iraq, when an improvised explosive device detonated near his vehicle during combat operations. Staff Sergeant Webb was assigned to the 2nd Battalion, 5th Cavalry Regiment, 1st Brigade, 1st Cavalry Division, Fort Hood, TX. He was from Winchester, CA.

SP Adam J. Rosema, 27, died on March 14, in Balad, Iraq, of injuries sustained when an improvised explosive device detonated near his military vehicle. Specialist Rosema was assigned to the 215th Brigade Support Battalion, 1st Cavalry Division, Fort Hood, TX. He was from Pasadena, CA.

SP Stephen M. Kowalczyk, 32, died on March 14, in Muqdadiyah, Iraq, of injuries sustained from small arms fire. Specialist Kowalczyk was assigned to C Troop, 6th Squadron, 9th Cavalry Regiment, 1st Cavalry Division, Fort Hood, TX. He was from San Diego, CA.

PFC Alberto Garcia, Jr., 23, died on March 13, in Baghdad, Iraq, when a vehicle-borne improvised explosive device detonated near his military vehicle was followed by small arms fire. Private First Class Garcia was assigned to C Company, 1st Battalion, 26th Infantry Regiment, 1st Infantry Division, Schweinfurt, Germany. He was from Bakersfield, CA.

LCpl Steven M. Chavez, 20, died March 14, from a nonhostile incident in Al Anbar Province, Iraq. Lance Corporal Chavez was assigned to 2nd Battalion, 4th Marine Regiment, 1st Marine Division, I Marine Expeditionary Force, Camp Pendleton, CA.

LCpl Harry H. Timberman, 20, died March 17, from wounds received while conducting combat operations in Al Anbar Province, Iraq. Lance Corporal Timberman was assigned to 2nd Battalion, 7th Marine Regiment, 1st Marine Division, I Marine Expeditionary Force, Twentynine Palms, CA.

SGT John E. Allen, 25, died on March 17, in Baghdad, Iraq, of injuries sustained when an improvised explosive device detonated near his military vehicle. Sergeant Allen was assigned to the 2nd Battalion, 12th Cavalry Regiment, 1st Cavalry Division, Fort Bliss, TX. He was from Palmdale, CA.

SSG Darrell R. Griffin Jr., 36, died on March, 21, in Balad, Iraq, from wounds suffered when his unit came in contact with small arms fire during combat operations. Staff Sergeant Griffin was assigned to the 2nd Battalion, 3rd Infantry Regiment, 3rd Stryker Brigade Combat Team, 2nd Infantry Division, Fort Lewis, WA. He was from Alhambra, CA.

LCpl Daniel R. Olsen, 20, died April 2, while conducting combat operations in Al Anbar Province, Iraq. Lance Corporal Olsen was assigned to 2nd Battalion, 7th Marine Regiment, 1st Marine Division, I Marine Expeditionary Force, Twentynine Palms, CA.

SP Curtis R. Spivey, 25, died on April 2, in San Diego, CA, of injuries sustained on September 16, 2006, in Baghdad, Iraq, when an improvised explosive device detonated near his military vehicle. Specialist Spivey was assigned to B Troop, 1st Squadron, 10th Cavalry Regiment, 4th Infantry Division, Fort Hood, TX. He was from Chula Vista, CA.

PFC Gabriel J. Figueroa, 20, died on April 3, in Baghdad, Iraq, when he received small arms fire while on dismounted patrol. Private First Class Figueroa was assigned to Headquarters and Headquarters Company, 1st Battalion, 8th Cavalry Regiment, 1st Cavalry Division, Fort Hood, TX. He was from Baldwin Park, CA.

PFC James J. Coon, 22, died April 4, in Balad, Iraq, of wounds suffered when in improvised explosive device detonated near his vehicle. Private First Class Coon was assigned to the 1st Battalion, 8th Cavalry Regiment, 2nd Brigade, 1st Cavalry Division, Fort Hood, TX. He was from Walnut Creek, CA.

PFC Walter Freeman Jr., 20, died April 4, in Baghdad, Iraq, when an improvised explosive device detonated near his vehicle during combat operations. Private First Class Freeman was assigned to the 2nd Battalion, 12th Infantry Regiment, 2nd Brigade Combat Team, 2nd Infantry Division, Fort Carson, CO. He was from Lancaster, CA.

SSG Jesse L. Williams, 25, died April 8 in Balad, Iraq, of wounds suffered from small arms fire while conducting combat operations in Baqubah, Iraq. Staff Sergeant Williams was assigned to the 5th Battalion, 20th Infantry Regiment, 3rd Brigade, 2nd Infantry Division, Stryker Brigade Combat Team, Fort Lewis, WA. He was from Santa Rosa, CA.

LCpl Daniel J. Santee, 21, died April 14, from a nonhostile vehicle accident in Al Anbar Province, Iraq. Lance Corporal Santee was assigned to Combat Logistics Regiment 27, 2nd Marine Logistics Group, II Marine Expeditionary Force, Camp Lejeune, NC. He was from Mission Viejo, CA.

1LT Shaun M. Blue, 25, died April 16, while conducting combat operations in Al Anbar Province, Iraq. First Lieutenant Blue was assigned to 2nd Battalion, 7th Marine Regiment, 1st Marine Division, I Marine Expeditionary Force, Twentynine Palms, CA.

LCpl Jesse D. Delatorre, 29, died April 16, from wounds suffered while conducting combat operations in Al Anbar Province, Iraq. Lance Corporal Delatorre was assigned to 2nd Battalion, 7th Marine Regiment, 1st Marine Division, I Marine Expeditionary Force, Twentynine Palms, CA.

PFC Steven J. Walberg, 18, died April 15, in Baghdad, Iraq, of wounds sustained from enemy small arms fire. Private First Class Walberg was assigned to the 1st Squadron, 4th Cavalry Regiment, 4th Infantry Brigade Combat Team, 1st Infantry Division, Fort Riley, KS. He was from Paradise, CA.

SGT Mario K. De Leon, 26, died April 16, in Baghdad, Iraq, of wounds sustained from enemy small arms fire. Sergeant De Leon was assigned to the 1st Battalion, 18th Infantry Regiment, 2nd Brigade Combat Team, 1st Infantry Division, Schweinfurt, Germany. He was from San Francisco, CA.

PFC Jason M. Morales, 20, died April 18, in Baghdad, Iraq, of injuries sustained when his unit came in contact with enemy forces using small arms fire. Private First Class Morales was assigned to the 1st Battalion, 28th Infantry Regiment, 4th Brigade Combat Team, 1st Infantry Division, Fort Riley, KS. He was from La Puente, CA.

CPL Michael M. Rojas, 21, died on April 18, in Taji, Iraq, when an improvised explosive device detonated near his military vehicle. Corporal Rojas was assigned to C Battery, 1st Battalion, 37th Field Artillery Regiment, 2nd Infantry Division, Fort Lewis, WA. He was from Fresno, CA.

I would also like to pay tribute to the two soldiers from California who have died while serving our country in Operation Enduring Freedom since January 30.

PFC Kristofer D. S. Thomas, 18, died February 18, in southeastern Afghanistan when the Chinook helicopter he was in crashed. Private First Class Thomas was assigned to the 3rd Battalion, 75th Ranger Regiment, Fort Benning, GA. He was from Roseville, CA.

SP Agustin Gutierrez, 19, died on March 29, in Kabul, Afghanistan, when his military vehicle overturned. Specialist Gutierrez was assigned to the 782nd Brigade Support Battalion, 82nd Airborne Division, Fort Bragg, NC. He was from San Jacinto, CA.

Mrs. BOXER. Mr. President, if you come to my office—I think you have had the opportunity to do so—you will see in front of the entrance at 112 Hart four huge placards with very small print paying tribute to those from California who have died in this conflict. The sadness of all sadness is that we keep having to send these posters back to be printed in yet smaller print because we keep having to add so many to it, and we are actually running out of space. We will have to get special permission from the Architect of the Capitol to place yet another placard in front of our door.

But we will do it regardless because we must put names on this conflict, ages on this conflict, we must pay tribute to those who are being sacrificed, in my opinion, by a President who simply will not change course, for whatever reason, from a failed course.

Anyone who reads the Constitution—I highly recommend it; it is a very

readable document; it is a very concise document—will see that when it comes to war, there is a shared responsibility. As a matter of fact, if you read the Constitution, you will see Congress mentioned far more times, far many more times than the President. The President cannot act as if he is king. We already had a king, King George. We have a democracy. This is what the President says our young people are dying for in Iraq. Yet at home he acts as if he is a one-man show when it comes to Iraq.

Mr. President, the American people said no to that this past election. Yet it continues as if there is no Congress, there has been no election, there has been no change of heart by the American people, when, in fact, there has been an enormous change of heart by the American people. That change of heart is reflected in the election, in the composition of this Senate, and you, Mr. President, actually are part of that change, that message that we wanted a change in the leadership. With all of this, it just goes on and on.

Today is the fourth anniversary of the President's speech that major combat operations are over. Four years ago he said that, in a military outfit. Yet, still, in today's paper: April toll is highest of 2007 for U.S. troops. Over 100 killed this month. The Iraqi deaths are far higher.

Three years ago the President said: Major combat operations are over. Today we read: The deadliest month in 2007. As a matter of fact, in the past 3 days—as of yesterday, 3 days prior to that, we had 14 dead. That is about one for almost every person in the President's Cabinet.

What would it be like if 14 people sat around the President's Cabinet table, and every one of them had lost a child? How long would this war last? How long would this war last? But who is paying the price? Who is paying the price? Our military families. They want a change. We want success.

How do you get success? It is by changing course. It is what we sent the President. If you read what we sent the President in this emergency bill—I say to the Presiding Officer, I know you are so aware of it—it is a change in course. We are going to shift, as the Iraq Study Group suggested, from a combat mission to a support mission. We are going to gradually redeploy our troops out of there—not overnight—but sensibly. We are going to leave forces in Iraq to target al-Qaida, which never was in Iraq before this war, and now they are all over it because they want to go after our troops. So we are going to leave troops there in Iraq. That is what the Feingold-Reid-Boxer bill does as well. It says we have to have a mission there to go after al-Qaida when this war is over. We say training the troops is OK. Going after al-Qaida is what we want to do, and we want to have enough troops there for force protection.

So anyone reading this—when the President says it is irresponsible, maybe he has not read it. There is time, Mr. President. You have not gotten this bill yet. Read it again. Look at it. We are changing course in a responsible way, the way the Iraqi Study Group that you praised says we should do. That was a bipartisan group. We all remember it: Secretary Baker, Lee Hamilton, and the others.

Do you know why we have to change course? Because the mission you have given our military cannot be accomplished militarily. The mission now is—and since the mission has changed so many times, we have to go back. The mission now is: Bring stability and democracy to Iraq, and Iraq at peace within its own borders and with its neighbors, and an ally in the war against terror. That is the President's goal. That is a political and diplomatic goal, I say to you, Mr. President. It is not a military goal. The military cannot do that. The military has done everything asked of it, and more.

The first mission: Find the weapons of mass destruction. They went into every nook and cranny of Iraq. There were none. So that mission: done, accomplished.

The President said: Go get Saddam. They did it. That mission: accomplished. That tyrant is gone forever.

He said: Go get his sons because maybe they will get the idea we mean business. The military got his sons, put the pictures on television of their dead bodies. It did not do the job.

What was the next mission? We have to hold elections. The military did a magnificent job. Three elections were actually held, and they have a government. Now, that Government will go on vacation, as I understand it, for 2 months while our troops are dying.

The fact is, the military has done every single thing asked of it. We are now at a point where the only way to win this war is to win it diplomatically, politically. Yet, this President will not change course. His solution is, more military action, a surge, which was supposed to last a few weeks—now we are being told a few months—and our military is paying the price. They are paying the price.

I want to read from this news article today: ''April Toll Is Highest of '07 for U.S. Troops'':

On Monday, U.S. troops at Camp Victory, a sprawling base near Baghdad International Airport, reflected on April's deadly toll on their comrades. . . .

''It makes me feel depressed to be in Iraq right now,'' said [Private Richard] Gonzalez, [22 years old,] who is on his second deployment. ''It's a whole lot different than last time.''

Now, he said, soldiers at the base must carry weapons. Return addresses on letters from home must be ripped off and burned, so as not to fall into the wrong hands. On his first deployment, eight months passed before his Baghdad base was hit by mortar fire.

This time, incoming fire every single day—4 years after ''mission accomplished.''

''There's a whole lot more activity,'' said Spec. Krystal Fowler, 21, of Hampton, Va. She said it ''kind of bothers'' her to know other troops are taking hits in the field and she can't help.

SPC Natisha Jetter said:

Our fellow soldiers are out there dying, and we're here. . . .

Gonzales said the deaths made him realize that ''there's a war going on out there.''

Fowler sighed. It's a war between Iraqis, she said.

''We are just interfering, and letting our soldiers die.''

''I'd rather be out there helping people survive,'' Fowler said. . . .

There was a pause, as the soldiers mulled that.

''It's just terrifying, because you can drive the same road for eight months, and then one day it's over,'' Gonzalez said.

''Over,'' Fowler echoed.

I ask, rhetorically, in light of what our troops are feeling, saying—going there for a second deployment, third deployment and more, and the increased number of deaths of our troops, and the horrific things that are happening in Iraq, detailed in the Red Cross report, which I ask unanimous consent to be printed in the RECORD, Mr. President, this International Red Cross report.

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

CIVILIANS WITHOUT PROTECTION

THE EVER-WORSENING HUMANITARIAN CRISIS IN IRAQ

The humanitarian situation is steadily worsening and it is affecting, directly or indirectly, all Iraqis.

Protecting Iraq's civilian population must be a priority, and the ICRC urgently calls for better respect for international humanitarian law. It appeals to all those with military or political influence on the ground to act now to ensure that the lives of ordinary Iraqis are spared and protected. This is an obligation under international humanitarian law for both States and non-State actors.

The ICRC aims to ensure that Iraqis receive the aid they need most. It cooperates closely with the Iraqi Red Crescent. However, humanitarian aid is clearly not enough when it comes to addressing the immense needs of Iraqis in the present disastrous security situation.

A CONFLICT THAT SPARES NO ONE

The conflict in Iraq is inflicting immense suffering on the entire population. Civilians bear the brunt of the relentless violence and the extremely poor security conditions that are disrupting the lives and livelihoods of millions. Every day, dozens of people are killed and many more wounded. The plight of Iraqi civilians is a daily reminder of the fact that there has long been a failure to respect their lives and dignity.

Shootings, bombings, abductions, murders, military operations and other forms of violence are forcing thousands of people to flee their homes and seek safety elsewhere in Iraq or in neighbouring countries. The hundreds of thousands of displaced people scattered across Iraq find it particularly difficult to cope with the ongoing crisis, as do the families who generously agree to host them.

Health-care facilities are stretched to the limit as they struggle to cope with mass casualties day-in, day-out. Many sick and injured people do not go to hospital because it's too dangerous, and the patients and medical staff in those facilities are frequently threatened or targeted.

Food shortages have been reported in several areas. According to the Iraqi Red Crescent, malnutrition has increased over the

past year. The vastly inadequate water, sewage and electricity infrastructure is presenting a risk to public health.

Unemployment and poverty levels are rising and many families continue to rely on government food distributions to cover their immediate needs. According to government sources, an estimated one third of the population lives in poverty, while over five percent live in extreme poverty.

Much of Iraq's vital infrastructure is in a poor state of repair owing to lack of maintenance and because security constraints have impeded repair work on electrical power grids, water and sanitation systems, medical facilities and other essential facilities.

Power shortages are growing worse throughout the country, including northern areas, owing largely to the failure to carry out maintenance and to increase generation capacity. Fuel shortages affecting power stations and acts of sabotage are further aggravating the crisis. As a result, water-treatment plants, primary health-care centres and hospitals rely mainly on back-up generators, which often break down owing to excess usage or fall victim to the chronic fuel shortages.

The destructive legacy of previous conflicts, from 1980 onwards, and the years of international sanctions imposed on Iraq after its invasion of Kuwait in 1990 are further exacerbating the current crisis.

THE ICRC IN IRAQ

Despite the difficult security situation, the ICRC spares no effort to help the families most in need. It works closely with the Iraqi Red Crescent, which regularly distributes relief provided by the ICRC and collects and delivers Red Cross messages (brief personal messages to relatives made otherwise unreachable by armed conflict).

The ICRC—a strictly humanitarian organization committed to the principles of neutrality, independence and impartiality—strives to monitor and promote respect for international humanitarian law and other legal standards applicable to the current situation in Iraq.

SLIDING TO DISASTER

Since the bombing of the sacred Shiite shrine of Samarra in February 2006 and the subsequent increase in violence, the problem of displacement in Iraq has become particularly acute. Thousands of Iraqis continue to be forced out of their homes owing to military operations, general poor security and the destruction of houses. And the outlook is bleak, particularly in Baghdad and other areas with mixed communities, where the situation is likely to worsen.

Most displaced people have taken refuge with host families, who often struggle to cope with the additional burden on their limited resources. Some have found refuge in camps, public buildings and abandoned military barracks. Where displaced people decide to seek refuge often depends on the presence of relatives or friends and, because of the prevailing sectarian violence, on the religious or ethnic make-up of the host community.

Frequently, both the displaced families and the communities hosting them are badly in need of shelter materials, access to clean water, adequate sanitation, food and other essentials.

The displacement of hundreds of thousands of people places an additional burden on Iraq's basic infrastructure, which is barely sufficient to serve the resident population.

Humanitarian aid is needed by a wide range of particularly vulnerable. civilians, including elderly and disabled people and female-headed households.

MEDICAL CARE UNDER THREAT

Medical professionals are fleeing the country in large numbers following the murder or abduction of colleagues. Hospitals and other key services are desperately short of qualified staff. According to the Iraqi Ministry of Health, more than half the doctors have left the country.

The mass influx of casualties to hospitals following the daily attacks against civilians and other violent incidents is putting the health-care system under tremendous additional strain. Staff and resources are often stretched to the limit.

The failure to observe the special status of medical staff and facilities is a major concern. A hospital director in Baghdad told the ICRC that poor security conditions were preventing staff from providing medical services. And there have been frequent reports of armed men storming hospitals and forcing doctors to give their companions priority treatment at the expense of others in more urgent need.

Road-blocks and check-points sometimes prevent doctors and patients from reaching health-care centres in time. The lack of security also hampers the distribution of medical supplies in many parts of Iraq.

DIRTY AND SCARCE—THE WATER CRISIS

Both the quantity and quality of drinking water in Iraq remain insufficient despite limited improvements in some areas, mainly in the south. Water is often contaminated owing to the poor repair of sewage and water-supply networks and the discharge of untreated sewage into rivers, which are the main source of drinking water. Electricity and fuel shortages and the poor maintenance of infrastructure mean that there is no regular and reliable supply of clean water and that sewage is often not properly disposed of.

TORN APART—THE FATE OF SEPARATED FAMILIES

Tens of thousands of people are currently being detained by the Iraqi authorities and the multinational forces in Iraq. Many families remain without news of relatives who went missing during past conflicts or the current hostilities.

Visiting people detained in connection with the armed conflict in Iraq remains a humanitarian priority for the ICRC. Persons held by the multinational forces or the Kurdish regional government are regularly visited to assess their conditions of detention and treatment.

THE ICRC IN 2006

Over 227,000 people, mostly members of displaced families, received food aid in various parts of Iraq. Over 161,000 people received essential household items.

Some 83,000 people, including members of displaced families, had their water supply ensured through emergency ICRC water and sanitation projects.

In all, over four million people benefited from water and sanitation projects.

Twenty major hospitals in Hilla, Baghdad, Diwaniya, Karbala, Najaf and Tal Afar received medical and surgical supplies for the treatment of wounded patients.

Eight limb-fitting centres in Baghdad, Hilla, Najaf and Basra were supported by the ICRC, as was an Iraqi Red Crescent centre in Mosul. This was in addition to the Arbil centre, which is run entirely by the ICRC. In all, these centres helped nearly 21,000 patients, who received 7,300 artificial and some 460 pairs of crutches.

Twelve hospital emergency wards received new equipment.

Ten hospitals, with a combined capacity to treat some 5,000 inpatients, had their water and sanitation systems repaired.

Sixty-seven primary health-care centres in Anbar, Babel, Baghdad, Diwaniya, Karbala, Salah AI Deen and Wasit governorates had their sanitation facilities repaired or upgraded. They treat an average of over 9,000 patients per day.

More than 32,000 detainees were visited, almost 9,000 of them individually, during 109 visits to 28 places of detention.

Nearly 6,400 detainees held in Camp Bucca and in the Shaiba facility benefited from the ICRC family-visit programme.

Nearly 37,000 Red Cross messages were delivered and over 30,500 collected by the ICRC in conjunction with the Iraqi Red Crescent.

Mrs. BOXER. This report is called ''Civilians Without Protection.'' I will go into it in a minute. But in light of everything that is happening, how on Earth could the President sit in the Oval Office and say: ''I am vetoing this bill that is coming to me, and I want to just continue what I am doing''? A military solution is what he is doing, and he is going to continue it.

In light of everything that has gone on, doesn't this President understand it is time for a change? Doesn't he listen to the voters? Doesn't he read these articles? ''Send me the bill. I am going to veto it''—very macho like. I do not think it is macho like. I think it is wrong. I do not think it is brave to continue a policy that is failing. I do not think it is courageous not to admit it is time for a change. I do not think it shows strength. I think it is stubborn. I think it is wrong. And, worst of all, our troops are paying the price for this stubbornness. This is not the same as being stubborn in an argument we might have about some small matter. Oh, I think this book is better than this book, and I think this singer is better than this one. This is involving the lives of our soldiers.

Now, this ''Civilians Without Protection'' report is very tough to read, by the International Red Cross. Let me share some of it with you: the pictures, the headlines, the words.

One section is called ''A conflict that spares no one.''

In some regions, particularly Baghdad and area, families are often too afraid to leave their homes to go to work or to shop and too afraid to send their children to school because of random violence and the threat of kidnapping for ransom.

This one is very tough to take—very tough to take. It is written by a young humanitarian worker from Baghdad. It is in the Red Cross report.

Once I was called to an explosion site. There I saw a four-year-old boy sitting beside his mother's body, which had been decapitated by the explosion. He was talking to her, asking her what had happened. He had been taken out shopping by his mom.

How do you sit back and say ''status quo''? How? How? Why not welcome a change? Why not welcome the Iraq Study Group? Why not welcome the work that has been done here in 50, 60 different hearings which we have held?

Another part: ''Sliding to disaster,'' in the International Red Cross report. Another part: ''Medical care under threat.'' Another part: ''Dirty and scarce—the water crisis.'' Another part: ''Torn apart—The fate of separated families.'' It goes into the agony. I ask us all to imagine what it would

be like to worry about our kids for even 15 minutes, let alone days and months.

This Red Cross report is printed in the RECORD.

Mr. President, also, I ask unanimous consent that the entire article I referred to from the newspaper be printed in the RECORD.

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

[From the Washington Post Foreign Service, Tuesday, May 1, 2007]

APRIL TOLL IS HIGHEST OF '07 FOR U.S. TROOPS

(By Sudarsan Raghavan and Karin Brulliard)

BAGHDAD, April 30.—The deaths of more than 100 American troops in April made it the deadliest month so far this year for U.S. forces in Iraq, underscoring the growing exposure of Americans as thousands of reinforcements arrive for an 11-week-old offensive to tame sectarian violence.

More than 60 Iraqis also were killed or found dead across Iraq on Monday. Casualties among Iraqi civilians and security forces have outstripped those of Americans throughout the war. In March, a total of 2,762 Iraqi civilians and policemen were killed, down 4 percent from the previous month, when 2,864 were killed. Iraq's government has yet to release any monthly totals for April.

Attacks killed a total of nine U.S. troops over the weekend, including five whose deaths were announced Monday. The weekend's fatalities brought the toll for the month to 104 Americans killed, in the sixth most-lethal month for American forces since the U.S.-led invasion four years ago.

Under the new counterinsurgency plan, many U.S. forces have left large, more secure bases to live in small combat outposts and to patrol hostile neighborhoods where the risk of insurgents targeting them has multiplied.

Highlighting the vulnerability of American forces, a series of explosions Monday night rocked Baghdad's Green Zone, the most heavily secured enclave in the capital and home to thousands of U.S. troops, Western diplomats and Iraqi government officials.

''There is a duck-and-cover going on right now,'' said Lt. Col. Christopher C. Garver, a U.S. military spokesman, before quickly getting off the phone. Later, Garver confirmed there had been an assault on the Green Zone, but it was unclear what had happened. Local Iraqi television stations reported 10 explosions inside the zone. There were no immediate reports of casualties, Garver said.

In eastern Baghdad on Sunday, a roadside bomb killed three U.S. soldiers and an Iraqi interpreter who were on patrol, the military said. Attackers shot dead another soldier in the same section of the capital on Saturday. Meanwhile, a Marine was killed in the Sunni insurgent bastion of Anbar province, west of Baghdad. On Saturday, the military reported four U.S. soldiers had been killed on that day.

Before the deaths announced Monday, 99 U.S. soldiers had been killed during April, according to iCasualties.org, an independent Web site that monitors military deaths. Nearly half have died in and around Baghdad, with the next greatest number of deaths occurring in Anbar and Diyala provinces. In December, 112 U.S. soldiers were killed.

With 11 combat deaths, April also was the deadliest month for British troops in Iraq since the beginning of the war, when 27 soldiers were killed in March 2003. This month's British casualties highlighted the growing tensions in southern Iraq as Shiite groups clash for power and Britain prepares to draw down its forces.

The deaths came as the largest bloc of Sunnis in Iraq's parliament, the Iraqi Accordance Front, threatened to pull out its ministers from the cabinet, saying that it ''had lost hope'' in having Sunni concerns addressed by the Shiite-led government. The threat prompted President Bush to phone one of Iraq's two vice presidents, Tariq al-Hashimi, a Sunni, in an attempt to defuse the potential political crisis, Hashimi's office said in a statement. A Sunni withdrawal could seriously hamper efforts at national reconciliation and further weaken the government. Only two weeks ago, six cabinet ministers loyal to Shiite cleric Moqtada al-Sadr resigned from the cabinet.

In the province of Diyala, where scores of fighters have fled to escape the Baghdad security offensive, a car bomb exploded near a funeral tent in the town of Khalis, killing 22 and wounding 35, said Lt. Mohammed Hakman of the Diyala police Joint Coordination Center. Police said they expected the toll to rise.

The strike came four days after a suicide attacker detonated a car packed with bombs at a checkpoint in the town, 50 miles north of Baghdad, killing 10 Iraqi soldiers.

Near the Sunni insurgent stronghold of Ramadi, a car bomb exploded at a police checkpoint, killing four policemen and injuring six others, police said. In another attack near Ramadi, a truck exploded near a restaurant, killing four civilians, police said.

In Baghdad, a car bomb exploded in the al-Jihad neighborhood, killing four and wounding another seven, all civilians, while another car bomb detonated in a local market, killing five and wounding nine civilians. In the Shaab neighborhood, mortar shells rained down on a house, killing three and injuring eight, police said.

Meanwhile, police found 13 corpses—all blindfolded, handcuffed and shot in the head—in different parts of the capital.

On Monday, U.S. troops at Camp Victory, a sprawling base near Baghdad International Airport, reflected on April's deadly toll on their comrades.

Sitting at a picnic table outside a recreation center, four soldiers smoked Marlboros under a starry sky. Part of the Headquarters Headquarters Support Company for the 3rd Infantry Division out of Fort Stewart, Ga., they had arrived last month. They were on the base, just ''sweeping parking lots and waiting for a sandstorm,'' as Pfc. Richard Gonzalez, 22, put it.

Still, they said, frequent news of troop deaths made even their mission more frightening.

''It makes me feel depressed to be in Iraq right now,'' said Gonzalez, who is on his second deployment. ''It's a whole lot different than last time.''

Now, he said, soldiers at the base must carry weapons. Return addresses on letters from home must be ripped off and burned, so as not to fall into the wrong hands. On his first deployment, eight months passed before his Baghdad base was hit by mortar fire. This time, he said, it seems the Camp Victory intercom announces incoming fire every day.

''There's a whole lot more activity,'' said Spec. Krystal Fowler, 21, of Hampton, Va. She said it ''kind of bothers'' her to know other troops are taking hits in the field and she can't help.

Spec. Natisha Jetter, 23, of Charlotte Amalie, St Thomas, in the Virgin Islands, agreed.

''Our fellow soldiers are out there dying, and we're here not doing our job,'' Jetter said.

Gonzalez said the deaths made him realize that ''there's a war going on out there.''

Fowler sighed. It's a war between Iraqis, she said.

''We are just interfering, and letting our soldiers die.''

''I'd rather be out there helping people survive,'' Fowler said. ''The more of us that are out there, the more chances they have to survive.''

There was a pause, as the soldiers mulled that.

''It's just terrifying, because you can drive the same road for eight months, and then one day it's over,'' Gonzalez said.

''Over,'' Fowler echoed.

Mrs. BOXER. This President's policies left unchecked have been a disaster. And what does he want? More of the same. He criticizes us for coming up with a new policy, and this new policy will work because it combines a gradual redeployment of troops, a focus on getting al-Qaida, a focus on training the Iraqis, with a focus on diplomacy and a political solution, which is exactly what everyone says we need.

General Petraeus says we must have a political and diplomatic solution. Well, everyone has heard it, but obviously not this President. Mr. President, sign this bill. Have a change of heart. Read the paper today. Read the quote from this humanitarian worker. Read what our troops are saying. Read about it. Reconsider.

Also, Mr. President, take a look at what we have done for our people here at home in this bill. You deride it. You make it sound as though we are spending on things we should not. Why shouldn't we fix Walter Reed? Why shouldn't we fix the Veterans' Administration so when our soldiers come home they get mental health care? Why shouldn't we invest in better technologies to protect our troops from these horrific land mines, car bombs, et cetera? That is what is in this bill.

Why shouldn't we help our farmers who lost their money because of horrific droughts, horrific frosts? That is what these bills are for, emergencies. On Sunday, we all learned about the horror that happened in Oakland, with a gasoline tanker overturning on a major interstate connecter. It collapsed onto the freeway below. Miracle of miracles: the middle of the night, in the early morning, 3:40 or so a.m. No one killed. Thank you, God. And we pray that the driver survives.

But here is the point: There is money in this bill for emergencies such as that. There is a backlog of these emergency fixes that have had to be done to our freeways. So, Mr. President, there is real beef in this bill for our people, for our veterans, for our fighting men and women. And, most important, we change course. We change course. We don't have a hard-and-fast date to get out, as others have said. We have a goal to get out: in April of 2008.

When I went to Iraq 2 years ago, I met with General Petraeus at length. I watched how he was training the Iraqi soldiers. He was very complimentary. He said they are doing great. I said to him: If they are doing so great, why can't we go home? It is their country.

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

As Thomas Friedman said,

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

They are protecting the Sunnis from the Shia. When they are protecting the Shia, the Sunnis get them. That is an irresponsible policy. So what we need to do is get through to this President. I ask all the American people to keep on speaking out, to ask the President in these next couple of hours to sign this bill. We can finally change course. We have been in Iraq longer than World War II. We can't afford this conflict, and that doesn't mean you cut and run. Anyone who says that is what we are saying is wrong. Read the bill. We redeploy out of Iraq, we stay in the region to go after al-Qaida and to train the Iraqi forces.

We can't afford this anymore. Mr. President: Sign the bill.

I yield the floor.

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

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

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

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

POLICE CHASES

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

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

In the middle of working on this, over the years, a county sheriff called me one day. He heard me speak about it. He said: You know, just last week we had a man who was a drunk driver in our community who had two little children in the backseat. The sheriff's department attempted to apprehend that driver, and he took off at a high rate of speed. The sheriff's office decided to discontinue the chase immediately. They got a license number. They discontinued the chase. Three hours later, they arrested the man.

He said: It could have turned out differently. We could have chased that man at 80 to 100 miles an hour, and the end of that chase could have resulted in the death of those children in the backseat of that car. But we didn't do that because we had guidelines and we had training.

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

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

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

Law enforcement needs guidelines. They need training to understand what the consequences are—when to chase, when not to chase. Regrettably, I believe the Supreme Court ruling yesterday will result in more high-speed police chases and more deaths of innocent Americans. That is a profound disappointment, not just to me but to many others in this country who have seen the results of these high-speed chases.

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is closed.

PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

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

The legislative clerk read as follows:

A bill (S. 1082) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

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

The Senator from North Dakota is recognized.

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

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

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

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

Mr. President, I ask unanimous consent to show a couple of bottles of medicine.

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

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

The difference? No difference—same plastic in the bottle, same medicine inside—except the price. The Canadian pays $1.83 per tablet, and the American pays $3.57—96 percent more. Let me say that again: No difference, same medicine, same bottle, same price, made in the same plant, FDA approved. Difference? The American consumer is told: Guess what, we have a special deal for you, you get to pay 96 percent more for the same medicine.

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

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

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

We have a population that receives a lot of benefit from miracle drugs. There are prescription drugs that allow you to manage your disease without having to go to an acute care bed in a hospital. It is a wonderful thing.

A substantial portion of the research to develop those drugs is done in the National Institutes of Health, paid for by us. We turn that research over to the prescription drug industry, they produce medicine from it, and then they sell us the medicine.

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

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

The issue is pricing. I have described what is happening with respect to pricing. This is Canada, but I can describe it for other countries as well. The percent of adults, ages 19 to 64, not filling a prescription because of cost, 43 percent of the uninsured in this country—that is 45, 46 million—do not take their medicine because they do not have the money. They say it costs too much.

The result? Well, often many of them will end up in the priciest kind of health care, some kind of an acute care bed through an emergency room in a hospital.

The legislation we have developed in Congress is bipartisan. It stretches from—I shouldn't say stretches because I am not describing the polls in Congress. But we have TED KENNEDY, Democrat; CHUCK GRASSLEY, Republican; DEBBIE STABENOW, Democrat; JOHN MCCAIN, Republican; back and forth. Bipartisan support for a piece of legislation we have crafted very carefully that says: Why shouldn't the American people be able to take advantage of FDA-approved drugs by reimporting them from another country where that same drug is sold for a fraction of the price? Why shouldn't the global economy work for consumers as well? This is bipartisan legislation that has substantial areas of safety built into it, so there is no safety issue. This is from Dr. David Kessler, who was head of the FDA for 8 years, 1990 to 1997. ''The Dorgan-Snowe bill''—OLYMPIA SNOWE is the principal cosponsor, along with me and many others who have worked on this—Senator STABENOW and Senator MCCAIN and others for a long time, Senator KENNEDY.

The Dorgan-Snowe bill provides a sound framework for assuring that imported drugs are safe and effective. Most notably, it provides additional resources to the agency to run such a program, oversight by the FDA of the chain of custody of imported drugs back to the FDA-inspected plants, a mechanism to review imported drugs to ensure that they meet FDA's approval standards, and the registration and oversight of importers and exporters to assure that the imported drugs meet these standards and are not counterfeit.

Let me show you where your prescription drugs come from. The pharmaceutical industry is engaged in a full court press with Members of this Chamber. They have a fair number of friends in this Chamber who would want to help them derail this legislation and continue to be able to charge the highest prices to the American consumer.

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

The legislation we have introduced is very simple. It gives the American consumer the opportunity to take advantage of lower prices for an FDA-approved drug; in many cases, by the way, a drug that was created with the very research that the American people paid for through the National Institutes of Health.

Some have said, as a result of the pharmaceutical industry's entreaties here, well, this can't be done safely. It cannot be done safely. Well, apparently, they do it safely. The chain of custody, for example, in Canada is virtually identical. I had a quote that I do not have here. I had a quote from Dr. McClelland, the former head of the FDA, virtually identical chain of custody from Canada as opposed to the United States between the pharmaceutical manufacturer, the wholesaler, and the retailer.

So is the chain of custody in Canada safe with respect to prescription drugs being sold to Canadian consumers? The answer is yes. So why would you not be able to establish a regime, just as they have in Europe for many years, called parallel trading? This is not new. If you are in Europe and you are living in Germany and want to buy a prescription from Spain, or living in Italy and find a prescription drug priced lower in France through a parallel trading system, you can easily do that.

To my knowledge, we have testimony from one of the people involved. To my knowledge, there have been no issues of safety at all. They have done it for 20 years. Are those who oppose this saying, well, the Europeans are smarter than we are, they can do it but we can't? I don't understand that. That is not the case. I don't understand that.

This is a very simple case. We propose an amendment that would allow drug reimportation and would make it safe. That is the fact.

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

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

That is why we have put together a bipartisan piece of legislation, the Dorgan-Snowe bill, that is supported by Republicans and Democrats, which now has 33 cosponsors. It is one that should pass in the Senate. The House has already passed a similar piece of legislation in the last session. I believe, finally, given a fair opportunity—and I believe we will be given that fair opportunity whether it is on this bill or perhaps with some consent to do it on another bill, I believe we will get this done.

This is important. There are some things we do that are not very important at all. My criticism—it is a great privilege to serve here. My criticism of this place is from time to time we treat the light way too seriously, and we treat the serious far too lightly. This is a serious issue that deserves to be treated seriously.

It has been around for a long time. We have not had a vote on it only because we have been blocked by, I would say, Senator Frist, the majority leader, for a long time, despite what I thought and my colleagues thought was a representation by him that he would allow us to have this on the Senate floor. He continued to block it.

I understand the pharmaceutical industry is pulling out all of the stops. They have a full court press, trying to find as many Members of the Senate as they can who will stand up for their current pricing strategy. And they will find a few, no question about that. I think there are some Members of the Congress who like the pricing strategy of saying let's price drugs so that the American people pay the highest prices in the world. But I am very anxious to get them here to the floor to debate them on that subject because they are wrong. It is just wrong. It is wrong to do this to the American people.

One final point. I don't disrespect the pharmaceutical industry. I say good for you when you produce a miracle drug, a lifesaving drug. But miracle drugs offer no miracles to people who can't afford to buy them. My problem with the pharmaceutical industry is the pricing strategy, the pricing strategy which says to the American people: You pay the highest prices in the world, and there is nothing we will let you do that can alter that. That is wrong. That is why I and others come to the floor of the Senate to say let's fix this. Not later, let's fix this now.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from California is recognized.

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

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

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

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

Most Americans who turn to imported drugs do so because of the cost. We need to answer a lot of questions before we open our borders to imported drugs to be sure we don't endanger consumers or jeopardize research or jeopardize the development of new lifesaving products. Senator DORGAN, of course, introduced a bill last year. He made the statement that miracle drugs provide no miracles for those who can't afford them. I don't think there is anybody in this Chamber who couldn't agree more with that statement, but I am sure they would agree that a counterfeit or tainted drug is unsafe at any price.

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

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

I was talking to the Senator from Colorado, Mr. ALLARD, who is a veterinarian, and he was pointing out this morning that if you take a fingernail, that is 100 percent protein. If you take the liver, that is 100 percent protein. One of the differences is if you grind liver up and you put it in food, it is digestible. If you grind a fingernail up and put it in food, it isn't digestible at all. So you are not getting any protein out of it. So kids have died in China who thought they were getting sufficient food, and they weren't. The cause of death was starvation. One of the countries that could be getting drugs to the United States would be China. If they are fooling with our food supply, do you think they would hesitate a minute to fool with our prescription drug supply? It worries me a lot. There is a lot of risk that is involved in this.

The Senator from North Dakota held up two bottles. The bottles were identical. One was cheaper in Canada than the same bottle in the United States. In a minute, I will go into how that price difference happens. I could hold up two bottles that would look exactly the same. One would appear to come from Canada, but it might very well come through Canada from Saudi Arabia, have exactly the same packaging, labeling, colors, seals, even the same look of a pill. But one of the things we found out from some of these drugs that have come from other countries through Canada is that they don't work. If you grind them up, they have exactly the same chemicals in them, but it isn't just the chemicals that do it, it is the way they are put together that makes it possible for them to solve a medical problem. If they are put together wrong, they may not even digest. If they don't digest, similar to a fingernail, you don't get the benefit from the drug. If you don't get the benefit from the drug, you shouldn't pay anything for it. In fact, there ought to be some pretty severe action taken against the person or country or company that produced that kind of a drug. We are not able to do that.

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

We know each one of us takes a risk every time we take a drug, but Americans who buy prescription drugs in Canada and other countries or purchase drugs from Internet pharmacies

that operate outside the United States are taking an even greater risk by obtaining their prescription medicine from pharmacies and Internet sites that don't always meet the high standards we require here at home. Here is where my concern lies. We already have a problem with counterfeit and substandard drugs in the United States. Concern about the quickly growing counterfeit market is not limited to the United States. In Europe, dangerous counterfeit drugs are already a problem, and the problem is growing as the European Union expands. In addition, we have little knowledge of the extent of counterfeiting in Asian markets such as India, Pakistan, and China, other than that it may be the best.

Now, prior to legalizing an untested, drug importation project on a large scale across our Nation, we must consider any new vulnerabilities in our drug distribution system, especially since those vulnerabilities could be massive in size. I know we all share the same goals. We want to ensure that drugs are safe, effective, and will not compromise the integrity of our Nation's prescription drug supply or our world-leading pharmaceutical research, and we want it to be at the lowest possible cost. Similar to many Americans, I am concerned about the high and rising cost of prescription drugs. However, I doubt the importation of drugs from other countries will solve that problem all by itself. We better be certain about exactly what we are doing and how we are going to do it. We have had some hearings on that. We have also gotten some phone calls from the Canadian Minister in charge of the program who has said: Do you realize that if America suddenly started buying its drugs from Canada, we would have to prohibit Americans from doing it. We are a small country. We could not take the amount of orders we might possibly get because we do have price fixing.

We talk about negotiated prices and we talk about that in the context of Medicare drugs. Congress passed and the President implemented Medicare Part D that actually came in considerably lower in cost for drugs for American seniors than what we or the Government Accountability Office had ever anticipated—dramatically lower. Why? Because of competition. How does a country negotiate drug prices? Well, the way Canada did it was they said: If there are five drugs that treat heart problems, we make a bid for one drug against another drug. If there are five heart drugs, they all don't do the same thing. Some doctors would prescribe one and others would prescribe another. But if you are going to negotiate prices, you make the five bid against each other and you pick one or two, and you tell the rest of them they can't sell their drugs there, that the Government would not have any part of it. This eliminates choices.

Then there is another little caveat that some of the countries add to that which says: If you don't come in with a low enough price, we are going to give your patent away and you would not get anything for it. We have some real patent issues if we are going to have people investing in the research to get new drugs passed and approved, and we should take a little look at the process that you have to go through to get a drug approved. It is about a $1 billion project to get a drug approved. They don't do that because they are wanting to donate $1 billion; they are doing it because they expect there will be some profit on the other end of selling the drug. Otherwise they wouldn't go through all that research, all the trouble, all the clinical trials, and then turn it over to people for free. They give away quite a few drugs, but that is to people who can't afford them. There is a lot to the fact that we have more pharmaceutical companies developing more drugs than anywhere else. I am pleased that through our committee we found out there are over 650 clinical trials happening right now on various cancer drugs. That is just in the area of cancer: 650 drugs in the pipeline. That is a lot of billions of dollars being spent for us.

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

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

So I look forward to a spirited discussion. I think it will answer some of my questions about the legislation and will hopefully inform us all on the best direction we can take from here. There are possibilities for solutions on drug importation. I hope it will be a separate discussion from how the Food and Drug Administration administers the safety of pharmaceuticals and medical devices and particularly when they concern children. We actually forced the pharmaceutical companies and the medical device companies to pay to have their products tested and reviewed. That is what a big portion of this bill is about: how they will pay for having the products tested and reviewed.

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

There is also a portion on that which deals with pharmaceuticals for children. It is important that tests be done with the pharmaceuticals to be sure they are safe for children and in what dosage they are safe for children. There is a portion of the bill which gives incentives to companies that will go to that extra length to see which of the drugs can be used for children as well. That is another potential for a fascinating discussion over the next couple of days.

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

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

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

Another problem is biosimilars. There is a whole new area of drugs that has come out because the genome has

been unlocked and proteins can be developed which can be used as medication which will solve some of those genetic problems. Those are called biologics. There are people who would like them to become generics right away because that would bring the cost down. Again, we want to make sure we have a bill that takes care of the safety of the biosimilars, to be sure they truly are similar and will have the same effect. The Europeans have been working on that for a while. We have looked at their model and a number of Senators—again from both sides of the aisle—have been working on that problem. Senator CLINTON and Senator HATCH have been very involved in that, providing guidance from both sides of the aisle. We appreciate their efforts on it. I do not expect that to be a part of this bill.

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

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

I thank everybody for their cooperation and patience.

I yield the floor.

The PRESIDING OFFICER (Mr. CASEY). The Senator from Idaho is recognized.

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

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

ENERGY

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

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

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

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

I do believe that is what the American consumer is saying today—help me. And to the Congress of the United States and to this Senate, that sound ought to be echoing through this Chamber and certainly through the halls and the committee rooms that deal with national energy policy.

We are where we are today for absence of policy and for some policy that has driven us to less production and becoming increasingly more reliant upon someone else to produce our energy for us. It is in that context of a Mayday appeal that I speak for a few moments during this noon hour.

Here is what the chart shows us very clearly. From 1890 to 2030, these are the trend lines. In 1950, we crossed a unique point when we began to see our demand outstrip our supply, and this now—well over 50 percent of our consumption—is being picked up by other countries in the world that are, in many instances, less friendly to us than we would like.

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

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

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

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

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

But the one that hasn't yet been marked up and the one I wish to spend a little time on today is the area of continued production of hydrocarbons in the Outer Continental Shelf. I have called this in the past the ''no zone'' speech. Let me combine that with Mayday. While we are saying no, our consumers are saying: Help me, help me, because I am spending more of my discretionary income on consumables and in the form of energy at a rate and level I never had to before. It is causing the American economy to shift significantly.

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

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

I came to the floor some time ago and spoke of what is going on in Cuba, and I said that was an unacceptable thing and we ought to do something about it. So in the legislation we are talking about, for greater flexibility

and opportunity in the Outer Continental Shelf, what we are really talking about in the SAFE Act—that last title yet to be introduced—that really balances conservation with new biofuels and increased production in this area, better known as the northern Cuban basin. It is an area that is off limits to our producers, and Cuba is now moving to produce it. They are going to do so by reaching out to other countries—other than ours because we have a prohibition on our companies doing business there—and they are looking at the French, Spaniards, the Chinese, and others to come and drill.

Here is my frustration: While we are saying no, all around our coastlines, just 45 miles off our coastline, the Cubans have let leases for the purpose of drilling.

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

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

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

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

I yield the floor.

The PRESIDING OFFICER. The Senator from Texas.

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

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

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

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

This nation now accounts for 14 percent of America's oil imports, and Mr. Chavez has promised to use his ''strong oil card'' to, in his words, ''finish off the U.S. empire,'' even if that means colluding with some of the most nefarious regimes on Earth.

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

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

President Chavez hopes that the profits from the Orinoco Belt will flood his coffers for other foreign adventures. But by asserting government control over this coveted region, he is actually killing the golden goose that feeds his socialist-inspired revolution.

President Chavez's national oil company has already shown signs of stress. Despite record oil prices that should be a boon for the industry, the state-run company has been forced to accumulate a rapid increase in debt to pay for a doubling of ''social development spending.'' Meanwhile, its spending on energy exploration and production badly trails its global peers.

In addition, the Orinoco Belt pronouncement has made ExxonMobil, Conoco Phillips, and other energy companies extremely cautious about putting their employees and billions of dollars in assets under Venezuelan management, and for good reason.

If those American corporations decide to withhold their expertise and investment, it could further weaken the Chavez Government's pursuit of socialist dreams and redistribution of wealth. ''It seems as if they are going to strangle themselves with their own rope,'' said a foreign oil analyst who chose not to be identified for fear of retaliation.

President Chavez's gross mismanagement of the economy should be no surprise to anyone who has followed the career of his Cuban mentor, Fidel Castro. In less than half a century, Fidel Castro has turned what was once the third richest nation in Latin America into one of the poorest nations in the world, a real-life prison for 11 million people who rely on remittances from abroad to avoid starvation and collapse.

If President Chavez continues to adopt the Castro economic model, the greatest victims will be the Venezuelan people, but America will also suffer. That is because the deterioration of Venezuela's oil industry could spark a surge in oil prices for American consumers, and we all know that prices have already jumped in the last 30 days. Anyone who has filled a gasoline tank knows this would be a huge hit on the American economy. In fact, some economists say every time oil prices rise by 10 percent, an average of 150,000 Americans lose their jobs because it presses the economy. Margins are narrowed, and that means people are laid off.

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

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

Using the comprehensive energy legislation we passed last year, I was very pleased to see the announcement yesterday by the Department of the Interior that we would, in fact, increase production of the natural resources in this country. The Secretary, Dirk Kempthorne, who was once a Member of this body, announced that there would be 21 lease sales in eight planning areas which could produce 10 billion barrels of oil and 45 trillion cubic feet of natural gas over 40 years. That would generate about $170 billion in today's dollars.

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

They are doing exactly what Congress has authorized them to do—looking in the Outer Continental Shelf. Even the Commonwealth of Virginia is

positive about this move because there are now incentives for States to allow production in the waters they control. This is one part of what we must do as part of a comprehensive approach to energy independence.

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

We have the resources to achieve energy independence—the resources underneath our land and water—and the best resource of all, the ingenuity of our free, creative minds. Now we need the willpower to use it.

President Chavez's announcement today is a tremendous challenge to America's energy future, but if we choose to be proactive, as we've always been throughout our history, we can regain control of our energy resources, and be the strongest Nation on Earth.

We can write our own history, and today is the wake-up call that assures we must do it.

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

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

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

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

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

EMERGENCY SUPPLEMENTAL APPROPRIATIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

So we have a mission. It is a sacred and important mission. We must change the mission in Iraq away from

policing a civil war and toward counterterrorism, which requires fewer troops and gets many more of them out of harm's way. That is what our bill does. It is what the American people want. It is what the facts on the ground demand.

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

I yield the floor.

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

RECESS

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

Thereupon, the Senate, at 12:46 p.m., recessed until 2:15 p.m. and reassembled when called to order by the Presiding Officer (Mr. CARPER).

PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007—Continued

The PRESIDING OFFICER. The Senator from Oklahoma is recognized.

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

Briefly, what is the order right now?

The PRESIDING OFFICER. The Senator is recognized. The Senator has as much time as he may consume.

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

Secondly, briefly, as I see the manager of the bill is here, we will be introducing an amendment No. 988, having to do with protecting children from parents being coerced into administering a controlled substance or psychotropic drug in order to attend school.

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

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

The PRESIDING OFFICER. The Senator from Oklahoma is recognized.

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

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

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

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

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

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. REED. Mr. President, I believe the Food and Drug Administration Revitalization Act before us today raises and addresses issues that are critically important to the public's health and well-being. Congress has a historic opportunity to strengthen and increase knowledge about drug safety and effectiveness, bring more transparency to the process of drug approval and surveillance, as well as reassess the goals of the prescription drug and medical device user fee programs, and fortify and expand essential safety programs for children. The FDA Revitalization Act strikes a careful balance between these many important priorities and objectives.

Recent serious adverse drug events related to several widely used drugs on the market underscore the urgency with which we should address and improve drug safety in this country. Moreover, as the population ages and science inevitably advances, more and more drugs will come to market, presenting potentially groundbreaking health benefits to the public, but simultaneously increasing the need for sophisticated mechanisms for monitoring and assuring drug safety.

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

The primary mechanism this bill uses to strengthen drug safety is to strengthen and rearticulate the FDA's authority. The bill clarifies, and in some cases fortifies, the FDA's authority with regard to drug safety. Currently, if the FDA detects a problem, or a potential problem with a drug post approval, they have few options beyond what is often referred to as the ''nuclear option.'' That is, pulling a drug from the market. While the FDA's authority to pull a drug from the marketplace is a powerful tool, it is a blunt instrument. In order to prevent problems from spiraling into major public health crises, the FDA needs intermediary authority. The FDA's reluctance to pull a drug, potentially a drug upon which millions of Americans depend to manage an illness, unless it is overwhelmingly certain that the action is necessary, is understandable. However, prescription drug users suffer as a result since the ''nuclear option'' offers a forceful, but ultimately limited response. Pulling a drug from the market potentially delays action and places individuals at major health risks in the interim. On the flip side, pulling a drug prematurely may needlessly deny patients important, and in some cases, singular, treatments for their health needs. This bill offers what I believe is a good solution to this paradox; one that considers input from patients rights organizations, industry representatives, and the FDA, but ultimately places patients at the top of the list.

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

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

Another important objective of the FDA Revitalization Act is to improve the integrity of the agency and to enhance transparency on its actions. I am pleased that this bill improves the public's access to information about clinical trials and, more importantly, the results of those trials. The bill enhances patient enrollment in trials by requiring late phase II, as well as phase III and phase IV clinical trials on drugs are registered in a publicly available database. This will improve the public's knowledge of important and potentially life saving clinical studies. The bill also creates a publicly available database of the results of those trials. This means, for instance, that a parent who wishes to understand why a much-talked about treatment for juvenile diabetes failed to advance past a clinical trial stage can track the progress of a treatment using this database. It is important that we empower patients and consumers to gather information from primary sources so

that they can engage in treatment decisions and make informed choices regarding their family's health care needs.

I am also pleased to see efforts to increase research on pediatric drug safety, pediatric clinical trials, and pediatric medical devices in title IV of the FDA Revitalization Act. The bill includes reauthorizations of the Best Pharmaceuticals for Children Act, BPCA, championed by my colleague, Senator DODD, which I have cosponsored, and the Pediatric Research Improvement Act, PRIA, championed by my colleague, Senator CLINTON, which have been particularly successful at increasing the availability of pediatric specific data on drug products, as well as greatly expanding the number of treatments that have been tested and labeled for use in pediatric populations. The bill also includes a new proposal to expand the collection and availability of pediatric data on medical devices, an area of the medical device market that remains seriously underdeveloped, and as a result places infants and children at risk for inferior or inadequate care at best, and tragic and needless loss of life at worst. Moreover, BPCA also includes a new provision on patent exclusivity for blockbuster drugs that strikes a sound compromise between creating an appropriate financial incentive for drug companies to conduct much needed research, while also providing the FDA with important information about pediatric drugs.

Mr. President, the FDA is responsible for overseeing the safety of a wide range of products consumed by millions of Americans each and every day. We can and must ensure that this critical agency has the tools and resources it needs to perform the myriad of tasks under its purview. We need to get this right for the millions of Americans who rely on the FDA to approve the drugs that they take to treat serious illnesses. The FDA Revitalization Act creates an opportunity to improve science at the FDA, strengthen drug safety by devoting resources to postmarket surveillance, and ''revitalize'' the FDA's authority.

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

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

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

MODIFICATION TO REPORTED COMMITTEE SUBSTITUTE

Mr. KENNEDY. Mr. President, on behalf of the HELP Committee, I send to the desk a modification to the committee substitute.

The PRESIDING OFFICER. The committee substitute is so modified.

The modification is as follows:

(Purpose: To provide a complete substitute)

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Food and Drug Administration Revitalization Act''.

TITLE I—PRESCRIPTION DRUG USER FEES

SEC. 101. SHORT TITLE; REFERENCES IN TITLE.

(a) SHORT TITLE.—This title may be cited as the ''Prescription Drug User Fee Amendments of 2007''.

(b) REFERENCES IN TITLE.—Except as otherwise specified, whenever in this title an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 102. DRUG FEES.

Section 735 (21 U.S.C. 379g) is amended—

(1) by striking the section designation and all that follows through ''For purposes of this subchapter:'' and inserting the following:

''SEC. 735. DRUG FEES.

''(a) PURPOSE.—It is the purpose of this part that the fees authorized under this part be dedicated toward expediting the drug development process, the process for the review of human drug applications, and postmarket drug safety, as set forth in the goals identified for purposes of this part in the letters from the Secretary to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

''(b) REPORTS.—

''(1) PERFORMANCE REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in subsection (a) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

''(2) FISCAL REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

''(3) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet website of the Food and Drug Administration.

''(c) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Energy and Commerce of the House of Representatives;

''(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(C) scientific and academic experts;

''(D) health care professionals;

''(E) representatives of patient and consumer advocacy groups; and

''(F) the regulated industry.

''(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

''(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

''(B) publish such recommendations in the Federal Register;

''(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

''(D) hold a meeting at which the public may present its views on such recommendations; and

''(E) after consideration of such public views and comments, revise such recommendations as necessary.

''(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

''(d) DEFINITIONS.—For purposes of this part:'';

(2) in subsection (d)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking ''505(b)(1),'' and inserting ''505(b), or'';

(ii) by striking subparagraph (B);

(iii) by redesignating subparagraph (C) as subparagraph (B); and

(iv) in the matter following subparagraph (B), as so redesignated, by striking ''subparagraph (C)'' and inserting ''subparagraph (B)'';

(B) in paragraph (3)(C), by—

(i) striking ''the list'' and inserting ''the list (not including the discontinued section of such list)''; and

(ii) striking ''a list'' and inserting ''a list (not including the discontinued section of such a list)'';

(C) in paragraph (4), by inserting before the period at the end the following: ''(such as capsules, tablets, and lyophilized products before reconstitution)'';

(D) by amending paragraph (6)(F) to read as follows:

''(F) In the case of drugs approved under human drug applications or supplements, postmarket safety activities, including—

''(i) collecting, developing, and reviewing safety information on approved drugs (including adverse event reports);

''(ii) developing and using improved adverse event data collection systems (including information technology systems); and

''(iii) developing and using improved analytical tools to assess potential safety problems (including by accessing external data bases).'';

(E) in paragraph (8)—

(i) by striking ''April of the preceding fiscal year'' and inserting ''October of the preceding fiscal year''; and

(ii) by striking ''April 1997'' and inserting ''October 1996'';

(F) by redesignating paragraph (9) as paragraph (10); and

(G) by inserting after paragraph (8) the following:

''(9) The term 'person' includes an affiliate of such person.''.

SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(1) in the matter preceding paragraph (1), by striking ''2003'' and inserting ''2008'';

(2) in paragraph (1)—

(A) in subparagraph (D)—

(i) in the heading, by inserting ''OR WITHDRAWN BEFORE FILING'' after ''REFUND OF FEE IF APPLICATION REFUSED FOR FILING''; and

(ii) by inserting before the period at the end the following: ''or withdrawn without a waiver before filing'';

(B) by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively; and

(C) by inserting after subparagraph (D) the following:

''(E) FEE FOR APPLICATION PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—An application or supplement that has been refused for filing or that was withdrawn before filing, if filed under protest or resubmitted, shall be subject to the fee under subparagraph (A) (unless an exception under subparagraph (C) or (F) applies or the fee is waived or reduced under subsection (d)), without regard to previous payment of such a fee and the refund of 75 percent of that fee under subparagraph (D).''; and

(3) in paragraph (2)—

(A) in subparagraph (A), by striking ''subparagraph (B)'' and inserting ''subparagraphs (B) and (C)''; and

(B) by adding at the end the following:

''(C) SPECIAL RULES FOR COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS.—

''(i) IN GENERAL.—Except as provided in clause (ii), each person who is named as the applicant in an approved human drug application for a compounded positron emission tomography drug shall be subject under subparagraph (A) to one-fifth of an annual establishment fee with respect to each such establishment identified in the application as producing compounded positron emission tomography drugs under the approved application.

''(ii) EXCEPTION FROM ANNUAL ESTABLISHMENT FEE.—Each person who is named as the applicant in an application described in clause (i) shall not be assessed an annual establishment fee for a fiscal year if the person certifies to the Secretary, at a time specified by the Secretary and using procedures specified by the Secretary, that—

''(I) the person is a not-for-profit medical center that has only 1 establishment for the production of compounded positron emission tomography drugs; and

''(II) at least 95 percent of the total number of doses of each compounded positron emission tomography drug produced by such establishment during such fiscal year will be used within the medical center.''.

(b) FEE REVENUE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

''(b) FEE REVENUE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), fees under subsection (a) shall be established to generate the following revenue amounts, in each fiscal year beginning with fiscal year 2008 and continuing through fiscal year 2012: $392,783,000, plus an adjustment for workload on $354,893,000 of this amount. Such adjustment shall be made in accordance with the workload adjustment provisions in effect for fiscal year 2007, except that instead of commercial investigational new drug applications submitted to the Secretary, all commercial investigational new drug applications with a submission during the previous 12-month period shall be used in the determination. One-third of the revenue amount shall be derived from application fees, one-third from establishment fees, and one-third from product fees.''.

(c) ADJUSTMENTS TO FEES.—

(1) INFLATION ADJUSTMENT.—Section 736(c)(1) (21 U.S.C. 379h(c)(1)) is amended—

(A) in the matter preceding subparagraph (A) by striking ''The revenues established in subsection (b)'' and inserting ''Beginning with fiscal year 2009, the revenues established in subsection (b)'';

(B) in subparagraph (A) by striking ''or'' at the end;

(C) in subparagraph (B) by striking the period at the end and inserting '', or,'';

(D) by inserting after subparagraph (B) the following:

''(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions, for the first 5 fiscal years of the previous 6 fiscal years.''; and

(E) in the matter following subparagraph (C) (as added by this paragraph), by striking ''fiscal year 2003'' and inserting ''fiscal year 2008''.

(2) WORKLOAD ADJUSTMENT.—Section 736(c)(2) (21 U.S.C. 379h(c)(2)) is amended—

(A) in the matter preceding subparagraph (A,) by striking ''2004'' and inserting ''2009'';

(B) in the first sentence of subparagraph (A)—

(i) by striking '', commercial investigational new drug applications'' and inserting ''(adjusted for changes in review activities)''; and

(ii) by inserting before the period at the end '', and the change in the number of commercial investigational new drug applications with a submission during the previous 12-month period (adjusted for changes in review activities)'';

(C) in subparagraph (B), by adding at the end the following new sentence: ''Further, any adjustment for changes in review activities made in setting fees and fee revenue amounts for fiscal year 2009 may not result in the total workload adjustment being more than 2 percentage points higher than it would be absent the adjustment for changes in review activities.''; and

(D) by adding at the end the following:

''(C) The Secretary shall contract with an independent accounting firm to study the adjustment for changes in review activities applied in setting fees for fiscal year 2009 and to make recommendations, if warranted, on future changes in the methodology for calculating the adjustment for changes in review activity. After review of the recommendations by the independent accounting firm, the Secretary shall make appropriate changes to the workload adjustment methodology in setting fees for fiscal years 2010 through 2012. If the study is not conducted, no adjustment for changes in review activities shall be made after fiscal year 2009.''.

(3) RENT AND RENT-RELATED COST ADJUSTMENT.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(A) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), respectively; and

(B) by inserting after paragraph (2) the following:

''(3) RENT AND RENT-RELATED COST ADJUSTMENT.—Beginning with fiscal year 2010, the Secretary shall, before making the adjustments under paragraphs (1) and (2), reduce the fee amounts established in subsection (b), if actual costs paid for rent and rent-related expenses are less than $11,721,000. The reductions made under this paragraph, if any, shall not exceed the amounts by which costs fell below $11,721,000, and shall not exceed $11,721,000 in any fiscal year.''.

(4) FINAL YEAR ADJUSTMENT.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(A) in paragraph (4), as redesignated by this subsection—

(i) by striking ''2007'' each place it appears and inserting ''2012''; and

(ii) by striking ''2008'' and inserting ''2013''; and

(B) in paragraph (5), as redesignated by this subsection, by striking ''2002'' and inserting ''2007''.

(d) FEE WAIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(1) in paragraph (1), in the matter preceding subparagraph (A), by—

(A) inserting ''to a person who is named as the applicant'' after ''The Secretary shall grant'';

(B) inserting ''to that person'' after ''a waiver from or a reduction of one or more fees assessed''; and

(C) striking ''finds'' and inserting ''determines'';

(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;

(3) by inserting after paragraph (1) the following:

''(2) EVALUATION.—For the purpose of determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant and any affiliate of the applicant.''; and

(4) in paragraph (4), as redesignated by this subsection, in subparagraph (A), by inserting before the period at the end '', and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce''.

(e) CREDITING AND AVAILABILITY OF FEES.—

(1) AUTHORIZATION OF APPROPRIATIONS.—Section 736(g)(3) (21 U.S.C. 379h(g)(3)) is amended to read as follows:

''(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section such sums as are authorized to be assessed and collected under this section in each of fiscal years 2008 through 2012.''.

(2) OFFSET.—Section 736(g)(4) (21 U.S.C. 379h(g)(4)) is amended to read as follows:

''(4) OFFSET.—If the cumulative amount of fees collected during fiscal years 2008, 2009, and 2010, plus the amount estimated to be collected for fiscal year 2011, exceeds the amount of fees specified in aggregate in appropriation Acts for such fiscal years, the aggregate amount in excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.''.

(f) CONFORMING AMENDMENTS.—

(1) Section 736(a) (21 U.S.C. 379h(a)), as amended by this section, is amended—

(A) in paragraph (1)(A), by striking ''subsection (c)(4)'' each place it appears and inserting ''subsection (c)(5)'';

(B) in paragraph (2), by striking ''subsection (c)(4)'' and inserting ''subsection (c)(5)''; and

(C) in paragraph (3), by striking ''subsection (c)(4)'' and inserting ''subsection (c)(5)''.

(2) Section 736A(h)(3), as added by section 104 of this title, is amended by striking ''735(3)'' and inserting ''735(d)(3)''.

SEC. 104. AUTHORITY TO ASSESS AND USE PRESCRIPTION DRUG ADVERTISING FEES.

Chapter VII, subchapter C, part 2 (21 U.S.C. 379g et seq.) is amended by adding after section 736 the following new section:

''SEC. 736A. PROGRAM TO ASSESS AND USE FEES FOR THE ADVISORY REVIEW OF PRESCRIPTION DRUG ADVERTISING.

''(a) TYPES OF DIRECT-TO-CONSUMER TELEVISION ADVERTISEMENT REVIEW FEES.—Beginning with fiscal year 2008, the Secretary

shall assess and collect fees in accordance with this section as follows:

''(1) ADVISORY REVIEW FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), each person that on or after October 1, 2007, submits a proposed direct-to-consumer television advertisement for advisory review by the Secretary prior to its initial public dissemination shall be subject to a fee established under subsection (c)(3).

''(B) EXCEPTION FOR REQUIRED SUBMISSIONS.—A direct-to-consumer television advertisement that is required to be submitted to the Secretary prior to initial public dissemination shall not be assessed a fee unless the sponsor designates it as a submission for advisory review.

''(C) PAYMENT.—The fee required by subparagraph (A) shall be due not later than October 1 of the fiscal year in which the direct-to-consumer television advertisement shall be submitted to the Secretary for advisory review.

''(D) MODIFICATION OF ADVISORY REVIEW FEE.—

''(i) LATE PAYMENT.—If, on or before November 1 of the fiscal year in which the fees are due, a person has not paid all fees that were due and payable for advisory reviews identified in response to the Federal Register notice described in subsection (c)(3)(A), the fees shall be regarded as late. Such fees shall be due and payable 20 days before any direct-to-consumer television advertisement is submitted by such person to the Secretary for advisory review. Notwithstanding any other provision of this section, such fees shall be due and payable for each of those advisory reviews in the amount of 150 percent of the advisory review fee established for that fiscal year pursuant to subsection (c)(3).

''(ii) LATE NOTICE OF SUBMISSION.—If any person submits any direct-to-consumer television advertisements for advisory review that are in excess of the number identified by that person in response to the Federal Register notice described in subsection (c)(3)(A), that person must pay a fee for each of those advisory reviews in the amount of 150 percent of the advisory review fee established for that fiscal year pursuant to subsection (c)(3). Fees under this subparagraph shall be due 20 days before the direct-to-consumer television advertisement is submitted by such person to the Secretary for advisory review.

''(E) LIMITS.—

''(i) IN GENERAL.—The payment of a fee under this paragraph for a fiscal year entitles the person that pays the fee to acceptance for advisory review by the Secretary of 1 direct-to-consumer television advertisement and acceptance of 1 resubmission for advisory review of the same advertisement. The advertisement shall be submitted for review in the fiscal year for which the fee was assessed, except that a person may carry over no more than 1 paid advisory review submission to the next fiscal year. Resubmissions may be submitted without regard to the fiscal year of the initial advisory review submission.

''(ii) NO REFUND.—Except as provided by subsection (f), fees paid under this paragraph shall not be refunded.

''(iii) NO WAIVER, EXEMPTION, OR REDUCTION.—The Secretary shall not grant a waiver, exemption, or reduction of any fees due or payable under this section.

''(iv) NON-TRANSFERABILITY.—The right to an advisory review is not transferable, except to a successor in interest.

''(2) OPERATING RESERVE FEE.—

''(A) IN GENERAL.—Each person that, on or after October 1, 2007, is assessed an advisory review fee under paragraph (1) shall be subject to an operating reserve fee established under subsection (d)(2) only in the first fiscal year in which an advisory review fee is assessed.

''(B) PAYMENT.—Except as provided in subparagraph (C), the fee required by subparagraph (A) shall be due not later than October 1 of the first fiscal year in which the person is required to pay an advisory review fee under paragraph (1).

''(C) LATE NOTICE OF SUBMISSION.—If, in the first fiscal year of a person's participation in the Program, that person submits any direct-to-consumer television advertisements for advisory review that are in excess of the number identified by that person in response to the Federal Register notice described in subsection (c)(3)(A), that person must pay an operating reserve fee for each of those advisory reviews equal to the advisory review fee for each submission established under paragraph (1)(D)(ii). Fees required by this subparagraph shall be in addition to the fees required under subparagraph (B), if any. Fees under this subparagraph shall be due 20 days before any direct-to-consumer television advertisement is submitted by such person to the Secretary for advisory review.

''(b) ADVISORY REVIEW FEE REVENUE AMOUNTS.—Fees under subsection (a)(1) shall be established to generate revenue amounts of $6,250,000 for each of fiscal years 2008 through 2012, as adjusted pursuant to subsection (c).

''(c) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—Beginning with fiscal year 2009, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

''(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average), for the 12-month period ending June 30 preceding the fiscal year for which fees are being established;

''(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia; or

''(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions, for the first 5 fiscal years of the previous 6 fiscal years.

The adjustment made each fiscal year by this paragraph shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2008 under this subsection.

''(2) WORKLOAD ADJUSTMENT.—

''(A) IN GENERAL.—Beginning with fiscal year 2009, after the fee revenues established in subsection (b) of this section are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary with respect to the submission of proposed direct-to-consumer television advertisements for advisory review prior to initial broadcast.

''(B) DETERMINATION OF WORKLOAD ADJUSTMENT.—

''(i) IN GENERAL.—The workload adjustment under this paragraph for a fiscal year shall be determined by the Secretary—

''(I) based upon the number of direct-to-consumer television advertisements identified pursuant to paragraph (3)(A) for that fiscal year, excluding allowable previously paid carry over submissions; and

''(II) by multiplying the number of such advertisements projected for that fiscal year that exceeds 150 by $27,600 (adjusted each year beginning with fiscal year 2009 for inflation in accordance with paragraph (1)).

''(ii) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register, as part of the notice described in paragraph (1), the fee revenues and fees resulting from the adjustment made under this paragraph and the supporting methodologies.

''(C) LIMITATION.—Under no circumstances shall the adjustment made under this paragraph result in fee revenues for a fiscal year that are less than the fee revenues established for the prior fiscal year.

''(3) ANNUAL FEE SETTING.—

''(A) NUMBER OF ADVERTISEMENTS.—The Secretary shall, 120 days before the start of each fiscal year, publish a notice in the Federal Register requesting any person to notify the Secretary within 30 days of the number of direct-to-consumer television advertisements the person intends to submit for advisory review by the Secretary in the next fiscal year. Notification to the Secretary of the number of advertisements a person intends to submit for advisory review prior to initial broadcast shall be a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions on or before October 1 of the fiscal year in which the advertisement is intended to be submitted. A person shall at the same time also notify the Secretary if such person intends to use a paid submission from the previous fiscal year under subsection (a)(1)(E)(i). If such person does not so notify the Secretary, all submissions for advisory review shall be subject to advisory review fees.

''(B) ANNUAL FEE.—The Secretary shall, 60 days before the start of each fiscal year, establish, for the next fiscal year, the direct-to-consumer television advertisement advisory review fee under subsection (a)(1), based on the revenue amounts established under subsection (b), the adjustments provided under this subsection and the number of direct-to-consumer television advertisements identified pursuant to subparagraph (A), excluding allowable previously paid carry over submissions. The annual advisory review fee shall be established by dividing the fee revenue for a fiscal year (as adjusted pursuant to this subsection) by the number of direct-to-consumer television advertisements identified pursuant to subparagraph (A), excluding allowable previously paid carry over submissions.

''(C) FISCAL YEAR 2008 FEE LIMIT.—Notwithstanding subsection (b), the fee established under subparagraph (B) for fiscal year 2008 may not be more than $83,000 per submission for advisory review.

''(D) ANNUAL FEE LIMIT.—Notwithstanding subsection (b), the fee established under subparagraph (B) for a fiscal year after fiscal year 2008 may not be more than 50 percent more than the fee established for the prior fiscal year.

''(E) LIMIT.—The total amount of fees obligated for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the advisory review of prescription drug advertising.

''(d) OPERATING RESERVES.—

''(1) IN GENERAL.—The Secretary shall establish in the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation a Direct-to-Consumer Advisory Review Operating Reserve, of at least $6,250,000 in fiscal year 2008, to continue the Program in the event the fees collected in any subsequent fiscal year pursuant to subsection (c)(3) do not generate the fee revenue amount established for that fiscal year.

''(2) FEE SETTING.—The Secretary shall establish the operating reserve fee under subsection (a)(2)(A) for each person required to pay the fee by multiplying the number of direct-to-consumer television advertisements identified by that person pursuant to subsection (c)(3)(A) by the advisory review fee established pursuant to subsection (c)(3) for that fiscal year. In no case shall the operating reserve fee assessed be less than the operating reserve fee assessed if the person had first participated in the Program in fiscal year 2008.

''(3) USE OF OPERATING RESERVE.—The Secretary may use funds from the reserves under this subsection only to the extent necessary in any fiscal year to make up the difference between the fee revenue amount established for that fiscal year under subsection (b) and the amount of fees collected for that fiscal year pursuant to subsection (a), or to pay costs of ending the Program if it is terminated pursuant to subsection (f) or if it is not reauthorized after fiscal year 2012.

''(4) REFUND OF OPERATING RESERVES.—Within 120 days of the end of fiscal year 2012, or if the Program is terminated pursuant to subsection (f), the Secretary, after setting aside sufficient operating reserve amounts to terminate the Program, shall refund all amounts remaining in the operating reserve on a pro rata basis to each person that paid an operating reserve fee assessment. In no event shall the refund to any person exceed the total amount of operating reserve fees paid by such person pursuant to subsection (a)(2).

''(e) EFFECT OF FAILURE TO PAY FEES.—Notwithstanding any other law or regulation of the Secretary, a submission for advisory review of a direct-to-consumer television advertisement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person under this section have been paid.

''(f) EFFECT OF INADEQUATE FUNDING OF PROGRAM.—

''(1) FIRST FISCAL YEAR.—If on November 1, 2007, or 120 days after enactment of the Prescription Drug User Fee Amendments of 2007, whichever is later, the Secretary has received less than $11,250,000 in advisory review fees and operating reserve fees combined, the Program shall be terminated and all collected fees shall be refunded.

''(2) SUBSEQUENT FISCAL YEARS.—Beginning in fiscal year 2009, if, on November 1 of a fiscal year, the combination of the operating reserves, annual fee revenues from that fiscal year, and unobligated fee revenues from prior fiscal years is less than $9,000,000, adjusted for inflation (in accordance with subsection (c)(1)), the Program shall be terminated, and the Secretary shall notify all participants, retain any money from the unused advisory review fees and the operating reserves needed to terminate the Program, and refund the remainder of the unused fees and operating reserves. To the extent required to terminate the Program, the Secretary shall first use unobligated advisory review fee revenues from prior fiscal years, then the operating reserves, and then unused advisory review fees from the relevant fiscal year.

''(g) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the advisory review of prescription drug advertising.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—The fees authorized by this section—

''(A) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

''(B) shall be available for obligation only if appropriated budget authority continues to support at least the total combined number of full-time equivalent employees in the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, and the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch supported in fiscal year 2007.

''(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section not less than $6,250,000 for each of fiscal years 2008, 2009, 2010, 2011, and 2012, as adjusted to reflect adjustments in the total fee revenues made under this section, plus amounts collected for the reserve fund under subsection (d).

''(4) OFFSET.—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

''(h) DEFINITIONS.—For purposes of this section:

''(1) The term 'advisory review' means reviewing and providing advisory comments regarding compliance of a proposed advertisement with the requirements of this Act prior to its initial public dissemination.

''(2) The term 'carry over submission' means a submission for an advisory review for which a fee was paid in a fiscal year that is submitted for review in the following fiscal year.

''(3) The term 'direct-to-consumer television advertisement' means an advertisement for a prescription drug product as defined in section 735(3) intended to be displayed on any television channel for less than 2 minutes.

''(4) The term 'person' includes an individual, a partnership, a corporation, and an association, and any affiliate thereof or successor in interest.

''(5) The term 'process for the advisory review of prescription drug advertising' means the activities necessary to review and provide advisory comments on proposed direct-to-consumer television advertisements prior to public dissemination and, to the extent the Secretary has additional staff resources available under the Program that are not necessary for the advisory review of direct-to-consumer television advertisements, the activities necessary to review and provide advisory comments on other proposed advertisements and promotional material prior to public dissemination.

''(6) The term 'Program' means the Program to assess, collect, and use fees for the advisory review of prescription drug advertising established by this section.

''(7) The term 'resources allocated for the process for the advisory review of prescription drug advertising' means the expenses incurred in connection with the process for the advisory review of prescription drug advertising for—

''(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees, and to contracts with such contractors;

''(B) management of information, and the acquisition, maintenance, and repair of computer resources;

''(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies;

''(D) collection of fees under this section and accounting for resources allocated for the advisory review of prescription drug advertising; and

''(E) terminating the Program under subsection (f)(2), if necessary.

''(8) The term 'resubmission' means a subsequent submission for advisory review of a direct-to-consumer television advertisement that has been revised in response to the Secretary's comments on an original submission. A resubmission may not introduce significant new concepts or creative themes into the television advertisement.

''(9) The term 'submission for advisory review' means an original submission of a direct-to-consumer television advertisement for which the sponsor voluntarily requests advisory comments before the advertisement is publicly disseminated.

"SEC. 736B. SUNSET.

''This part shall cease to be effective on October 1, 2012, except that subsection (b) of section 736 with respect to reports shall cease to be effective on January 31, 2013.''.

SEC. 105. SAVINGS CLAUSE.

Notwithstanding section 509 of the Prescription Drug User Fee Amendments of 2002 (21 U.S.C. 379g note), and notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.

SEC. 106. TECHNICAL AMENDMENT.

Section 739 (21 U.S.C. 379j–11) is amended in the matter preceding paragraph (1), by striking ''subchapter'' and inserting ''part''.

SEC. 107. EFFECTIVE DATES.

(a) IN GENERAL.—Except as provided in subsection (b), the amendments made by this title shall take effect October 1, 2007.

(b) EXCEPTION.—The amendment made by section 104 of this title shall take effect on the date of enactment of this title.

TITLE II—DRUG SAFETY

SEC. 200. SHORT TITLE.

This title may be cited as the ''Enhancing Drug Safety and Innovation Act of 2007''.

Subtitle A—Risk Evaluation and Mitigation Strategies

SEC. 201. ROUTINE ACTIVE SURVEILLANCE AND ASSESSMENT.

(a) IN GENERAL.—Subsection (k) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(3) ROUTINE ACTIVE SURVEILLANCE AND ASSESSMENT.—

''(A) DEVELOPMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—The Secretary shall, not later than 2 years after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, act

in collaboration with academic institutions and private entities to—

''(i) establish minimum standards for collection and transmission of postmarketing data elements from electronic health data systems; and

''(ii) establish, through partnerships, a validated and integrated postmarket risk identification and analysis system to integrate and analyze safety data from multiple sources, with the goals of including, in aggregate—

''(I) at least 25,000,000 patients by July 1, 2010; and

''(II) at least 100,000,000 patients by July 1, 2012.

''(B) DATA COLLECTION ACTIVITIES.—

''(i) IN GENERAL.—The Secretary shall, not later than 1 year after the establishment of the minimum standards and the identification and analysis system under subparagraph (A), establish and maintain an active surveillance infrastructure—

''(I) to collect and report data for pharmaceutical postmarket risk identification and analysis, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996; and

''(II) that includes, in addition to the collection and monitoring (in a standardized form) of data on all serious adverse drug experiences (as defined in subsection (o)(2)(C)) required to be submitted to the Secretary under paragraph (1), and those events voluntarily submitted from patients, providers, and drug, when appropriate, procedures to—

''(aa) provide for adverse event surveillance by collecting and monitoring Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

''(bb) provide for adverse event surveillance by collecting and monitoring private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data);

''(cc) provide for adverse event surveillance by monitoring standardized electronic health records, as available;

''(dd) provide for adverse event surveillance by collecting and monitoring other information as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

''(ee) enable the program to identify certain trends and patterns with respect to data reported to the program;

''(ff) enable the program to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, laboratory data, and other information determined appropriate, which may include data on comparative national adverse event trends; and

''(gg) enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

''(ii) TIMELINESS OF REPORTING.—The procedures developed under clause (i) shall ensure that such data are collected, monitored, and reported in a timely, routine, and automatic manner, taking into consideration the need for data completeness, coding, cleansing, and transmission.

''(iii) PRIVATE SECTOR RESOURCES.—To ensure the establishment of the active surveillance infrastructure by the date described under clause (i), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

''(iv) COMPLEMENTARY APPROACHES.—To the extent the active surveillance infrastructure established under clause (i) is not sufficient to gather data and information relevant to priority drug safety questions, the Secretary shall develop, support, and participate in complementary approaches to gather and analyze such data and information, including—

''(I) approaches that are complementary with respect to assessing the safety of use of a drug in domestic populations not included in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and

''(II) existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

''(v) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

''(C) RISK IDENTIFICATION AND ANALYSIS.—

''(i) PURPOSE.—To carry out this paragraph, the Secretary shall establish collaborations with other Government, academic, and private entities, including the Centers for Education and Research on Therapeutics under section 912 of the Public Health Service Act, to provide for the risk identification and analysis of the data collected under subparagraph (B) and data that is publicly available or is provided by the Secretary, in order to—

''(I) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

''(II) provide the Secretary with routine access to expertise to study advanced drug safety data; and

''(III) enhance the ability of the Secretary to make timely assessments based on drug safety data.

''(ii) PUBLIC PROCESS FOR PRIORITY QUESTIONS.—At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on—

''(I) priority drug safety questions; and

''(II) mechanisms for answering such questions, including through—

''(aa) routine active surveillance under subparagraph (B); and

''(bb) when such surveillance is not sufficient, postmarket studies under subsection (o)(4)(B) and postapproval clinical trials under subsection (o)(4)(C).

''(iii) PROCEDURES FOR THE DEVELOPMENT OF DRUG SAFETY COLLABORATIONS.—

''(I) IN GENERAL.—Not later than 180 days after the date of the establishment of the active surveillance infrastructure under subparagraph (B), the Secretary shall establish and implement procedures under which the Secretary may routinely collaborate with a qualified entity to—

''(aa) clean, classify, or aggregate data collected under subparagraph (B) and data that is publicly available or is provided by the Secretary;

''(bb) allow for prompt investigation of priority drug safety questions, including—

''(AA) unresolved safety questions for drugs or classes of drugs; and

''(BB) for a newly-approved drug: safety signals from clinical trials used to approve the drug and other preapproval trials; rare, serious drug side effects; and the safety of use in domestic populations not included in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children);

''(cc) perform advanced research and analysis on identified drug safety risks;

''(dd) convene an expert advisory committee to oversee the establishment of standards for the ethical and scientific uses for, and communication of, postmarketing data collected under subparagraph (B), including advising on the development of effective research methods for the study of drug safety questions;

''(ee) focus postmarket studies under subsection (o)(4)(B) and postapproval clinical trials under subsection (o)(4)(C) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

''(ff) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

''(II) REQUEST FOR SPECIFIC METHODOLOGY.—The procedures described in subclause (I) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

''(iv) USE OF ANALYSES.—The Secretary shall provide the analyses described under this subparagraph, including the methods and results of such analyses, about a drug to the sponsor or sponsors of such drug.

''(v) QUALIFIED ENTITIES.—

''(I) IN GENERAL.—The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

''(II) QUALIFICATION.—The Secretary shall enter into a contract with an entity under subclause (I) only if the Secretary determines that the entity—

''(aa) has the research capability and expertise to conduct and complete the activities under this paragraph;

''(bb) has in place an information technology infrastructure to support adverse event surveillance data and operational standards to provide security for such data;

''(cc) has experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data;

''(dd) has an understanding of drug development and risk/benefit balancing in a clinical setting; and

''(ee) has a significant business presence in the United States.

''(vi) CONTRACT REQUIREMENTS.—Each contract with a qualified entity shall contain the following requirements:

''(I) ENSURING PRIVACY.—The qualified entity shall provide assurances that the entity will not use the data provided by the Secretary in a manner that violates—

''(aa) the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996; or

''(bb) sections 552 or 552a of title 5, United States Code, with regard to the privacy of individually-identifiable beneficiary health information.

''(II) COMPONENT OF ANOTHER ORGANIZATION.—If a qualified entity is a component of another organization—

''(aa) the qualified entity shall maintain the data related to the activities carried out under this paragraph separate from the other components of the organization and establish appropriate security measures to maintain the confidentiality and privacy of such data; and

''(bb) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

''(III) TERMINATION OR NONRENEWAL.—If a contract with a qualified entity under this subparagraph is terminated or not renewed, the following requirements shall apply:

''(aa) CONFIDENTIALITY AND PRIVACY PROTECTIONS.—The entity shall continue to comply with the confidentiality and privacy requirements under this paragraph with respect to all data disclosed to the entity.

''(bb) DISPOSITION OF DATA.—The entity shall return to the Secretary all data disclosed to the entity or, if returning the data is not practicable, destroy the data.

''(vii) COMPETITIVE PROCEDURES.—The Secretary shall use competitive procedures (as defined in section 4(5) of the Federal Procurement Policy Act) to enter into contracts under clause (v).

''(viii) REVIEW OF CONTRACT IN THE EVEN OF A MERGER OR ACQUISITION.—The Secretary shall review the contract with a qualified entity under this paragraph in the event of a merger or acquisition of the entity in order to ensure that the requirements under this subparagraph will continue to be met.

''(D) COORDINATION.—In carrying out this paragraph, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and provide for the coordination of the activities of private entities, professional associations, or other entities that may have sources of surveillance data.''.

(b) AUTHORIZATION OF APPROPRIATIONS.—To carry out activities under the amendment made by this section for which funds are made available under section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h), there are authorized to be appropriated to carry out the amendment made by this section, in addition to such funds, $25,000,000 for each of fiscal years 2008 through 2012.

SEC. 202. RISK EVALUATION AND MITIGATION STRATEGIES.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(o) RISK EVALUATION AND MITIGATION STRATEGY.—

''(1) IN GENERAL.—In the case of any drug subject to subsection (b) or to section 351 of the Public Health Service Act for which a risk evaluation and mitigation strategy is approved as provided for in this subsection, the applicant shall comply with the requirements of such strategy.

''(2) DEFINITIONS.—In this subsection:

''(A) ADVERSE DRUG EXPERIENCE.—The term 'adverse drug experience' means any adverse event associated with the use of a drug in humans, whether or not considered drug related, including—

''(i) an adverse event occurring in the course of the use of the drug in professional practice;

''(ii) an adverse event occurring from an overdose of the drug, whether accidental or intentional;

''(iii) an adverse event occurring from abuse of the drug;

''(iv) an adverse event occurring from withdrawal of the drug; and

''(v) any failure of expected pharmacological action of the drug.

''(B) NEW SAFETY INFORMATION.—The term 'new safety information' with respect to a drug means information about—

''(i) a serious risk or an unexpected serious risk with use of the drug that the Secretary has become aware of since the later of—

''(I) the date of initial approval of the drug under this section or initial licensure of the drug under section 351 of the Public Health Service Act; or

''(II) if applicable, the last assessment of the approved risk evaluation and mitigation strategy for the drug; or

''(ii) the effectiveness of the approved risk evaluation and mitigation strategy for the drug obtained since the later of—

''(I) the approval of such strategy; or

''(II) the last assessment of such strategy.

''(C) SERIOUS ADVERSE DRUG EXPERIENCE.—The term 'serious adverse drug experience' is an adverse drug experience that—

''(i) results in—

''(I) death;

''(II) the placement of the patient at immediate risk of death from the adverse drug experience as it occurred (not including an adverse drug experience that might have caused death had it occurred in a more severe form);

''(III) inpatient hospitalization or prolongation of existing hospitalization;

''(IV) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or

''(V) a congenital anomaly or birth defect; or

''(ii) based on appropriate medical judgment, may jeopardize the patient and may require a medical or surgical intervention to prevent an outcome described under clause (i).

''(D) SERIOUS RISK.—The term 'serious risk' means a risk of a serious adverse drug experience.

''(E) SIGNAL OF A SERIOUS RISK.—The term 'signal of a serious risk' means information related to a serious adverse drug experience derived from—

''(i) a clinical trial;

''(ii) adverse event reports under subsection (k)(1);

''(iii) routine active surveillance under subsection (k)(3);

''(iv) a postapproval study, including a study under paragraph (4)(B); or

''(v) peer-reviewed biomedical literature.

''(F) UNEXPECTED SERIOUS RISK.—The term 'unexpected serious risk' means a serious adverse drug experience that—

''(i) is not listed in the labeling of a drug; or

''(ii) is symptomatically and pathophysiologically related to an adverse drug experience listed in the labeling of the drug, but differs from such adverse drug experience because of greater severity, specificity, or prevalence.

''(3) REQUIRED ELEMENTS OF A RISK EVALUATION AND MITIGATION STRATEGY.—If a risk evaluation and mitigation strategy for a drug is required, such strategy shall include—

''(A) the labeling for the drug for use by health care providers as approved under subsection (c);

''(B) a timetable for submission of assessments of the strategy, that—

''(i) for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act—

''(I) shall be no less frequently than 18 months and 3 years after the drug is initially approved and at a frequency specified in the strategy for subsequent years; and

''(II) may be eliminated after the first 3 years if the Secretary determines that serious risks of the drug have been adequately identified and assessed and are being adequately managed;

''(ii) for a drug other than a drug described under clause (i), shall occur at a frequency determined by the Secretary; and

''(iii) may be increased or reduced in frequency as necessary as provided for in paragraph (7)(B)(v)(VI).

''(4) ADDITIONAL POTENTIAL EVALUATION ELEMENTS OF A RISK EVALUATION AND MITIGATION STRATEGY.—

''(A) RISK EVALUATION.—If a risk evaluation and mitigation strategy for a drug is required, such strategy may include 1 or more of the additional evaluation elements described in this paragraph, so long as the Secretary makes the determination required with respect to each additional included element.

''(B) POSTAPPROVAL STUDIES.—If the Secretary determines that the reports under subsection (k)(1) and routine active surveillance as available under subsection (k)(3) (including available complementary approaches under subsection (k)(3)(B)(iv)) will not be sufficient to—

''(i) assess a signal of a serious risk with use of a drug; or

''(ii) identify, based on a review of a demonstrated pattern of use of the drug, unexpected serious risks in a domestic population, including older people, people with comorbidities, pregnant women, or children, the risk evaluation and mitigation strategy for the drug may require that the applicant conduct an appropriate postapproval study, such as a prospective or retrospective observational study, of the drug (which shall include a timeframe specified by the Secretary for completing the study and reporting the results to the Secretary).

''(C) POSTAPPROVAL CLINICAL TRIALS.—If the Secretary determines that the reports under subsection (k)(1), routine active surveillance as available under subsection (k)(3) (including available complementary approaches under subsection (k)(3)(B)(iv)), and a study or studies under subparagraph (B) will likely be inadequate to assess a signal of a serious risk with use of a drug, and there is no effective approved application for the drug under subsection (j) as of the date that the requirement is first imposed, the risk evaluation and mitigation strategy for the drug may require that the applicant conduct an appropriate postapproval clinical trial of the drug (which shall include a timeframe specified by the Secretary for completing the clinical trial and reporting the results to the Secretary) to be included in the clinical trial registry data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act.

''(5) ADDITIONAL POTENTIAL COMMUNICATION ELEMENTS OF A RISK EVALUATION AND MITIGATION STRATEGY.—

''(A) RISK COMMUNICATION.—If a risk evaluation and mitigation strategy for a drug is required, such strategy may include 1 or more of the additional communication elements described in this paragraph, so long as the Secretary makes the determination required with respect to each additional included element.

''(B) MEDGUIDE; PATIENT PACKAGE INSERT.—The risk evaluation and mitigation strategy for a drug may require that the applicant develop for distribution to each patient when the drug is dispensed either or both of the following:

''(i) A Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations).

''(ii) A patient package insert, if the Secretary determines that such insert may help mitigate a serious risk listed in the labeling of the drug.

''(C) COMMUNICATION PLAN.—If the Secretary determines that a communication plan to health care providers may support implementation of an element of the risk evaluation and mitigation strategy for a drug, such as a labeling change, the strategy may require that the applicant conduct such a plan, which may include—

''(i) sending letters to health care providers;

''(ii) disseminating information about the elements of the strategy to encourage implementation by health care providers of components that apply to such health care providers, or to explain certain safety protocols

(such as medical monitoring by periodic laboratory tests); or

''(iii) disseminating information to health care providers through professional societies about any serious risks of the drug and any protocol to assure safe use.

''(D) PREREVIEW.—

''(i) IN GENERAL.—If the Secretary determines that prereview of advertisements is necessary to ensure the inclusion of a true statement in such advertisements of information in brief summary relating to a serious risk listed in the labeling of a drug, or relating to a protocol to ensure the safe use described in the labeling of the drug, the risk evaluation and mitigation strategy for the drug may require that the applicant submit to the Secretary advertisements of the drug for prereview not later than 45 days before dissemination of the advertisement

''(ii) SPECIFICATION OF ADVERTISEMENTS.—The Secretary may specify the advertisements required to be submitted under clause (i).

''(E) SPECIFIC DISCLOSURES.—

''(i) SERIOUS RISK; SAFETY PROTOCOL.—If the Secretary determines that advertisements lacking a specific disclosure about a serious risk listed in the labeling of a drug or about a protocol to ensure safe use described in the labeling of the drug would be false or misleading, the risk evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug such disclosure.

''(ii) DATE OF APPROVAL.—If the Secretary determines that advertisements lacking a specific disclosure of the date a drug was approved and notification that the existing information may not have identified or allowed for full assessment of all serious risks of using the drug would be false or misleading, the risk evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug such disclosure

''(iii) SPECIFICATION OF ADVERTISEMENTS.—The Secretary may specify the advertisements required to include a specific disclosure under clause (i) or (ii).

''(F) TEMPORARY MORATORIUM.—

''(i) IN GENERAL.—To the extent consistent with the Constitution, the risk evaluation and mitigation strategy for a drug may require that the applicant not issue or cause to be issued direct-to-consumer advertisements of the drug for a fixed period after initial approval of the drug, not to exceed 2 years.

''(ii) CONDITIONS.—The Secretary may require the strategy for a drug to include such a temporary moratorium on direct-to-consumer advertising only if the Secretary determines that—

''(I) direct-to-consumer advertisements of the drug would be inherently misleading even if the disclosure under subparagraph (E)(ii) were required; and

''(II) other elements under this subsection would not be sufficient to mitigate the concern that clinical trials used to approve the drug may not have identified serious risks that might occur among patients expected to be treated with the drug.

''(iii) CONSIDERATIONS.—Before making such determinations, the Secretary shall consider—

''(I) the number of patients who may be treated with the drug;

''(II) the seriousness of the condition for which the drug will be used; and

''(III) the serious risks listed in the labeling of the drug.

''(iv) REQUIRED SAFETY MONITORING.—If the approved risk evaluation and mitigation strategy for a drug includes a temporary moratorium on direct-to-consumer advertisements of the drug under this subparagraph, the Secretary shall—

''(I) consider the concern identified under clause (ii)(II) with respect to such drug to be a priority drug safety question under subsection (k)(3)(B);

''(II) no less frequently than every 3 months, evaluate the reports under subsection (k)(1) and the routine active surveillance as available under subsection (k)(3) with respect to such concern to determine whether serious risks that might occur among patients expected to be treated with the drug have been adequately identified; and

''(III) if such serious risks have been adequately identified, remove such temporary moratorium as an element of such strategy.

''(6) PROVIDING SAFE ACCESS FOR PATIENTS TO DRUGS WITH KNOWN SERIOUS RISKS THAT WOULD OTHERWISE BE UNAVAILABLE.—

''(A) ALLOWING SAFE ACCESS TO DRUGS WITH KNOWN SERIOUS RISKS.—The Secretary may require that the risk evaluation and mitigation strategy for a drug include such elements as are necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness, if the Secretary determines that—

''(i) the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug; and

''(ii) for a drug initially approved without elements to assure safe use, other elements under paragraphs (3), (4), and (5) are not sufficient to mitigate such serious risk.

''(B) ASSURING ACCESS AND MINIMIZING BURDEN.—Such elements to assure safe use under subparagraph (A) shall—

''(i) be commensurate with the specific serious risk listed in the labeling of the drug;

''(ii) within 30 days of the date on which any element under subparagraph (A) is imposed, be posted publicly by the Secretary with an explanation of how such elements will mitigate the observed safety risk;

''(iii) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular—

''(I) patients with serious or life-threatening diseases or conditions; and

''(II) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and

''(iv) to the extent practicable, so as to minimize the burden on the health care delivery system—

''(I) conform with elements to assure safe use for other drugs with similar, serious risks; and

''(II) be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

''(C) ELEMENTS TO ASSURE SAFE USE.—The elements to assure safe use under subparagraph (A) shall include 1 or more goals to mitigate a specific serious risk listed in the labeling of the drug and, to mitigate such risk, may require that—

''(i) health care providers that prescribe the drug have particular training or experience, or are specially certified (which training or certification shall be available to any willing provider from a frontier area);

''(ii) pharmacies, practitioners, or health care settings that dispense the drug are specially certified (which certification shall be available to any willing provider from a frontier area);

''(iii) the drug be dispensed to patients only in certain health care settings, such as hospitals;

''(iv) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, such as laboratory test results;

''(v) each patient using the drug be subject to certain monitoring; or

''(vi) each patient using the drug be enrolled in a registry.

''(D) IMPLEMENTATION SYSTEM.—The elements to assure safe use under subparagraph (A) that are described in clauses (ii), (iii), or (iv) of subparagraph (C) may include a system through which the applicant is able to take reasonable steps to—

''(i) monitor and evaluate implementation of such elements by health care providers, pharmacists, and other parties in the health care system who are responsible for implementing such elements; and

''(ii) work to improve implementation of such elements by such persons.

''(E) EVALUATION OF ELEMENTS TO ASSURE SAFE USE.—The Secretary, through the Drug Safety and Risk Management Advisory Committee (or successor committee) of the Food and Drug Administration, shall—

''(i) seek input from patients, physicians, pharmacists, and other health care providers about how elements to assure safe use under this paragraph for 1 or more drugs may be standardized so as not to be—

''(I) unduly burdensome on patient access to the drug; and

''(II) to the extent practicable, minimize the burden on the health care delivery system;

''(ii) at least annually, evaluate, for 1 or more drugs, the elements to assure safe use of such drug to assess whether the elements—

''(I) assure safe use of the drug;

''(II) are not unduly burdensome on patient access to the drug; and

''(III) to the extent practicable, minimize the burden on the health care delivery system; and

''(iii) considering such input and evaluations—

''(I) issue or modify agency guidance about how to implement the requirements of this paragraph; and

''(II) modify elements under this paragraph for 1 or more drugs as appropriate.

''(F) ADDITIONAL MECHANISMS TO ASSURE ACCESS.—The mechanisms under section 561 to provide for expanded access for patients with serious or life-threatening diseases or conditions may be used to provide access for patients with a serious or life-threatening disease or condition, the treatment of which is not an approved use for the drug, to a drug that is subject to elements to assure safe use under this paragraph.

''(G) WAIVER IN PUBLIC HEALTH EMERGENCIES.—The Secretary may waive any requirement of this paragraph during the period described in section 319(a) of the Public Health Service Act with respect to a qualified countermeasure described under section 319F-1(a)(2) of such Act, to which a requirement under this paragraph has been applied, if the Secretary has—

''(i) declared a public health emergency under such section 319; and

''(ii) determined that such waiver is required to mitigate the effects of, or reduce the severity of, such public health emergency.

''(7) SUBMISSION AND REVIEW OF RISK EVALUATION AND MITIGATION STRATEGY.—

''(A) PROPOSED RISK EVALUATION AND MITIGATION STRATEGY.—

''(i) VOLUNTARY PROPOSAL.—If there is a signal of a serious risk with a drug, an applicant may include a proposed risk evaluation and mitigation strategy for the drug in an application, including in a supplemental application, for the drug under subsection (b) or section 351 of the Public Health Service Act.

''(ii) REQUIRED PROPOSAL.—

''(I) DETERMINATION NECESSARY TO REQUIRE A PROPOSAL.—

''(aa) IN GENERAL.—The Secretary may require that the applicant for a drug submit a proposed risk evaluation and mitigation strategy for a drug if the Secretary (acting through the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug) determines that, based on a signal of a serious risk with the drug, a risk evaluation and mitigation strategy is necessary to assess such signal or mitigate such serious risk.

''(bb) NON-DELEGATION.—A determination under item (aa) for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

''(II) CIRCUMSTANCES IN WHICH A PROPOSAL MAY BE REQUIRED.—The applicant shall submit a proposed risk evaluation and mitigation strategy for a drug—

''(aa) in response to a letter from the Secretary (acting through the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug) sent regarding an application, including a supplemental application, for the drug, if the Secretary determines that data or information in the application indicates that an element under paragraph (4), (5), or (6) should be included in a strategy for the drug;

''(bb) within a timeframe specified by the Secretary, not to be less than 45 days, when ordered by the Secretary (acting through such offices), if the Secretary determines that new safety information indicates that—

''(AA) the labeling of the drug should be changed; or

''(BB) an element under paragraph (4) or (5) should be included in a strategy for the drug; or

''(cc) within 90 days when ordered by the Secretary (acting through such offices), if the Secretary determines that new safety information indicates that an element under paragraph (6) should be included in a strategy for the drug.

''(iii) CONTENT OF LETTER.—A letter under clause (ii)(II)(aa) shall describe—

''(I) the data or information in the application that warrants the proposal of a risk evaluation and mitigation strategy for the drug; and

''(II) what elements under paragraphs (4), (5), or (6) should be included in a strategy for the drug.

''(iv) CONTENT OF ORDER.—An order under item (aa) or (bb) of clause (ii)(II) shall describe—

''(I) the new safety information with respect to the drug that warrants the proposal of a risk evaluation and mitigation strategy for the drug; and

''(II) whether and how the labeling of the drug should be changed and what elements under paragraphs (4), (5), or (6) should be included in a strategy for the drug.

''(v) CONTENT OF PROPOSAL.—A proposed risk evaluation and mitigation strategy—

''(I) shall include a timetable as described under paragraph (3)(B); and

''(II) may also include additional elements as provided for under paragraphs (4), (5), and (6).

''(B) ASSESSMENT AND MODIFICATION OF A RISK EVALUATION AND MITIGATION STRATEGY.—

''(i) VOLUNTARY ASSESSMENTS.—If a risk evaluation and mitigation strategy for a drug is required, the applicant may submit to the Secretary an assessment of, and propose a modification to, such approved strategy for the drug at any time.

''(ii) REQUIRED ASSESSMENTS.—If a risk evaluation and mitigation strategy for a drug is required, the applicant shall submit an assessment of, and may propose a modification to, such approved strategy for the drug—

''(I) when submitting an application, including a supplemental application, for a new indication under subsection (b) or section 351 of the Public Health Service Act;

''(II) when required by the strategy, as provided for in the timetable under paragraph (3)(B);

''(III) within a timeframe specified by the Secretary, not to be less than 45 days, when ordered by the Secretary (acting through the offices described in subparagraph (A)(ii)(I)), if the Secretary determines that new safety information indicates that an element under paragraph (3) or (4) should be modified or added to the strategy;

''(IV) within 90 days when ordered by the Secretary (acting through such offices), if the Secretary determines that new safety information indicates that an element under paragraph (6) should be modified or added to the strategy; or

''(V) within 15 days when ordered by the Secretary (acting through such offices), if the Secretary determines that there may be a cause for action by the Secretary under subsection (e).

''(iii) CONTENT OF ORDER.—An order under subclauses (III), (IV), or (V) of clause (ii) shall describe—

''(I) the new safety information with respect to the drug that warrants an assessment of the approved risk evaluation and mitigation strategy for the drug; and

''(II) whether and how such strategy should be modified because of such information.

''(iv) ASSESSMENT.—An assessment of the approved risk evaluation and mitigation strategy for a drug shall include—

''(I) a description of new safety information, if any, with respect to the drug;

''(II) whether and how to modify such strategy because of such information;

''(III) with respect to any postapproval study required under paragraph (4)(B) or otherwise undertaken by the applicant to investigate a safety issue, the status of such study, including whether any difficulties completing the study have been encountered;

''(IV) with respect to any postapproval clinical trial required under paragraph (4)(C) or otherwise undertaken by the applicant to investigate a safety issue, the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act; and

''(V) with respect to any goal under paragraph (6) and considering input and evaluations, if applicable, under paragraph (6)(E), an assessment of how well the elements to assure safe use are meeting the goal of increasing safe access to drugs with known serious risks or whether the goal or such elements should be modified.

''(v) MODIFICATION.—A modification (whether an enhancement or a reduction) to the approved risk evaluation and mitigation strategy for a drug may include the addition or modification of any element under subparagraph (A) or (B) of paragraph (3) or the addition, modification, or removal of any element under paragraph (4), (5), or (6), such as—

''(I) a labeling change, including the addition of a boxed warning;

''(II) adding a postapproval study or clinical trial requirement;

''(III) modifying a postapproval study or clinical trial requirement (such as a change in trial design due to legitimate difficulties recruiting participants);

''(IV) adding, modifying, or removing an element on advertising under subparagraph (D), (E), or (F) of paragraph (5);

''(V) adding, modifying, or removing an element to assure safe use under paragraph (6); or

''(VI) modifying the timetable for assessments of the strategy under paragraph (3)(B), including to eliminate assessments.

''(C) REVIEW.—The Secretary (acting through the offices described in subparagraph (A)(ii)(I)) shall promptly review the proposed risk evaluation and mitigation strategy for a drug submitted under subparagraph (A), or an assessment of the approved risk evaluation and mitigation strategy for a drug submitted under subparagraph (B).

''(D) DISCUSSION.—The Secretary (acting through the offices described in subparagraph (A)(ii)(I)) shall initiate discussions of the proposed risk evaluation and mitigation strategy for a drug submitted under subparagraph (A), or of an assessment of the approved risk evaluation and mitigation strategy for a drug submitted under subparagraph (B), with the applicant to determine a strategy—

''(i) if the proposed strategy or assessment is submitted as part of an application (including a supplemental application) under subparagraph (A)(i), (A)(ii)(II)(aa), or (B)(ii)(I), by the target date for communication of feedback from the review team to the applicant regarding proposed labeling and postmarketing study commitments, as set forth in the letters described in section 735(a);

''(ii) if the proposed strategy is submitted under subparagraph (A)(ii)(II)(bb) or the assessment is submitted under subclause (II) or (III) of subparagraph (B)(ii), not later than 20 days after such submission;

''(iii) if the proposed strategy is submitted under subparagraph (A)(ii)(II)(cc) or the assessment is submitted under subparagraph (B)(i) or under subparagraph (B)(ii)(IV), not later than 30 days after such submission; or

''(iv) if the assessment is submitted under subparagraph (B)(ii)(V), not later than 10 days after such submission.

''(E) ACTION.—

''(i) IN GENERAL.—Unless the applicant requests the dispute resolution process as described under subparagraph (F) or (G), the Secretary (acting through the offices described in subparagraph (A)(ii)(I)) shall approve and include the risk evaluation and mitigation strategy for a drug, or any modification to the strategy (including a timeframe for implementing such modification), with—

''(I) the action letter on the application, if a proposed strategy is submitted under subparagraph (A)(i) or (A)(ii)(II)(aa) or an assessment of the strategy is submitted under subparagraph (B)(ii)(I); or

''(II) an order, which shall be made public, issued not later than 50 days after the date discussions of such proposed strategy or modification begin under subparagraph (D), if a proposed strategy is submitted under item (bb) or (cc) of subparagraph (A)(ii)(II) or an assessment of the strategy is submitted under subparagraph (B)(i) or under subclause (II), (III), (IV), or (V) of subparagraph (B)(ii).

''(ii) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided under clause (i).

''(F) DISPUTE RESOLUTION AT INITIAL APPROVAL.—If a proposed risk evaluation and mitigation strategy is submitted under subparagraph (A)(i) or (A)(ii)(II)(aa) in an application for initial approval of a drug and

there is a dispute about the strategy, the applicant shall use the major dispute resolution procedures as set forth in the letters described in section 735(a).

''(G) DISPUTE RESOLUTION IN ALL OTHER CASES.—

''(i) REQUEST FOR REVIEW.—In any case other than a submission under subparagraph (A)(i) or (A)(ii)(II)(aa) in an application for initial approval of a drug if there is a dispute about the strategy, not earlier than 15 days, and not later than 35 days, after discussions under subparagraph (D) have begun, the applicant shall request in writing that the dispute be reviewed by the Drug Safety Oversight Board.

''(ii) SCHEDULING REVIEW.—If the applicant requests review under clause (i), the Secretary—

''(I)(aa) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whichever meeting date is more practicable; or

''(bb) may convene a special meeting of the Drug Safety Oversight Board to review the matter more promptly, including to meet an action deadline on an application (including a supplemental application);

''(II) shall give advance notice to the public through the Federal Register and on the Internet website of the Food and Drug Administration—

''(aa) that the drug is to be discussed by the Drug Safety Oversight Board; and

''(bb) of the date on which the Drug Safety Oversight Board shall discuss such drug; and

''(III) shall apply section 301(j), section 552 of title 5, and section 1905 of title 18, United States Code, to any request for information about such review.

''(iii) AGREEMENT AFTER DISCUSSION OR ADMINISTRATIVE APPEALS.—

''(I) FURTHER DISCUSSION OR ADMINISTRATIVE APPEALS.—A request for review under clause (i) shall not preclude—

''(aa) further discussions to reach agreement on the risk evaluation and mitigation strategy; or

''(bb) the use of administrative appeals within the Food and Drug Administration to reach agreement on the strategy, including the major dispute resolution procedures as set forth in the letters described in section 735(a).

''(II) AGREEMENT TERMINATES DISPUTE RESOLUTION.—At any time before a decision and order is issued under clause (vi), the Secretary (acting through the offices described in subparagraph (A)(ii)(I)) and the applicant may reach an agreement on the risk evaluation and mitigation strategy through further discussion or administrative appeals, terminating the dispute resolution process, and the Secretary shall issue an action letter or order, as appropriate, that describes the strategy.

''(iv) MEETING OF THE BOARD.—At the meeting of the Drug Safety Oversight Board described in clause (ii), the Board shall—

''(I) hear from both parties; and

''(II) review the dispute.

''(v) RECOMMENDATION OF THE BOARD.—Not later than 5 days after such meeting of the Drug Safety Oversight Board, the Board shall provide a written recommendation on resolving the dispute to the Secretary.

''(vi) ACTION BY THE SECRETARY.—

''(I) ACTION LETTER.—With respect to a proposed risk evaluation and mitigation strategy submitted under subparagraph (A)(i) or (A)(ii)(II)(aa) or to an assessment of the strategy submitted under subparagraph (B)(ii)(I), the Secretary shall issue an action letter that resolves the dispute not later than the later of—

''(aa) the action deadline for the action letter on the application; or

''(bb) 7 days after receiving the recommendation of the Drug Safety Oversight Board.

''(II) ORDER.—With respect to a proposed risk evaluation and mitigation strategy submitted under item (bb) or (cc) of subparagraph (A)(ii)(II) or an assessment of the risk evaluation and mitigation strategy under subparagraph (B)(i) or under subclause (II), (III), (IV), or (V) of subparagraph (B)(ii), the Secretary shall issue an order, which (with the recommendation of the Drug Safety Oversight Board) shall be made public, that resolves the dispute not later than 7 days after receiving the recommendation of the Drug Safety Oversight Board.

''(vii) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided for under clause (vi).

''(viii) EFFECT ON ACTION DEADLINE.—With respect to the application or supplemental application in which a proposed risk evaluation and mitigation strategy is submitted under subparagraph (A)(i) or (A)(ii)(II)(aa) or in which an assessment of the strategy is submitted under subparagraph (B)(ii)(I), the Secretary shall be considered to have met the action deadline for the action letter on such application if the applicant requests the dispute resolution process described in this subparagraph and if the Secretary—

''(I) has initiated the discussions described under subparagraph (D) by the target date referred to in subparagraph (D)(i); and

''(II) has complied with the timing requirements of scheduling review by the Drug Safety Oversight Board, providing a written recommendation, and issuing an action letter under clauses (ii), (v), and (vi), respectively.

''(ix) DISQUALIFICATION.—No individual who is an employee of the Food and Drug Administration and who reviews a drug or who participated in an administrative appeal under clause (iii)(I) with respect to such drug may serve on the Drug Safety Oversight Board at a meeting under clause (iv) to review a dispute about the risk evaluation and mitigation strategy for such drug.

''(x) ADDITIONAL EXPERTISE.—The Drug Safety Oversight Board may add members with relevant expertise from the Food and Drug Administration, including the Office of Pediatrics, the Office of Women's Health, or the Office of Rare Diseases, or from other Federal public health or health care agencies, for a meeting under clause (iv) of the Drug Safety Oversight Board.

''(H) USE OF ADVISORY COMMITTEES.—The Secretary (acting through the offices described in subparagraph (A)(ii)(I)) may convene a meeting of 1 or more advisory committees of the Food and Drug Administration to—

''(i) review a concern about the safety of a drug or class of drugs, including before an assessment of the risk evaluation and mitigation strategy or strategies of such drug or drugs is required to be submitted under subclause (II), (III), (IV), or (V) of subparagraph (B)(ii);

''(ii) review the risk evaluation and mitigation strategy or strategies of a drug or group of drugs; or

''(iii) with the consent of the applicant, review a dispute under subparagraph (G).

''(I) PROCESS FOR ADDRESSING DRUG CLASS EFFECTS.—

''(i) IN GENERAL.—When a concern about a serious risk of a drug may be related to the pharmacological class of the drug, the Secretary (acting through the offices described in subparagraph (A)(ii)(I)) may defer assessments of the approved risk evaluation and mitigation strategies for such drugs until the Secretary has—

''(I) convened, after appropriate public notice, 1 or more public meetings to consider possible responses to such concern; or

''(II) gathered additional information or data about such concern.

''(ii) PUBLIC MEETINGS.—Such public meetings may include—

''(I) 1 or more meetings of the applicants for such drugs;

''(II) 1 or more meetings of 1 or more advisory committees of the Food and Drug Administration, as provided for under subparagraph (H); or

''(III) 1 or more workshops of scientific experts and other stakeholders.

''(iii) ACTION.—After considering the discussions from any meetings under clause (ii), the Secretary may—

''(I) announce in the Federal Register a planned regulatory action, including a modification to each risk evaluation and mitigation strategy, for drugs in the pharmacological class;

''(II) seek public comment about such action; and

''(III) after seeking such comment, issue an order addressing such regulatory action.

''(J) INTERNATIONAL COORDINATION.—The Secretary (acting through the offices described in subparagraph (A)(ii)(I)) may coordinate the timetable for submission of assessments under paragraph (3)(B), a study under paragraph (4)(B), or a clinical trial under paragraph (4)(C), with efforts to identify and assess the serious risks of such drug by the marketing authorities of other countries whose drug approval and risk management processes the Secretary deems comparable to the drug approval and risk management processes of the United States.

''(K) EFFECT.—Use of the processes described in subparagraphs (I) and (J) shall not delay action on an application or a supplement to an application for a drug.

''(L) NO EFFECT ON LABELING CHANGES THAT DO NOT REQUIRE PREAPPROVAL.—In the case of a labeling change to which section 314.70 of title 21, Code of Federal Regulations (or any successor regulation), applies for which the submission of a supplemental application is not required or for which distribution of the drug involved may commence upon the receipt by the Secretary of a supplemental application for the change, the submission of an assessment of the approved risk evaluation and mitigation strategy for the drug under this subsection is not required.

''(8) DRUG SAFETY OVERSIGHT BOARD.—

''(A) IN GENERAL.—There is established a Drug Safety Oversight Board.

''(B) COMPOSITION; MEETINGS.—The Drug Safety Oversight Board shall—

''(i) be composed of scientists and health care practitioners appointed by the Secretary, each of whom is an employee of the Federal Government;

''(ii) include representatives from offices throughout the Food and Drug Administration (including the offices responsible for postapproval safety of drugs);

''(iii) include at least 1 representative each from the National Institutes of Health, the Department of Health and Human Services (other than the Food and Drug Administration), and the Veterans Health Administration; and

''(iv) meet at least monthly to provide oversight and advice to the Secretary on the management of important drug safety issues.''.

SEC. 203. ENFORCEMENT.

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(x) If it is a drug subject to an approved risk evaluation and mitigation strategy

under section 505(o) and the applicant for such drug fails to—

''(1) make a labeling change required by such strategy after the Secretary has approved such strategy or completed review of, and acted on, an assessment of such strategy under paragraph (7) of such section; or

''(2) comply with a requirement of such strategy with respect to advertising as provided for under subparagraph (D), (E), or (F) of paragraph (5) of such section.''.

(b) CIVIL PENALTIES.—Section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) is amended—

(1) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), respectively;

(2) by inserting after paragraph (2) the following:

''(3) An applicant (as such term is used in section 505(o)) who knowingly fails to comply with a requirement of an approved risk evaluation and mitigation strategy under such section 505(o) shall be subject to a civil money penalty of not less than $15,000 and not more than $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.'';

(3) in paragraph (2)(C), by striking ''paragraph (3)(A)'' and inserting ''paragraph (4)(A)'';

(4) in paragraph (4), as so redesignated, by striking ''paragraph (1) or (2)'' each place it appears and inserting ''paragraph (1), (2), or (3)''; and

(5) in paragraph (6), as so redesignated, by striking ''paragraph (4)'' each place it appears and inserting ''paragraph (5)''.

SEC. 204. REGULATION OF DRUGS THAT ARE BIOLOGICAL PRODUCTS.

Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(2), by adding at the end the following:

''(D) RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license for a drug under this paragraph may submit to the Secretary as part of the application a proposed risk evaluation and mitigation strategy as described under section 505(o) of the Federal Food, Drug, and Cosmetic Act.''; and

(2) in subsection (j), by inserting '', including the requirements under section 505(o) of such Act,'' after '', and Cosmetic Act''.

SEC. 205. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF APPROVAL.

Section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) is amended by adding at the end the following: ''The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under subsection (o)(7)(B)(ii)(V).''.

SEC. 206. DRUGS SUBJECT TO AN ABBREVIATED NEW DRUG APPLICATION.

Section 505(j)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)) is amended by adding at the end the following:

''(E) RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENT.—

''(i) IN GENERAL.—A drug that is the subject of an abbreviated new drug application under this subsection shall be subject to only the following elements of the approved risk evaluation and mitigation strategy if required under subsection (o) for the applicable listed drug:

''(I) Labeling, as required under subsection (o)(3)(A) for the applicable listed drug.

''(II) A Medication Guide or patient package insert, if required under subsection (o)(5)(B) for the applicable listed drug.

''(III) Prereview of advertising, if required under subsection (o)(5)(D) for the applicable listed drug.

''(IV) Specific disclosures in advertising, if required under subsection (o)(5)(E) for the applicable listed drug.

''(V) A temporary moratorium on direct-to-consumer advertising, if required under subsection (o)(5)(F) for the applicable listed drug.

''(VI) Elements to assure safe use, if required under subsection (o)(6) for the applicable listed drug, except that such drug may use a different, comparable aspect of such elements as are necessary to assure safe use of such drug if —

''(aa) the corresponding aspect of the elements to assure safe use for the applicable listed drug is claimed by a patent that has not expired or is a method or process that as a trade secret is entitled to protection; and

''(bb) the applicant certifies that it has sought a license for use of such aspect of the elements to assure safe use for the applicable listed drug.

''(ii) ACTION BY SECRETARY.—For an applicable listed drug for which a drug is approved under this subsection, the Secretary—

''(I) shall undertake any communication plan to health care providers required under section (o)(5)(C) for the applicable listed drug;

''(II) shall conduct, or contract for, any postapproval study required under subsection (o)(4)(B) for the applicable listed drug;

''(III) shall inform the applicant for a drug approved under this subsection if the approved risk evaluation and mitigation strategy for the applicable listed drug is modified; and

''(IV) in order to minimize the burden on the health care delivery system of different elements to assure safe use for the drug approved under this subsection and the applicable listed drug, may seek to negotiate a voluntary agreement with the owner of the patent, method, or process for a license under which the applicant for such drug may use an aspect of the elements to assure safe use, if required under subsection (o)(6) for the applicable listed drug, that is claimed by a patent that has not expired or is a method or process that as a trade secret is entitled to protection.''.

SEC. 207. RESOURCES.

(a) USER FEES.—Subparagraph (F) of section 735(d)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(d)(6)), as amended by section 103, as amended—

(1) in clause (ii), by striking ''systems); and'' and inserting ''systems);''

(2) in clause (iii), by striking ''bases).'' and inserting ''bases); and''; and

(3) by adding at the end the following:

''(iv) reviewing, implementing, and ensuring compliance with risk evaluation and mitigation strategies.''.

(b) ADDITIONAL FEE REVENUES FOR DRUG SAFETY.—Section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h), as amended by section 103, is amended by—

(1) striking the subsection designation and all that follows through ''.—Except'' and inserting the following:

''(b) FEE REVENUE AMOUNTS.—

''(1) IN GENERAL.—Except''; and

(2) adding at the end the following:

''(2) ADDITIONAL FEE REVENUES FOR DRUG SAFETY.—

''(A) IN GENERAL.—Subject to subparagraph (C), in each of fiscal years 2008 through 2012, paragraph (1) shall be applied by substituting the amount determined under subparagraph (B) for '$392,783,000'.

''(B) AMOUNT DETERMINED.—For any fiscal year 2008 through 2012, the amount determined under this subparagraph is the sum of—

''(i) $392,783,000; plus

''(ii) the amount equal to—

''(I)(aa) for fiscal year 2008, $25,000,000;

''(bb) for fiscal year 2009, $35,000,000;

''(cc) for fiscal year 2010, $45,000,000;

''(dd) for fiscal year 2011, $55,000,000; and

''(ee) for fiscal year 2012, $65,000,000; minus

''(II) the amount equal to one-fifth of the amount by which the appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceed the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2007 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under subsection (c)(1).

In making the adjustment under subclause (II) for any fiscal year 2008 through 2012, subsection (c)(1) shall be applied by substituting '2007' for '2008'.

''(C) LIMITATION.—This paragraph shall not apply for any fiscal year if the amount described under subparagraph (B)(ii) is less than 0.''.

(c) STRATEGIC PLAN FOR INFORMATION TECHNOLOGY.—Not later than 1 year after the date of enactment of this title, the Secretary of Health and Human Services (referred to in this title as the ''Secretary'') shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a strategic plan on information technology that includes—

(1) an assessment of the information technology infrastructure, including systems for data collection, access to data in external health care databases, data mining capabilities, personnel, and personnel training programs, needed by the Food and Drug Administration to—

(A) comply with the requirements of this subtitle (and the amendments made by this subtitle);

(B) achieve interoperability within and among the centers of the Food and Drug Administration and between the Food and Drug Administration and product application sponsors;

(C) utilize electronic health records;

(D) implement routine active surveillance under section 505(k)(3) (including complementary approaches under subsection (c) of such section) of the Federal Food, Drug, and Cosmetic Act, as added by section 201 of this Act; and

(E) communicate drug safety information to physicians and other health care providers;

(2) an assessment of the extent to which the current information technology assets of the Food and Drug Administration are sufficient to meet the needs assessments under paragraph (1);

(3) a plan for enhancing the information technology assets of the Food and Drug Administration toward meeting the needs assessments under paragraph (1); and

(4) an assessment of additional resources needed to so enhance the information technology assets of the Food and Drug Administration.

SEC. 208. SAFETY LABELING CHANGES.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506C the following:

''SEC. 506D. SAFETY LABELING CHANGES.

''(a) NEW SAFETY INFORMATION.—

''(1) NOTIFICATION.—The holder of an approved application under section 505 of this

Act or a license under section 351 of the Public Health Service Act (referred to in this section as a 'holder') shall promptly notify the Secretary if the holder becomes aware of new safety information that the holder believes should be included in the labeling of the drug. The Secretary shall promptly notify the holder if the Secretary becomes aware of new safety information that the Secretary believes should be included in the labeling of the drug.

''(2) DISCUSSION REGARDING LABELING CHANGES.—Following notification pursuant to paragraph (1), the Secretary and holder shall initiate discussions of the new safety information in order to reach agreement on whether the labeling for the drug should be modified to reflect the new safety information and, if so, on the contents of such labeling changes.

''(3) SUPPLEMENT.—If the Secretary determines that there is reasonable scientific evidence that an adverse event is associated with use of the drug, the Secretary may request the holder to submit a supplement to an application under section 505 of this Act or to a license under section 351 of the Public Health Service Act (referred to in this section as a 'supplement') proposing changes to the approved labeling to reflect the new safety information, including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions (referred to in this section as a 'safety labeling change'). If the Secretary determines that no safety labeling change is necessary or appropriate based upon the new safety information, the Secretary shall notify the holder of this determination in writing.

''(b) LABELING SUPPLEMENTS.—

''(1) IN GENERAL.—The holder shall submit a supplement whenever the holder seeks, either at the holder's own initiative or at the request of the Secretary, to make a safety labeling change.

''(2) NONACCELERATED PROCESS.—Unless the accelerated labeling review process described in subsection (c) is initiated, any supplement proposing a safety labeling change shall be reviewed and acted upon by the Secretary not later than 30 days after the date the Secretary receives the supplement. Until the Secretary acts on such a supplement proposing a safety labeling change, the existing approved labeling shall remain in effect and be distributed by the holder without change.

''(3) NEW SAFETY INFORMATION.—Nothing in this section shall prohibit the Secretary from informing health care professionals or the public about new safety information prior to approval of a supplement proposing a safety labeling change.

''(c) ACCELERATED LABELING REVIEW PROCESS.—An accelerated labeling review process shall be available to resolve disagreements in a timely manner between the Secretary and a holder about the need for, or content of, a safety labeling change, as follows:

''(1) REQUEST TO INITIATE ACCELERATED PROCESS.—The accelerated labeling review process shall be initiated upon the written request of either the Secretary or the holder. Such request may be made at any time after the notification described in subsection (a)(1), including during the Secretary's review of a supplement proposing a safety labeling change.

''(2) SCIENTIFIC DISCUSSION AND MEETINGS.—

''(A) IN GENERAL.—Following initiation of the accelerated labeling review process, the Secretary and holder shall immediately initiate discussions to review and assess the new safety information and to reach agreement on whether safety labeling changes are necessary and appropriate and, if so, the content of such safety labeling changes.

''(B) TIME PERIOD.—The discussions under this paragraph shall not extend for more than 45 calendar days after the initiation of the accelerated labeling review process.

''(C) DISPUTE PROCEEDINGS.—If the Secretary and holder do not reach an agreement regarding the safety labeling changes by not later than 25 calendar days after the initiation of the accelerated labeling review process, the dispute automatically shall be referred to the director of the drug evaluation office responsible for the drug under consideration, who shall be required to take an active role in such discussions.

''(3) REQUEST FOR SAFETY LABELING CHANGE AND FAILURE TO AGREE.—If the Secretary and holder fail to reach an agreement on appropriate safety labeling changes by not later than 45 calendar days after the initiation of the accelerated labeling review process—

''(A) on the next calendar day (other than a weekend or Federal holiday) after such period, the Secretary shall—

''(i) request in writing that the holder make any safety labeling change that the Secretary determines to be necessary and appropriate based upon the new safety information; or

''(ii) notify the holder in writing that the Secretary has determined that no safety labeling change is necessary or appropriate; and

''(B) if the Secretary fails to act within the specified time, or if the holder does not agree to make a safety labeling change requested by the Secretary or does not agree with the Secretary's determination that no labeling change is necessary or appropriate, the Secretary (on his own initiative or upon request by the holder) shall refer the matter for expedited review to the Drug Safety Oversight Board.

''(4) ACTION BY THE DRUG SAFETY OVERSIGHT BOARD.—Not later than 45 days after receiving a referral under paragraph (3)(B), the Drug Safety Oversight Board shall—

''(A) review the new safety information;

''(B) review all written material submitted by the Secretary and the holder;

''(C) convene a meeting to hear oral presentations and arguments from the Secretary and holder; and

''(D) make a written recommendation to the Secretary—

''(i) concerning appropriate safety labeling changes, if any; or

''(ii) stating that no safety labeling changes are necessary or appropriate based upon the new safety information.

''(5) CONSIDERATION OF RECOMMENDATIONS.—

''(A) ACTION BY THE SECRETARY.—The Secretary shall consider the recommendation of the Drug Safety Oversight Board made under paragraph (4)(D) and, not later than 20 days after receiving the recommendation—

''(i) issue an order requiring the holder to make any safety labeling change that the Secretary determines to be necessary and appropriate; or

''(ii) if the Secretary determines that no safety labeling change is necessary or appropriate, the Secretary shall notify the holder of this determination in writing.

''(B) FAILURE TO ACT.—If the Secretary fails to act by not later than 20 days after receiving the recommendation of the Drug Safety Oversight Board, the written recommendation of the Drug Safety Oversight Board shall be considered the order of the Secretary under this paragraph.

''(C) NONDELEGATION.—The Secretary's authority under this paragraph shall not be redelegated to an individual below the level of the Director of the Center for Drug Evaluation and Research, or the Director of the Center for Biologics Evaluation and Research, of the Food and Drug Administration.

''(6) MISBRANDING.—If the holder, not later than 10 days after receiving an order under subparagraph (A) or (B) of paragraph (5), does not agree to make a safety labeling change ordered by the Secretary, the Secretary may deem the drug that is the subject of the request to be misbranded.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to change the standards in existence on the date of enactment of this section for determining whether safety labeling changes are necessary or appropriate.''.

(b) CONFORMING AMENDMENT.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352 et seq.), as amended by section 203, is further amended by adding at the end the following:

''(y) If it is a drug and the holder does not agree to make a safety labeling change ordered by the Secretary under section 506D(c) within 10 days after issuance of such an order.''.

SEC. 209. POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 251, is amended by adding at the end the following:

''(r) POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.—

''(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, the Secretary shall improve the transparency of pharmaceutical data and allow patients and health care providers better access to pharmaceutical data by developing and maintaining an Internet website that—

''(A) provides comprehensive drug safety information for prescription drugs that are approved by the Secretary under this section or licensed under section 351 of the Public Health Service Act; and

''(B) improves communication of drug safety information to patients and providers.

''(2) INTERNET WEBSITE.—The Secretary shall carry out paragraph (1) by—

''(A) developing and maintaining an accessible, consolidated Internet website with easily searchable drug safety information, including the information found on United States Government Internet websites, such as the United States National Library of Medicine's Daily Med and Medline Plus websites, in addition to other such websites maintained by the Secretary;

''(B) ensuring that the information provided on the Internet website is comprehensive and includes, when available and appropriate—

''(i) patient labeling and patient packaging inserts;

''(ii) a link to a list of each drug, whether approved under this section or licensed under such section 351, for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

''(iii) a link to the clinical trial registry data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act;

''(iv) the most recent safety information and alerts issued by the Food and Drug Administration for drugs approved by the Secretary under this section, such as product recalls, warning letters, and import alerts;

''(v) publicly available information about implemented RiskMAPs and risk evaluation and mitigation strategies under subsection (o);

''(vi) guidance documents and regulations related to drug safety; and

''(vii) other material determined appropriate by the Secretary;

''(C) including links to non-Food and Drug Administration Internet resources that provide access to relevant drug safety information, such as medical journals and studies;

''(D) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under subsection (k)(3) to provide information of known and serious side-effects for drugs approved by the Secretary under this section or licensed under such section 351;

''(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet website;

''(F) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

''(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet website.

''(3) POSTING OF DRUG LABELING.—The Secretary shall post on the Internet website established under paragraph (1) the approved professional labeling and any required patient labeling of a drug approved under this section or licensed under such section 351 not later than 21 days after the date the drug is approved or licensed, including in a supplemental application with respect to a labeling change.

''(4) PRIVATE SECTOR RESOURCES.—To ensure development of the Internet website by the date described in paragraph (1), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

''(5) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subsection.

''(6) REVIEW.—The Advisory Committee on Risk Communication under section 566 shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information provided on the Internet website established under paragraph (1) and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to patients and providers, and shall recommend ways for the Food and Drug Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.''.

SEC. 210. ACTION PACKAGE FOR APPROVAL.

Section 505(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(l)) is amended by—

(1) redesignating paragraphs (1), (2), (3), (4), and (5) as subparagraphs (A), (B), (C), (D), and (E), respectively;

(2) striking ''(l) Safety and'' and inserting ''(l)(1) Safety and''; and

(3) adding at the end the following:

''(2) ACTION PACKAGE FOR APPROVAL.—

''(A) ACTION PACKAGE.—The Secretary shall publish the action package for approval of an application under subsection (b) or section 351 of the Public Health Service Act on the Internet website of the Food and Drug Administration–

''(i) not later than 30 days after the date of approval of such application for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act; and

''(ii) not later than 30 days after the third request for such action package for approval received under section 552 of title 5, United States Code, for any other drug.

''(B) IMMEDIATE PUBLICATION OF SUMMARY REVIEW.—Notwithstanding subparagraph (A), the Secretary shall publish, on the Internet website of the Food and Drug Administration, the materials described in subparagraph (C)(iv) not later than 48 hours after the date of approval of the drug, except where such materials require redaction by the Secretary.

''(C) CONTENTS.—An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:

''(i) Documents generated by the Food and Drug Administration related to review of the application.

''(ii) Documents pertaining to the format and content of the application generated during drug development.

''(iii) Labeling submitted by the applicant.

''(iv) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and how they were resolved, recommendation for action, and an explanation of any nonconcurrence with review conclusions.

''(v) If applicable, a separate review from a supervisor who does not concur with the summary review.

''(vi) Identification by name of each officer or employee of the Food and Drug Administration who—

''(I) participated in the decision to approve the application; and

''(II) consents to have his or her name included in the package.

''(D) DISAGREEMENTS.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final. Disagreements by team leaders, division directors, or office directors with any or all of the major conclusions of a reviewer shall be document in a separate review or in an addendum to the review.

''(E) CONFIDENTIAL INFORMATION.—This paragraph does not authorize the disclosure of any trade secret or confidential commercial or financial information described in section 552(b)(4) of title 5, United States Code, unless the Secretary declares an emergency under section 319 of the Public Health Service Act and such disclosure is necessary to mitigate the effects of such emergency.''.

SEC. 211. RISK COMMUNICATION.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

''SEC. 566. RISK COMMUNICATION.

''(a) ADVISORY COMMITTEE ON RISK COMMUNICATION.—

''(1) IN GENERAL.—The Secretary shall establish an advisory committee to be known as the 'Advisory Committee on Risk Communication' (referred to in this section as the 'Committee').

''(2) DUTIES OF COMMITTEE.—The Committee shall advise the Commissioner on methods to effectively communicate risks associated with the products regulated by the Food and Drug Administration.

''(3) MEMBERS.—The Secretary shall ensure that the Committee is composed of experts on risk communication, experts on the risks described in subsection (b), and representatives of patient, consumer, and health professional organizations.

''(4) PERMANENCE OF COMMITTEE.—Section 14 of the Federal Advisory Committee Act shall not apply to the Committee established under this subsection.

''(b) PARTNERSHIPS FOR RISK COMMUNICATION.—

''(1) IN GENERAL.—The Secretary shall partner with professional medical societies, medical schools, academic medical centers, and other stakeholders to develop robust and multi-faceted systems for communication to health care providers about emerging postmarket drug risks.

''(2) PARTNERSHIPS.—The systems developed under paragraph (1) shall—

''(A) account for the diversity among physicians in terms of practice, affinity for technology, and focus; and

''(B) include the use of existing communication channels, including electronic communications, in place at the Food and Drug Administration.''.

SEC. 212. REFERRAL TO ADVISORY COMMITTEE.

Section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by section 202, is further amended by adding at the end the following:

''(p) REFERRAL TO ADVISORY COMMITTEE.—

''(1) IN GENERAL.—Prior to the approval of a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act, the Secretary shall refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee.

''(2) EXCEPTION.—Notwithstanding paragraph (1), an advisory committee review of a drug described under such paragraph may occur within 1 year after approval of such a drug if—

''(A) the clinical trial that formed the primary basis of the safety and efficacy determination was halted by a drug safety monitoring board or an Institutional Review Board before its scheduled completion due to early unanticipated therapeutic results; or

''(B) the Secretary determines that it would be beneficial to the public health.''.

SEC. 213. RESPONSE TO THE INSTITUTE OF MEDICINE.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this title, the Secretary shall issue a report responding to the 2006 report of the Institute of Medicine entitled ''The Future of Drug Safety—Promoting and Protecting the Health of the Public''.

(b) CONTENT OF REPORT.—The report issued by the Secretary under subsection (a) shall include—

(1) an update on the implementation by the Food and Drug Administration of its plan to respond to the Institute of Medicine report described under such subsection; and

(2) an assessment of how the Food and Drug Administration has implemented—

(A) the recommendations described in such Institute of Medicine report; and

(B) the requirement under paragraph (7) of section 505(o) of the Federal Food, Drug, and Cosmetic Act (as added by this title), that the appropriate office responsible for reviewing a drug and the office responsible for post-approval safety with respect to the drug act together to assess, implement, and ensure compliance with the requirements of such section 505(o).

SEC. 214. EFFECTIVE DATE AND APPLICABILITY.

(a) EFFECTIVE DATES.—

(1) IN GENERAL.—Except as provided in paragraph (2), this subtitle shall take effect 180 days after the date of enactment of this title.

(2) USER FEES.—The amendments made by subsections (a) through (c) of section 207 shall take effect on October 1, 2007.

(b) DRUGS DEEMED TO HAVE RISK EVALUATION AND MITIGATION STRATEGIES.—

(1) IN GENERAL.—A drug that was approved before the effective date of this subtitle shall be deemed to have an approved risk evaluation and mitigation strategy under section 505(o) of the Federal Food, Drug, and Cosmetic Act (as added by this subtitle) if there are in effect on the effective date of this subtitle restrictions on distribution or use—

(A) required under section 314.520 or section 601.42 of title 21, Code of Federal Regulations; or

(B) otherwise agreed to by the applicant and the Secretary for such drug.

(2) RISK EVALUATION AND MITIGATION STRATEGY.—The approved risk evaluation and mitigation strategy deemed in effect for a drug under paragraph (1) shall consist of the elements described in subparagraphs (A) and (B) of paragraph (3) of such section 505(o) and any other additional elements under paragraphs (4), (5), and (6) in effect for such drug on the effective date of this subtitle.

(3) NOTIFICATION.—Not later than 30 days after the effective date of this subtitle, the Secretary shall notify the applicant for each drug described in paragraph (1)—

(A) that such drug is deemed to have an approved risk evaluation and mitigation strategy pursuant to such paragraph; and

(B) of the date, which, unless a safety issue with the drug arises, shall be no earlier than 6 months after the applicant is so notified, by which the applicant shall submit to the Secretary an assessment of such approved strategy under paragraph (7)(B) of such section 505(o).

(4) ENFORCEMENT ONLY AFTER ASSESSMENT AND REVIEW.—Neither the Secretary nor the Attorney General may seek to enforce a requirement of a risk evaluation and mitigation strategy deemed in effect under paragraph (1) before the Secretary has completed review of, and acted on, the first assessment of such strategy under such section 505(o).

(c) NO EFFECT ON VETERINARY MEDICINE.—This subtitle, and the amendments made by this subtitle, shall have no effect on the use of drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act by, or on the lawful written or oral order of, a licensed veterinarian within the context of a veterinarian-client-patient relationship, as provided for under section 512(a)(5) of such Act.

Subtitle B—Reagan-Udall Foundation for the Food and Drug Administration

SEC. 221. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"Subchapter I—Reagan-Udall Foundation for the Food and Drug Administration

"SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE FOUNDATION.

''(a) IN GENERAL.—A nonprofit corporation to be known as the Reagan-Udall Foundation for the Food and Drug Administration (referred to in this subchapter as the 'Foundation') shall be established in accordance with this section. The Foundation shall be headed by an Executive Director, appointed by the members of the Board of Directors under subsection (e). The Foundation shall not be an agency or instrumentality of the United States Government.

''(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation is to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

''(c) DUTIES OF THE FOUNDATION.—The Foundation shall—

''(1) taking into consideration the Critical Path reports and priorities published by the Food and Drug Administration, identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness, including postapproval, of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics;

''(2) establish goals and priorities in order to meet the unmet needs identified in paragraph (1);

''(3) in consultation with the Secretary, identify existing and proposed Federal intramural and extramural research and development programs relating to the goals and priorities established under paragraph (2), coordinate Foundation activities with such programs, and minimize Foundation duplication of existing efforts;

''(4) award grants to, or enter into contracts, memoranda of understanding, or cooperative agreements with, scientists and entities, which may include the Food and Drug Administration, university consortia, public-private partnerships, institutions of higher education, entities described in section 501(c)(3) of the Internal Revenue Code (and exempt from tax under section 501(a) of such Code), and industry, to efficiently and effectively advance the goals and priorities established under paragraph (2);

''(5) recruit meeting participants and hold or sponsor (in whole or in part) meetings as appropriate to further the goals and priorities established under paragraph (2);

''(6) release and publish information and data and, to the extent practicable, license, distribute, and release material, reagents, and techniques to maximize, promote, and coordinate the availability of such material, reagents, and techniques for use by the Food and Drug Administration, nonprofit organizations, and academic and industrial researchers to further the goals and priorities established under paragraph (2);

''(7) ensure that—

''(A) action is taken as necessary to obtain patents for inventions developed by the Foundation or with funds from the Foundation;

''(B) action is taken as necessary to enable the licensing of inventions developed by the Foundation or with funds from the Foundation; and

''(C) executed licenses, memoranda of understanding, material transfer agreements, contracts, and other such instruments, promote, to the maximum extent practicable, the broadest conversion to commercial and noncommercial applications of licensed and patented inventions of the Foundation to further the goals and priorities established under paragraph (2);

''(8) provide objective clinical and scientific information to the Food and Drug Administration and, upon request, to other Federal agencies to assist in agency determinations of how to ensure that regulatory policy accommodates scientific advances and meets the agency's public health mission;

''(9) conduct annual assessments of the unmet needs identified in paragraph (1); and

''(10) carry out such other activities consistent with the purposes of the Foundation as the Board determines appropriate.

''(d) BOARD OF DIRECTORS.—

''(1) ESTABLISHMENT.—

''(A) IN GENERAL.—The Foundation shall have a Board of Directors (referred to in this subchapter as the 'Board'), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

''(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be the following individuals or their designees:

''(i) The Commissioner.

''(ii) The Director of the National Institutes of Health.

''(iii) The Director of the Centers for Disease Control and Prevention.

''(iv) The Director of the Agency for Healthcare Research and Quality.

''(C) APPOINTED MEMBERS.—

''(i) IN GENERAL.—The ex officio members of the Board under subparagraph (B) shall, by majority vote, appoint to the Board 12 individuals, from a list of candidates to be provided by the National Academy of Sciences. Of such appointed members—

''(I) 4 shall be representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries;

''(II) 3 shall be representatives of academic research organizations;

''(III) 2 shall be representatives of Government agencies, including the Food and Drug Administration and the National Institutes of Health;

''(IV) 2 shall be representatives of patient or consumer advocacy organizations; and

''(V) 1 shall be a representative of health care providers.

''(ii) REQUIREMENT.—The ex officio members shall ensure the Board membership includes individuals with expertise in areas including the sciences of developing, manufacturing, and evaluating the safety and effectiveness of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics.

''(D) INITIAL MEETING.—

''(i) IN GENERAL.—Not later than 30 days after the date of the enactment of the Enhancing Drug Safety and Innovation Act of 2007, the Secretary shall convene a meeting of the ex officio members of the Board to—

''(I) incorporate the Foundation; and

''(II) appoint the members of the Board in accordance with subparagraph (C).

''(ii) SERVICE OF EX OFFICIO MEMBERS.—Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.

''(iii) CHAIR.—The ex officio members of the Board under subparagraph (B) shall designate an appointed member of the Board to serve as the Chair of the Board.

''(2) DUTIES OF BOARD.—The Board shall—

''(A) establish bylaws for the Foundation that—

''(i) are published in the Federal Register and available for public comment;

''(ii) establish policies for the selection of the officers, employees, agents, and contractors of the Foundation;

''(iii) establish policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation, including appropriate limits on the ability of donors to designate, by stipulation or restriction, the use or recipient of donated funds;

''(iv) establish policies that would subject all employees, fellows, and trainees of the Foundation to the conflict of interest standards under section 208 of title 18, United States Code;

''(v) establish licensing, distribution, and publication policies that support the widest and least restrictive use by the public of information and inventions developed by the Foundation or with Foundation funds to carry out the duties described in paragraphs (6) and (7) of subsection (c), and may include charging cost-based fees for published material produced by the Foundation;

''(vi) specify principles for the review of proposals and awarding of grants and contracts that include peer review and that are consistent with those of the Foundation for the National Institutes of Health, to the extent determined practicable and appropriate by the Board;

''(vii) specify a cap on administrative expenses for recipients of a grant, contract, or cooperative agreement from the Foundation;

''(viii) establish policies for the execution of memoranda of understanding and cooperative agreements between the Foundation and other entities, including the Food and Drug Administration;

''(ix) establish policies for funding training fellowships, whether at the Foundation, academic or scientific institutions, or the Food

and Drug Administration, for scientists, doctors, and other professionals who are not employees of regulated industry, to foster greater understanding of and expertise in new scientific tools, diagnostics, manufacturing techniques, and potential barriers to translating basic research into clinical and regulatory practice;

''(x) specify a process for annual Board review of the operations of the Foundation; and

''(xi) establish specific duties of the Executive Director;

''(B) prioritize and provide overall direction to the activities of the Foundation;

''(C) evaluate the performance of the Executive Director; and

''(D) carry out any other necessary activities regarding the functioning of the Foundation.

''(3) TERMS AND VACANCIES.—

''(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C) shall be 4 years, except that the terms of offices for the initial appointed members of the Board shall expire on a staggered basis as determined by the ex officio members.

''(B) VACANCY.—Any vacancy in the membership of the Board—

''(i) shall not affect the power of the remaining members to execute the duties of the Board; and

''(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

''(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

''(D) SERVING PAST TERM.—A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

''(4) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

''(e) INCORPORATION.—The ex officio members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

''(f) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c) of the Internal Revenue Code of 1986, and shall be subject to the provisions of such section.

''(g) EXECUTIVE DIRECTOR.—

''(1) IN GENERAL.—The Board shall appoint an Executive Director who shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

''(2) COMPENSATION.—The compensation of the Executive Director shall be fixed by the Board but shall not be greater than the compensation of the Commissioner.

''(h) ADMINISTRATIVE POWERS.—In carrying out this subchapter, the Board, acting through the Executive Director, may—

''(1) adopt, alter, and use a corporate seal, which shall be judicially noticed;

''(2) hire, promote, compensate, and discharge 1 or more officers, employees, and agents, as may be necessary, and define their duties;

''(3) prescribe the manner in which—

''(A) real or personal property of the Foundation is acquired, held, and transferred;

''(B) general operations of the Foundation are to be conducted; and

''(C) the privileges granted to the Board by law are exercised and enjoyed;

''(4) with the consent of the applicable executive department or independent agency, use the information, services, and facilities of such department or agencies in carrying out this section;

''(5) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

''(6) hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation under subsection (i);

''(7) enter into such other contracts, leases, cooperative agreements, and other transactions as the Board considers appropriate to conduct the activities of the Foundation;

''(8) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this subchapter;

''(9) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

''(10) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

''(11) appoint other groups of advisors as may be determined necessary to carry out the functions of the Foundation; and

''(12) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this subchapter.

''(i) ACCEPTANCE OF FUNDS FROM OTHER SOURCES.—The Executive Director may solicit and accept on behalf of the Foundation, any funds, gifts, grants, devises, or bequests of real or personal property made to the Foundation, including from private entities, for the purposes of carrying out the duties of the Foundation.

''(j) SERVICE OF FEDERAL EMPLOYEES.—Federal Government employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities.

''(k) DETAIL OF GOVERNMENT EMPLOYEES; FELLOWSHIPS.—

''(1) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies to the Foundation at any time, and such detail shall be without interruption or loss of civil service status or privilege. Each such employee shall abide by the statutory, regulatory, ethical, and procedural standards applicable to the employees of the agency from which such employee is detailed and those of the Foundation.

''(2) VOLUNTARY SERVICE; ACCEPTANCE OF FEDERAL EMPLOYEES.—

''(A) FOUNDATION.—The Executive Director of the Foundation may accept the services of employees detailed from Federal agencies with or without reimbursement to those agencies.

''(B) FOOD AND DRUG ADMINISTRATION.—The Commissioner may accept the uncompensated services of Foundation fellows or trainees. Such services shall be considered to be undertaking an activity under contract with the Secretary as described in section 708.

''(l) ANNUAL REPORTS.—

''(1) REPORTS TO FOUNDATION.—Any recipient of a grant, contract, fellowship, memorandum of understanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation a report on an annual basis for the duration of such grant, contract, fellowship, memorandum of understanding, or cooperative agreement, that describes the activities carried out under such grant, contract, fellowship, memorandum of understanding, or cooperative agreement.

''(2) REPORT TO CONGRESS AND THE FDA.—Beginning with fiscal year 2009, the Executive Director shall submit to Congress and the Commissioner an annual report that—

''(A) describes the activities of the Foundation and the progress of the Foundation in furthering the goals and priorities established under subsection (c)(2), including the practical impact of the Foundation on regulated product development;

''(B) provides a specific accounting of the source and use of all funds used by the Foundation to carry out such activities; and

''(C) provides information on how the results of Foundation activities could be incorporated into the regulatory and product review activities of the Food and Drug Administration.

''(m) SEPARATION OF FUNDS.—The Executive Director shall ensure that the funds received from the Treasury are held in separate accounts from funds received from entities under subsection (i).

''(n) FUNDING.—From amounts appropriated to the Food and Drug Administration for each fiscal year, the Commissioner shall transfer not less than $500,000 and not more than $1,250,000, to the Foundation to carry out subsections (a), (b), and (d) through (m).''.

(b) OTHER FOUNDATION PROVISIONS.—Chapter VII (21 U.S.C. 371 et seq.) (as amended by subsection (a)) is amended by adding at the end the following:

''SEC. 771. LOCATION OF FOUNDATION.

''The Foundation shall, if practicable, be located not more than 20 miles from the District of Columbia.

''SEC. 772. ACTIVITIES OF THE FOOD AND DRUG ADMINISTRATION.

''(a) IN GENERAL.—The Commissioner shall receive and assess the report submitted to the Commissioner by the Executive Director of the Foundation under section 770(l)(2).

''(b) REPORT TO CONGRESS.—Beginning with fiscal year 2009, the Commissioner shall submit to Congress an annual report summarizing the incorporation of the information provided by the Foundation in the report described under section 770(l)(2) and by other recipients of grants, contracts, memoranda of understanding, or cooperative agreements into regulatory and product review activities of the Food and Drug Administration.

''(c) EXTRAMURAL GRANTS.—The provisions of this subchapter shall have no effect on any grant, contract, memorandum of understanding, or cooperative agreement between the Food and Drug Administration and any other entity entered into before, on, or after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007.''.

(c) CONFORMING AMENDMENT.—Section 742(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 3791(b)) is amended by adding at the end the following: ''Any such fellowships and training programs under this section or under section 770(d)(2)(A)(ix) may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or employees of the Department of Health and Human Services.''.

SEC. 222. OFFICE OF THE CHIEF SCIENTIST.

Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 910. OFFICE OF THE CHIEF SCIENTIST.

''(a) ESTABLISHMENT; APPOINTMENT.—The Secretary shall establish within the Office of the Commissioner an office to be known as the Office of the Chief Scientist. The Secretary shall appoint a Chief Scientist to lead such Office.

''(b) DUTIES OF THE OFFICE.—The Office of the Chief Scientist shall—

''(1) oversee, coordinate, and ensure quality and regulatory focus of the intramural research programs of the Food and Drug Administration;

''(2) track and, to the extent necessary, coordinate intramural research awards made by each center of the Administration or science-based office within the Office of the Commissioner, and ensure that there is no duplication of research efforts supported by the Reagan-Udall Foundation for the Food and Drug Administration;

''(3) develop and advocate for a budget to support intramural research;

''(4) develop a peer review process by which intramural research can be evaluated; and

''(5) identify and solicit intramural research proposals from across the Food and Drug Administration through an advisory board composed of employees of the Administration that shall include—

''(A) representatives of each of the centers and the science-based offices within the Office of the Commissioner; and

''(B) experts on trial design, epidemiology, demographics, pharmacovigilance, basic science, and public health.''.

Subtitle C—Clinical Trials

SEC. 231. EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended by—

(1) redesignating subsections (j) and (k) as subsections (k) and (l), respectively; and

(2) inserting after subsection (i) the following:

''(j) EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.—

''(1) DEFINITIONS; REQUIREMENT.—

''(A) DEFINITIONS.—In this subsection:

''(i) APPLICABLE DEVICE CLINICAL TRIAL.—The term 'applicable device clinical trial' means—

''(I) a prospective study of health outcomes comparing an intervention against a control in human subjects intended to support an application under section 515 or 520(m), or a report under section 510(k), of the Federal Food, Drug, and Cosmetic Act (other than a limited study to gather essential information used to refine the device or design a pivotal trial and that is not intended to determine safety and effectiveness of a device); and

''(II) a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

''(ii) APPLICABLE DRUG CLINICAL TRIAL.—

''(I) IN GENERAL.—The term 'applicable drug clinical trial' means a controlled clinical investigation, other than a phase I clinical investigation, of a product subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act.

''(II) CLINICAL INVESTIGATION.—For purposes of subclause (I), the term 'clinical investigation' has the meaning given that term in section 312.3 of title 21, Code of Federal Regulations.

''(III) PHASE I.—The term 'phase I' has the meaning given that term in section 312.21 of title 21, Code of Federal Regulations.

''(iii) CLINICAL TRIAL INFORMATION.—The term 'clinical trial information' means those data elements that are necessary to complete an entry in the clinical trial registry data bank under paragraph (2).

''(iv) COMPLETION DATE.—The term 'completion date' means, with respect to an applicable drug clinical trial or an applicable device clinical trial, the date on which the last patient enrolled in the clinical trial has completed his or her last medical visit of the clinical trial, whether the clinical trial concluded according to the prespecified protocol plan or was terminated.

''(v) DEVICE.—The term 'device' means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

''(vi) DRUG.—The term 'drug' means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act or a biological product as defined in section 351 of this Act.

''(vii) RESPONSIBLE PARTY.—The term 'responsible party', with respect to a clinical trial of a drug or device, means—

''(I) the sponsor of the clinical trial (as defined in section 50.3 of title 21, Code of Federal Regulations (or any successor regulations)) or the principal investigator of such clinical trial if so designated by such sponsor; or

''(II) if no sponsor exists, the grantee, contractor, or awardee for a trial funded by a Federal agency or the principal investigator of such clinical trial if so designated by such grantee, contractor, or awardee.

''(B) REQUIREMENT.—The Secretary shall develop a mechanism by which—

''(i) the responsible party for each applicable drug clinical trial and applicable device clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information under paragraph (2); and

''(ii) other Federal agencies may identify the responsible party for an applicable drug clinical trial or applicable device clinical trial.

''(2) EXPANSION OF CLINICAL TRIAL REGISTRY DATA BANK WITH RESPECT TO CLINICAL TRIAL INFORMATION.—

''(A) IN GENERAL.—

''(i) EXPANSION OF DATA BANK.—To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials, the Secretary, acting through the Director of NIH, shall expand, in accordance with this subsection, the clinical trials registry of the data bank described under subsection (i)(3)(A) (referred to in this subsection as the 'registry data bank'). The Director of NIH shall ensure that the registry data bank is made publicly available through the Internet.

''(ii) CONTENT.—Not later than 18 months after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, and after notice and comment, the Secretary shall promulgate regulations to expand the registry data bank to require the submission to the registry data bank of clinical trial information for applicable drug clinical trials and applicable device clinical trials that—

''(I) conforms to the International Clinical Trials Registry Platform trial registration data set of the World Health Organization;

''(II) includes the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed;

''(III) if the drug is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act, specifies whether or not there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act for those who do not qualify for enrollment in the clinical trial and how to obtain information about such access;

''(IV) requires the inclusion of such other data elements to the registry data bank as appropriate; and

''(V) becomes effective 90 days after issuance of the final rule.

''(B) FORMAT AND STRUCTURE.—

''(i) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the public may search the entries in the registry data bank by 1 or more of the following criteria:

''(I) The disease or condition being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.

''(II) The treatment being studied in the clinical trial.

''(III) The location of the clinical trial.

''(IV) The age group studied in the clinical trial, including pediatric subpopulations.

''(V) The study phase of the clinical trial.

''(VI) The source of support for the clinical trial, which may be the National Institutes of Health or other Federal agency, a private industry source, or a university or other organization.

''(VII) The recruitment status of the clinical trial.

''(VIII) The National Clinical Trial number or other study identification for the clinical trial.

''(ii) FORMAT.—The Director of the NIH shall ensure that the registry data bank is easily used by the public, and that entries are easily compared.

''(C) DATA SUBMISSION.—The responsible party for an applicable drug clinical trial shall submit to the Director of NIH for inclusion in the registry data bank the clinical trial information described in subparagraph (A)(ii).

''(D) TRUTHFUL CLINICAL TRIAL INFORMATION.—

''(i) IN GENERAL.—The clinical trial information submitted by a responsible party under this paragraph shall not be false or misleading in any particular.

''(ii) EFFECT.—Clause (i) shall not have the effect of requiring clinical trial information with respect to an applicable drug clinical trial or an applicable device clinical trial to include information from any source other than such clinical trial involved.

''(E) CHANGES IN CLINICAL TRIAL STATUS.—

''(i) ENROLLMENT.—The responsible party for an applicable drug clinical trial or an applicable device clinical trial shall update the enrollment status not later than 30 days after the enrollment status of such clinical trial changes.

''(ii) COMPLETION.—The responsible party for an applicable drug clinical trial or applicable device clinical trial shall report to the Director of NIH that such clinical trial is complete not later than 30 days after the completion date of the clinical trial.

''(F) TIMING OF SUBMISSION.—The clinical trial information for an applicable drug clinical trial or an applicable device clinical trial required to be submitted under this paragraph shall be submitted not later than 21 days after the first patient is enrolled in such clinical trial.

''(G) POSTING OF DATA.—

''(i) APPLICABLE DRUG CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable drug clinical trial submitted in accordance with this paragraph is posted publicly within 30 days of such submission.

''(ii) APPLICABLE DEVICE CLINICAL TRIAL.—The Director of NIH shall ensure that clinical trial information for an applicable device clinical trial submitted in accordance with this paragraph is posted publicly within 30 days of clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act, or approval under section 515 or section 520(m) of such Act, as applicable.

''(H) VOLUNTARY SUBMISSIONS.—A responsible party for a clinical trial that is not an applicable drug clinical trial or an applicable device clinical trial may submit clinical trial information to the registry data bank in accordance with this subsection.

''(3) EXPANSION OF REGISTRY DATA BANK TO INCLUDE RESULTS OF CLINICAL TRIALS.—

''(A) LINKING REGISTRY DATA BANK TO EXISTING RESULTS.—

''(i) IN GENERAL.—Beginning not later than 90 days after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, for those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug involved is approved or after the device involved is cleared or approved, the Secretary shall ensure that the registry data bank includes links to results information for such clinical trial—

''(I) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

''(II) not later than 30 days after such information becomes publicly available, as applicable.

''(ii) REQUIRED INFORMATION.—

''(I) FDA INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

''(aa) If an advisory committee considered at a meeting an applicable drug clinical trial or an applicable device clinical trial, any posted Food and Drug Administration summary document regarding such applicable drug clinical trial or applicable clinical device trial.

''(bb) If an applicable drug clinical trial was conducted under section 505A or 505B of the Federal Food, Drug, and Cosmetic Act, a link to the posted Food and Drug Administration assessment of the results of such trial.

''(cc) Food and Drug Administration public health advisories regarding the drug or device that is the subject of the applicable drug clinical trial or applicable device clinical trial, respectively, if any.

''(dd) For an applicable drug clinical trial, the Food and Drug Administration action package for approval document required under section 505(l)(2) of the Food Drug and Cosmetic Act.

''(ee) For an applicable device clinical trial, in the case of a premarket application, the detailed summary of information respecting the safety and effectiveness of the device required under section 520(h)(1) of the Federal Food, Drug, and Cosmetic Act, or, in the case of a report under section 510(k) of such Act, the section 510(k) summary of the safety and effectiveness data required under section 807.95(d) of title 21, Code of Federal Regulations (or any successor regulations).

''(II) NIH INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

''(aa) Medline citations to any publications regarding each applicable drug clinical trial and applicable device clinical trial.

''(bb) The entry for the drug that is the subject of an applicable drug clinical trial in the National Library of Medicine database of structured product labels, if available.

''(iii) RESULTS FOR EXISTING DATA BANK ENTRIES.—The Secretary may include the links described in clause (ii) for data bank entries for clinical trials submitted to the data bank prior to enactment of the Enhancing Drug Safety and Innovation Act of 2007, as available.

''(B) FEASIBILITY STUDY.—The Director of NIH shall—

''(i) conduct a study to determine the best, validated methods of making the results of clinical trials publicly available after the approval of the drug that is the subject of an applicable drug clinical trial; and

''(ii) not later than 18 months after initiating such study, submit to the Secretary any findings and recommendations of such study.

''(C) NEGOTIATED RULEMAKING.—

''(i) IN GENERAL.—The Secretary shall establish a negotiated rulemaking process pursuant to subchapter IV of chapter 5 of title 5, United States Code, to determine, for applicable drug clinical trials—

''(I) how to ensure quality and validate methods of expanding the registry data bank to include clinical trial results information for trials not within the scope of this Act;

''(II) the clinical trials of which the results information is appropriate for adding to the expanded registry data bank; and

''(III) the appropriate timing of the posting of such results information.

''(ii) TIME REQUIREMENT.—The process described in paragraph (1) shall be conducted in a timely manner to ensure that—

''(I) any recommendation for a proposed rule—

''(aa) is provided to the Secretary not later than 21 months after the date of the enactment of the Enhancing Drug Safety and Innovation Act of 2007; and

''(bb) includes an assessment of the benefits and costs of the recommendation; and

''(II) a final rule is promulgated not later than 30 months after the date of the enactment of the Enhancing Drug Safety and Innovation Act of 2007, taking into account the recommendations under subclause (I) and the results of the feasibility study conducted under subparagraph (B).

''(iii) REPRESENTATION ON NEGOTIATED RULEMAKING COMMITTEE.—The negotiated rulemaking committee established by the Secretary pursuant to clause (i) shall include members representing—

''(I) the Food and Drug Administration;

''(II) the National Institutes of Health;

''(III) other Federal agencies as the Secretary determines appropriate;

''(IV) patient advocacy and health care provider groups;

''(V) the pharmaceutical industry;

''(VI) contract clinical research organizations;

''(VII) the International Committee of Medical Journal Editors; and

''(VIII) other interested parties, including experts in privacy protection, pediatrics, health information technology, health literacy, communication, clinical trial design and implementation, and health care ethics.

''(iv) CONTENT OF REGULATIONS.—The regulations promulgated pursuant to clause (i) shall establish—

''(I) procedures to determine which clinical trials results information data elements shall be included in the registry data bank, taking into account the needs of different populations of users of the registry data bank;

''(II) a standard format for the submission of clinical trials results to the registry data bank;

''(III) a standard procedure for the submission of clinical trial results information, including the timing of submission and the timing of posting of results information, to the registry data bank, taking into account the possible impacts on publication of manuscripts based on the clinical trial;

''(IV) a standard procedure for the verification of clinical trial results information, including ensuring that free text data elements are non-promotional; and

''(V) an implementation plan for the prompt inclusion of clinical trials results information in the registry data bank.

''(D) CONSIDERATION OF WORLD HEALTH ORGANIZATION DATA SET.—The Secretary shall consider the status of the consensus data elements set for reporting clinical trial results of the World Health Organization when promulgating the regulations under subparagraph (C).

''(E) TRUTHFUL CLINICAL TRIAL INFORMATION.—

''(i) IN GENERAL.—The clinical trial information submitted by a responsible party under this paragraph shall not be false or misleading in any particular.

''(ii) EFFECT.—Clause (i) shall not have the effect of requiring clinical trial information with respect to an applicable drug clinical trial or an applicable device clinical trial to include information from any source other than such clinical trial involved.

''(F) WAIVERS REGARDING CERTAIN CLINICAL TRIAL RESULTS.—The Secretary may waive any applicable requirements of this paragraph for an applicable drug clinical trial or an applicable device clinical trial, upon a written request from the responsible person, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is in the public interest, consistent with the protection of public health, or in the interest of national security. Not later than 30 days after any part of a waiver is granted, the Secretary shall notify, in writing, the appropriate committees of Congress of the waiver and provide an explanation for why the waiver was granted.

''(4) COORDINATION AND COMPLIANCE.—

''(A) CLINICAL TRIALS SUPPORTED BY GRANTS FROM FEDERAL AGENCIES.—

''(i) IN GENERAL.—No Federal agency may release funds under a research grant to an awardee who has not complied with paragraph (2) for any applicable drug clinical trial or applicable device clinical trial for which such person is the responsible party.

''(ii) GRANTS FROM CERTAIN FEDERAL AGENCIES.—If an applicable drug clinical trial or applicable device clinical trial is funded in whole or in part by a grant from the Food and Drug Administration, National Institutes of Health, the Agency for Healthcare Research and Quality, or the Department of Veterans Affairs, any grant or progress report forms required under such grant shall include a certification that the responsible party has made all required submissions to the Director of NIH under paragraph (2).

''(iii) VERIFICATION BY FEDERAL AGENCIES.—The heads of the agencies referred to in clause (ii), as applicable, shall verify that the clinical trial information for each applicable drug clinical trial or applicable device clinical trial for which a grantee is the responsible party has been submitted under paragraph (2) before releasing any remaining funding for a grant or funding for a future grant to such grantee.

''(iv) NOTICE AND OPPORTUNITY TO REMEDY.—If the head of an agency referred to in clause (ii), as applicable, verifies that a grantee has not submitted clinical trial information as described in clause (iii), such agency head shall provide notice to such grantee of such non-compliance and allow such grantee 30 days to correct such non-compliance and submit the required clinical trial information.

''(v) CONSULTATION WITH OTHER FEDERAL AGENCIES.—The Secretary shall—

''(I) consult with other agencies that conduct research involving human subjects in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulations), to determine if any such research is an applicable drug clinical trial or an applicable device clinical trial under paragraph (1); and

''(II) develop with such agencies procedures comparable to those described in clauses (ii), (iii), and (iv) to ensure that clinical trial information for such applicable drug clinical trials and applicable device clinical trial is submitted under paragraph (2).

''(B) CERTIFICATION TO ACCOMPANY DRUG, BIOLOGICAL PRODUCT, AND DEVICE SUBMISSIONS.—At the time of submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, section 520(m) of such Act, or section 351 of this Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of this subsection have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

''(C) VERIFICATION OF SUBMISSION PRIOR TO POSTING.—In the case of clinical trial information that is submitted under paragraph (2), but is not made publicly available pending regulatory approval or clearance, as applicable, the Director of NIH shall respond to inquiries from other Federal agencies and peer-reviewed scientific journals to confirm that such clinical trial information has been submitted but has not yet been posted.

''(5) LIMITATION ON DISCLOSURE OF CLINICAL TRIAL INFORMATION.—

''(A) IN GENERAL.—Nothing in this subsection (or under section 552 of title 5, United States Code) shall require the Secretary to publicly disclose, from any record or source other than the registry data bank expanded under this subsection, information described in subparagraph (B).

''(B) INFORMATION DESCRIBED.—Information described in this subparagraph is—

''(i) information submitted to the Director of NIH under this subsection, or information of the same general nature as (or integrally associated with) the information so submitted; and

''(ii) not otherwise publicly available, including because it is protected from disclosure under section 552 of title 5, United States Code.

''(6) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $10,000,000 for each fiscal year.''.

(b) CONFORMING AMENDMENTS.—

(1) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(jj)(1) The failure to submit the certification required by section 402(j)(4)(B) of the Public Health Service Act, or knowingly submitting a false certification under such section.

''(2) The submission of clinical trial information under subsection (i) or (j) of section 402 of the Public Health Service Act that is promotional or false or misleading in any particular under paragraph (2) or (3) of such subsection (j).''.

(2) CIVIL MONEY PENALTIES.—Section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)), as amended by section 203, is further amended by—

(A) redesignating paragraphs (4), (5), and (6) as paragraphs (5), (6), and (7), respectively;

(B) inserting after paragraph (3) the following:

''(4) Any person who violates section 301(jj) shall be subject to a civil monetary penalty of not more than $10,000 for the first violation, and not more than $20,000 for each subsequent violation.'';

(C) in paragraph (2)(C), by striking ''paragraph (4)(A)'' and inserting ''paragraph (5)(A)'';

(D) in paragraph (5), as so redesignated, by striking ''paragraph (1), (2), or (3)'' each place it appears and inserting ''paragraph (1), (2), (3), or (4)''; and

(E) in paragraph (7), as so redesignated, by striking ''paragraph (5)'' each place it appears and inserting ''paragraph (6)''.

(3) NEW DRUGS AND DEVICES.—

(A) INVESTIGATIONAL NEW DRUGS.—Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended in paragraph (4), by adding at the end the following: ''The Secretary shall update such regulations to require inclusion in the informed consent form a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsections (i) and (j) of section 402 of the Public Health Service Act.''.

(B) NEW DRUG APPLICATIONS.—Section 505(b) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following:

''(6) An application submitted under this subsection shall be accompanied by the certification required under section 402(j)(4)(B) of the Public Health Service Act. Such certification shall not be considered an element of such application.''.

(C) DEVICE REPORTS UNDER SECTION 510(k).—Section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is amended by adding at the end the following:

''A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 402(j)(1) of the Public Health Service Act) shall be accompanied by the certification required under section 402(j)(4)(B) of such Act. Such certification shall not be considered an element of such notification.''.

(D) DEVICE PREMARKET APPROVAL APPLICATION.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended—

(i) in subparagraph (F), by striking ''; and'' and inserting a semicolon;

(ii) by redesignating subparagraph (G) as subparagraph (H); and

(iii) by inserting after subparagraph (F) the following:

''(G) the certification required under section 402(j)(4)(B) of the Public Health Service Act (which shall not be considered an element of such application); and''.

(E) HUMANITARIAN DEVICE EXEMPTION.—Section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended in the first sentence in the matter following subparagraph (C), by inserting at the end before the period ''and such application shall include the certification required under section 402(j)(4)(B) of the Public Health Service Act (which shall not be considered an element of such application)''.

(c) PREEMPTION.—

(1) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database.

(2) RULE OF CONSTRUCTION.—The fact of submission of clinical trial information, if submitted in compliance with subsection (i) and (j) of section 402 of the Public Health Service Act (as amended by this section), that relates to a use of a drug or device not included in the official labeling of the approved drug or device shall not be construed by the Secretary or in any administrative or judicial proceeding, as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. The availability of clinical trial information through the data bank under such subsections (i) and (j), if submitted in compliance with such subsections, shall not be considered as labeling, adulteration, or misbranding of the drug or device under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(d) TRANSITION RULE; EFFECTIVE DATE OF FUNDING RESTRICTIONS.—

(1) TRANSITION RULE FOR CLINICAL TRIALS INITIATED PRIOR TO EXPANSION OF REGISTRY DATA BANK.—The responsible party (as defined in paragraph (1) of section 402(j) of the Public Health Service Act (as added by this section)) for an applicable drug clinical trial or applicable device clinical trial (as defined under such paragraph (1)) that is initiated after the date of enactment of this subtitle and before the effective date of the regulations promulgated under paragraph (2) of such section 402(j), shall submit required clinical trial information under such section not later than 120 days after such effective date.

(2) FUNDING RESTRICTIONS.—Subparagraph (A) of paragraph (4) of such section 402(j) shall take effect 210 days after the effective date of the regulations promulgated under paragraph (2) of such section 402(j).

(e) EFFECTIVE DATE.—

(1) IN GENERAL.—Beginning 90 days after the date of enactment of this title, the responsible party for an applicable drug clinical trial or an applicable device clinical trial (as that term is defined in such section 402(j)) that is initiated after the date of enactment of this title and before the effective date of the regulations issued under subparagraph (A) of paragraph (2) of such subsection, shall submit clinical trial information under such paragraph (2).

(2) RULEMAKING.—

(A) IN GENERAL.—Except as provided in subparagraph (B), subsection (c)(1) shall become effective on the date on which the regulation promulgated pursuant to section 402(j)(3)(C)(i) of the Public Health Service Act, as added by this section, becomes effective.

(B) EXCEPTION.—Subsection (c)(1) shall apply with respect to any clinical trial for which the registry data bank includes links to results information, as provided for under section 402(j)(3)(A) of such Act, as added by this section.

Subtitle D—Conflicts of Interest

SEC. 241. CONFLICTS OF INTEREST.

(a) IN GENERAL.—Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by inserting at the end the following:

''SEC. 712. CONFLICTS OF INTEREST.

''(a) DEFINITIONS.—For purposes of this section:

''(1) ADVISORY COMMITTEE.—The term 'advisory committee' means an advisory committee under the Federal Advisory Committee Act that provides advice or recommendations to the Secretary regarding activities of the Food and Drug Administration.

''(2) FINANCIAL INTEREST.—The term 'financial interest' means a financial interest under section 208(a) of title 18, United States Code.

''(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

''(1) RECRUITMENT.—

''(A) IN GENERAL.—Given the importance of advisory committees to the review process at the Food and Drug Administration, the Secretary shall carry out informational and recruitment activities for purposes of recruiting individuals to serve as advisory committee members. The Secretary shall seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities. The Secretary shall also take into account the advisory committees with the greatest number of vacancies.

''(B) RECRUITMENT ACTIVITIES.—The recruitment activities under subparagraph (A) may include—

''(i) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

''(ii) making widely available, including by using existing electronic communications channels, the contact information for the Food and Drug Administration point of contact regarding advisory committee nominations; and

''(iii) developing a method through which an entity receiving National Institutes of Health funding can identify a person who the Food and Drug Administration can contact regarding the nomination of individuals to serve on advisory committees.

''(2) EVALUATION AND CRITERIA.—When considering a term appointment to an advisory committee, the Secretary shall review the expertise of the individual and the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978 for each individual under consideration for the appointment, so as to reduce the likelihood that an appointed individual will later require a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in subsection (c)(3) of this section for service on the committee at a meeting of the committee.

''(c) GRANTING AND DISCLOSURE OF WAIVERS.—

''(1) IN GENERAL.—Prior to a meeting of an advisory committee regarding a 'particular matter' (as that term is used in section 208 of title 18, United States Code), each member of the committee who is a full-time Government employee or special Government employee shall disclose to the Secretary financial interests in accordance with subsection (b) of such section 208.

''(2) FINANCIAL INTEREST OF ADVISORY COMMITTEE MEMBER OR FAMILY MEMBER.—No member of an advisory committee may vote with respect to any matter considered by the advisory committee if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such matter, excluding interests exempted in regulations issued by the Director of the Office of Government Ethics as too remote or inconsequential to affect the integrity of the services of the Government officers or employees to which such regulations apply.

''(3) WAIVER.—The Secretary may grant a waiver of the prohibition in paragraph (2) if such waiver is necessary to afford the advisory committee essential expertise.

''(4) LIMITATION.—The Secretary may not grant a waiver under paragraph (3) for a member of an advisory committee when the member's own scientific work is involved.

''(5) DISCLOSURE OF WAIVER.—Notwithstanding section 107(a)(2) of the Ethics in Government Act (5 U.S.C. App.), the following shall apply:

''(A) 15 OR MORE DAYS IN ADVANCE.—As soon as practicable, but in no case later than 15 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (3) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code (popularly known as the Freedom of Information Act and the Privacy Act of 1974, respectively)) on the Internet website of the Food and Drug Administration—

''(i) the type, nature, and magnitude of the financial interests of the advisory committee member to which such determination, certification, or waiver applies; and

''(ii) the reasons of the Secretary for such determination, certification, or waiver.

''(B) LESS THAN 30 DAYS IN ADVANCE.—In the case of a financial interest that becomes known to the Secretary less than 30 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (3) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code) on the Internet website of the Food and Drug Administration, the information described in clauses (i) and (ii) of subparagraph (A) as soon as practicable after the Secretary makes such determination, certification, or waiver, but in no case later than the date of such meeting.

''(d) PUBLIC RECORD.—The Secretary shall ensure that the public record and transcript of each meeting of an advisory committee includes the disclosure required under subsection (c)(5) (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code).

''(e) ANNUAL REPORT.—Not later than February 1 of each year, the Secretary shall submit to the Inspector General of the Department of Health and Human Services, the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives, a report that describes—

''(1) with respect to the fiscal year that ended on September 30 of the previous year, the number of vacancies on each advisory committee, the number of nominees received for each committee, and the number of such nominees willing to serve;

''(2) with respect to such year, the aggregate number of disclosures required under subsection (c)(5) for each meeting of each advisory committee and the percentage of individuals to whom such disclosures did not apply who served on such committee for each such meeting;

''(3) with respect to such year, the number of times the disclosures required under subsection (c)(5) occurred under subparagraph (B) of such subsection; and

''(4) how the Secretary plans to reduce the number of vacancies reported under paragraph (1) during the fiscal year following such year, and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by the Food and Drug Administration as academicians or practitioners.

''(f) PERIODIC REVIEW OF GUIDANCE.—Not less than once every 5 years, the Secretary shall review guidance of the Food and Drug Administration regarding conflict of interest waiver determinations with respect to advisory committees and update such guidance as necessary.''.

(b) CONFORMING AMENDMENT.—Section 505(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(n)) is amended by—

(1) striking paragraph (4); and

(2) redesignating paragraphs (5), (6), (7), and (8) as paragraphs (4), (5), (6), and (7), respectively.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on October 1, 2007.

Subtitle E—Other Drug Safety Provisions

SEC. 251. DATABASE FOR AUTHORIZED GENERIC DRUGS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this title, is further amended by adding at the end the following:

''(q) DATABASE FOR AUTHORIZED GENERIC DRUGS.—

''(1) IN GENERAL.—

''(A) PUBLICATION.—The Commissioner shall—

''(i) not later than 9 months after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, publish a complete list on the Internet website of the Food and Drug Administration of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

''(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

''(B) NOTIFICATION.—The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, any time the Commissioner updates the information described in subparagraph (A).

''(2) INCLUSION.—The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 1999.

''(3) AUTHORIZED GENERIC DRUG.—In this section, the term 'authorized generic drug' means a listed drug (as that term is used in subsection (j)) that—

''(A) has been approved under subsection (c); and

''(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.''.

SEC. 252. MEDICAL MARIJUANA.

The Secretary shall require that State-legalized medical marijuana be subject to the full regulatory requirements of the Food and Drug Administration, including a risk evaluation and mitigation strategy and all other requirements and penalties of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) regarding safe and effective reviews, approval, sale, marketing, and use of pharmaceuticals.

TITLE III—MEDICAL DEVICES

SEC. 300. REFERENCES.

Except as otherwise specified, whenever in this title an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

Subtitle A—Device User Fees

SEC. 301. SHORT TITLE.

This subtitle may be cited as the ''Medical Device User Fee Amendments of 2007''.

SEC. 302. DEVICE FEES.

Section 737 (21 U.S.C. 379i) is amended—

(1) by striking the section designation and all that follows through ''For purposes of this subchapter'' and inserting the following:

''SEC. 737. DEVICE FEES.

''(a) PURPOSE.—It is the purpose of this part that the fees authorized under this part be dedicated toward expediting the process

for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of this part in the letters from the Secretary to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

''(b) REPORTS.—

''(1) PERFORMANCE REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in subsection (a) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications, supplements, and premarket notifications in the cohort.

''(2) FISCAL REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

''(3) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet website of the Food and Drug Administration.

''(c) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Energy and Commerce of the House of Representatives;

''(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(C) scientific and academic experts;

''(D) health care professionals;

''(E) representatives of patient and consumer advocacy groups; and

''(F) the regulated industry.

''(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

''(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

''(B) publish such recommendations in the Federal Register;

''(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

''(D) hold a meeting at which the public may present its views on such recommendations; and

''(E) after consideration of such public views and comments, revise such recommendations as necessary.

''(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

''(d) DEFINITIONS.—For purposes of this part:'';

(2) by redesignating paragraphs (5), (6), (7), and (8), as paragraphs (7), (8), (9), and (11), respectively;

(3) in paragraph (4)—

(A) in subparagraph (A), by striking ''or an efficacy supplement,'' and inserting ''an efficacy supplement, or a 30-day notice,''; and

(B) by adding at the end the following:

''(F) The term '30-day notice' means a supplement to an approved premarket application or premarket report under section 515 that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.'';

(4) by inserting after paragraph (4) the following:

''(5) The term 'request for classification information' means a request made under section 513(g) for information respecting the class in which a device has been classified or the requirements applicable to a device.

''(6) The term 'annual fee for periodic reporting concerning a class III device' means the fee associated with reports imposed by a premarket application approval order (as described in section 814.82(a)(7) of title 21, Code of Federal Regulations), usually referred to as 'annual reports.' '';

(5) in paragraph (9), as redesignated by paragraph (2)—

(A) by striking ''April of'' and inserting ''October of''; and

(B) by striking ''April 2002'' and inserting ''October 2001'';

(6) by inserting after paragraph (9), as redesignated by paragraph (2), the following:

''(10) The term 'person' includes an affiliate of such person.''; and

(7) by adding at the end the following:

''(12) The term 'establishment subject to a registration fee' means an establishment required to register with the Secretary under section 510 at which any of the following types of activities are conducted:

''(A) MANUFACTURER.—An establishment that makes by any means any article that is a device including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.

''(B) SINGLE-USE DEVICE REPROCESSOR.—An establishment that performs manufacturing operations on a single-use device that has previously been used on a patient.

''(C) SPECIFICATION DEVELOPER.—An establishment that develops specifications for a device that is distributed under the establishment's name but that performs no manufacturing, including establishments that, in addition to developing specifications, arrange for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.

''(13) The term 'establishment registration fee' means a fee assessed under section 738(a)(3) for the registration of an establishment subject to a registration fee.

''(e) SUNSET.—This part shall cease to be effective on October 1, 2012, except that subsection (b) with respect to reports shall cease to be effective January 31, 2013.''.

SEC. 303. AUTHORITY TO ASSESS AND USE DEVICE FEES.

Section 738 (21 U.S.C. 379j) is amended—

(1) in subsection (a)—

(A) in paragraph (2)—

(i) in the header, by inserting '', AND ANNUAL FEE FOR PERIODIC REPORTING CONCERNING A CLASS III DEVICE'' after ''FEE'';

(ii) in subparagraph (A)—

(I) in clause (iii), by inserting ''75 percent of'' after ''a fee equal to'';

(II) in clause (iv), by striking ''21.5'' and inserting ''15'';

(III) in clause (v), by striking ''7.2'' and inserting ''7'';

(IV) by redesignating clauses (vi) and (vii) as clauses (vii) and (viii), respectively;

(V) by inserting after clause (v) the following:

''(vi) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).'';

(VI) in clause (viii), as redesignated by subclause (IV)—

(aa) by striking ''1.42'' and inserting ''1.84''; and

(bb) by striking '', subject to any adjustment under subsection (e)(2)(C)(ii)''; and

(VII) by adding at the end the following:

''(ix) For a request for classification information, a fee equal to 1.35 percent of the fee that applies under clause (i).

''(x) For periodic reporting concerning a class III device, the annual fee shall be equal to 3.5 percent of the fee that applies under clause (i).'';

(iii) in subparagraph (C)—

(I) in the first sentence—

(aa) by striking ''or''; and

(bb) by striking ''except that'' and all that follows through the period and inserting '', 30-day notice, request for classification information, or periodic report concerning a class III device.''; and

(II) by striking the third sentence; and

(iv) in subparagraph (D)—

(I) in clause (iii), by striking the last two sentences; and

(II) by adding at the end the following:

''(iv) MODULAR APPLICATION WITHDRAWN BEFORE FIRST ACTION.—The Secretary shall refund 75 percent of the application fee paid for a modular application submitted under section 515(c)(4) that is withdrawn before a second module is submitted and before a first action on the first module. If the modular application is withdrawn after a second or subsequent module is submitted but before any first action, the Secretary may return a portion of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of the modules submitted.

''(v) SOLE DISCRETION TO REFUND.—The Secretary shall have sole discretion to refund a fee or portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.''; and

(B) by adding at the end the following:

''(3) ANNUAL ESTABLISHMENT REGISTRATION FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration beginning with its registration for fiscal year 2008.

''(B) EXCEPTION FOR FEDERAL OR STATE GOVERNMENT ESTABLISHMENT.—No fee shall be required under subparagraph (A) for an establishment operated by a Federal or State government entity unless a device manufactured by the establishment is to be distributed commercially.

''(C) PAYMENT.—The annual establishment registration fee shall be due once each fiscal year, upon the initial registration of the establishment or upon the annual registration under section 510.'';

(2) by striking subsection (b) and inserting the following:

''(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), and (e), the fees under subsection (a) shall be based on the following fee amounts:

Fee Type	Fiscal Year 2008	Fiscal Year 2009	Fiscal Year 2010	Fiscal Year 2011	Fiscal Year 2012
Premarket Application	$185,000	$200,725	$217,787	$236,298	$256,384
Establishment Registration Fee	$1,706	$1,851	$2,008	$2,179	$2,364'';

(3) in subsection (c)—

(A) in the heading, by striking ''Annual Fee Setting.—'' and inserting ''ANNUAL FEE SETTING.—'';

(B) in paragraph (1), by striking the second sentence;

(C) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;

(D) by inserting after paragraph (1) the following:

''(2) ADJUSTMENT OF ANNUAL ESTABLISHMENT REGISTRATION FEE.—

''(A) IN GENERAL.—When setting the fees for fiscal year 2010, the Secretary may increase the establishment registration fee specified in subsection (b) only if the Secretary estimates that the number of establishments submitting fees for fiscal year 2009 is less than 12,250. The percent increase shall be the percent by which the estimate of establishments submitting fees in fiscal year 2009 is less than 12,750, but in no case shall the percent increase be more than 8.5 percent over the amount for such fee specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the establishment registration fee for fiscal year 2010, then the establishment registration fee for fiscal years 2011 and 2012 under subsection (b) shall be adjusted as follows: the fee for fiscal year 2011 shall be equal to the adjusted fee for fiscal year 2010, increased by 8.5 percent, and the fee for fiscal year 2012 shall be equal to the adjusted fee for fiscal year 2011, increased by 8.5 percent.

''(B) PUBLICATION IN THE FEDERAL REGISTER.—The Secretary shall publish any determination with respect to any establishment registration fee adjustment made under subparagraph (A), and the rationale for such determination, in the Federal Register.''; and

(E) in paragraph (4)(A), as so redesignated—

(i) by striking ''For fiscal years 2006 and 2007, the'' and inserting ''The''; and

(ii) by striking ''of fiscal year 2008'' and inserting ''of the next fiscal year'';

(4) in subsection (d)—

(A) in paragraph (1), by striking '', partners, and parent firms'';

(B) in paragraph (2)—

(i) in subparagraph (A), by striking '', partners, and parent firms'';

(ii) in subparagraph (B)—

(I) by striking ''An applicant shall'' and inserting the following:

''(i) IN GENERAL.—An applicant shall'';

(II) by striking ''The applicant shall support'' and inserting the following:

''(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support'';

(III) by striking '', partners, and parent firms'' both places the term appears;

(IV) by striking ''partners, or parent firms, the'' and inserting ''the'';

(V) by striking '', partners, or parent firms, respectively''; and

(VI) by adding at the end the following:

''(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of the following:

''(I) A signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant meets the criteria for a small business.

''(II) A certification, in English, from the national taxing authority of the country in which it is headquartered. Such certification shall provide the applicant's gross receipts and sales for the most recent year, in both the local currency and in United States dollars, the exchange rate used in making this conversion to dollars, and the dates during which these receipts and sales were collected, and it shall bear the official seal of the national taxing authority.

''(III) Identical certifications shall be provided for each of the applicant's affiliates.

''(IV) A statement signed by the head of the applicant or its chief financial officer that it has submitted certifications for all of its affiliates, or that it had no affiliates, whichever is applicable.''; and

(iii) in subparagraph (C)—

(I) by striking ''reduced rate of'' and inserting ''reduced rate of—''; and

(II) by striking ''38 percent'' and all that follows through the period and inserting the following:

''(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, a supplement, or a periodic report concerning a class III device; and

''(ii) 50 percent of the fee established under such subsection for a 30-day notice or a request for classification information.'';

(5) in subsection (e)—

(A) in paragraph (1), by striking ''2004'' and inserting ''2008''; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking '', partners, and parent firms'';

(ii) by striking subparagraph (B) and inserting the following:

''(B) EVIDENCE OF QUALIFICATION.—

''(i) IN GENERAL.—An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for the lower fee rate.

''(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for affiliates, the applicant shall certify that the applicant has no affiliates.

''(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of the following:

''(I) A signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant meets the criteria for a small business.

''(II) A certification, in English, from the national taxing authority of the country in which it is headquartered. Such certification shall provide the applicant's gross receipts and sales for the most recent year, in both the local currency and in United States dollars, and the exchange rate used in making such conversion to dollars, and the dates during which such receipts and sales were collected, and it shall bear the official seal of the national taxing authority.

''(III) Identical certifications shall be provided for each of the applicant's affiliates.

''(IV) A statement signed by the head of the applicant or its chief financial officer that it has submitted certifications for all of its affiliates, or that it had no affiliates, whichever is applicable.''; and

(iii) by striking subparagraph (C) and inserting the following:

''(C) REDUCED FEES.—For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 50 percent of the fee that applies under subsection (a)(2)(A)(viii) and as established under subsection (c)(1).'';

(6) by striking subsection (f) and inserting the following:

''(f) EFFECT OF FAILURE TO PAY FEES.—

''(1) IN GENERAL.—A premarket application, premarket report, supplement, or premarket notification submission, 30-day notice, request for classification information, or periodic report concerning a class III device submitted by a person subject to fees under paragraphs (2) and (3) of subsection (a) shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.

''(2) REGISTRATION INFORMATION.—Registration information submitted by an establishment subject to a registration fee under subsection (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until the registration fee owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment shall be deemed to have failed to register in accordance with section 510.'';

(7) in subsection (g)—

(A) by striking paragraph (1) and inserting the following:

''(1) PERFORMANCE GOALS; TERMINATION OF PROGRAM.—With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

''(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than $205,720,000 multiplied by the adjustment factor applicable to such fiscal year; or

''(B) fees were not assessed under subsection (a) for the previous fiscal year.''; and

(B) in paragraph (2), by striking ''and premarket notification submissions, and'' and inserting ''premarket notification submissions, 30-day notices, requests for classification information, periodic reports concerning a class III device, and establishment registrations''; and

(8) in subsection (h), by striking paragraphs (3) and (4) and inserting the following:

''(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

''(A) $48,431,000 for fiscal year 2008;

''(B) $52,547,000 for fiscal year 2009;

''(C) $57,014,000 for fiscal year 2010;

''(D) $61,860,000 for fiscal year 2011; and

''(E) $67,118,000 for fiscal year 2012.

''(4) OFFSET.—If the cumulative amount of fees collected during fiscal years 2008, 2009, and 2010, added to the amount estimated to be collected for fiscal year 2011 (which estimate shall be based upon the amount of fees received by the Secretary through June 30, 2011), exceeds the amount of fees specified in aggregate in paragraph (3) for such 4 fiscal years, the aggregate amount in excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.''.

SEC. 304. SAVINGS CLAUSE.

Notwithstanding section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), and notwithstanding the amendments made by this subtitle, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of enactment of this subtitle, shall continue to be in effect with respect to premarket applications, premarket reports, premarket notification submissions, and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.

SEC. 305. EFFECTIVE DATE.

The amendments made by this subtitle shall take effect on October 1, 2007.

Subtitle B—Amendments Regarding Regulation of Medical Devices

SEC. 311. INSPECTIONS BY ACCREDITED PERSONS.

Section 704(g) (21 U.S.C. 374(g)) is amended—

(1) in paragraph (1), by striking ''Not later than one year after the date of enactment of this subsection, the Secretary'' and inserting ''The Secretary'';

(2) in paragraph (2), by—

(A) striking ''Not later than 180 days after the date of enactment of this subsection, the'' and inserting ''The Secretary''; and

(B) striking the fifth sentence;

(3) in paragraph (3), by adding at the end the following:

''(F) Such person shall notify the Secretary of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems standard referred to in paragraph (7) for any device establishment that such person inspects under this subsection not later than 30 days after such withdrawal, suspension, restriction, or expiration.

''(G) Such person may conduct audits to establish conformance with the quality systems standard referred to in paragraph (7).'';

(4) by amending paragraph (6) to read as follows:

''(6)(A) Subject to subparagraphs (B) and (C), a device establishment is eligible for inspection by persons accredited under paragraph (2) if the following conditions are met:

''(i) The Secretary classified the results of the most recent inspection of the establishment as 'no action indicated' or 'voluntary action indicated'.

''(ii) With respect to inspections of the establishment to be conducted by an accredited person, the owner or operator of the establishment submits to the Secretary a notice that—

''(I) provides the date of the last inspection of the establishment by the Secretary and the classification of that inspection;

''(II) states the intention of the owner or operator to use an accredited person to conduct inspections of the establishment;

''(III) identifies the particular accredited person the owner or operator intends to select to conduct such inspections; and

''(IV) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

''(aa) at least 1 of such devices is marketed in the United States; and

''(bb) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries, 1 of which countries certifies, accredits, or otherwise recognizes the person accredited under paragraph (2) and identified under subclause (III) as a person authorized to conduct inspections of device establishments.

''(B)(i) Except with respect to the requirement of subparagraph (A)(i), a device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 30 days after receiving such notice, issues a response that—

''(I) denies clearance to participate as provided under subparagraph (C); or

''(II) makes a request under clause (ii).

''(ii) The Secretary may request from the owner or operator of a device establishment in response to the notice under subparagraph (A)(ii) with respect to the establishment, or from the particular accredited person identified in such notice—

''(I) compliance data for the establishment in accordance with clause (iii)(I); or

''(II) information concerning the relationship between the owner or operator of the establishment and the accredited person identified in such notice in accordance with clause (iii)(II).

The owner or operator of the establishment, or such accredited person, as the case may be, shall respond to such a request not later than 60 days after receiving such request.

''(iii)(I) The compliance data to be submitted by the owner or operation of a device establishment in response to a request under clause (ii)(I) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 501(h) and with other applicable provisions of this Act. Such data shall include complete reports of inspectional findings regarding good manufacturing practice or other quality control audits that, during the preceding 2-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other compliance data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

''(II) A request to an accredited person under clause (ii)(II) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1).

''(iv) A device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 60 days after receiving the information requested under clause (ii), issues a response that denies clearance to participate as provided under subparagraph (C).

''(C)(i) The Secretary may deny clearance to a device establishment if the Secretary has evidence that the certification under subparagraph (A)(ii)(IV) is untrue and the Secretary provides to the owner or operator of the establishment a statement summarizing such evidence.

''(ii) The Secretary may deny clearance to a device establishment if the Secretary determines that the establishment has failed to demonstrate consistent compliance for purposes of subparagraph (B)(iii)(I) and the Secretary provides to the owner or operator of the establishment a statement of the reasons for such determination.

''(iii)(I) The Secretary may reject the selection of the accredited person identified in the notice under subparagraph (A)(ii) if the Secretary provides to the owner or operator of the establishment a statement of the reasons for such rejection. Reasons for the rejection may include that the establishment or the accredited person, as the case may be, has failed to fully respond to the request, or that the Secretary has concerns regarding the relationship between the establishment and such accredited person.

''(II) If the Secretary rejects the selection of an accredited person by the owner or operator of a device establishment, the owner or operator may make an additional selection of an accredited person by submitting to the Secretary a notice that identifies the additional selection. Clauses (i) and (ii) of subparagraph (B), and subclause (I) of this clause, apply to the selection of an accredited person through a notice under the preceding sentence in the same manner and to the same extent as such provisions apply to a selection of an accredited person through a notice under subparagraph (A)(ii).

''(iv) In the case of a device establishment that is denied clearance under clause (i) or (ii) or with respect to which the selection of the accredited person is rejected under clause (iii), the Secretary shall designate a person to review the statement of reasons, or statement summarizing such evidence, as the case may be, of the Secretary under such clause if, during the 30-day period beginning on the date on which the owner or operator of the establishment receives such statement, the owner or operator requests the review. The review shall commence not later than 30 days after the owner or operator requests the review, unless the Secretary and the owner or operator otherwise agree.'';

(5) in paragraph (7)—

(A) by amending subparagraph (A) to read as follows:

''(A) Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall present the observations to the device establishment's designated representative and describe each observation. Additionally, such accredited person shall prepare an inspection report in a form and manner designated by the Secretary to conduct inspections, taking into consideration the goals of international harmonization of quality systems standards. Any official classification of the inspection shall be determined by the Secretary.''; and

(B) by adding at the end the following:

''(F) For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality systems standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an establishment elects to submit audit reports under this subparagraph, the owner or operator shall submit all such audit reports with

respect to the establishment during the preceding 2-year periods.''; and

(6) in paragraphs (10)(C)(iii), by striking ''based'' and inserting ''base''.

SEC. 312. EXTENSION OF AUTHORITY FOR THIRD PARTY REVIEW OF PREMARKET NOTIFICATION.

Section 523(c) (21 U.S.C. 360m(c)) is amended by striking ''2007'' and inserting ''2012''.

SEC. 313. REGISTRATION.

(a) ANNUAL REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES.—Section 510(b) (21 U.S.C. 359(b)) is amended—

(1) by redesignating the existing text as paragraph (1), and indenting and relocating it appropriately;

(2) in paragraph (1), as so redesignated, by striking ''or a device or devices''; and

(3) by adding at the end the following new paragraph:

''(2) Between October 1 and December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices shall register with the Secretary his name, places of business, and all such establishments.''.

(b) REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 510(i)(1) (21 U.S.C. 359(i)(1)) is amended—

(1) by redesignating the existing text as subparagraph (A), and indenting and relocating it appropriately;

(2) in subparagraph (A), as so redesignated—

(A) by striking ''processing of a drug or a device that is imported'' and inserting ''processing of a drug that is imported''; and

(B) by striking ''or device'' each place it appears; and

(3) by adding after such subparagraph (A) the following new subparagraph:

''(B) Between October 1 and December 31 of each year, any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary, register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such device in the United States that is known to the establishment, and the name of each person who imports or offers for import such device to the United States for purposes of importation.''.

SEC. 314. FILING OF LISTS OF DRUGS AND DEVICES MANUFACTURED PREPARED, PROPAGATED AND COMPOUNDED BY REGISTRANTS; STATEMENTS; ACCOMPANYING DISCLOSURES.

Section 510(j)(2) (21 U.S.C. 360(j)(2) is amended, in the matter preceding subparagraph (A), to read as follows:

''(2) Each person who registers with the Secretary under this section shall report to the Secretary (i) with regard to drugs, once during the month of June of each year and once during the month of December of each year, and (ii) with regard to devices, once each year between October 1 and December 31, the following information:''.

SEC. 315. ELECTRONIC REGISTRATION AND LISTING.

Section 510(p) (21 U.S.C. 360(p)) is amended to read as follows:

''(p)(1) With regard to any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug, registrations under subsections (b), (c), (d), and (i) of this section (including the submission of updated information) shall be submitted to the Secretary by electronic means, upon a finding by the Secretary that the electronic receipt of such registrations is feasible, unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.

''(2) With regard to any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, the registration and listing information required by this section shall be submitted to the Secretary by electronic means, unless the Secretary grants a waiver because electronic registration and listing is not reasonable for the person requesting such waiver.''.

TITLE IV—PEDIATRIC MEDICAL PRODUCTS

Subtitle A—Best Pharmaceuticals for Children

SEC. 401. SHORT TITLE.

This subtitle may be cited as the ''Best Pharmaceuticals for Children Amendments of 2007''.

SEC. 402. PEDIATRIC STUDIES OF DRUGS.

(a) IN GENERAL.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsection (a), by inserting before the period at the end the following: '', and, at the discretion of the Secretary, may include preclinical studies'';

(2) in subsection (b)—

(A) in paragraph (1)(A)(i), by striking ''(D)'' both places it appears and inserting ''(E)'';

(B) in paragraph (1)(A)(ii), by striking ''(D)'' and inserting ''(E)'';

(C) by striking ''(1)(A)(i)'' and inserting ''(A)(i)(I)'';

(D) by striking ''(ii) the'' and inserting ''(II) the'';

(E) by striking ''(B) if the drug is designated'' and inserting ''(ii) if the drug is designated'';

(F) by striking ''(2)(A)'' and inserting ''(B)(i)'';

(G) by striking ''(i) a listed patent'' and inserting ''(I) a listed patent'';

(H) by striking ''(ii) a listed patent'' and inserting ''(II) a listed patent'';

(I) by striking ''(B) if the drug is the subject'' and inserting ''(ii) if the drug is the subject'';

(J) by striking ''If'' and all that follows through ''subsection (d)(3)'' and inserting the following:

''(1) IN GENERAL.—Except as provided in paragraph (2), if, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(3), and if the Secretary determines that labeling changes are appropriate, such changes are made within the timeframe requested by the Secretary—''; and

(K) by adding at the end the following:

''(2) EXCEPTION.—The Secretary shall not extend a period referred to in paragraph (1)(A) or in paragraph (1)(B) later than 9 months prior to the expiration of such period.'';

(3) in subsection (c)—

(A) in paragraph (1)(A)(i), by striking ''(D)'' both places it appears and inserting ''(E)'';

(B) in paragraph (1)(A)(ii), by striking ''(D)'' and inserting ''(E)'';

(C) by striking ''(1)(A)(i)'' and inserting ''(A)(i)(I)'';

(D) by striking ''(ii) the'' and inserting ''(II) the'';

(E) by striking ''(B) if the drug is designated'' and inserting ''(ii) if the drug is designated'';

(F) by striking ''(2)(A)'' and inserting ''(B)(i)'';

(G) by striking ''(i) a listed patent'' and inserting ''(I) a listed patent'';

(H) by striking ''(ii) a listed patent'' and inserting ''(II) a listed patent'';

(I) by striking ''(B) if the drug is the subject'' and inserting ''(ii) if the drug is the subject'';

(J) by striking ''If'' and all that follows through ''subsection (d)(3)'' and inserting the following:

''(1) IN GENERAL.—Except as provided in paragraph (2), if the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with subsection (d)(3), and if the Secretary determines that labeling changes are appropriate, such changes are made within the timeframe requested by the Secretary—''; and

(K) by adding at the end the following:

''(2) EXCEPTION.—The Secretary shall not extend a period referred to in paragraph (1)(A) or in paragraph (1)(B) later than 9 months prior to the expiration of such period.'';

(4) by striking subsection (d) and inserting the following:

''(d) CONDUCT OF PEDIATRIC STUDIES.—

''(1) REQUEST FOR STUDIES.—

''(A) IN GENERAL.—The Secretary may, after consultation with the sponsor of an application for an investigational new drug under section 505(i), the sponsor of an application for a new drug under section 505(b)(1), or the holder of an approved application for a drug under section 505(b)(1), issue to the sponsor or holder a written request for the conduct of pediatric studies for such drug. In issuing such request, the Secretary shall take into account adequate representation of children of ethnic and racial minorities. Such request to conduct pediatric studies shall be in writing and shall include a timeframe for such studies and a request to the sponsor or holder to propose pediatric labeling resulting from such studies.

''(B) SINGLE WRITTEN REQUEST.—A single written request—

''(i) may relate to more than 1 use of a drug; and

''(ii) may include uses that are both approved and unapproved.

''(2) WRITTEN REQUEST FOR PEDIATRIC STUDIES.—

''(A) REQUEST AND RESPONSE.—

''(i) IN GENERAL.—If the Secretary makes a written request for pediatric studies (including neonates, as appropriate) under subsection (b) or (c), the applicant or holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the applicant or holder to act on the request by—

''(I) indicating when the pediatric studies will be initiated, if the applicant or holder agrees to the request; or

''(II) indicating that the applicant or holder does not agree to the request and the reasons for declining the request.

''(ii) DISAGREE WITH REQUEST.—If, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the applicant or holder does not agree

to the request on the grounds that it is not possible to develop the appropriate pediatric formulation, the applicant or holder shall submit to the Secretary the reasons such pediatric formulation cannot be developed.

''(B) ADVERSE EVENT REPORTS.—An applicant or holder that, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, agrees to the request for such studies shall provide the Secretary, at the same time as submission of the reports of such studies, with all postmarket adverse event reports regarding the drug that is the subject of such studies and are available prior to submission of such reports.

''(3) MEETING THE STUDIES REQUIREMENT.—Not later than 180 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 180 days, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.

''(4) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.'';

(5) by striking subsections (e) and (f) and inserting the following:

''(e) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—

''(1) IN GENERAL.—The Secretary shall publish a notice of any determination, made on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section. Such notice shall be published not later than 30 days after the date of the Secretary's determination regarding market exclusivity and shall include a copy of the written request made under subsection (b) or (c).

''(2) IDENTIFICATION OF CERTAIN DRUGS.—The Secretary shall publish a notice identifying any drug for which, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population (or specified subpopulation) if the pediatric formulation for such drug is not introduced onto the market within 1 year of the date that the Secretary publishes the notice described in paragraph (1). Such notice identifying such drug shall be published not later than 30 days after the date of the expiration of such 1 year period.

''(f) INTERNAL REVIEW OF WRITTEN REQUESTS AND PEDIATRIC STUDIES.—

''(1) INTERNAL REVIEW.—

''(A) IN GENERAL.—The Secretary shall create an internal review committee to review all written requests issued and all reports submitted on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, in accordance with paragraphs (2) and (3).

''(B) MEMBERS.—The committee under subparagraph (A) shall include individuals, each of whom is an employee of the Food and Drug Administration, with the following expertise:

''(i) Pediatrics.

''(ii) Biopharmacology.

''(iii) Statistics.

''(iv) Drugs and drug formulations.

''(v) Legal issues.

''(vi) Appropriate expertise pertaining to the pediatric product under review.

''(vii) One or more experts from the Office of Pediatric Therapeutics, including an expert in pediatric ethics.

''(viii) Other individuals as designated by the Secretary.

''(2) REVIEW OF WRITTEN REQUESTS.—All written requests under this section shall be reviewed and approved by the committee established under paragraph (1) prior to being issued.

''(3) REVIEW OF PEDIATRIC STUDIES.—The committee established under paragraph (1) shall review all studies conducted pursuant to this section to determine whether to accept or reject such reports under subsection (d)(3).

''(4) TRACKING PEDIATRIC STUDIES AND LABELING CHANGES.—The committee established under paragraph (1) shall be responsible for tracking and making available to the public, in an easily accessible manner, including through posting on the website of the Food and Drug Administration—

''(A) the number of studies conducted under this section;

''(B) the specific drugs and drug uses, including labeled and off-labeled indications, studied under this section;

''(C) the types of studies conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

''(D) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons such formulations were not developed;

''(E) the labeling changes made as a result of studies conducted under this section;

''(F) an annual summary of labeling changes made as a result of studies conducted under this section for distribution pursuant to subsection (k)(2); and

''(G) information regarding reports submitted on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007.'';

(6) in subsection (g)—

(A) in paragraph (1)—

(i) by striking ''(c)(1)(A)(ii)'' and inserting ''(c)(1)(A)(i)(II)''; and

(ii) by striking ''(c)(2)'' and inserting ''(c)(1)(B)'';

(B) in paragraph (2), by striking ''(c)(1)(B)'' and inserting ''(c)(1)(A)(ii)'';

(C) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(D) by striking ''LIMITATIONS.—A drug'' and inserting ''LIMITATIONS.—

''(1) IN GENERAL.—Notwithstanding subsection (c)(2), a drug''; and

(E) by adding at the end the following:

''(2) EXCLUSIVITY ADJUSTMENT.—

''(A) ADJUSTMENT.—

''(i) IN GENERAL.—With respect to any drug, if the organization designated under subparagraph (B) notifies the Secretary that the combined annual gross sales for all drugs with the same active moiety exceeded $1,000,000,000 in any calendar year prior to the time the sponsor or holder agrees to the initial written request pursuant to subsection (d)(2), then each period of market exclusivity deemed or extended under subsection (b) or (c) shall be reduced by 3 months for such drug.

''(ii) DETERMINATION.—The determination under clause (i) of the combined annual gross sales shall be determined—

''(I) taking into account only those sales within the United States; and

''(II) taking into account only the sales of all drugs with the same active moiety of the sponsor or holder and its affiliates.

''(B) DESIGNATION.—The Secretary shall designate an organization other than the Food and Drug Administration to evaluate whether the combined annual gross sales for all drugs with the same active moiety exceeded $1,000,000,000 in a calendar year as described in subparagraph (A). Prior to designating such organization, the Secretary shall determine that such organization is independent and is qualified to evaluate the sales of pharmaceutical products. The Secretary shall re-evaluate the designation of such organization once every 3 years.

''(C) NOTIFICATION.—Once a year at a time designated by the Secretary, the organization designated under subparagraph (B) shall notify the Food and Drug Administration of all drugs with the same active moiety with combined annual gross sales that exceed $1,000,000,000 during the previous calendar year.'';

(7) in subsection (i)—

(A) in the heading, by striking ''SUPPLEMENTS'' and inserting ''CHANGES'';

(B) in paragraph (1)—

(i) in the heading, by inserting ''APPLICATIONS AND'' after ''PEDIATRIC'';

(ii) by inserting ''application or'' after ''Any'';

(iii) by striking ''change pursuant to a report on a pediatric study under'' and inserting ''change as a result of any pediatric study conducted pursuant to''; and

(iv) by inserting ''application or'' after ''to be a priority''; and

(C) in paragraph (2)(A), by—

(i) striking ''If the Commissioner'' and inserting ''If, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Commissioner''; and

(ii) striking ''an application with'' and all that follows through ''on appropriate'' and inserting ''the sponsor and the Commissioner have been unable to reach agreement on appropriate'';

(8) by striking subsection (m);

(9) by redesignating subsections (j), (k), (l), and (n), as subsections (k), (m), (o), and (p), respectively;

(10) by inserting after subsection (i) the following:

''(j) OTHER LABELING CHANGES.—If, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary determines that a pediatric study conducted under this section does or does not demonstrate that the drug that is the subject of the study is safe and effective, including whether such study results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the study and a statement of the Secretary's determination.'';

(11) in subsection (k), as redesignated by paragraph (9)—

(A) in paragraph (1)—

(i) by striking ''a summary of the medical and'' and inserting ''the medical, statistical, and''; and

(ii) by striking ''for the supplement'' and all that follows through the period and inserting ''under subsection (b) or (c).'';

(B) by redesignating paragraph (2) as paragraph (3); and

(C) by inserting after paragraph (1) the following:

''(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary shall require that the sponsors of the studies that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(4)(F) distribute, at least annually (or more frequently if the Secretary determines that it would be beneficial to the public health), such information to physicians and other health care providers.'';

(12) by inserting after subsection (k), as redesignated by paragraph (9), the following:

''(l) ADVERSE EVENT REPORTING.—

''(1) REPORTING IN YEAR ONE.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, during the 1-year period beginning on the date a labeling change is made pursuant to subsection (i), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering such reports, the Director of such Office shall provide for the review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such Committee regarding whether the Secretary should take action under this section in response to such reports.

''(2) REPORTING IN SUBSEQUENT YEARS.—Following the 1-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports.

''(3) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.'';

(13) by inserting after subsection (m), as redesignated by paragraph (9), the following:

''(n) REFERRAL IF PEDIATRIC STUDIES NOT COMPLETED.—

''(1) IN GENERAL.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, if pediatric studies of a drug have not been completed under subsection (d) and if the Secretary, through the committee established under subsection (f), determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates, as appropriate), the Secretary shall carry out the following:

''(A) For a drug for which a listed patent has not expired, make a determination regarding whether an assessment shall be required to be submitted under section 505B. Prior to making such determination, the Secretary may take not more than 60 days to certify whether the Foundation for the National Institutes of Health has sufficient funding at the time of such certification to initiate 1 or more of the pediatric studies of such drug referred to in the sentence preceding this paragraph and fund 1 or more of such studies in their entirety. Only if the Secretary makes such certification in the affirmative, the Secretary shall refer such pediatric study or studies to the Foundation for the National Institutes of Health for the conduct of such study or studies.

''(B) For a drug that has no listed patents or has 1 or more listed patents that have expired, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of studies.

''(2) PUBLIC NOTICE.—The Secretary shall give the public notice of—

''(A) a decision under paragraph (1)(A) not to require an assessment under section 505B and the basis for such decision; and

''(B) any referral under paragraph (1)(B) of a drug for inclusion on the list established under section 409I of the Public Health Service Act.

''(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.''; and

(14) in subsection (p), as redesignated by paragraph (9)—

(A) striking ''6-month period'' and inserting ''3-month or 6-month period'';

(B) by striking ''subsection (a)'' and inserting ''subsection (b)''; and

(C) by striking ''2007'' both places it appears and inserting ''2012''.

(b) EFFECTIVE DATE.—Except as otherwise provided in the amendments made by subsection (a), such amendments shall apply to written requests under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) made after the date of enactment of this subtitle.

SEC. 403. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

Section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended—

(1) by striking subsections (a) and (b) and inserting the following:

''(a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs or indications that require study. The list shall be revised every 3 years.

''(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary shall consider—

''(A) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

''(B) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

''(C) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators.

''(b) PEDIATRIC STUDIES AND RESEARCH.—The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.'';

(2) in subsection (c)—

(A) in the heading, by striking ''CONTRACTS'' and inserting ''PROPOSED PEDIATRIC STUDY REQUESTS'';

(B) by striking paragraphs (4) and (12);

(C) by redesignating paragraphs (1), (2), and (3), as paragraphs (2), (3), and (4);

(D) by inserting before paragraph (2), as redesignated by subparagraph (C), the following:

''(1) SUBMISSION OF PROPOSED PEDIATRIC STUDY REQUEST.—The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—

''(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act; or

''(ii) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act;

''(B) there is no patent protection or market exclusivity protection for at least 1 form of the drug under the Federal Food, Drug, and Cosmetic Act; and

''(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.'';

(E) in paragraph (2), as redesignated by subparagraph (C)—

(i) by inserting ''based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1)'' after ''issue a written request'';

(ii) by striking ''in the list described in subsection (a)(1)(A) (except clause (iv))'' and inserting ''under subsection (a)''; and

(iii) by inserting ''and using appropriate formulations for each age group for which the study is requested'' before the period at the end;

(F) in paragraph (3), as redesignated by subparagraph (C)—

(i) in the heading, by striking ''CONTRACT'';

(ii) by striking ''paragraph (1)'' and inserting ''paragraph (2)'';

(iii) by striking ''or if a referral described in subsection (a)(1)(A)(iv) is made,'';

(iv) by striking ''for contract proposals'' and inserting ''for proposals''; and

(v) by inserting ''in accordance with subsection (b)'' before the period at the end;

(G) in paragraph (4), as redesignated by subparagraph (C)—

(i) by striking ''contract''; and

(ii) by striking ''paragraph (2)'' and inserting ''paragraph (3)'';

(H) in paragraph (5)—

(i) by striking the heading and inserting ''CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS''; and

(ii) by striking ''A contract'' and all that follows through ''is submitted'' and inserting ''A contract, grant, or other funding may be awarded under this section only if a proposal is submitted'';

(I) in paragraph (6)(A)—

(i) by striking ''a contract awarded'' and inserting ''an award''; and

(ii) by inserting '', including a written request if issued'' after ''with the study''; and

(3) by inserting after subsection (c) the following:

''(d) DISSEMINATION OF PEDIATRIC INFORMATION.—Not later than 1 year after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary, acting through the Director of the National Institutes of Health, shall study the feasibility of establishing a compilation of information on pediatric drug use and report the findings to Congress.''

''(e) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—There are authorized to be appropriated to carry out this section—

''(A) $200,000,000 for fiscal year 2008; and

''(B) such sums as are necessary for each of the 4 succeeding fiscal years.

''(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.''.

SEC. 404. REPORTS AND STUDIES.

(a) GAO REPORT.—Not later than January 31, 2011, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report that addresses the effectiveness of section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) in ensuring that medicines used by children are tested and properly labeled, including—

(1) the number and importance of drugs for children that are being tested as a result of the amendments made by this subtitle and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(2) the number and importance of drugs for children that are not being tested for their use notwithstanding the provisions of this subtitle and the amendments made by this subtitle, and possible reasons for the lack of testing, including whether the number of written requests declined by sponsors or holders of drugs subject to section 505A(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(g)(2)), has increased or decreased as a result of the amendments made by this subtitle;

(3) the number of drugs for which testing is being done and labeling changes required, including the date labeling changes are made and which labeling changes required the use of the dispute resolution process established pursuant to the amendments made by this subtitle, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Committee;

(4) any recommendations for modifications to the programs established under section 505A of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355a) and section 409I of the Public Health Service Act (42 U.S.C. 284m) that the Secretary determines to be appropriate, including a detailed rationale for each recommendation; and

(5)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonate population; and

(B) the results of those efforts, including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of the studies ethical and safe.

(b) IOM STUDY.—Not later than 3 years after the date of enactment of this subtitle, the Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine to conduct a study and report to Congress regarding the written requests made and the studies conducted pursuant to section 505A of the Federal Food, Drug, and Cosmetic Act. The Institute of Medicine may devise an appropriate mechanism to review a representative sample of requests made and studies conducted pursuant to such section in order to conduct such study. Such study shall—

(1) review such representative written requests issued by the Secretary since 1997 under subsections (b) and (c) of such section 505A;

(2) review and assess such representative pediatric studies conducted under such subsections (b) and (c) since 1997 and labeling changes made as a result of such studies; and

(3) review the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, and ethical issues in pediatric clinical trials.

SEC. 405. TRAINING OF PEDIATRIC PHARMACOLOGISTS.

(a) INVESTMENT IN TOMORROW'S PEDIATRIC RESEARCHERS.—Section 452G(2) of the Public Health Service Act (42 U.S.C. 285g–10(2)) is amended by adding before the period at the end the following: '', including pediatric pharmacological research''.

(b) PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM.—Section 487F(a)(1) of the Public Health Service Act (42 U.S.C. 288–6(a)(1)) is amended by inserting ''including pediatric pharmacological research,'' after ''pediatric research,''.

SEC. 406. FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH.

Section 499(c)(1)(C) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by striking ''and studies listed by the Secretary pursuant to section 409I(a)(1)(A) of the is Act and referred under section 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(a)(d)(4)(C)'' and inserting ''and studies for which the Secretary issues a certification under section 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(n)(1)(A))''.

SEC. 407. CONTINUATION OF OPERATION OF COMMITTEE.

Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by adding at the end the following:

''(d) CONTINUATION OF OPERATION OF COMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the advisory committee shall continue to operate during the 5-year period beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007.''.

SEC. 408. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.

Section 15 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (B), by striking ''and'' after the semicolon;

(ii) in subparagraph (C), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following:

''(D) provide recommendations to the internal review committee created under section 505A(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(f)) regarding the implementation of amendments to sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a and 355c) with respect to the treatment of pediatric cancers.''; and

(B) by adding at the end the following:

''(3) CONTINUATION OF OPERATION OF SUBCOMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Subcommittee shall continue to operate during the 5-year period beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007.''; and

(2) in subsection (d), by striking ''2003'' and inserting ''2009''.

SEC. 409. EFFECTIVE DATE AND LIMITATION FOR RULE RELATING TO TOLL-FREE NUMBER FOR ADVERSE EVENTS ON LABELING FOR HUMAN DRUG PRODUCTS.

(a) IN GENERAL.—Notwithstanding subchapter II of chapter 5, and chapter 7, of title 5, United States Code (commonly known as the ''Administrative Procedure Act'') and any other provision of law, the proposed rule issued by the Commissioner of Food and Drugs entitled ''Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products'', 69 Fed. Reg. 21778, (April 22, 2004) shall take effect on January 1, 2008, unless such Commissioner issues the final rule before such date.

(b) LIMITATION.—The proposed rule that takes effect under subsection (a), or the final rule described under subsection (a), shall, notwithstanding section 17(a) of the Best Pharmaceuticals for Children Act (21 U.S.C. 355b(a)), not apply to a drug—

(1) for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(2) that is not described under section 503(b)(1) of such Act (21 U.S.C. 353(b)(1)); and

(3) the packaging of which includes a toll-free number through which consumers can report complaints to the manufacturer or distributor of the drug.

Subtitle B—Pediatric Research Improvement

SEC. 411. SHORT TITLE.

This subtitle may be cited as the ''Pediatric Research Improvement Act''.

SEC. 412. PEDIATRIC FORMULATIONS, EXTRAPOLATIONS, AND DEFERRALS.

Section 505B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)) is amended—

(1) in paragraph (4)(C), by adding at the end the following: ''An applicant seeking either a partial or full waiver on this ground shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed, and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the website of the Food and Drug Administration'';

(2) in paragraph (2)(B), by adding at the end the following:

''(iii) INFORMATION ON EXTRAPOLATION.—A brief documentation of the scientific data supporting the conclusion under clauses (i) and (ii) shall be included in any pertinent reviews for the application under section 505 or section 351 of the Public Health Service Act.''; and

(3) by striking paragraph (3) and inserting the following:

''(3) DEFERRAL.—

''(A) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

''(i) the Secretary finds that—

''(I) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

''(II) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

''(III) there is another appropriate reason for deferral; and

''(ii) the applicant submits to the Secretary—

''(I) certification of the grounds for deferring the assessments;

''(II) a description of the planned or ongoing studies;

''(III) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time; and

''(IV) a timeline for the completion of such studies.

''(B) ANNUAL REVIEW.—

''(i) IN GENERAL.—On an annual basis following the approval of a deferral under subparagraph (A), the applicant shall submit to the Secretary the following information:

''(I) Information detailing the progress made in conducting pediatric studies.

''(II) If no progress has been made in conducting such studies, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time.

''(ii) PUBLIC AVAILABILITY.—The information submitted through the annual review under clause (i) shall promptly be made available to the public in an easily accessible manner, including through the website of the Food and Drug Administration.''.

SEC. 413. IMPROVING AVAILABILITY OF PEDIATRIC DATA FOR ALREADY MARKETED PRODUCTS.

Section 505B(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(b)) is amended—

(1) by striking paragraph (1) and inserting the following:

''(1) IN GENERAL.—After providing notice in the form of a letter, or a written request under section 505A that was declined by the sponsor or holder, and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may (by order in the form of a letter) require the sponsor or holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the assessments described in subsection (a)(2) and the written request, as appropriate, if the Secretary finds that—

''(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

''(ii) adequate pediatric labeling could confer a benefit on pediatric patients;

''(B) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; or

''(C) the absence of adequate pediatric labeling could pose a risk to pediatric patients.'';

(2) in paragraph (2)(C), by adding at the end the following: ''An applicant seeking either a partial or full waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed, and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the website of the Food and Drug Administration.''; and

(3) by striking paragraph (3) and inserting the following:

''(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.''.

SEC. 414. SUNSET; REVIEW OF PEDIATRIC ASSESSMENTS; ADVERSE EVENT REPORTING; LABELING CHANGES; AND PEDIATRIC ASSESSMENTS.

Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended—

(1) redesignating subsection (h) as subsection (j);

(2) in subsection (j), as so redesignated, by striking ''505A(n)'' and inserting ''505A(p)'';

(3) by redesignating subsection (f) as subsection (k);

(4) by redesignating subsection (g) as subsection (l); and

(5) by inserting after subsection (e) the following:

''(f) REVIEW OF PEDIATRIC ASSESSMENT REQUESTS, PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—

''(1) REVIEW.—The Secretary shall create an internal committee to review all pediatric assessment requests issued under this section, all pediatric assessments conducted under this section, and all deferral and waiver requests made pursuant to this section. Such internal committee shall include individuals, each of whom is an employee of the Food and Drug Administration, with the following expertise:

''(A) Pediatrics.

''(B) Biopharmacology.

''(C) Statistics.

''(D) Drugs and drug formulations.

''(E) Pediatric ethics.

''(F) Legal issues.

''(G) Appropriate expertise pertaining to the pediatric product under review.

''(H) 1 or more experts from the Office of Pediatric Therapeutics.

''(I) Other individuals as designated by the Secretary.

''(2) REVIEW OF REQUESTS FOR PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—All written requests for a pediatric assessment issued pursuant to this section and all requests for deferrals and waivers from the requirement to conduct a pediatric assessment under this section shall be reviewed and approved by the committee established under paragraph (1).

''(3) REVIEW OF ASSESSMENTS.—The committee established under paragraph (1) shall review all assessments conducted under this section to determine whether such assessments meet the requirements of this section.

''(4) TRACKING OF ASSESSMENTS AND LABELING CHANGES.—The committee established under paragraph (1) is responsible for tracking and making public in an easily accessible manner, including through posting on the website of the Food and Drug Administration—

''(A) the number of assessments conducted under this section;

''(B) the specific drugs and drug uses assessed under this section;

''(C) the types of assessments conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

''(D) the total number of deferrals requested and granted under this section, and, if granted, the reasons for such deferrals, the timeline for completion, and the number completed and pending by the specified date, as outlined in subsection (a)(3);

''(E) the number of waivers requested and granted under this section, and, if granted, the reasons for the waivers;

''(F) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons any such formulations were not developed;

''(G) the labeling changes made as a result of assessments conducted under this section;

''(H) an annual summary of labeling changes made as a result of assessments conducted under this section for distribution pursuant to subsection (i)(2); and

''(I) an annual summary of the information submitted pursuant to subsection (a)(3)(B).

''(g) LABELING CHANGES.—

''(1) PRIORITY STATUS FOR PEDIATRIC SUPPLEMENT.—Any supplement to an application under section 505 and section 351 of the Public Health Service Act proposing a labeling change as a result of any pediatric assessments conducted pursuant to this section—

''(A) shall be considered a priority supplement; and

''(B) shall be subject to the performance goals established by the Commissioner for priority drugs.

''(2) DISPUTE RESOLUTION.—

''(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If the Commissioner determines that a sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application or supplement, not later than 180 days after the date of the submission of the application or supplement—

''(i) the Commissioner shall request that the sponsor make any labeling change that the Commissioner determines to be appropriate; and

''(ii) if the sponsor does not agree to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.

''(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—

''(i) review the pediatric study reports; and

''(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

''(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application or supplement to make any labeling changes that the Commissioner determines to be appropriate.

''(D) MISBRANDING.—If the sponsor, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application or supplement to be misbranded.

''(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

''(3) OTHER LABELING CHANGES.—If the Secretary makes a determination that a pediatric assessment conducted under this section does or does not demonstrate that the drug that is the subject of such assessment is safe and effective, including whether such assessment results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the assessment and a statement of the Secretary's determination.

''(h) DISSEMINATION OF PEDIATRIC INFORMATION.—

''(1) IN GENERAL.—Not later than 180 days after the date of submission of a pediatric assessment under this section, the Secretary shall make available to the public in an easily accessible manner the medical, statistical, and clinical pharmacology reviews of such pediatric assessments and shall post such assessments on the website of the Food and Drug Administration.

''(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—The Secretary shall require that the sponsors of the assessments that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(4)(H) distribute such information to physicians and other health care providers.

''(3) EFFECT OF SUBSECTION.—Nothing in this subsection shall alter or amend section 301(j) of this Act or section 552 of title 5, United States Code, or section 1905 of title 18, United States Code.

''(i) ADVERSE EVENT REPORTING.—

''(1) REPORTING IN YEAR 1.—During the 1-year period beginning on the date a labeling change is made pursuant to subsection (g), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics. In considering such reports, the Director of such Office shall provide for the review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee

regarding whether the Secretary should take action under this Act in response to such report.

''(2) REPORTING IN SUBSEQUENT YEARS.—Following the 1-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics with all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such report.

''(3) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.''.

SEC. 415. MEANINGFUL THERAPEUTIC BENEFIT.

Section 505B(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended—

(1) by striking ''estimates'' and inserting ''determines''; and

(2) by striking ''would'' and inserting ''could''.

SEC. 416. REPORTS.

(a) INSTITUTE OF MEDICINE STUDY.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this subtitle, the Secretary shall contract with the Institute of Medicine to conduct a study and report to Congress regarding the pediatric studies conducted pursuant to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) since 1997.

(2) CONTENT OF STUDY.—The study under paragraph (1) shall review and assess—

(A) pediatric studies conducted pursuant to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) since 1997 and labeling changes made as a result of such studies; and

(B) the use of extrapolation for pediatric subpopulations, the use of alternative endpoints for pediatric populations, neonatal assessment tools, number and type of pediatric adverse events, and ethical issues in pediatric clinical trials.

(3) REPRESENTATIVE SAMPLE.—The Institute of Medicine may devise an appropriate mechanism to review a representative sample of studies conducted pursuant to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) from each review division within the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in order to make the required assessment.

(b) GAO REPORT.—Not later than September 1, 2010, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report that addresses the effectiveness of section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) in ensuring that medicines used by children are tested and properly labeled, including—

(1) the number and importance of drugs for children that are being tested as a result of this provision and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(2) the number and importance of drugs for children that are not being tested for their use notwithstanding the provisions of such section 505B, and possible reasons for the lack of testing; and

(3) the number of drugs for which testing is being done and labeling changes required, including the date labeling changes are made and which labeling changes required the use of the dispute resolution process established under such section 505B, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Committee.

SEC. 417. TECHNICAL CORRECTIONS.

Section 505B(a)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(2)(B)(ii)) is amended by striking ''one'' and inserting ''1''.

Subtitle C—Pediatric Medical Devices

SEC. 421. SHORT TITLE.

This subtitle may be cited as the ''Pediatric Medical Device Safety and Improvement Act of 2007''.

SEC. 422. TRACKING PEDIATRIC DEVICE APPROVALS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515 the following:

''SEC. 515A. PEDIATRIC USES OF DEVICES.

''(a) NEW DEVICES.—

''(1) IN GENERAL.—A person that submits to the Secretary an application under section 520(m), or an application (or supplement to an application) or a product development protocol under section 515, shall include in the application or protocol the information described in paragraph (2).

''(2) REQUIRED INFORMATION.—The application or protocol described in paragraph (1) shall include, with respect to the device for which approval is sought and if readily available—

''(A) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

''(B) the number of affected pediatric patients.

''(3) ANNUAL REPORT.—Not later than 18 months after the date of enactment of this section, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

''(A) the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;

''(B) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;

''(C) the number of pediatric devices approved in the year preceding the year in which the report is submitted, exempted from a fee pursuant to section 738(a)(2)(B)(v); and

''(D) the review time for each device described in subparagraphs (A), (B), and (C).

''(b) DETERMINATION OF PEDIATRIC EFFECTIVENESS BASED ON SIMILAR COURSE OF DISEASE OR CONDITION OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

''(1) IN GENERAL.—If the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients, the Secretary may conclude that adult data may be used to support a determination of a reasonable assurance of effectiveness in pediatric populations, as appropriate.

''(2) EXTRAPOLATION BETWEEN SUBPOPULATIONS.—A study may not be needed in each pediatric subpopulation if data from one subpopulation can be extrapolated to another subpopulation.

''(c) PEDIATRIC SUBPOPULATION.—In this section, the term 'pediatric subpopulation' has the meaning given the term in section 520(m)(6)(E)(ii).''.

SEC. 423. MODIFICATION TO HUMANITARIAN DEVICE EXEMPTION.

(a) IN GENERAL.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (3), by striking ''No'' and inserting ''Except as provided in paragraph (6), no'';

(2) in paragraph (5)—

(A) by inserting '', if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met,'' after ''public health''; and

(B) by adding at the end the following: ''If the person granted an exemption under paragraph (2) fails to demonstrate continued compliance with the requirements of this subsection, the Secretary may suspend or withdraw the exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device only after providing notice and an opportunity for an informal hearing.'';

(3) by striking paragraph (6) and inserting the following:

''(6)(A) Except as provided in subparagraph (D), the prohibition in paragraph (3) shall not apply with respect to a person granted an exemption under paragraph (2) if each of the following conditions apply:

''(i)(I) The device with respect to which the exemption is granted is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs.

''(II) The device was not previously approved under this subsection for the pediatric patients or the pediatric subpopulation described in subclause (I) prior to the date of enactment of the Pediatric Medical Device Safety and Improvement Act of 2007.

''(ii) During any calendar year, the number of such devices distributed during that year does not exceed the annual distribution number specified by the Secretary when the Secretary grants such exemption. The annual distribution number shall be based on the number of individuals affected by the disease or condition that such device is intended to treat, diagnose, or cure, and of that number, the number of individuals likely to use the device, and the number of devices reasonably necessary to treat such individuals. In no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

''(iii) Such person immediately notifies the Secretary if the number of such devices distributed during any calendar year exceeds the annual distribution number referred to in clause (ii).

''(iv) The request for such exemption is submitted on or before October 1, 2012.

''(B) The Secretary may inspect the records relating to the number of devices distributed during any calendar year of a person granted an exemption under paragraph (2) for which the prohibition in paragraph (3) does not apply.

''(C) A person may petition the Secretary to modify the annual distribution number specified by the Secretary under subparagraph (A)(ii) with respect to a device if additional information on the number of individuals affected by the disease or condition arises, and the Secretary may modify such number but in no case shall the annual distribution number exceed the number identified in paragraph (2)(A).

''(D) If a person notifies the Secretary, or the Secretary determines through an inspection under subparagraph (B), that the number of devices distributed during any calendar year exceeds the annual distribution

number, as required under subparagraph (A)(iii), and modified under subparagraph (C), if applicable, then the prohibition in paragraph (3) shall apply with respect to such person for such device for any sales of such device after such notification.

''(E)(i) In this subsection, the term 'pediatric patients' means patients who are 21 years of age or younger at the time of the diagnosis or treatment.

''(ii) In this subsection, the term 'pediatric subpopulation' means 1 of the following populations:

''(I) Neonates.

''(II) Infants.

''(III) Children.

''(IV) Adolescents.''; and

(4) by adding at the end the following:

''(7) The Secretary shall refer any report of an adverse event regarding a device for which the prohibition under paragraph (3) does not apply pursuant to paragraph (6)(A) that the Secretary receives to the Office of Pediatric Therapeutics, established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109)). In considering the report, the Director of the Office of Pediatric Therapeutics, in consultation with experts in the Center for Devices and Radiological Health, shall provide for periodic review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to the report.''.

(b) REPORT.—Not later than January 1, 2012, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the impact of allowing persons granted an exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) with respect to a device to profit from such device pursuant to section 520(m)(6) of such Act (21 U.S.C. 360j(m)(6)) (as amended by subsection (a)), including—

(1) an assessment of whether such section 520(m)(6) (as amended by subsection (a)) has increased the availability of pediatric devices for conditions that occur in small numbers of children, including any increase or decrease in the number of—

(A) exemptions granted under such section 520(m)(2) for pediatric devices; and

(B) applications approved under section 515 of such Act (21 U.S.C. 360e) for devices intended to treat, diagnose, or cure conditions that occur in pediatric patients or for devices labeled for use in a pediatric population;

(2) the conditions or diseases the pediatric devices were intended to treat or diagnose and the estimated size of the pediatric patient population for each condition or disease;

(3) the costs of the pediatric devices, based on a survey of children's hospitals;

(4) the extent to which the costs of such devices are covered by health insurance;

(5) the impact, if any, of allowing profit on access to such devices for patients;

(6) the profits made by manufacturers for each device that receives an exemption;

(7) an estimate of the extent of the use of the pediatric devices by both adults and pediatric populations for a condition or disease other than the condition or disease on the label of such devices;

(8) recommendations of the Comptroller General of the United States regarding the effectiveness of such section 520(m)(6) (as amended by subsection (a)) and whether any modifications to such section 520(m)(6) (as amended by subsection (a)) should be made;

(9) existing obstacles to pediatric device development; and

(10) an evaluation of the demonstration grants described in section 425, which shall include an evaluation of the number of pediatric medical devices—

(A) that have been or are being studied in children; and

(B) that have been submitted to the Food and Drug Administration for approval, clearance, or review under such section 520(m) (as amended by this Act) and any regulatory actions taken.

(c) GUIDANCE.—Not later than 180 days after the date of enactment of this subtitle, the Commissioner of Food and Drugs shall issue guidance for institutional review committees on how to evaluate requests for approval for devices for which a humanitarian device exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) has been granted.

SEC. 424. CONTACT POINT FOR AVAILABLE FUNDING.

Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (21), by striking ''and'' after the semicolon at the end;

(2) in paragraph (22), by striking the period at the end and inserting ''; and''; and

(3) by inserting after paragraph (22) the following:

''(23) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development.''.

SEC. 425. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY.

(a) IN GENERAL.—

(1) REQUEST FOR PROPOSALS.—Not later than 90 days after the date of enactment of this subtitle, the Secretary of Health and Human Services shall issue a request for proposals for 1 or more grants or contracts to nonprofit consortia for demonstration projects to promote pediatric device development.

(2) DETERMINATION ON GRANTS OR CONTRACTS.—Not later than 180 days after the date the Secretary of Health and Human Services issues a request for proposals under paragraph (1), the Secretary shall make a determination on the grants or contracts under this section.

(b) APPLICATION.—A nonprofit consortium that desires to receive a grant or contract under this section shall submit an application to the Secretary of Health and Human Services at such time, in such manner, and containing such information as the Secretary may require.

(c) USE OF FUNDS.—A nonprofit consortium that receives a grant or contract under this section shall facilitate the development, production, and distribution of pediatric medical devices by—

(1) encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers;

(2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;

(3) connecting innovators and physicians to existing Federal and non-Federal resources, including resources from the Food and Drug Administration, the National Institutes of Health, the Small Business Administration, the Department of Energy, the Department of Education, the National Science Foundation, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and the National Institute of Standards and Technology;

(4) assessing the scientific and medical merit of proposed pediatric device projects; and

(5) providing assistance and advice as needed on business development, personnel training, prototype development, postmarket needs, and other activities consistent with the purposes of this section.

(d) COORDINATION.—

(1) NATIONAL INSTITUTES OF HEALTH.—Each consortium that receives a grant or contract under this section shall—

(A) coordinate with the National Institutes of Health's pediatric device contact point or office, designated under section 424; and

(B) provide to the National Institutes of Health any identified pediatric device needs that the consortium lacks sufficient capacity to address or those needs in which the consortium has been unable to stimulate manufacturer interest.

(2) FOOD AND DRUG ADMINISTRATION.—Each consortium that receives a grant or contract under this section shall coordinate with the Commissioner of Food and Drugs and device companies to facilitate the application for approval or clearance of devices labeled for pediatric use.

(3) EFFECTIVENESS AND OUTCOMES.—Each consortium that receives a grant or contract under this section shall annually report to the Secretary of Health and Human Services on—

(A) the effectiveness of activities conducted under subsection (c);

(B) the impact of activities conducted under subsection (c) on pediatric device development; and

(C) the status of pediatric device development that has been facilitated by the consortium.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $6,000,000 for each of fiscal years 2008 through 2012.

SEC. 426. AMENDMENTS TO OFFICE OF PEDIATRIC THERAPEUTICS AND PEDIATRIC ADVISORY COMMITTEE.

(a) IN GENERAL.—

(1) OFFICE OF PEDIATRIC THERAPEUTICS.—Section 6(b) of the Best Pharmaceuticals for Children Act (21 U.S.C. 393a(b)) is amended by inserting '', including increasing pediatric access to medical devices'' after ''pediatric issues''.

(2) PLAN FOR PEDIATRIC MEDICAL DEVICE RESEARCH.—

(A) IN GENERAL.—Not later than 270 days after the date of enactment of this subtitle, the Office of Pediatric Therapeutics, in collaboration with the Director of the National Institutes of Health and the Director of the Agency for Healthcare Research and Quality, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a plan for expanding pediatric medical device research and development. In developing such plan, the Commissioner of Food and Drugs shall consult with individuals and organizations with appropriate expertise in pediatric medical devices.

(B) CONTENTS.—The plan under subparagraph (A) shall include—

(i) the current status of federally funded pediatric medical device research;

(ii) any gaps in such research, which may include a survey of pediatric medical providers regarding unmet pediatric medical device needs, as needed; and

(iii) a research agenda for improving pediatric medical device development and Food and Drug Administration clearance or approval of pediatric medical devices, and for evaluating the short- and long-term safety and effectiveness of pediatric medical devices.

(b) PEDIATRIC ADVISORY COMMITTEE.—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a), by inserting ''(including drugs and biological products) and medical devices'' after ''therapeutics''; and

(2) in subsection (b)—

(A) in paragraph (1), by inserting ''(including drugs and biological products) and medical devices'' after ''therapeutics''; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking ''and 505B'' and inserting ''505B, 510(k), 515, and 520(m)'';

(ii) by striking subparagraph (B) and inserting the following:

''(B) identification of research priorities related to therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions; and''; and

(iii) in subparagraph (C), by inserting ''(including drugs and biological products) and medical devices'' after ''therapeutics''.

SEC. 427. SURVEILLANCES.

(a) POSTMARKET SURVEILLANCES.—Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) is amended—

(1) by striking subsection (a) and inserting the following:

''(a) POSTMARKET SURVEILLANCE.—

''(1) IN GENERAL.—

''(A) CONDUCT.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer that is a class II or class III device—

''(i) the failure of which would be reasonably likely to have serious adverse health consequences;

''(ii) that is expected to have significant use in pediatric populations; or

''(iii) that is intended to be implanted in the human body for more than 1 year, or a life sustaining or life supporting device used outside a device user facility.

''(B) CONDITION.—The Secretary may order a postmarket surveillance under subparagraph (A) as a condition to approval of an application (or a supplement to an application) or a product development protocol under section 515 or as a condition to clearance of a premarket notification under section 510(k) only for a device described in subparagraph (A)(ii).

''(2) RULE OF CONSTRUCTION.—The provisions of paragraph (1) shall have no effect on authorities otherwise provided under the Act or regulations issued under this Act.''; and

(2) in subsection (b)—

(A) by striking ''(b) SURVEILLANCE APPROVAL.—Each'' and inserting the following:

''(b) SURVEILLANCE APPROVAL.—

''(1) IN GENERAL.—Each'';

(B) by striking ''The Secretary, in consultation'' and inserting ''Except as provided in paragraph (2), the Secretary, in consultation'';

(C) by striking ''Any determination'' and inserting ''Except as provided in paragraph (2), any determination''; and

(D) by adding at the end the following:

''(2) LONGER SURVEILLANCES FOR PEDIATRIC DEVICES.—The Secretary may by order require a prospective surveillance period of more than 36 months with respect to a device that is expected to have significant use in pediatric populations if such period of more than 36 months is necessary in order to assess the impact of the device on growth and development, or the effects of growth, development, activity level, or other factors on the safety of the device.''.

TITLE V—OTHER PROVISIONS

SEC. 501. POLICY ON THE REVIEW AND CLEARANCE OF SCIENTIFIC ARTICLES PUBLISHED BY FDA EMPLOYEES.

Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.), as amended by section 241, is further amended by adding at the end the following:

''SEC. 713. POLICY ON THE REVIEW AND CLEARANCE OF SCIENTIFIC ARTICLES PUBLISHED BY FDA EMPLOYEES.

''(a) DEFINITION.—In this section, the term 'article' means a paper, poster, abstract, book, book chapter, or other published writing.

''(b) POLICIES.—The Secretary, through the Commissioner of Food and Drugs, shall establish and make publicly available clear written policies to implement this section and govern the timely submission, review, clearance, and disclaimer requirements for articles.

''(c) TIMING OF SUBMISSION FOR REVIEW.—If an officer or employee, including a Staff Fellow and a contractor who performs staff work, of the Food and Drug Administration is required by the policies established under subsection (b) to submit an article to the supervisor of such officer or employee, or to some other official of the Food and Drug Administration, for review and clearance before such officer or employee may seek to publish or present such an article at a conference, such officer or employee shall submit such article for such review and clearance not less than 30 days before submitting the article for publication or presentation.

''(d) TIMING FOR REVIEW AND CLEARANCE.—The supervisor or other reviewing official shall review such article and provide written clearance, or written clearance on the condition of specified changes being made, to such officer or employee not later than 30 days after such officer or employee submitted such article for review.

''(e) NON-TIMELY REVIEW.—If, 31 days after such submission under subsection (c), the supervisor or other reviewing official has not cleared or has not reviewed such article and provided written clearance, such officer or employee may consider such article not to have been cleared and may submit the article for publication or presentation with an appropriate disclaimer as specified in the policies established under subsection (b).''.

SEC. 502. TECHNICAL AMENDMENTS.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended—

(1) in section 319C–2(j)(3)(B), by striking ''section 319C–1(h)'' and inserting ''section 319C–1(i)'';

(2) in section 402(b)(4), by inserting ''minority and other'' after ''reducing'';

(3) in section 403(a)(4)(C)(iv)(III), by inserting ''and post doctoral training funded through investigator-initiated research grant awards'' before the semicolon; and

(4) in section 403C(a)—

(A) in the matter preceding paragraph (1), by inserting ''graduate students supported by NIH for'' after ''with respect to'';

(B) in paragraph (1), by inserting ''such'' after ''percentage of''; and

(C) in paragraph (2), by inserting ''(not including any leaves of absence)'' after ''average time''.

SEC. 503. SEVERABILITY CLAUSE.

If any provision of this Act, an amendment made this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such to any person or circumstances shall not be affected thereby.

Amend the title so as to read: ''To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to reauthorize drug and device user fees and ensure the safety of medical products, and for other purposes.''.

Mr. KENNEDY. Mr. President, this basically incorporates a number of the adjustments and changes that we had indicated during the course of our markup. We had a number of amendments that were offered. We indicated to the members we would try to work through some of the points that were raised. I commend our staffs on both sides who have been diligent in doing so.

These are alterations, changes that are known to the majority and the minority and all the staff members. Later on in the discussion and debate we can go into some in greater detail. Most of them are clarifications. Some of them are simplifications. I think all of them are worthy and justified, and I think they help to strengthen the legislation. So we are very grateful to all of our colleagues on our committee who offered the amendments, and, most particularly, we are very grateful for their willingness to work with us to try to work through these alterations and changes.

Mr. President, this legislation, as was pointed out in the excellent statement made by our friend and colleague from Rhode Island, Mr. REED, and others, is complex, but it is incredibly important in terms of American families, most precisely with regard to drug safety. We have reviewed those provisions. Senator ENZI made an excellent presentation yesterday. We tried to go through those in some detail yesterday afternoon. I might go through some of those again this afternoon.

But we want our Members to know we are ready to consider amendments. We know there are several that are just about ready to be offered. We urge those who are considering bringing them to the floor, let's begin the debate and discussion. We have one or two that are still being worked on. So even though it does not appear like we are making progress on this legislation at the moment, progress is being made in making sure we are going to have strong FDA reauthorization legislation. But we do hope we can get to the amendments very soon, and we expect to be able to do so.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Mr. President, I rise at this moment to support the substitute that has been put into S. 1082, the Food and Drug Administration Revitalization Act. I have said a lot about this important bill, and I do intend to say more. The most important thing I can say right now is this is the product of a lot of bipartisan work by members of the Senate Committee on Health, Education, Labor, and Pensions. We have a great process that wound up with a work in progress, which wound up with this substitute bill.

Now we do have one major outstanding issue to figure out; that is, the direct consumer advertising for prescription drugs. I do believe we will work something out, but we are not quite there yet. So I would ask my colleagues' indulgence to work that out, and I hope I have the assurance of the

chairman that we will engage in a serious dialog about the various provisions that are included in that direct consumer issue. That will be a real key to finishing up.

I congratulate the Senator from Massachusetts, Mr. KENNEDY, for the outstanding way he and his staff have worked with all the Members on our side of the aisle to clear up. As he said, in some cases, clarifications were needed, and in some cases it was the expansion of wording; in some cases, a reduction in wording. But, at any rate, we got it to where I think both sides understand and agree on many of the issues that are included. I hope we can have other amendments brought to the floor so we can debate them and get them worked out.

Of course, it would be nice if any Senator thinking about offering an amendment would share their idea with us prior to filing it. We might be able to save some time that way and make sure debate flows in an orderly process. We are trying to keep the bill to relevant amendments.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I am pleased to continue working with my colleague from Kansas, Senator ROBERTS, and my colleague from Iowa, Senator HARKIN, on the important issue of direct-to-consumer advertising.

We have to strike an important balance between seeing that consumers get accurate information on drug safety and seeing that we do not improperly restrain free speech.

Senator HARKIN has a proposal to add safety information to drug ads. Senator ROBERTS has an idea to allow FDA to impose fines for inaccurate ads. Our bill includes a moratorium—only to be used in rare cases—on DTC ads. The IOM went further and recommended a moratorium on DTC for all new drugs. We rejected that recommendation due to the first amendment concerns but included more limited authority that we believe meets the constitutional test.

Still, some have raised concerns about our current proposal, and we take those concerns seriously. We will continue to work on this important issue with our colleagues and constitutional experts. I think we are making progress through the afternoon and, hopefully, by tomorrow we will have some recommendation.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

The PRESIDING OFFICER (Mrs. MCCASKILL). Without objection, it is so ordered.

Ms. KLOBUCHAR. Madam President, I ask unanimous consent to speak as in morning business and that my remarks be printed at the appropriate place in the RECORD.

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

IRAQ SUPPLEMENTAL FUNDING

Ms. KLOBUCHAR. Madam President, I come to the floor today to express my deep disappointment and the disappointment of so many people in my State with the President's expected decision to veto the supplemental funding bill delivered to him by the bipartisan majority in Congress. This bill provided our troops in Iraq and Afghanistan with all the equipment and the resources they need to continue the duties they have been so bravely performing for more than 4 years. The amount appropriated by Congress rose well above the amount the President requested to give our soldiers on the battlefield. Let it be clear: Congress has given our soldiers on the battlefield all the funding they need. It is the President who will now be blocking it.

A few weeks ago, I was driving in Minnesota. It was a beautiful spring day outside of Ortonville, MN, and as has happened too many times in my short time as a Senator, I called one of the mothers of the Minnesota soldiers who died in this war. Of the 22,000 troops the President has included in this surge, 3,000 of them are Minnesota Guard and Reserves who were expected to come home in January and February and now have been extended. Now the moms I am calling are the moms of these soldiers who would have been home in January or February.

I asked this mother: How are you doing?

She said: You know, people keep asking me that, and I don't really know what to say. Do you have any ideas about what I should say?

I thought, and I told her: Well, I can tell you what all the other mothers have been saying. They have been saying that they wake up every morning and they try hard to hang together for their family, and then something happens. They see a picture or they remember something, and they are never the same for the rest of the day. They have their good moments, but their lives will never be the same.

I told her that her son stood tall, and that now is the time for people in Washington to stand tall.

After 4 years of extensive American military involvement in Iraq, the President refuses to accept the prudent change of course recommended by the bipartisan Iraq Study Group and supported by a clear majority of the American people. By passing this bill, we in Congress fulfilled our constitutional duties to, first, continue funding for America's Armed Forces in harm's way and, second, to ensure that our Government pursues policies in the best interests of our soldiers and of our Nation.

As we work with the President in the days and weeks and months to come, we must continue to advocate for the necessary changes in our strategy in Iraq. It is with this spirit that we in Congress continue to reach out to the President for a responsible change of course in Iraq.

Last month, I visited Baghdad and Fallujah. I saw firsthand the bravery and commitment of our troops. The very best thing we can do for these young men and women is not only give them the equipment they deserve but to get this policy right. This means sending a clear message to the Iraqi Government that we are not staying there indefinitely. This means, as recommended by the bipartisan Iraq Study Group, that we begin the process of redeploying our troops, with the goal of withdrawing combat forces by next year, while acknowledging that some troops may remain to train the Iraqi police and special forces to provide security for those who remain and to conduct special operations. This means not a surge in troops but a surge in diplomacy and economy and Iraqi responsibility.

When I was over in Baghdad and Fallujah, I saw many things, including the bravery of our troops. I was struck a few weeks later when another delegation of people from Congress went there, and one of the Congressmen returned and said he had been visiting a market there. He said it reminded him of a farmers market in Indiana.

Those are not the enduring memories of my trip to Iraq. My most enduring memory is standing on the tarmac in the Baghdad Airport with nine firefighters from the Duluth National Guard, who called me over to stand with them while they saluted as six caskets draped in the American flag were loaded onto a plane. As every casket was loaded on, they saluted. They were standing tall for their fallen soldiers that day. Now is our time for Congress to stand tall. Our troops have done everything they have been asked to do. They have deposed an evil dictator, and they gave the Iraqi people the opportunity to vote and establish a new government. It is now the Iraqi Government's responsibility to govern.

But stability and progress in Iraq depend on the political reforms Iraqi leaders have promised many times yet failed to deliver. After 4 years, despite many promises, Iraq has yet to approve a provincial election law. After 4 years, despite many promises, Iraq has yet to approve a law to share oil revenues. After 4 years, despite many promises, Iraq has yet to approve a debaathification law to promote reconciliation. After 4 years, despite many promises, Iraq has yet to approve a law reining in the militia. Our men and women in uniform cannot deliver these kinds of reforms to Iraq. This is up to the Iraqis themselves.

As the bipartisan Iraq Study Group recommended, Iraqi leaders must pay a price if they continue to fail to make good on key reforms they have promised the Iraqi people. After 4 years, what have we gotten? Benchmarks

without progress, promises without results, claims of accountability without any consequences. Why should we expect the Iraqi leaders to do any better when they know the President continues to accept their excuses for inaction and fails to impose any penalties for their lack of progress.

That is why the bipartisan Iraq Study Group made clear that ''if the Iraqi government does not make substantial progress toward the achievement of milestones on national reconciliation, security, and governance, the United States should reduce its political, military, or economic support for the Iraqi government.'' That report was issued 5 months ago. Meanwhile, the President has simply stayed the course he has continued to pursue for the past 4 years and, not surprisingly, little progress has been achieved in Iraq. The Iraqi Government will understand and finally take responsibility only when it is crystal clear to them that our combat presence is not indefinite and that American combat troops are going to leave. That is the responsible change of course we in Congress are seeking. The American people are looking to their leaders in Washington at both ends of Pennsylvania Avenue to work together to get this policy right.

Two weeks ago, I went to the White House and met with the President, along with three other Senators, including two Republicans. I appreciated the time he took to honestly discuss our points of agreement and disagreement on the war. I told him that now is the time to forge cooperation with our Democrats in Congress. But the President has chosen instead to veto this bill.

As we move forward on the funding of this war, we in Congress will do nothing that threatens the safety of American soldiers in the field. But we must continue to fulfill our constitutional duty to exercise oversight of American policies in Iraq. A critical part of this oversight must be demanding accountability for the way in which funds are spent on the reconstruction projects in Iraq.

For the past 4 years, the administration has demanded—and received—a blank check to spend in Iraq. Now we are seeing the consequences of this lack of planning, management, and responsibility.

On Monday, the Special Inspector General for Iraq Reconstruction released a report that details widespread failures in the most basic reconstruction projects. The report finds that, in many cases, Iraq's infrastructure and utility systems are worse off than they were before the war.

On closer inspection, it turns out that even projects which were declared ''success stories'' were considerably less than that. In fact, seven out of eight of these projects which were called success stories were not operating properly due to plumbing and electrical failures, improper maintenance, possible looting, and the fact that expensive equipment was available but never used.

Prior to the 2003 invasion, Iraq's power system produced 4,500 megawatts a day. Today, the same system produces 3,832 megawatts a day. In Baghdad, the city enjoys an average of 6.5 hours of electricity a day. A year ago, Baghdad received 8 hours of electricity a day. Before the war, the city received an average of 16 to 24 hours a day.

Congress has provided $4.2 billion for reconstruction of Iraq's power system, and the result has been a more than 50 percent decrease in the length of time the citizens of Baghdad have access to electricity on any given day.

Congress has provided nearly $2 billion to provide clean drinking water and repair sewer systems. But according to the World Health Organization, 70 percent of Iraqis lack access to clean drinking water.

The Defense Department has estimated that the unemployment rate in Iraq is anywhere between 13.6 percent to 60 percent. In a recent survey, only 16 percent of Iraqis said their current incomes met their basic needs.

So after 4 years, we are facing a security situation that continues to deteriorate, an economic situation that continues to stagnate, and a reconstruction effort that cannot provide even the most basic services.

My colleagues and I have been asking the difficult questions and demanding answers from this administration. The supplemental bill demonstrates that Congress is reclaiming its rightful role in setting Iraq policy and, more broadly, in our system of government. The President's veto only strengthens our resolve.

Madam President, I also wish to speak briefly in support of a few other provisions in this bill that I believe respond to critical challenges our Nation faces and that the administration has deemed unnecessary.

The White House and many of my friends on the other side of the aisle have argued that this bill should not contain funding for anything other than the current war. If we were sacrificing funding for our troops in order to meet domestic priorities, I would agree. But having given our troops all they need and continuing to ignore crises at home would be irresponsible.

Veterans funding is one of the key parts of this bill. This bill adds an increase in veterans funding that was long overdue. In the last 2 years in my State, veterans would come up to me—particularly from the Iraq and Afghanistan wars—and they would tell me about how they had difficulty getting treatment. They clearly had mental health issues. I didn't know if there was truth to this. I wasn't sure, because of the state of their minds, whether this was true. Then I got here, and I started looking at the numbers.

In 2005, the Department of Defense estimated that about 24,000 soldiers coming back from Iraq and Afghanistan would need health care. The actual number is four times that amount. Last year, they were 87,000 soldiers short in their estimate of how many soldiers would need help coming back from this war. Now I know why those people were wandering around asking for help. It is because they weren't getting the help they deserve.

Another critical problem that has been ignored by this administration—and one that is particularly important to the people of my State—has been the tremendous damage recent national disasters have been inflicting on our farmers and ranchers. The supplemental spending bill was a combination of a 2-year effort to secure disaster assistance for America's farmers. Minnesota farmers have been hit with heavy losses for 2 consecutive years—storms and flooding in 2005 and, again, drought in 2006. All told, they lost more than $700 million in crop and livestock losses.

The supplemental funding would have provided $3.5 billion to compensate farmers for a portion of their crop and livestock losses over the past 2 years. Our farmers have waited too long for this disaster relief. I am deeply disappointed that the President has turned his back on the urgent need for their assistance.

The bill we sent to the President of the United States provided the resources and support our soldiers need on the battlefield and after they return home. A few months ago, I attended a funeral of one of the brave men who was killed in the line of duty. The priest stood up, and he said to the thousand people in the cathedral: You know, this was a good kid. He was 6 feet 2 inches tall, but he was still our child.

When we send our kids to war and they are 6 feet tall, they are still our kids and they are standing tall. We need to stand tall.

The traumatic brain injury victims I have seen at the veterans hospital in Minnesota, even in their wheelchairs, are standing tall.

Those moms whom I talked to on the phone, as they struggle every day just to get out of bed to deal with the loss of their kids who were killed in this war, are standing tall.

Now it is time for the President of the United States to stand tall.

Madam President, I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

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

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

IRAQ

Mr. KERRY. Madam President, 4 years ago today, as we know, the President stood on an aircraft carrier underneath a banner that read ''Mission Accomplished.'' He declared that the major combat operations in Iraq were over. When he spoke those words, 140

American troops had been killed in Iraq. Since then, over 3,200 more American troops have given their lives. Just today, we learned that April was the deadliest month this year, with 104 Americans dead.

With every passing day, it becomes more obvious that the President really should have said: My fellow Americans, major combat operations in Iraq are just beginning. On that day, he should have had a plan to match the rhetoric with reality. But we are where we are, as the saying goes, and it is even more tragically clear to all but a few that if we want to accomplish our mission in Iraq—and we all do—if we want an Iraq that has any chance of stability and some sense of democracy, any sense of it, we have to change course.

In the past 4 years, we have lost at least 3,342 of our best young men and women, and nearly 25,000 others have been wounded and many wounded severely. We have spent nearly $400 billion, and the cost is rising at a rate of over $2 billion per week. There is no end in sight.

ADM William Fallon, the top U.S. commander in the Middle East, recently said:

> We are losing ground every day.

And even General Petraeus, the top commander in Iraq, now says that we can expect the situation to get worse before it gets better.

We were treated to a spectacle a week and a half ago with news reports, a front-page story, I think, in the Washington Post, that Stephen Hadley, the President's security adviser, was casting about to find a general to be the sort of supreme organizer, if you will, of the war in Afghanistan and the war in Iraq.

What struck me about that story is here is our Nation at war, here is a series of four-star generals whose lives are committed to Nation, to service, to duty, and to military, who under normal circumstances would be honored to be asked to become the point person to organize our Nation's efforts in two wars in a front that is of serious consequence to this Nation. Yet all four retired four-star generals said no. One was even quoted publicly as saying they don't know what the hell they are doing, or they don't know what direction they are going in.

That is a pretty remarkable statement for a career military person to make about the current effort. But we also know the history of what has brought us here with retired generals—a whole host of them—who publicly rebelled postservice against the leadership of Secretary Rumsfeld, who is now gone.

It is a rather remarkable statement about the lack of planning, about the lack of candor, about the scapegoating that has gone on, about the unwillingness of people's careers to be judged not by their ability to tell the truth but, rather, their willingness to tell the civilian leaders what they want to hear.

As we know from our own intelligence agencies, the war in Iraq has increased the threat of terrorism by creating a breeding ground for terrorists that didn't exist before the invasion and by serving as a rallying point for extremists around the world. In fact, the State Department's annual terrorism report released yesterday shows that terrorist attacks worldwide were up 25 percent last year after increasing nearly fourfold the year before that.

How does the leadership come to the country and suggest that this war is accomplishing our larger goals? How does it help the war on terror to be creating more terrorists? How can you tell the American people we have made you safer, when the number of terrorist incidents have gone up and the number of terrorists who want to kill Americans is larger today than it was on 9/11?

Any businessperson, any tourist, anybody of any curiosity who has traveled abroad and who has asked a few simple questions or read the newspapers and listened to the news knows that our Nation, which we love passionately, is now less followed, less listened to, and less feared—less listened to by our friends and less feared by our enemies. The fact is, we are less safe as a result. We are less unified at home, less respected abroad, and we are less strong as a result.

Obviously, there is no way we can make up for what has happened in the last few years, certainly not in terms of the lives lost and the pain and suffering endured by those wounded and by families who have suffered those losses, but the fact is, we can find a responsible strategy to try to deal with not just Iraq but the whole Middle East and, indeed, releverage America's position in the world.

The President today, tonight, is going to veto crucial funding for the troops passed by both Houses of Congress, legislation that gives our soldiers all they need to complete the mission and receive the care they deserve once they get home. The President is going to veto it, but that is not all he is going to do. Then he is going to try to pin the blame on those who have pushed for a new direction. He is going to try to pin the blame for his failures, for his lack of planning, for his lack of leadership on those who are providing the only way to try to resolve what is happening in Iraq.

Instead of pressuring Iraqi politicians, this administration is practicing the politics of division at home, a brand of American sectarianism that undermines our national unity, a unity required to make decisions in time of war.

Last week, Vice President CHENEY accused Senator HARRY REID of putting politics ahead of our national security. I suppose we have grown used to this Vice President, who has pioneered the politics of fear, who oversaw the politicization of the intelligence used to mislead the country into war, who claimed that we would be greeted like liberators, who told us the insurgency was in its last throws, who continues to insist that everything is on track and growing fine, I think we have grown used to this Vice President not being candid with the American people.

Clearly, he didn't hesitate to impugn the integrity of the Senate's majority leader who is standing for an appropriate new direction with respect to our policy in Iraq.

Certainly, we can disagree about those tactics or strategies without impugning the motives and challenging the integrity of those who speak those different possibilities.

If the President insists on continuing down the wrong path, it seems to me Congress has no choice but to be as resolute in demanding the right path forward for our troops, for our country, and for the Iraqis themselves. I believe we have to continue to fight for the legislation that gives us the best chance of bringing our troops home with some measure of success in the region.

Four years after ''mission accomplished,'' it is time for us to acknowledge the implications of what General Petraeus and every other military commander, the Secretary of State and even the President have told us. All of them have said there is no military solution to the violence in Iraq. I don't know how many times I have heard that on Sunday shows, I hear it out here in the corridors with individual Senators talking to the press. Everybody mouths the words: ''There is no military solution.'' But if there is no military solution and we are all agreed on that, then what is the military doing? Why is the military and an escalation in the number of troops so critical if there is no military solution?

The administration, even after telling you there is no military solution, then gives you a rationale for a military solution, which is: We have to put additional troops in to have the security, in order to have the compromises. But the fact is, the security which, first of all, is proving illusive and probably impossible to secure with the troops alone, cannot be secured without the political compromises. This is a classic chicken-and-egg situation: Which comes first? You are not going to get the security until the stakeholders in this civil struggle feel confident enough that what they are struggling about can be resolved to their safety and future security. That is sort of a fundamental issue. You are not going to change the on-the-ground security situation and stop people from bombing and militias from killing unless those fundamental stakes are properly addressed and defined.

It is long since time that we started to measure progress on the ground in Iraq by the one metric that will ultimately determine our success or our failure, and that metric is this: Are the Iraqis making the tough political compromises necessary to keep their country together?

It has been nearly a year since the Maliki Government took power. At that time, General Casey and Ambassador Khalilzad said that the Maliki Government had 6 months to make the political compromises necessary to win the public confidence.

So here we have the commanding general of our forces and our trusted Ambassador to Iraq both saying they have 6 months to make the compromises. But guess what. The 6 months went by and nothing happened—nothing happened in Iraq to make those compromises happened, and nothing happened afterwards because the compromises didn't happen. That sends a message that there is no consequence to delay, there is no consequence to procrastination.

After that, the Iraqi Government agreed to a set of benchmarks because people were growing frustrated and those benchmarks, guess what, were pegged to specific dates for making progress toward national reconciliation.

In January, the President announced the troop escalation, and he told the American people the following:

> America will hold the Iraqi Government to the benchmarks it has announced. Now is the time to act. The Prime Minister understands this.

But, once again, no real consequences, no real leverage, no real diplomacy. The result is, those benchmarks proved meaningless. You can take a look at the benchmarks the Iraqis agreed to. What did they agree to do at that point in time?

October 2006, over 6 months ago, that was the deadline for Iraqis to approve a new oil law and a provincial election law. As of today, the oil law has yet to even be introduced in Parliament, and that is an improvement over the provincial election law which hasn't even been drafted yet.

November 2006 was the deadline for new debaathification law to help bring Sunnis into the Government. A draft proposal was recently denounced by Ayatollah Sistani and a national commission to oversee the process, and guess what. It is nowhere near completion. In fact, 5 months after the deadline, the Shiite leader of the SCIRI Party recently described the Baathists as ''the first enemy of the Iraqi people.'' So much for debaathification and reconciliation.

December 2006 was the deadline for the Iraqis to approve legislation to address the militias. To date, absolutely no progress has been made on this crucial legislation, and the militias continue to wreak havoc.

January 2007 was the deadline for Iraqis to complete a constitutional review process. There was supposed to be a referendum on constitutional amendments by March. Guess what. The constitutional committee hasn't even drafted the proposed amendments, and the Iraqis remain far apart on key issues such as federalism and the fate of the divided city of Kirkut.

We are no closer to a political solution today than we were when the Maliki Government took power 1 year ago, but there were more than 940 additional American troops who gave their lives in that process to wait for the Iraqis to procrastinate.

Did the President actually hold the Iraqi Government to those benchmarks as promised? No. I hope the President tonight, when he addresses us after the veto, will address the benchmarks and where we are with respect to the failure of the Government to make the choices they said they had to make while our soldiers continue to die.

The administration still refuses to get genuinely tough with Iraqi politicians. They keep moving the goalposts, deflect the criticism of a failed strategy which they refuse to abandon. Instead, we get more vague assertions that our presence is not open-ended and outright rejection of any proposal that would leverage that threat.

The administration, it seems to me, has reached a point where it has to stop pretending the lack of political will in America is the problem. It is not the lack of political will in America that is the problem, it is the lack of political will in Iraq that is the problem.

It is impossible to make any other judgment when you look at that entire series of benchmarks. I remember Secretary Rice coming before the Foreign Relations Committee, I believe, several months ago now, and I asked her the question about the oil law. She said: Oh, yes, the oil law is almost done, just about done; wrapped up, we are about to proceed forward, we are confident it is going to be done in a few days. Here we are, several months later, and there is no oil law. It is not even before the Parliament yet.

The administration needs to accept the basic reality that the Congress has acknowledged: Iraqi politicians, if they are capable, if they are capable of making these decisions, have shown they will not do it without a reason to do it, without a rationale that feels some heat. A deadline is the only thing they have responded to so far. It took a deadline to be able to get them to do a constitution. It took a deadline to have each of their elections.

Incidentally, they protested against each of the deadlines. Each time they said: Don't do this to us; we can't meet it; we can't make it; it is too much. But each time, because we set the deadline and kept pushing, they did meet it.

American security is not a security blanket for Iraqis who want to procrastinate while American soldiers die. The longer the President continues to give them the sense that he is not going to change, he is not going to move on them, the more they are secure in the sense that they can just continue to jockey and play their political game at the expense of American dollars and American interests and American lives. Without real deadlines to force them, there is no way to actually determine that we can make the progress we need to make. Since January, when the President decided to disregard key elements of the Iraq Study Group and announced the escalation, over 340 American troops have died, and there is still no fundamental progress.

The legislation we have sent to the President would change this dynamic. It would force the Iraqis to either stand up for Iraq and meet the political benchmarks they have agreed to or decide they can't do it and have their fight.

It calls for a flexible timetable for the redeployment in 2008, and I underscore ''flexible.'' Every time we try to do something, we get into this totally phony, polarized debate where the President and his henchmen go out and talk about reckless abandonment and surrender and defeatism when, in fact, what we are proposing gives the President all the discretion in the world—to leave troops there to finish the training of Iraqis, which is the fundamental reason we are there; to leave troops there to chase al-Qaida, to prosecute the war on terror, which is in our interests, and to leave troops to protect American forces and protect American facilities. After 6 years of the war, what other fundamental mission should there be for American forces?

It seems to me the real debate is one that should center around the failures of this administration to face that reality and the few choices we have now to try to achieve success. The most important choice that has to be made to achieve success is to engage in full-throated diplomacy, not dissimilar to the kind of meeting that will be held in Sharm el-Sheikh this week. We hope Secretary Rice will take advantage of that and that the countries of the region will come together around a new security arrangement and a new understanding of what has to happen.

The timetable for the redeployment in the legislation sent to the President is not arbitrary, and it is not precipitous. It is consistent with the Iraq Study Group's recommendations and with the timeframe for transferring control of Iraq to the Iraqis that was set forth by General Casey. It also has the schedule agreed upon by the Iraqi Government itself. There is nothing arbitrary in a schedule to which your own commanding general and the Iraqi Government have agreed.

Even the President has said, under his new strategy, responsibility for security would be transferred to Iraqis before the end of this year. So they are willing to set a date. The administration can set a date for the transfer of the security, but it is unwilling to set a date for the beginning of the drawdown of some troops so you guarantee that date for the transfer of security is actually meaningful. The President has said it. Our generals have said it. The Iraq Study Group has said it. Now it is

time for the President to embrace legislation that makes those words reality.

Instead of accepting the change that is necessary, we keep hearing we need more of the same; we have to give the surge time to work; the Iraqis need just a little more breathing space to start making political progress.

General Petraeus has said, however, that he won't be able to make any progress assessment on the ground until September. Guess what. We hear that Iraq's Parliament, which has only been able to muster a quorum to even consider legislation about once every week or two—the Iraqi Parliament plans to take a 2-month vacation this summer, a vacation in the middle of a civil war. You sort of wonder what Abraham Lincoln would think of that. Iraq is descending further into chaos as thousands of Iraqis die each month. If the Iraqis go on vacation without making the key political compromises, it will absolutely guarantee that there is not going to be any meaningful political progress until next fall. I do not believe that America should be sending our troops to die for somebody else's vacation.

How many more American soldiers are going to give their lives without any hope of achieving a real political solution? 300? 400? 500? How many more doors are going to be knocked on and phone calls made? How many more visits to Arlington and other cemeteries across America, while the Iraqis procrastinate and refuse to settle their differences?

How can any of us in the Chamber look in the eyes of the parents of any young American killed and tell them: Your son or daughter died so the Iraqis can take the summer off?

With every passing day it becomes clearer this Iraqi Government is not going to get the job done. It is not truly a unity government, it is a figleaf for politicians who are pursuing sectarian interests instead of protecting the nation they are charged with saving. Now it is starting to crumble under the weight of its own ineffectiveness and corruption.

Last week some prominent Iraqi legislators came out and said publicly that they have lost confidence in the Maliki government. That is not surprising since we recently learned that Prime Minister Maliki was responsible for a politically motivated purge of Iraqi military leaders who had the gumption to actually act against the Mahdi militia.

Yesterday the largest block of Sunni Arabs in the Parliament threatened to withdraw its Ministers from the Shiite-dominated Cabinet in frustration over the Government's failure to deal with Sunni concerns. As one Sunni legislator said:

> The problem is not just with sectarian practices but with the Government's ineffectiveness.

This Government we are supporting is spiraling downward into greater and greater ineffectiveness. In the process, Iraq is spiraling deeper and deeper into its sectarian divide.

It is not just the Iraqis. Last week we learned that several prominent Sunni countries are balking at complete debt relief for Iraq because of the lack of progress in political reconciliation. This past weekend the Saudis refused to allow Prime Minister Maliki to visit their country because he has not delivered on his promise to seek real reconciliation with Iraqi Sunnis. How can we expect progress and political reconciliation if the Iraqis have lost confidence in the Maliki government? How can we expect diplomatic progress when Iraq's neighbors have lost confidence in Iraqi leadership? This is a very serious issue.

The administration has finally done what they should have done years ago: engaged, this week, in the kind of diplomacy that is desperately needed. On the eve of the summit, we learned that some of the major players have no confidence in the political process. So if we really want to bring about the political and diplomatic solution that is the only solution, the time has come now for new leadership in Iraq.

When I was in Iraq in December, Prime Minister Maliki told me he was working on forming a new coalition that would isolate extremists unwilling to compromise and empower moderates who were. Since then we have heard from time to time that these negotiations continue behind the scenes. But nothing has happened. It is time to get out from behind the scenes. It is time to have a government that can put the pieces back together.

As one Iraqi Minister said yesterday, Mr. Maliki ''said he was going to appoint new Ministers; he needs to do that. . . . What is he waiting for?''

That is a question the U.S. Congress should echo. We simply cannot go on like this, day after day, news cycle after news cycle—more bombs, more murders, more assassinations, more suicide bombings, more killings, more American soldiers dead. We can't go on like this and expect the situation to miraculously get better. Time is not on our side. Time is not on anyone's side in the end because if this does go downward into greater sectarian violence, all of the Iraqis will lose.

If we are serious about a political solution, we need a fresh start. That is why I believe it is time for Prime Minister Maliki to make wholesale changes in his Cabinet. He already has to replace the six Muqtada al-Sadr Ministers, the Sadrist Ministers who recently resigned. He should use that as an opportunity to fire any other Minister who is not committed to political reconciliation and replace them with Ministers who are.

We should make it clear this truly is his last chance. If reshuffling the Cabinet does not produce meaningful political progress within a relatively short period of time, then he should step down and allow a new leader to step forward. Putting Mr. Maliki's personal political future on the line is perhaps one of the few ways left to try to create the leverage necessary to find out if he is capable of moving the reconciliation procession forward. If he proves unwilling or unable, then clearly someone else should be given a chance—if there is someone else.

This is the moment to put that to the test. I recognize that Iraqis must take responsibility for their own future and that any government we impose will lack legitimacy with their fellow Iraqis. But we can use our own influence behind the scenes to encourage the Iraqis to make the leadership changes so clearly needed in order to give their Government a chance to succeed. We certainly have a right to make that request, given the degree to which that Government is dependent on our troops and our money and our presence.

Congress has finally done what this administration has stubbornly refused to do. I am proud of my fellow Members of this body who had the courage to vote for this legislation. I know how divisive it can be. I know how the other side uses it and how people tend to try to personalize and even denigrate people's patriotism and concern for the Nation. The fact is, the Congress has done what needed to be done because this administration has not done it.

People say don't micromanage. Someone has to manage. They have clearly mismanaged every step of this war, and they have been absent from the diplomacy necessary. It is time to have a new strategy, time to hold Iraqi politicians responsible for their country's future, time to get deadly serious about finding a political solution, and finding it now.

Somehow this President still chooses to take a different tack. If President Bush vetoes this bill, which we understand he will, then he is the one standing in the way of a bipartisan strategy on Iraq. The Iraq Study Group was bipartisan. The Iraq Study Group had former Secretary of State Jim Baker, a Republican, a great friend of President Bush's father. It had Secretary of State Larry Eagleburger. It had Al Simpson, former Senator from Wyoming and Republican leader in the Senate. It had Bill Perry, former Secretary of Defense; Chuck Robb; it had Ed Meese, former Attorney General and Chief of Staff to a Republican President. All of these are moderate, thoughtful, respected, trusted voices in foreign policy and in the affairs of our country. They all came together in a consensus. That consensus was summarily rejected by the President, just pushed aside.

The President decided to go his own road, which even the generals and even Prime Minister Maliki did not want to do. I read one Senator's comment that there is no plan B, that there is just plan A, which is the surge. I disagree with that. Plan B is what plan B should

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.

Clinics will also be offered at the festival to help developing musicians improve their abilities and talents. Jazz students have a unique opportunity to meet with and learn from some of the most talented musicians and educators in the Nation.

Jazz has come a long way since I first listened to the music as a boy on the radio in Searchlight. This distinct musical form has developed from its humble origins in early 20th century New Orleans to touch music fans of all ages and backgrounds today. The personalities of the early days of Jazz continue to influence today's artists across the musical spectrum.

I wish the host and participants of the Reno Jazz Festival continued success in bringing Jazz to all members of the community.

HONORING OUR ARMED FORCES

STAFF SERGEANT KENNETH LOCKER

Mr. HAGEL. Mr. President, I rise to express my sympathy over the loss of U.S. Army SSG Kenneth Locker of Burwell, NE. Sergeant Locker was killed on April 23 in Diyala province, Iraq. He was 28 years old.

Sergeant Locker graduated from Burwell High School in 1997. He enlisted with the Army while he was still in high school. Bob Lee, his high school math teacher, said that after he enlisted, Sergeant Locker became a much more focused young man whose grades shot up.

After high school, Sergeant Locker spent 3 years in the Army, 2 years with the National Guard, and eventually reenlisted with the Army. He had been in Iraq since August 2006 with the Army's historic 82nd Airborne Division.

Sergeant Locker was previously injured in Iraq by a land mine. He was awarded a Purple Heart and lived with shrapnel in his neck. Thousands of brave men and women like Sergeant Locker are serving in Iraq.

In addition to his life as a soldier, Sergeant Locker was father to three young sons and believed he was making a safer world for his children. He is also survived by his father Ken, two sisters, and a half sister and half brother. We are proud of his service to our country.

I ask my colleagues to join me and all Americans in honoring SSG Kenneth Locker.

FIRST LIEUTENANT KEVIN GASPERS

I rise to express my sympathy over the loss of U.S. Army 1LT Kevin Gaspers of Hastings, NE. Lieutenant Gaspers was killed on April 23 in Diyala province, Iraq. He was 26 years old.

Lieutenant Gaspers was a 2000 graduate of St. Cecilia High School in Hastings, where he wrestled and played football. After graduation, he attended the University of Nebraska at Lincoln and enrolled in the ROTC program. As a senior at UNL, Lieutenant Gaspers was selected to lead the ROTC cadet's battalion. His colleagues remember him as low-key and professional in his leadership style. He earned his Army officer's commission in 2005, along with a degree from UNL in accounting.

Lieutenant Gaspers was a paratrooper with the Army's historic 82nd Airborne Division based at Fort Bragg, N.C. He had been serving in Iraq since August 2006.

Lieutenant Gaspers is survived by his parents, John and Pam, and sisters Katie and Audrey. We are proud of his service to our country.

I ask my colleagues to join me and all Americans in honoring 1LT Kevin Gaspers.

VOTE EXPLANATION

Mr. BROWNBACK. Mr. President, I regret that on April 25, I was unable to vote on certain provisions and passage of S. 761, the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act. I wish to address these votes, so that the people of the great State of Kansas, who elected me to serve them as U.S. Senator, may know my position.

Regarding vote No. 142, on amendment No. 930, I would not have voted in favor of this amendment. My vote would not have altered the final result of this vote.

Regarding vote No. 143, on amendment No. 918, I would not have voted in favor of this amendment. My vote would not have altered the final result of this vote.

Regarding vote No. 144, on amendment No. 921, I would have voted in favor of this amendment. My vote would not have altered the final result of this vote.

Regarding vote No. 145, on amendment No. 922, I would have voted in favor of this amendment. My vote would not have altered the final result of this vote.

Regarding vote No. 146, on passage of S. 761, the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act, I would have voted in favor of passage of this act. My vote would not have altered the final result of this vote.

HOLD ON INTERIOR DEPARTMENT NOMINATION

Mr. WYDEN. Mr. President, today I have placed a hold on the nomination of R. Lyle Laverty to be Assistant Secretary for Fish, Wildlife and Parks at the U.S. Interior Department. Consistent with my policy of publicly announcing whenever I place a hold on a nomination, I want to notify my colleagues of my objection to allowing Mr. Laverty's nomination to be considered under a unanimous-consent agreement. and to take a few minutes to explain to my colleagues why I am doing so.

The Interior Department has suffered no shortage of scandals in recent years. To name just two of the most egregious: Its former No. 2 official, a Deputy Interior Secretary who previously had been a coal industry lobbyist, pleaded guilty earlier this year to felony obstruction of justice for lying about his relationship with disgraced lobbyist Jack Abramoff. And we discovered that the Minerals Management Service, an agency within the Interior Department, has known for years about flawed drilling leases that allow companies to pay no royalties on valuable oil and gas they take from Federal land in the Gulf of Mexico, but the MMS did nothing until news reports brought the facts to the public last year. Indeed, the MMS has silenced auditors on its staff who tried to blow the whistle on companies not paying their fair share.

''Simply stated, short of a crime, anything goes at the highest levels of the Interior Department,'' the Interior Department's inspector general has warned us.

Last year, when Dirk Kempthorne was nominated to be Secretary of the Interior and he appeared before the Senate Energy and Natural Resources Committee for confirmation, I secured from him a pledge. He told me that he would reform that troubled department and introduce a higher ethical standard. The scandals would stop coming.

However, in late March, the inspector general once again released a scathingly critical report warning us about bad things happening at the Interior Department. This time the subject was Julie MacDonald, Deputy Assistant Secretary for Fish, Wildlife and Parks. Mr. Laverty would be the immediate supervisor of the position Ms. MacDonald held.

In detail, the inspector general told us two things about Ms. MacDonald. One, she violated Federal rules by leaking internal Fish and Wildlife Service records to business groups actively challenging the Government's environmental rulemaking process. In the process, she has been undermining her own agency's cases in court. Two, without any formal education in the natural sciences, she has bullied and threatened FWS scientists and forced changes in their reports to suit her own political and personal agendas. FWS attorneys no longer will sign off on reports if they know the reports passed through her hands because they no longer are certain of the accuracy.

This sort of conduct is simply unacceptable. If you agree to work in the Interior Department, your loyalty should be with the Interior Department and protecting this country's natural treasures. Ms. MacDonald's loyalty lay elsewhere.

The inspector general sent his report on Ms. MacDonald to the Interior Department for administrative action more than a month ago. The Interior Department had no public comment. Only after I announced that I would place a hold on Mr. Laverty's nomination did Ms. MacDonald resign. That removes her from the equation, but not the atmosphere that allowed her to operate as she did for so long.

In case I wasn't perfectly clear last year at his confirmation hearing, I want to be sure that Secretary Kempthorne knows that I am serious. The Interior Department has been a source of shame to this government for too long. It is failing in its mission to protect the public land and balance the needs of the American people with wisdom and integrity. It has stumbled from one misstep to another, from one scandal to another, and I have to question who is in charge over there.

I want to hear from Secretary Kempthorne what action he plans to take to be certain that we won't see this sort of problem again. I want to hear from Mr. Laverty what he would do, if he is confirmed to the post of Assistant Secretary, to end the politicization of the Fish and Wildlife Service. We cannot continue to have government scientists whose work is manipulated and conclusions are rewritten by political appointees. We cannot continue to have federal officials working secretly with groups challenging their own agencies.

Until I receive these assurances, I will object to any unanimous consent agreement to allow Mr. Laverty's nomination to come to a vote in the Senate.

IDAHO GUNFIGHTERS HONORED

Mr. CRAPO. Mr. President, on March 30, Secretary of Defense Robert Gates announced that Mountain Home Air Force Base in my home State of Idaho had earned the coveted 2007 Commander in Chief's Annual Award for Installation Excellence. This Presidential honor is given only to a single installation in each of the military branches for outstanding and innovative efforts by installation personnel. I am honored to be able to publicly herald this tremendous achievement by Colonel Rock and all the men and women of Mountain Home Air Force Base.

This high honor reflects a sustained level of excellence by all the Gunfighters of Mountain Home. Installation of the Year can only be achieved if everyone, from the wing commander to airmen working in all aspects of operations and support, has their priorities straight and expectations for personal duty performance at the highest level. Improving the structures that protect valuable aircraft, creative and responsible financial management with regard to improving facilities, and a commitment to Air Force families are just some of the ways in which Mountain Home Air Force Base demonstrated its excellence this year. The Gunfighters have maintained this strong tradition of superiority and excellence for over half a century. The missions have changed over the years, but Gunfighter commitment and performance has not.

Idahoans can be very proud of their Gunfighters. Mountain Home Air Force Base is as much a part of Idaho history as the magnificent valleys, rivers, and plateaus that surround the base. The 366th Fighter Wing is a force to be reckoned with when it comes to the national security of the United States. The missions currently headquartered at Mountain Home comprise a vital component of our comprehensive military defensive and offensive force. Idaho is fortunate to be host and home to these defenders of freedom.

Idaho benefits from Mountain Home Air Force Base, not just when the military men and women serving out their assignments there call our State ''home'' for a time in their military careers but also when some return to call Idaho home permanently in retirement.

I offer my sincere congratulations to the Gunfighters and my heartfelt gratitude for their service to our great country, in defense of my freedom and that of my family.

ADDITIONAL STATEMENTS

TRIBUTE TO BOB HUDSON

• Mr. DOMENICI. Mr. President, I would like to pay tribute to the public service of Bob Hudson, city manger of Farmington, NM.

Bob first came to New Mexico in 1982 to take on the job as director of parks, recreation & cultural affairs in Farmington. Since that time he has served the citizens of Farmington faithfully, eventually becoming city manager in 1999.

Bob's commitment to the community of Farmington did not end with his official duties. He has also served on the boards of several local organizations including the Boys & Girls Club, the Farmington Inter-tribal Indian Organization, and the Chamber of Commerce.

The citizens of Farmington are well aware of Bob's contributions to their community and have honored him with numerous awards, including the New Mexico Distinguished Public Service Award in 1991 and the Elks Citizen of the Year award in 1995. Bob was also inducted into the History Makers Hall of Fame by the Farmington Chamber of Commerce in 2001 and the recipient of the 2005 Public Employee of the Year award.

Bob is retiring in April to devote more time to his family, but I am sure his dedication to the community of Farmington will not end. I wish him the best in retirement and thank him for his long years of service.•

MESSAGE FROM THE HOUSE

ENROLLED BILL SIGNED

At 3:20 p.m., a message from the House of Representatives, delivered by one of its clerks, announced that the Speaker has signed the following enrolled bill:

H.R. 1591. An act making emergency supplemental appropriations for the fiscal year ending September 30, 2007, and for other purposes.

The enrolled bill was subsequently signed by the President pro tempore (Mr. BYRD).

MEASURES PLACED ON THE CALENDAR

The following bill was read the second time, and placed on the calendar:

H.R. 1332. An act to improve the access to capital programs of the Small Business Administration, and for other purposes.

INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second times by unanimous consent, and referred as indicated:

By Ms. MIKULSKI (for herself, Mr. VOINOVICH, and Mr. HARKIN):

S. 1254. A bill to amend title II of the Social Security Act to provide that the reductions in social security benefits which are required in the case of spouses and surviving spouses who are also receiving certain government pensions shall be equal to the amount by which two-thirds of the total amount of the combined monthly benefit (before reduction) and monthly pension exceeds $1,200, adjusted for inflation; to the Committee on Finance.

By Mr. McCAIN (for himself, Mr. KYL, Mr. THOMAS, and Mr. DOMENICI):

S. 1255. A bill to protect Indian arts and crafts through the improvement of applicable criminal proceedings, and for other purposes; to the Committee on Indian Affairs.

By Mr. KERRY (for himself, Ms. SNOWE, and Mr. LEVIN):

S. 1256. A bill to amend the Small Business Act to reauthorize loan programs under that Act, and for other purposes; to the Committee on Small Business and Entrepreneurship.

By Mr. LIEBERMAN (for himself, Mr. HATCH, and Mr. BENNETT):

S. 1257. A bill to provide the District of Columbia a voting seat and the State of Utah an additional seat in the House of Representatives; to the Committee on Homeland Security and Governmental Affairs.

By Ms. CANTWELL (for herself, Mr. HATCH, Mr. WYDEN, Mr. ALLARD, and Mr. SMITH):

S. 1258. A bill to amend the Reclamation Safety of Dams Act of 1978 to authorize improvements for the security of dams and other facilities; to the Committee on Energy and Natural Resources.

By Mrs. CLINTON (for herself and Mr. SMITH):

S. 1259. A bill to amend the Foreign Assistance Act of 1961 to provide assistance for developing countries to promote quality basic education and to establish the achievement of universal basic education in all developing countries as an objective of United States foreign assistance policy, and for other purposes; to the Committee on Foreign Relations.

By Mr. CARPER (for himself and Mr. BENNETT):

S. 1260. A bill to protect information relating to consumers, to require notice of security breaches, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

By Ms. CANTWELL (for herself, Mr. HARKIN, and Mr. BROWN):

S. 1261. A bill to amend title 10 and 38, United States Code, to repeal the 10-year

limit on use of Montgomery GI Bill educational assistance benefits, and for other purposes; to the Committee on Veterans' Affairs.

SUBMISSION OF CONCURRENT AND SENATE RESOLUTIONS

The following concurrent resolutions and Senate resolutions were read, and referred (or acted upon), as indicated:

By Mr. BINGAMAN:

S. Res. 178. A resolution expressing the sympathy of the Senate to the families of women and girls murdered in Guatemala, and encouraging the United States to work with Guatemala to bring an end to these crimes; to the Committee on Foreign Relations.

By Mr. BOND:

S. Res. 179. A resolution welcoming the Prime Minister of Singapore on the occasion of his visit to the United States and the 40th anniversary of the Association of Southeast Asian Nations (ASEAN), expressing gratitude to the Government of Singapore for its strong cooperation with the United States in the campaign against terrorism, and reaffirming the commitment of the United States to the continued expansion of friendship and cooperation between the United States and Singapore; to the Committee on Foreign Relations.

By Mr. CRAPO (for himself and Mr. CRAIG):

S. Res. 180. A resolution recognizing the 70th anniversary of the Idaho Potato Commission and designating May 2007 as ''Idaho Potato Month''; to the Committee on the Judiciary.

By Mr. ALLARD (for himself, Mr. PRYOR, and Mr. CRAIG):

S. Res. 181. A resolution honoring and recognizing the achievements of the United States Air Force Academy football program over the last 27 years; considered and agreed to.

By Mrs. FEINSTEIN (for herself, Mr. SPECTER, Mr. LEAHY, Mr. HATCH, Mrs. BOXER, Mr. CORNYN, Mr. KENNEDY, Mr. DURBIN, Mr. DODD, Mr. KERRY, Ms. STABENOW, Ms. CANTWELL, Mr. HARKIN, Ms. LANDRIEU, Mr. MENENDEZ, and Mr. COLEMAN):

S. Res. 182. A resolution honoring the life of Jack Valenti; considered and agreed to.

By Ms. LANDRIEU (for herself, Mr. ALEXANDER, Mr. LIEBERMAN, Mr. CARPER, Mr. BURR, Mr. DEMINT, Mr. VITTER, Mrs. DOLE, and Mr. GREGG):

S. Res. 183. A resolution supporting the goals and ideals of National Charter Schools Week, April 30, 2007, through May 4, 2007; considered and agreed to.

By Mr. CHAMBLISS (for himself and Mr. CASEY):

S. Res. 184. A resolution expressing the sense of the Senate with respect to childhood stroke and designating May 5, 2007, as ''National Childhood Stroke Awareness Day''; considered and agreed to.

ADDITIONAL COSPONSORS

S. 242

At the request of Mr. DORGAN, the name of the Senator from Missouri (Mrs. MCCASKILL) was added as a cosponsor of S. 242, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs, and for other purposes.

S. 329

At the request of Mr. CRAPO, the name of the Senator from California (Mrs. FEINSTEIN) was added as a cosponsor of S. 329, a bill to amend title XVIII of the Social Security Act to provide coverage for cardiac rehabilitation and pulmonary rehabilitation services.

S. 339

At the request of Mr. BAYH, the name of the Senator from Rhode Island (Mr. REED) was added as a cosponsor of S. 339, a bill to promote the national security and stability of the United States economy by reducing the dependence of the United States on oil through the use of alternative fuels and new technology, and for other purposes.

S. 543

At the request of Mr. NELSON of Nebraska, the names of the Senator from Idaho (Mr. CRAIG), the Senator from Florida (Mr. NELSON) and the Senator from Rhode Island (Mr. WHITEHOUSE) were added as cosponsors of S. 543, a bill to improve Medicare beneficiary access by extending the 60 percent compliance threshold used to determine whether a hospital or unit of a hospital is an inpatient rehabilitation facility under the Medicare program.

S. 578

At the request of Mr. KENNEDY, the name of the Senator from New Jersey (Mr. LAUTENBERG) was added as a cosponsor of S. 578, a bill to amend title XIX of the Social Security Act to improve requirements under the Medicaid program for items and services furnished in or through an educational program or setting to children, including children with developmental, physical, or mental health needs, and for other purposes.

S. 579

At the request of Mr. HATCH, the name of the Senator from Minnesota (Mr. COLEMAN) was added as a cosponsor of S. 579, a bill to amend the Public Health Service Act to authorize the Director of the National Institute of Environmental Health Sciences to make grants for the development and operation of research centers regarding environmental factors that may be related to the etiology of breast cancer.

S. 588

At the request of Mr. NELSON of Florida, the name of the Senator from Maine (Ms. COLLINS) was added as a cosponsor of S. 588, a bill to amend title XVIII of the Social Security Act to increase the Medicare caps on graduate medical education positions for States with a shortage of residents.

S. 589

At the request of Mr. ALLARD, the name of the Senator from Alaska (Mr. STEVENS) was added as a cosponsor of S. 589, a bill to provide for the transfer of certain Federal property to the United States Paralympics, Incorporated, a subsidiary of the United States Olympic Committee.

S. 604

At the request of Mr. LAUTENBERG, the names of the Senator from Michigan (Ms. STABENOW) and the Senator from South Dakota (Mr. JOHNSON) were added as cosponsors of S. 604, a bill to amend title 10, United States Code, to limit increases in the certain costs of health care services under the health care programs of the Department of Defense, and for other purposes.

S. 609

At the request of Mr. ROCKEFELLER, the name of the Senator from Minnesota (Ms. KLOBUCHAR) was added as a cosponsor of S. 609, a bill to amend section 254 of the Communications Act of 1934 to provide that funds received as universal service contributions and the universal service support programs established pursuant to that section are not subject to certain provisions of title 31, United States Code, commonly known as the Antideficiency Act.

S. 624

At the request of Ms. MIKULSKI, the name of the Senator from Washington (Mrs. MURRAY) was added as a cosponsor of S. 624, a bill to amend the Public Health Service Act to provide waivers relating to grants for preventive health measures with respect to breast and cervical cancers.

S. 689

At the request of Mr. LUGAR, the name of the Senator from North Dakota (Mr. DORGAN) was added as a cosponsor of S. 689, a bill to amend the Internal Revenue Code of 1986 to permanently extend and expand the charitable deduction for contributions of food inventory.

S. 691

At the request of Mr. CONRAD, the name of the Senator from Mississippi (Mr. LOTT) was added as a cosponsor of S. 691, a bill to amend title XVIII of the Social Security Act to improve the benefits under the Medicare program for beneficiaries with kidney disease, and for other purposes.

S. 695

At the request of Ms. SNOWE, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of S. 695, a bill to amend the International Claims Settlement Act of 1949 to allow for certain claims of nationals of the United States against Turkey, and for other purposes.

S. 721

At the request of Mr. ENZI, the name of the Senator from Vermont (Mr. SANDERS) was added as a cosponsor of S. 721, a bill to allow travel between the United States and Cuba.

S. 725

At the request of Mr. LEVIN, the name of the Senator from Michigan (Ms. STABENOW) was added as a cosponsor of S. 725, a bill to amend the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 to reauthorize and improve that Act.

S. 755

At the request of Mr. SCHUMER, the name of the Senator from Ohio (Mr. BROWN) was added as a cosponsor of S. 755, a bill to amend title XIX of the Social Security Act to require States to

provide diabetes screening tests under the Medicaid program for adult enrollees with diabetes risk factors, to ensure that States offer a comprehensive package of benefits under that program for individuals with diabetes, and for other purposes.

S. 774

At the request of Mr. DURBIN, the names of the Senator from New Mexico (Mr. BINGAMAN), the Senator from Washington (Ms. CANTWELL), the Senator from New York (Mrs. CLINTON), the Senator from Massachusetts (Mr. KERRY), the Senator from New Jersey (Mr. MENENDEZ), the Senator from Washington (Mrs. MURRAY) and the Senator from Nevada (Mr. REID) were added as cosponsors of S. 774, a bill to amend the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 to permit States to determine State residency for higher education purposes and to authorize the cancellation of removal and adjustment of status of certain alien students who are long-term United States residents and who entered the United States as children, and for other purposes.

S. 805

At the request of Mr. DURBIN, the name of the Senator from California (Mrs. FEINSTEIN) was added as a cosponsor of S. 805, a bill to amend the Foreign Assistance Act of 1961 to assist countries in sub-Saharan Africa in the effort to achieve internationally recognized goals in the treatment and prevention of HIV/AIDS and other major diseases and the reduction of maternal and child mortality by improving human health care capacity and improving retention of medical health professionals in sub-Saharan Africa, and for other purposes.

S. 831

At the request of Mr. DURBIN, the name of the Senator from Maryland (Ms. MIKULSKI) was added as a cosponsor of S. 831, a bill to authorize States and local governments to prohibit the investment of State assets in any company that has a qualifying business relationship with Sudan.

S. 847

At the request of Mrs. MURRAY, the name of the Senator from Vermont (Mr. SANDERS) was added as a cosponsor of S. 847, a bill to extend the period of time during which a veteran's multiple sclerosis is to be considered to have been incurred in, or aggravated by, military service during a period of war.

S. 848

At the request of Mrs. MURRAY, the name of the Senator from Vermont (Mr. SANDERS) was added as a cosponsor of S. 848, a bill to amend title 38, United States Code, to provide improved benefits for veterans who are former prisoners of war.

S. 871

At the request of Mr. LIEBERMAN, the name of the Senator from Michigan (Ms. STABENOW) was added as a cosponsor of S. 871, a bill to establish and provide for the treatment of Individual Development Accounts, and for other purposes.

S. 886

At the request of Mr. BINGAMAN, the name of the Senator from Texas (Mr. CORNYN) was added as a cosponsor of S. 886, a bill to amend chapter 22 of title 44, United States Code, popularly known as the Presidential Records Act, to establish procedures for the consideration of claims of constitutionally based privilege against disclosure of Presidential records.

S. 897

At the request of Ms. MIKULSKI, the name of the Senator from Washington (Mrs. MURRAY) was added as a cosponsor of S. 897, a bill to amend the Internal Revenue Code of 1986 to provide more help to Alzheimer's disease caregivers.

S. 898

At the request of Ms. MIKULSKI, the name of the Senator from Washington (Mrs. MURRAY) was added as a cosponsor of S. 898, a bill to amend the Public Health Service Act to fund breakthroughs in Alzheimer's disease research while providing more help to caregivers and increasing public education about prevention.

S. 901

At the request of Mr. KENNEDY, the names of the Senator from Illinois (Mr. DURBIN) and the Senator from Washington (Ms. CANTWELL) were added as cosponsors of S. 901, a bill to amend the Public Health Service Act to provide additional authorizations of appropriations for the health centers program under section 330 of such Act.

S. 903

At the request of Mr. DURBIN, the name of the Senator from California (Mrs. FEINSTEIN) was added as a cosponsor of S. 903, a bill to award a Congressional Gold Medal to Dr. Muhammad Yunus, in recognition of his contributions to the fight against global poverty.

S. 968

At the request of Mrs. BOXER, the name of the Senator from Washington (Mrs. MURRAY) was added as a cosponsor of S. 968, a bill to amend the Foreign Assistance Act of 1961 to provide increased assistance for the prevention, treatment, and control of tuberculosis, and for other purposes.

S. 969

At the request of Mr. DODD, the name of the Senator from New Jersey (Mr. LAUTENBERG) was added as a cosponsor of S. 969, a bill to amend the National Labor Relations Act to modify the definition of supervisor.

S. 970

At the request of Mr. SMITH, the name of the Senator from South Carolina (Mr. GRAHAM) was added as a cosponsor of S. 970, a bill to impose sanctions on Iran and on other countries for assisting Iran in developing a nuclear program, and for other purposes.

S. 999

At the request of Mr. COCHRAN, the names of the Senator from Delaware (Mr. CARPER), the Senator from Maryland (Mr. CARDIN), the Senator from Ohio (Mr. BROWN) and the Senator from South Dakota (Mr. JOHNSON) were added as cosponsors of S. 999, a bill to amend the Public Health Service Act to improve stroke prevention, diagnosis, treatment, and rehabilitation.

S. 1040

At the request of Mr. SHELBY, the name of the Senator from New Hampshire (Mr. SUNUNU) was added as a cosponsor of S. 1040, a bill to repeal the current Internal Revenue Code and replace it with a flat tax, thereby guaranteeing economic growth and greater fairness for all Americans.

S. 1092

At the request of Mr. HAGEL, the name of the Senator from New Hampshire (Mr. SUNUNU) was added as a cosponsor of S. 1092, a bill to temporarily increase the number of visas which may be issued to certain highly skilled workers.

S. 1149

At the request of Mr. KOHL, the name of the Senator from Wisconsin (Mr. FEINGOLD) was added as a cosponsor of S. 1149, a bill to amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to authorize the interstate distribution of State-inspected meat and poultry if the Secretary of Agriculture determines that the State inspection requirements are at least equal to Federal inspection requirements and to require the Secretary to reimburse State agencies for part of the costs of the inspections.

S. 1164

At the request of Mr. CARDIN, the name of the Senator from Rhode Island (Mr. WHITEHOUSE) was added as a cosponsor of S. 1164, a bill to amend title XVIII of the Social Security Act to improve patient access to, and utilization of, the colorectal cancer screening benefit under the Medicare Program.

S. 1183

At the request of Mr. HARKIN, the name of the Senator from Washington (Mrs. MURRAY) was added as a cosponsor of S. 1183, a bill to enhance and further research into paralysis and to improve rehabilitation and the quality of life for persons living with paralysis and other physical disabilities, and for other purposes.

S. 1202

At the request of Mr. SESSIONS, the name of the Senator from Arizona (Mr. KYL) was added as a cosponsor of S. 1202, a bill to require agencies and persons in possession of computerized data containing sensitive personal information, to disclose security breaches where such breach poses a significant risk of identity theft.

S. 1204

At the request of Mr. DODD, the name of the Senator from Ohio (Mr. BROWN) was added as a cosponsor of S. 1204, a bill to enhance Federal efforts focused on public awareness and education about the risks and dangers associated with Shaken Baby Syndrome.

S. 1210

At the request of Mrs. FEINSTEIN, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of S. 1210, a bill to extend the grant program for drug-endangered children.

S. 1211

At the request of Mrs. FEINSTEIN, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of S. 1211, a bill to amend the Controlled Substances Act to provide enhanced penalties for marketing controlled substances to minors.

S. 1232

At the request of Mr. DODD, the name of the Senator from Ohio (Mr. BROWN) was added as a cosponsor of S. 1232, a bill to direct the Secretary of Health and Human Services, in consultation with the Secretary of Education, to develop a voluntary policy for managing the risk of food allergy and anaphylaxis in schools, to establish school-based food allergy management grants, and for other purposes.

S. 1237

At the request of Mr. LAUTENBERG, the name of the Senator from Massachusetts (Mr. KENNEDY) was added as a cosponsor of S. 1237, a bill to increase public safety by permitting the Attorney General to deny the transfer of firearms or the issuance of firearms and explosives licenses to known or suspected dangerous terrorists.

S. 1243

At the request of Mr. KERRY, the name of the Senator from Maryland (Ms. MIKULSKI) was added as a cosponsor of S. 1243, a bill to amend title 10, United States Code, to reduce the age for receipt of military retired pay for nonregular service from 60 years of age to 55 years of age.

S. 1244

At the request of Mr. KENNEDY, the name of the Senator from Vermont (Mr. LEAHY) was added as a cosponsor of S. 1244, a bill to amend the Occupational Safety and Health Act of 1970 to expand coverage under the Act, to increase protections for whistleblowers, to increase penalties for certain violators, and for other purposes.

S. 1250

At the request of Ms. SNOWE, the name of the Senator from Maine (Ms. COLLINS) was added as a cosponsor of S. 1250, a bill to direct the United States Trade Representative to conduct an investigation of the personal exemption allowance that Canada provides for merchandise purchased abroad by Canadian residents, and for other purposes.

S. CON. RES. 3

At the request of Mr. SALAZAR, the name of the Senator from Vermont (Mr. SANDERS) was added as a cosponsor of S. Con. Res. 3, a concurrent resolution expressing the sense of Congress that it is the goal of the United States that, not later than January 1, 2025, the agricultural, forestry, and working land of the United States should provide from renewable resources not less than 25 percent of the total energy consumed in the United States and continue to produce safe, abundant, and affordable food, feed, and fiber.

S. RES. 125

At the request of Mrs. FEINSTEIN, the name of the Senator from Ohio (Mr. BROWN) was added as a cosponsor of S. Res. 125, a resolution designating May 18, 2007, as ''Endangered Species Day'', and encouraging the people of the United States to become educated about, and aware of, threats to species, success stories in species recovery, and the opportunity to promote species conservation worldwide.

S. RES. 146

At the request of Mr. ALEXANDER, the name of the Senator from Iowa (Mr. GRASSLEY) was added as a cosponsor of S. Res. 146, a resolution designating June 20, 2007, as ''American Eagle Day'', and celebrating the recovery and restoration of the American bald eagle, the national symbol of the United States.

S. RES. 162

At the request of Mr. LEAHY, the name of the Senator from New York (Mr. SCHUMER) was added as a cosponsor of S. Res. 162, a resolution commemorating and acknowledging the dedication and sacrifice made by the men and women who have lost their lives while serving as law enforcement officers.

S. RES. 171

At the request of Ms. COLLINS, the names of the Senator from Arkansas (Mr. PRYOR), the Senator from Washington (Mrs. MURRAY), the Senator from Connecticut (Mr. LIEBERMAN), and the Senator from Maine (Ms. SNOWE) were added as cosponsors of S. Res. 171, a resolution memorializing fallen firefighters by lowering the United States flag to half-staff on the day of the National Fallen Firefighter Memorial Service in Emmitsburg, Maryland.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. MCCAIN (for himself, Mr. KYL, Mr. THOMAS, and Mr. DOMENICI):

S. 1255. A bill to protect Indian arts and crafts through the improvement of applicable criminal proceedings, and for other purposes; to the Committee on Indian Affairs.

Mr. MCCAIN. Mr. President, I am pleased to be joined by my colleagues Senator THOMAS, Senator KYL, and Senator DOMENICI in introducing a bill to amend the Indian Arts and Crafts Act. This legislation would improve Federal laws that protect the integrity and originality of Native American arts and crafts.

The Indian Arts and Crafts Act prohibits the misrepresentation in marketing of Indian arts and crafts products, and makes it illegal to display or sell works in a manner that falsely suggests it is the product of an individual Indian or Indian Tribe.

Unfortunately, the law is written so that only the Federal Bureau of Investigation, FBI, acting on behalf of the Attorney General, can investigate and make arrests in cases of suspected Indian art counterfeiters. The bill we are introducing would amend the law to expand existing Federal investigative authority by authorizing other Federal investigative bodies, such as the BIA Office of Law Enforcement, in addition to the FBI, to investigate cases of misrepresentation of Indian arts and crafts. This bill is similar to provisions included in the Native American Omnibus Act, S. 536, and S. 1375, which passed the Senate at the end of the last Congress but were not acted on by the House.

A major source of tribal and individual Indian income is derived from the sale of handmade Indian arts and crafts. Yet millions of dollars are diverted each year from these original artists and Indian tribes by those who reproduce and sell counterfeit Indian goods. Few, if any, criminal prosecutions have been brought in Federal court for such violations. It is understandable that enforcing the criminal law under the Indian Arts and Crafts Act is often stalled by the other responsibilities of the FBI including investigating terrorism activity and violent crimes in Indian country. Therefore, expanding the investigative authority to include other Federal agencies is intended to promote the active investigation of alleged misconduct. It is my hope that this much needed change will deter those who choose to violate the law.

I urge my colleagues to support this bill.

By Mr. KERRY (for himself, Ms. SNOWE, and Mr. LEVIN):

S. 1256. A bill to amend the Small Business Act to reauthorize loan programs under that Act, and for other purposes; to the Committee on Small Business and Entrepreneurship.

Ms. SNOWE. Mr. President, as ranking member of the Senate Committee on Small Business and Entrepreneurship, I rise today to join with Senator KERRY in introducing, the Small Business Lending Reauthorization and Improvement Act of 2007. This bill is especially timely considering the Nation recently celebrated National Small Business Week, and this body just passed the America COMPETES Act, a bill that invests in innovation and education to improve the competitiveness of the United States in the global economy.

The impact small businesses have on our country's economy and the technological innovations they create simply cannot be overstated. Small hi-tech firms represent the most innovative sector in America. According to the Small Business Administration's Office of Advocacy, these businesses hold over 40 percent of the Nation's patents, obtain 13 to 14 times more patents per

employee than large businesses, and secure patents which are twice as technologically significant as larger firms. With American jobs and our security at stake, it is essential that we support innovation programs to meet national challenges in defense, healthcare, energy, and information technology.

A critical partner for small businesses is the Small Business Administration, SBA, whose fundamental purpose is to ''aid, counsel, assist, and protect the interests of small-business concerns.'' The SBA's methods for carrying out this mandate vary widely, but the agency's primary tool is found in its small business lending programs. The SBA's 7(a), 504, and Microloan programs are tailored to encourage small business growth and expansion. With small businesses representing 99 percent of all employers, creating nearly 75 percent of all net new jobs, and employing 51 percent of the private-sector workforce, it is essential that Congress affirms long-term stability in the lending programs the SBA provides to the small business community.

As it has in the past, the SBA continues to meet the demands of small businesses, both in my home state of Maine and across the county. In fiscal Year 2006, the SBA backed a net 100,197 loans totaling over $19.1 billion under the 7(a) and 504 programs. In fact, both the number of loans and the dollar amount represent record amounts for the agency—dramatically highlighting the significance of the SBA and the critical role it plays in our nation's economy.

The foundation for the bill Senator KERRY and I are introducing today started during the 109th Congress under an extensive reauthorization process which I led. This process ultimately culminated in the unanimous Small Business Committee passage of a comprehensive SBA reauthorization bill. I firmly believe that the Small Business Lending Reauthorization and Improvement Act of 2007 will help the SBA continue its legacy of achievement.

The SBA's loan and investment programs have produced success story after success story, which include assisting the founders of Intel, Staples, and Federal Express, as well as thousands of other successful businesses. Our bipartisan measure will build upon these past successes and make the SBA even more effective. As former Chair and now ranking member of the Small Business Committee, I believe we must do everything possible to sustain prosperity and job creation throughout the United States. To achieve that goal, I have long fought to solidify and expand the reach of the SBA's programs that have helped millions of aspiring entrepreneurs and existing small businesses.

Small businesses yearn to grow, flourish, and thrive, and the SBA has the experience and the resources to be their bridge to success. It is essential that we upgrade the SBA's core lending programs for the 21st century entrepreneur. The American economy needs a strong and vibrant Small Business Administration. The Small Business Lending Reauthorization and Improvement Act of 2007 will build on the previous success of the Agency, and help to ensure the success of tomorrow's entrepreneurs.

By Mr. LIEBERMAN (for himself, Mr. HATCH, and Mr. BENNETT):

S. 1257. A bill to provide the District of Columbia a voting seat and the State of Utah an additional seat in the House of Representatives; to the Committee on Homeland Security and Governmental Affairs.

Mr. LIEBERMAN. Mr. President, I rise today with my colleague from Utah, Senator HATCH, to introduce bipartisan legislation that I believe is the breakthrough we have been searching for to bring House voting representation to the residents of the District of Columbia, who have historically been denied this fundamental birthright.

I am proud to join with, DC Delegate ELEANOR HOLMES NORTON and Representative TOM DAVIS, and the many others from both parties and both houses who have worked without rest to remedy the disenfranchisement of District residents since the capital was established in Washington in 1800. I especially want to thank my friend Senator HATCH for his influential support of this voting rights proposal, which would bring to an end a gross inconsistency with the founding principles of our Nation.

Mr. President, we have a historic opportunity today to finally bestow upon the citizens of the District of Columbia the civic entitlement every other taxpaying American citizen enjoys no matter where he or she resides, democracy's most essential right, voting representation in Congress.

The bill is simple. It would increase the number of voting representatives in the House from 435 to 437 by providing the District with a voting representative and by adding another congressional seat for Utah, the next State in line to increase its representation based on the 2000 Census.

Working cooperatively in the spirit of service to the people of Washington, DC, and Utah, Congresswoman NORTON and Congressman DAVIS shepherded a similar proposal through the House Government Reform Committee on March 13 by a vote of 24–5. The full House approved the measure April 20 by a vote of 241–177, a historic day unlike any other since 1978 when Congress approved a constitutional amendment to give District residents voting rights in the House and Senate. Of course, that amendment came to naught when too few States ratified it.

The people of this city have waited far too long for this right. They have been the direct target of terrorist attacks, and yet they have no representative to vote in Congress on policies to protect their homeland security. Citizens of Washington, DC, pay income taxes just like everyone else. In fact, they pay more: Per capita, District residents have the second highest Federal tax obligation. And yet they have no voice in how high those taxes will be or how they will be spent. The District is also the only jurisdiction in the country that must seek congressional approval, through the appropriations process, before spending locally-generated tax dollars. When Congress fails to pass appropriations bills before the beginning of the fiscal year, the District's budget is essentially frozen. And yet DC has no say in that appropriations process.

DC residents fight and die for our democracy but they cannot participate fully in it. I ask you, how can we effectively promote democracy abroad while denying it to hundreds of thousands of citizens in our Nation's Capital?

There is no good reason why DC residents have been denied congressional representation. In 1800, when the nation's capital was established as the District of Columbia, an oversight left the area's residents without congressional representation. Maryland and Virginia ceded land for the capitol in 1788 and 1789, respectively, but it took another 10 years for Congress to establish the District of Columbia. In the interim, residents continued to vote either in Maryland or Virginia, but Congress withdrew those voting rights once the District was founded. Unfortunately, apparently by omission, Congress neglected to establish new voting rights for the citizens of the new district.

The right to be counted, to have your voice heard by your government is central to a functioning democracy and fundamental to a free society. If we are willing to sacrifice our young men and women in the name of freedom, we must be willing to protect their freedoms as well. This legislation would do just that.

In 2002, 10 cosponsors and I introduced the No Taxation without Representation Act. I held a hearing on the bill in the Governmental Affairs Committee, which I then chaired. It was the first hearing in Congress on DC voting rights since 1994. We reported the bill out of committee, but the Senate never took action on it.

Today, the tide has changed. Members from both parties have come together to find a solution to break the stalemates of the past that have denied DC residents equal representation in Congress. The State of Utah has united in favor of a fourth congressional seat, and Senator HATCH has lent his considerable support to this effort. Mr. President, this legislation represents an uncommon victory for fairness and a rare but hopefully increasingly more common example of what we can do if we work together to accomplish our mutual goals.

The essence of our work in the legislative branch is compromise, and the compromise reached by Senator HATCH

and I will bring partial voting representation to the District while ensuring Utah receives the additional representation it is due.

I know there are those who believe this bill is unconstitutional. But the District clause of the Constitution, which gives Congress the power to legislate ''in all cases whatsoever'' pertaining to the District, provides ample authority for the legislative branch to give DC residents voting rights.

Mr. President, this is our moment to do right here at home, just as we have done throughout our history for our democratic allies abroad. By giving the citizens of the District of Columbia a vote in the House, we will ensure not only that their voices will finally be heard. We will be following the imperative of our history and moral values. The Framers of our Constitution in effect placed with Congress the solemn responsibility of assuring that the rights of DC citizens would be protected in the future, just as it is our responsibility to protect the rights of all citizens throughout this great country. Congress has failed to meet this obligation for more than 200 years, and I am not prepared to make DC citizens wait another 200 years.

Mr. President, the tax-paying citizens of the District of Columbia have been without congressional voting representation for too long. The House has acted. Now it is time for the Senate to act. I urge my colleagues to join Senator HATCH and me in support of this essential legislation.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 1257

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''District of Columbia House Voting Rights Act of 2007''.

SEC. 2. TREATMENT OF DISTRICT OF COLUMBIA AS CONGRESSIONAL DISTRICT.

(a) IN GENERAL.—Notwithstanding any other provision of law, the District of Columbia shall be considered a Congressional district for purposes of representation in the House of Representatives.

(b) CONFORMING AMENDMENTS RELATING TO APPORTIONMENT OF MEMBERS OF HOUSE OF REPRESENTATIVES.—

(1) INCLUSION OF SINGLE DISTRICT OF COLUMBIA MEMBER IN REAPPORTIONMENT OF MEMBERS AMONG STATES.—Section 22 of the Act entitled ''An Act to provide for the fifteenth and subsequent decennial censuses and to provide for apportionment of Representatives in Congress'', approved June 28, 1929 (2 U.S.C. 2a), is amended by adding at the end the following new subsection:

''(d) This section shall apply with respect to the District of Columbia in the same manner as this section applies to a State, except that the District of Columbia may not receive more than one Member under any reapportionment of Members.''.

(2) CLARIFICATION OF DETERMINATION OF NUMBER OF PRESIDENTIAL ELECTORS ON BASIS OF 23RD AMENDMENT.—Section 3 of title 3, United States Code, is amended by striking ''come into office;'' and inserting the following: ''come into office (subject to the twenty-third article of amendment to the Constitution of the United States in the case of the District of Columbia);''.

SEC. 3. INCREASE IN MEMBERSHIP OF HOUSE OF REPRESENTATIVES.

(a) PERMANENT INCREASE IN NUMBER OF MEMBERS.—Effective with respect to the 111th Congress and each succeeding Congress, the House of Representatives shall be composed of 437 Members, including the Member representing the District of Columbia pursuant to section 2(a).

(b) REAPPORTIONMENT OF MEMBERS RESULTING FROM INCREASE.—

(1) IN GENERAL.—Section 22(a) of the Act entitled ''An Act to provide for the fifteenth and subsequent decennial censuses and to provide for apportionment of Representatives in Congress'', approved June 28, 1929 (2 U.S.C. 2a(a)), is amended by striking ''the then existing number of Representatives'' and inserting ''the number of Representatives established with respect to the 111th Congress''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply with respect to the regular decennial census conducted for 2010 and each subsequent regular decennial census.

(c) TRANSMITTAL OF REVISED APPORTIONMENT INFORMATION BY PRESIDENT.—

(1) STATEMENT OF APPORTIONMENT BY PRESIDENT.—Not later than 30 days after the date of the enactment of this Act, the President shall transmit to Congress a revised version of the most recent statement of apportionment submitted under section 22(a) of the Act entitled ''An Act to provide for the fifteenth and subsequent decennial censuses and to provide for apportionment of Representatives in Congress'', approved June 28, 1929 (2 U.S.C. 2a(a)), to take into account this Act and the amendments made by this Act and identifying the State of Utah as the State entitled to one additional Representative pursuant to this section.

(2) REPORT BY CLERK.—Not later than 15 calendar days after receiving the revised version of the statement of apportionment under paragraph (1), the Clerk of the House of Representatives shall submit a report to the Speaker of the House of Representatives identifying the State of Utah as the State entitled to one additional Representative pursuant to this section.

SEC. 4. EFFECTIVE DATE; TIMING OF ELECTIONS.

The general election for the additional Representative to which the State of Utah is entitled for the 111th Congress and 112th Congress and the general election for the Representative from the District of Columbia for the 111th Congress and the 112th Congress shall be subject to the following requirements:

(1) The additional Representative from the State of Utah will be elected pursuant to a redistricting plan enacted by the State, such as the plan the State of Utah signed into law on December 5, 2006, which—

(A) revises the boundaries of Congressional districts in the State to take into account the additional Representative to which the State is entitled under section 3; and

(B) remains in effect until the taking effect of the first reapportionment occurring after the regular decennial census conducted for 2010.

(2) The additional Representative from the State of Utah and the Representative from the District of Columbia shall be sworn in and seated as Members of the House of Representatives on the same date as other Members of the 111th Congress.

SEC. 5. CONFORMING AMENDMENTS.

(a) REPEAL OF OFFICE OF DISTRICT OF COLUMBIA DELEGATE.—

(1) REPEAL OF OFFICE.—

(A) IN GENERAL.—Sections 202 and 204 of the District of Columbia Delegate Act (Public Law 91–405; sections 1–401 and 1–402, D.C. Official Code) are repealed, and the provisions of law amended or repealed by such sections are restored or revived as if such sections had not been enacted.

(B) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date on which a Representative from the District of Columbia takes office for the 111th Congress.

(2) CONFORMING AMENDMENTS TO DISTRICT OF COLUMBIA ELECTIONS CODE OF 1955.—The District of Columbia Elections Code of 1955 is amended as follows:

(A) In section 1 (sec. 1–1001.01, D.C. Official Code), by striking ''the Delegate to the House of Representatives,'' and inserting ''the Representative in Congress,''.

(B) In section 2 (sec. 1–1001.02, D.C. Official Code)—

(i) by striking paragraph (6); and

(ii) in paragraph (13), by striking ''the Delegate to Congress for the District of Columbia,'' and inserting ''the Representative in Congress,''.

(C) In section 8 (sec. 1–1001.08, D.C. Official Code)—

(i) in the heading, by striking ''Delegate'' and inserting ''Representative''; and

(ii) by striking ''Delegate,'' each place it appears in subsections (h)(1)(A), (i)(1), and (j)(1) and inserting ''Representative in Congress,''.

(D) In section 10 (sec. 1–1001.10, D.C. Official Code)—

(i) in subsection (a)(3)(A)—

(I) by striking ''or section 206(a) of the District of Columbia Delegate Act''; and

(II) by striking ''the office of Delegate to the House of Representatives'' and inserting ''the office of Representative in Congress'';

(ii) in subsection (d)(1), by striking ''Delegate,'' each place it appears; and

(iii) in subsection (d)(2)—

(I) by striking ''(A) In the event'' and all that follows through ''term of office,'' and inserting ''In the event that a vacancy occurs in the office of Representative in Congress before May 1 of the last year of the Representative's term of office,''; and

(II) by striking subparagraph (B).

(E) In section 11(a)(2) (sec. 1–1001.11(a)(2), D.C. Official Code), by striking ''Delegate to the House of Representatives,'' and inserting ''Representative in Congress,''.

(F) In section 15(b) (sec. 1–1001.15(b), D.C. Official Code), by striking ''Delegate,'' and inserting ''Representative in Congress,''.

(G) In section 17(a) (sec. 1–1001.17(a), D.C. Official Code), by striking ''the Delegate to Congress from the District of Columbia'' and inserting ''the Representative in Congress''.

(b) REPEAL OF OFFICE OF STATEHOOD REPRESENTATIVE.—

(1) IN GENERAL.—Section 4 of the District of Columbia Statehood Constitutional Convention Initiative of 1979 (sec. 1–123, D.C. Official Code) is amended as follows:

(A) By striking ''offices of Senator and Representative'' each place it appears in subsection (d) and inserting ''office of Senator''.

(B) In subsection (d)(2)—

(i) by striking ''a Representative or'';

(ii) by striking ''the Representative or''; and

(iii) by striking ''Representative shall be elected for a 2-year term and each''.

(C) In subsection (d)(3)(A), by striking ''and 1 United States Representative''.

(D) By striking ''Representative or'' each place it appears in subsections (e), (f), (g), and (h).

(E) By striking ''Representative's or'' each place it appears in subsections (g) and (h).

(2) CONFORMING AMENDMENTS.—

(A) STATEHOOD COMMISSION.—Section 6 of such Initiative (sec. 1–125, D.C. Official Code) is amended—

(i) in subsection (a)—

(I) by striking ''27 voting members'' and inserting ''26 voting members'';

(II) by adding ''and'' at the end of paragraph (5); and

(III) by striking paragraph (6) and redesignating paragraph (7) as paragraph (6); and

(ii) in subsection (a-1)(1), by striking subparagraph (H).

(B) AUTHORIZATION OF APPROPRIATIONS.—Section 8 of such Initiative (sec. 1–127, D.C. Official Code) is amended by striking ''and House''.

(C) APPLICATION OF HONORARIA LIMITATIONS.—Section 4 of D.C. Law 8–135 (sec. 1–131, D.C. Official Code) is amended by striking ''or Representative'' each place it appears.

(D) APPLICATION OF CAMPAIGN FINANCE LAWS.—Section 3 of the Statehood Convention Procedural Amendments Act of 1982 (sec. 1–135, D.C. Official Code) is amended by striking ''and United States Representative''.

(E) DISTRICT OF COLUMBIA ELECTIONS CODE OF 1955.—The District of Columbia Elections Code of 1955 is amended—

(i) in section 2(13) (sec. 1–1001.02(13), D.C. Official Code), by striking ''United States Senator and Representative,'' and inserting ''United States Senator,''; and

(ii) in section 10(d) (sec. 1–1001.10(d)(3), D.C. Official Code), by striking ''United States Representative or''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date on which a Representative from the District of Columbia takes office for the 111th Congress.

(c) CONFORMING AMENDMENTS REGARDING APPOINTMENTS TO SERVICE ACADEMIES.—

(1) UNITED STATES MILITARY ACADEMY.—Section 4342 of title 10, United States Code, is amended—

(A) in subsection (a), by striking paragraph (5); and

(B) in subsection (f), by striking ''the District of Columbia,''.

(2) UNITED STATES NAVAL ACADEMY.—Such title is amended—

(A) in section 6954(a), by striking paragraph (5); and

(B) in section 6958(b), by striking ''the District of Columbia,''.

(3) UNITED STATES AIR FORCE ACADEMY.—Section 9342 of title 10, United States Code, is amended—

(A) in subsection (a), by striking paragraph (5); and

(B) in subsection (f), by striking ''the District of Columbia,''.

(4) EFFECTIVE DATE.—This subsection and the amendments made by this subsection shall take effect on the date on which a Representative from the District of Columbia takes office for the 111th Congress.

SEC. 6. NONSEVERABILITY OF PROVISIONS.

If any provision of this Act or any amendment made by this Act is declared or held invalid or unenforceable, the remaining provisions of this Act or any amendment made by this Act shall be treated and deemed invalid and shall have no force or effect of law.

Mr. HATCH. Mr. President, I rise today to join with Senate Committee on Homeland Security and Governmental Affairs Chairman JOSEPH LIEBERMAN and Senator ROBERT BENNETT in introducing the District of Columbia Voting House Rights Act of 2007. Our colleagues in the House of Representatives recently passed similar legislation, H.R. 1905, that would provide a fourth congressional seat for my home state of Utah and the first voting member for the District of Columbia. No doubt, this is a historic time for the citizens of the District of Columbia and a unique opportunity for Utah to receive a long overdue fourth congressional seat.

The Founding Fathers made clear in article 1, section 8 of the Constitution that the District of Columbia would be the seat of the national government and granted Congress the power ''[t]o exercise exclusive Legislation, in all Cases whatsoever, over such District (not exceeding ten Miles square) as may, by Cession of particular States, and the Acceptance of Congress become the Seat of the Government of the United States . . .'' This clause became effective in 1790 when Congress accepted land that Maryland and Virginia ceded to the United States to create the national capital. Ten years later, in December 1800, jurisdiction over the District of Columbia was vested in the Federal Government. Since then, District residents have not had the right to vote for Members of Congress. Additionally, article 1, section 2 and section 3 of the Constitution provides that citizens of States shall have voting representation in the House and Senate.

During my time in the Senate, I have heard from many District residents who believe strongly that their voice should be heard in Congress. They pay taxes, vote in presidential elections, and serve in the military. Yet these nearly 600,000 Americans do not have a voting representative in Congress. Many, including myself, have been reluctant to support previous proposals based upon the constitutional principle that States, not territories, are afforded congressional representation. I understand the argument that congressional representation is dependent on statehood and, therefore, the Constitution would need to be amended before the District is given a voting representative in Congress. While the Constitution does not affirmatively grant District residents the right to vote in congressional elections, it does affirmatively grant Congress plenary power to govern the District's affairs. Indeed, the Constitution grants Congress exclusive authority to legislate all matters concerning the District, and I believe this authority extends to the granting of congressional voting rights for District residents.

I support this legislation not only because it rectifies the District's undemocratic political status, but it gives my home State of Utah a long overdue fourth voting Member in the House of Representatives.

During the 2000 Census count, Utah missed out on a fourth House seat by only 857 people. The Census Bureau counted members of the military serving abroad as residents of their home State, but did not count an estimated 14,000 Utah missionaries from the Church of Jesus Christ of Latter-day Saints living abroad. Utah took its fight for a fourth seat all the way to the Supreme Court, but lost. Instead, North Carolina gained another seat in the House by 856 residents. Since then, I have heard from many Utahns and share their frustrations about the outcome of the 2000 Census.

Why push for an additional seat now? Under normal circumstances, Utah would have to wait until the 2010 Census to see if its growing population justifies another congressional seat. However, the proposed legislation provides Utah a chance to receive another voting member of Congress 5 years early. That is equivalent to two and a half terms for a Member of Congress and places the new Member well on his or her way in establishing seniority and influence for the benefit of Utah's citizens. I don't think this is an offer we should dismiss.

I have some constitutional concerns with H.R. 1905's attempt to impose an at-large seat upon my State of Utah. In States with more than one seat in the House, Members are expected to represent insular constituencies. Under H.R. 1905, residents of one State would be represented by two House Members while citizens in other States would have one. In addition, in our constitutional system, States are responsible for elections and Utah has chosen the approach it wants to take by redistricting. I see no warrant for Congress to undermine this balance and impose upon Utah a scheme it has not chosen for itself. For this reason, in the proposed Senate legislation, I insisted that Utah be required to redistrict to provide for the new seat. I believe that Utah's legislators deserve the freedom to determine their representatives' districts without unjustified intrusion or mandate of the Federal Government.

Additionally, the House bill would require Utah to hold a special election in 2007 if the bill passes. The Senate version requires that both seats be elected in the November 2008 general election. Thereafter, both new Members would begin their service at the start of the 111th Congress in 2009.

In conclusion, let me say that I recognize there are many who strongly oppose this legislation. There are many who wish the District voting rights issue would simply go away. The Democratic-controlled Congress could have simply pushed forward with legislation giving the District of Columbia a seat without balancing a ''Democrat'' seat with a ''Republican'' seat. I am pleased that this was not the case. The House of Representatives has already voted in favor of moving this legislation forward. Now it is up to the Senate. Let me be clear, the proposed legislation does not provide Senate representation for the District of Columbia. I am not in favor of granting two Senators for the District and would not support such a proposal.

As one who represents Utah, I have an important responsibility to ensure

that my State is dealt with properly and fairly. And, in light of the House's recent legislative action, I am determined to do all that I can to ensure that Utah's fourth seat configuration is done right. I want my fellow Utahns to know that the window of opportunity is quickly closing. In fact, I dare say there won't be another opportunity like this again. For this reason, I intend to make the most of it and hope that my Senate colleagues will support me in this endeavor.

By Mrs. CLINTON (for herself and Mr. SMITH):

S. 1259. A bill to amend the Foreign Assistance Act of 1961 to provide assistance for developing countries to promote quality basic education and to establish the achievement of universal basic education in all developing countries as an objective of United States foreign assistance policy, and for other purposes; to the Committee on Foreign Relations.

Mrs. CLINTON. Mr. President, today, I am proud to introduce, along with Senator GORDON SMITH, the Education for All Act of 2007. This bill would enable us to increase our spending on global education initiatives in order to help millions of children around the world have the opportunity to receive an education.

Worldwide, more than 77 million children do not have access to primary school education. The majority of these—approximately 44 million—are girls. Approximately half of the school-age children who start primary school do not complete it. And there are hundreds of millions more children who are denied the opportunity to complete a secondary school education—to become the next generation of doctors, nurses, lawyers, scientists, and teachers. These statistics represent a unconscionable misuse of human potential—a misuse that we can and must remedy.

In 2000, the United States, along with other governments around the world, committed to the goal of achieving universal basic education by 2015. Through some of the initiatives and partnership in which our government is participating, such as the Education for All Fast Track Initiative, we have made progress. Since the Fast Track Initiative was launched in 2002, approximately 4 million children each year have gained access to school.

Yet despite such gains, we are not on track to meet our 2015 goal. In order to do so, we would need to help millions more children enter school each year—requiring a global financial commitment of more than $7 billion every year.

The Education for All Act of 2007 would authorize $10 billion in spending over the next 5 years, enabling the U.S. Government to make a significant commitment to reach the 2015 goal, and help children in developing countries, particularly areas experiencing conflict or humanitarian emergencies, have access to a quality basic education. The bill that I am introducing today will make a tangible difference in the lives of children around the world, by helping them to attend school and receive a quality education. And its impact will go far beyond the individual, but will also benefit families, communities, and countries.

A 2004 report by Barbara Herz and Gene Sperling from the Center on Universal Education at the Council on Foreign Relations detailed the gains that are to be made when we invest in education, particularly for girls. A single year of primary education correlates with a 10–20 percent increase in women's wages later in life. An extra year of a woman's education has been shown to reduce the risk that her children will die in infancy by 5–10 percent, and a study of South Asia and Sub-Saharan Africa found that from 1960 to 1992, equality in education between men and women could have led to nearly 1 percent higher annual per capita GDP growth.

We have the data to show that education is the path to good jobs, strong democracies, and stable societies. We have the capacity, responsibility, and opportunity to help millions of children worldwide. All it takes now is the will to expand access to educational opportunity.

I believe with bipartisan support we can turn this bill into law, and lead the world in meeting the goal of universal basic education, and I look forward to working with my colleagues in Congress in making education for all a reality.

Mr. SMITH. Mr. President, I rise today to introduce the Education for All Act of 2007 with my colleague from New York, Senator HILLARY CLINTON. This legislation will focus U.S. efforts to help provide all children worldwide with a basic education. At this time, at least 77 million children of primary school age around the world are not in school.

Basic education is a critical part of a child's development. In addition to providing children the tools necessary to succeed in life, education provides a secondary purpose of helping to reduce poverty and inequality. A strong basic education system also lays the foundation for sound governance, civic participation, and strong familial institutions. Without an education, children are less able to contribute to a country's development, often becoming a burden on society.

A recent Government Accountability Office concluded there are seven U.S. Federal agencies providing international basic education services in approximately 70 countries. Unfortunately, the GAO also found instances when agencies did not coordinate the planning or delivery of international basic education activities. To maximize the impact of U.S. aid dollars, we must efficiently coordinate between government agencies to decrease redundant spending on overlapping programs. The Education for All Act will help achieve this.

In 2000, at the World Education Forum in Dakar, Senegal, the United States was one of 180 countries to commit to the goal of universal basic education by 2015. Since then, we have enhanced our efforts to provide basic education overseas. From fiscal years 2001 to 2006, USAID, the Departments of State and Defense and the Millennium Challenge Corporation allocated $2.2 billion to support our basic international education efforts. During this same period, the Departments of Agriculture and Labor further allocated an estimated $1 billion to programs with basic education as a component. I am proud of our country's generosity and commitment to this important goal.

Our bill will ensure the United States provides the resources and leadership necessary to supply all children with a quality basic education. It calls on the President to establish a comprehensive strategy for achieving universal basic education by 2015. This strategy should include actions toward improving coordination, reducing duplication, expanding public-private partnerships, leveraging resources and maximizing the use of American technical experts. The bill also establishes a U.S. Education for All Coordinator, an ambassador-level position appointed by the President and confirmed by the Senate. The Coordinator will manage U.S. efforts to ensure aid dollars are used in the most effective manner possible.

The bill further establishes a fellowship program at USAID which allows qualified individuals to serve 3-year terms as Basic Education fellows, helping establish and carry out basic education policy and programming. This fellowship will broaden U.S. capabilities in the areas of technical assistance and training. Finally, the bill authorizes $1 billion for fiscal year 2008, $1.5 billion for fiscal year 2009, $2 billion for fiscal year 2010, $2.5 billion for fiscal year 2011, and $3 billion for fiscal year 2012 for international basic education programs.

I hope my colleagues will join us in supporting the noble ambition of achieving universal basic education by endorsing the Education for All Act of 2007.

By Ms. CANTWELL (for herself, Mr. HARKIN, and Mr. BROWN):

S. 1261. A bill to amend title 10 and 38, United States Code, to repeal the 10–year limit on use of Montgomery GI Bill educational assistance benefits, and for other purposes; to the Committee on Veterans' Affairs.

Ms. CANTWELL. Mr. President, I rise today to speak about an investment program in lifelong education for our service members and veterans. The Montgomery GI Bill is consistently cited as an important reason people join the military and continues to be one of the most important benefits provided for military service today. There is no reason why 100 percent of our active duty, selected reserve, and veteran servicemembers should not have the

opportunity to take advantage of their earned education benefits.

That is why I'm reintroducing the Montgomery GI Bill for Life Act of 2007, which would allow Montgomery GI Bill participants an unlimited amount of time to use their earned benefits.

I am pleased that my colleague, Senator TOM HARKIN, is again joining me in sponsoring this legislation and that Senator SHERROD BROWN has also signed on to further extend MGIB benefits.

The MGIB is a program that provides up to 36 months of education benefits for educational opportunities ranging from college to apprenticeship and job training, and even flight training. Upon enlistment, the GI Bill also requires service members to contribute $100 per month for their first 12 months of services.

Basically, the MGIB is divided into two programs. One program targets active duty and veteran members, paying over $1,000 per month to qualified students. That's more than $36,000 for school. The other is directed at the Selected Reserve. This program provides educational benefits of $288 per month, for a total of $10,368.

If recruits are overwhelmingly declaring that education opportunity under the GI Bill is the key incentive for them to join the military, then it makes sense that most—if not all—of our troops, who signed up for the program, would also be cashing in on their benefits. But reports show that the majority, 40 to 60 percent, do not actually use the benefits they have earned.

Currently, MGIB participants have up to 10 years from their release date from the military to use their earned education benefits. Members of the Selected Reserve are able to use their MGIB benefit for 14 years. However, that means your earned education benefits expire if you don't use the within the required timeframe, closing your window of opportunity to go to school or finish your college education. Plus, you lose the $1,200 dedicated for your GI Bill during your first year of enlistment.

Originally, the intent of 1944 GI Bill of Rights was to help veterans successfully transition back into civilian life as education is the key to employment opportunities. Looking back now, we know that the GI Bill opened the door to higher education, helping millions of service members and veterans who wouldn't otherwise have had the chance to pay for college. That is, servicemembers benefited from the GI Bill because they used the payments within the 10 and 14 year limitation.

But there are many others who did not use their earned education benefits within that timeframe. For example, after leaving the military, some servicemembers postponed going to school because they had to go straight to work in order to support their family. Others unfortunately, were either homeless or incarcerated for long periods of time due to disability associated with military service, but are now ready to move forward in their lives, and going back to school is their first step. In some cases, due to random life circumstances, some people just lost track of time. Additionally, because of misinformation and bureaucratic language, the GI Bill is known as a complicated program to navigate.

A constituent of mine, Ruben Ruelas—who is a Local Veterans Employment Representative, LVER, for the WorkSource in Wenatchee, Washington, wrote to me saying, ''It's been my experience that most people don't know what they want to do in life or are placed in situations where, due to changing economic times, they are displaced and need further education and training to compete for jobs. But most don't have access to training resources to do so.''

In terms of Vietnam Era veterans, Mr. Ruelas goes on to say, ''many 50 year olds are unemployed, untrained and uneducated and could use their educational benefits to improve their skills to compete for better jobs. Many have come to realize, too late, that they need college or retraining and don't have the resources to do so.''

While times have changed remarkably, one thing remains constant: education is critical to employment opportunity. In the 21st Century global labor market, enhancing skills through education and job training is now more important than ever. The need for retraining is even more underscored for our military service members and veterans.

My legislation, the Montgomery GI Bill for Life, would ensure that educational opportunities are lifelong, allowing service members and veterans the flexibility to seek education and job training opportunities when it is the right time for them to do so.

Higher education not only serves as an individual benefit, but positive externalities have transpired: the GI Bill was instrumental in building our country's middle class and continues to help close the college education gap.

Today, employers are requiring higher qualifications from the workforce. The Bureau of Labor Statistics reports that six of the ten fastest-growing occupations require an associate's degree or bachelor's degree. By 2010, 40 percent of all job growth will require some form of postsecondary education. While a highly skilled workforce is one characteristic of the new economy, working for one employer throughout a lifetime is no longer routine, but rather an evanescent feature. According to findings by Brigham Young University, the average person changes jobs or careers eight times in his or her lifetime. To keep up with these trends, expanding access to education and training is a must do in the 21st Century global marketplace.

A 1999 report by the Congressional Commission on Service members and Veterans Transition Assistance stated that the GI Bill of the future must include the following: Provide veterans with access to post-secondary education that they use; assist the Armed forces in recruiting the high quality high school graduates needed; enhance the Nation's competitiveness by further educating American veterans, a population that is already self-disciplined, goal oriented, and steadfast; and attract the kind of service members who will go on to occupy leadership positions in government and the private sector.

Eliminating the GI Bill 10 and 14 year limitation for service members, veterans, and Selected Reserve moves one step toward improving the MGIB. The Montgomery GI Bill for Life would allow MGIB members, including qualified Vietnam Era Veterans, the flexibility to access their earned education benefits at any time.

As the nation's economy continues to recover and grow stronger, the GI Bill will continue to be the primary vehicle keeping our active duty service members and veterans of military service on track, helping to ensure our country's prosperity.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 178—EXPRESSING THE SYMPATHY OF THE SENATE TO THE FAMILIES OF WOMEN AND GIRLS MURDERED IN GUATEMALA, AND ENCOURAGING THE UNITED STATES TO WORK WITH GUATEMALA TO BRING AN END TO THESE CRIMES

Mr. BINGAMAN submitted the following resolution; which was referred to the Committee on Foreign Relations:

S. RES. 178

Whereas, since 2001, more than 2,000 women and girls have been murdered in Guatemala;

Whereas most of the victims are women ranging in age from 18 to 30, with many of the cases involving abduction, sexual violence, or brutal mutilation;

Whereas, from 2001 to 2006, the rate at which women have been murdered in Guatemala has almost doubled, increasing at a higher rate than the murder rate of men in Guatemala during the same period;

Whereas, according to data from Guatemala's Public Prosecutors Office, few arrests and fewer convictions have occurred, and prosecutors, forensics experts, and other state justice officials have not brought the perpetrators to justice;

Whereas, from 2001 to 2006, there were only 20 convictions for the murders of women and girls;

Whereas the Human Rights Ombudsman of the Government of Guatemala has reported that in 1 year alone police officers were implicated on 10 separate occasions in the murder of women in Guatemala, and recommended that such officers and other officials be held accountable for their acts;

Whereas an effective, transparent, and impartial judicial system is key to the administration of justice, and the failure to ensure proper investigations and prosecutions hampers the ability to solve crimes and punish perpetrators;

Whereas inadequate financial, human, and technical resources, as well as a lack of forensic and technical expertise, have impeded the arrest and prosecution of suspects;

Whereas the Special Prosecutor for Crimes Against Women of the Government of Guatemala has reported that her office has reviewed approximately 800 incidents of domestic violence per month, with some of those cases ending in murder, and that deaths could have been prevented if the legal system of Guatemala provided for prison sentences in cases of domestic violence;

Whereas the murders of women and girls in Guatemala have brought pain to the families and friends of the victims as they struggle to cope with the loss of their loved ones and the fact that the perpetrators of these heinous acts remain unknown to the proper authorities;

Whereas many countries in Latin America face significant challenges in combating violence against women, and international cooperation is essential in addressing this serious issue;

Whereas the United States Agency for International Development (USAID) has provided assistance to the Government of Guatemala to implement judicial reform and rule of law programs, and in fiscal year 2006, Congress provided $1,500,000 for programs to combat impunity, corruption, and crimes of violence, of which $500,000 is to be allocated to strengthen the special prosecutorial units charged with investigating the murders of women in Guatemala;

Whereas the Government of Guatemala has undertaken efforts to prevent violence against women, as evidenced by its ratification of the United Nations Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, done at New York December 10, 1984, the United Nations Convention on the Elimination of All Forms of Discrimination Against Women, done at New York December 18, 1979, the Inter-American Convention on the Prevention, Punishment, and Eradication of Violence Against Women, done at Belem do Para, Brazil June 9, 1994, and other international human rights treaties, and the enactment of laws and the creation of state institutions to promote and protect the rights of women;

Whereas the Government of Guatemala has created special police and prosecutorial units to address the brutal murders of women in Guatemala;

Whereas, in June 2006, the Government of Guatemala successfully abolished the ''Rape Law'' which had absolved perpetrators of criminal responsibility for rape and certain other crimes of violence upon the perpetrator's marriage with the victim;

Whereas legislators from various parties in Guatemala have joined lawmakers from Mexico and Spain to form the ''Interparliamentary Network against 'Femicide' '';

Whereas the Government of Guatemala and the United Nations recently entered into an agreement to establish the International Commission Against Impunity in Guatemala (CICIG), which has a mandate to investigate and promote the prosecution of illegal security groups and clandestine security organizations that function with impunity and are suspected of attacking human rights defenders, justice officials, and other civil society actors; and

Whereas continuing impunity for crimes against women is a threat to the rule of law, democracy, and stability in Guatemala: Now, therefore, be it

Resolved, That the Senate—

(1) expresses its sincerest condolences and deepest sympathy to the families of women and girls murdered in Guatemala, and recognizes their courageous struggle in seeking justice for the victims;

(2) expresses the solidarity of the people of the United States with the people of Guatemala in the face of these tragic and senseless acts;

(3) condemns the ongoing murders of women and girls in Guatemala, and encourages the Government of Guatemala to act with due diligence in order to promptly investigate these killings, prosecute those responsible, and continue to work toward eliminating violence against women;

(4) urges the Government of Guatemala to recognize domestic violence and sexual harassment as criminal acts and to provide the resources and commitment necessary to strengthen the integrity of the prosecutorial and judicial systems;

(5) urges the President and the Secretary of State to incorporate the investigative and preventative efforts of the Government of Guatemala regarding the murder of women and girls into the bilateral agenda between the Governments of Guatemala and the United States;

(6) encourages the Secretary of State to support efforts by the Government of Guatemala to train and equip the special police and prosecutorial units of the Government of Guatemala to conduct thorough and proper investigations of crimes of violence against women, and to implement judicial reform and rule of law programs;

(7) encourages the Secretary of State and the Attorney General to provide assistance in establishing a comprehensive missing persons system and an effective state protection program for witnesses, victims' relatives, and human rights defenders;

(8) urges the Government of Guatemala to hold accountable those law enforcement and judicial officials whose failure to investigate and prosecute the murders adequately, whether through negligence, omission, or abuse, has led to impunity for these crimes;

(9) encourages the Secretary of State to support efforts to identify perpetrators and unknown victims through forensic analysis, including assisting the Government of Guatemala in adequately funding the National Institute for Forensic Science (INACIF) and training lab personnel in investigatory and evidence gathering protocols;

(10) urges the Secretary of State—

(A) to express support for the efforts of the victims' families and loved ones to seek justice for the victims,

(B) to express concern relating to any harassment of these families and the human rights defenders with whom they work, and

(C) to express concern with respect to impediments in the ability of the families to receive prompt and accurate information in their cases;

(11) encourages the Secretary of State to continue to include in the Department of State's annual Country Reports on Human Rights Practices all instances of improper investigatory methods, threats against human rights activists, and the use of torture with respect to cases involving the murder and abduction of women and girls in Guatemala;

(12) recommends that the United States Ambassador to Guatemala continue to meet with the families of the victims, women's rights organizations, and the officials of the Government of Guatemala who are responsible for investigating these crimes; and

(13) recommends that the Secretary of State develop a comprehensive plan to address and combat the growing problem of violence against women in Latin America.

Mr. BINGAMAN. Mr. President, I rise today to speak about the tragic deaths of women and girls in Guatemala, and to submit a resolution urging increased U.S. involvement in addressing this serious issue.

Since 2001, more than 2,000 women and girls have been murdered in Guatemala. The murder rate of these women almost doubled from 2001 to 2006, increasing at a higher rate than the murder rate of men. While these killings may be due to a variety of factors, what clearly unifies these cases is the fact that very few of the perpetrators have been brought to justice. Indeed, it is my understanding that as of 2006 there have been only 20 convictions for these killings. In some of the cases police have been implicated in the crimes.

The lack of respect for the rule of law, inadequate legal protections for women, ongoing violence in the country, corruption, insufficient resources, substandard investigations, and the lack of independent and effective judicial and prosecutorial systems, all contribute to the inability of the Government of Guatemala to hold those responsible for these killings accountable for their crimes. The result is a general sense of impunity for crimes against women in the country.

The Government of Guatemala has taken some steps to address these killings. Guatemala has created special police and prosecutorial units to investigate these murders, and repealed the so called ''Rape Law'' which had absolved perpetrators of criminal responsibility for rape upon the perpetrator's marriage with the victim. The Government also recently entered into an agreement with the United Nations to establish the International Commission Against Impunity in Guatemala, CICIG, which has a mandate to investigate and prosecute illegal security groups operating with impunity. And Guatemala established the National Institute for Forensic Sciences to improve investigatory and evidence gathering efforts.

The resolution I am submitting today is aimed at raising awareness of this issue and encouraging the governments of Guatemala and the United States to work together to stop these killings. Among other things, the resolution: condemns these murders and expresses the sympathy of the Senate to the families of women and girls murdered in Guatemala; encourages the Government of Guatemala to act with due diligence in investigating and prosecuting those responsible for these crimes; urges the Government of Guatemala to recognize domestic violence as a criminal act and to provide adequate resources necessary to strengthen the integrity of the prosecutorial and judicial systems; urges the President and the Secretary of State to incorporate this issue into the bilateral agenda between the governments of Guatemala and the United States; and encourages the Secretary of State to provide assistance in training and

equipping special police units to investigate these crimes, implementing judicial reforms and rule of law programs, establishing a missing persons system, creating an effective witness protection program, and supporting efforts to enhance forensic capabilities.

Mr. President, I urge my colleagues to support this important resolution and give this issue the attention it deserves.

SENATE RESOLUTION 179—WELCOMING THE PRIME MINISTER OF SINGAPORE ON THE OCCASION OF HIS VISIT TO THE UNITED STATES AND THE 40TH ANNIVERSARY OF THE ASSOCIATION OF SOUTHEAST ASIAN NATIONS (ASEAN), EXPRESSING GRATITUDE TO THE GOVERNMENT OF SINGAPORE FOR ITS STRONG COOPERATION WITH THE UNITED STATES IN THE CAMPAIGN AGAINST TERRORISM, AND REAFFIRMING THE COMMITMENT OF THE UNITED STATES TO THE CONTINUED EXPANSION OF FRIENDSHIP AND COOPERATION BETWEEN THE UNITED STATES AND SINGAPORE

Mr. BOND submitted the following resolution; which was referred to the Committee on Foreign Relations:

S. RES. 179

Whereas Singapore is a great friend of the United States;

Whereas the United States and Singapore share a common vision of promoting peace, stability, security, and prosperity in the Asia-Pacific region;

Whereas Singapore was a founding member of the Association of Southeast Asian Nations (ASEAN);

Whereas Singapore is a member of the Proliferation Security Initiative, an initiative launched by the United States in 2003 to respond to the challenges posed by the proliferation of weapons of mass destruction, and a committed partner of the United States in preventing the spread of weapons of mass destruction;

Whereas Singapore is a leader in the Radiation Detection Initiative, an effort by the United States to develop technology to safeguard maritime security by detecting trafficking of nuclear and radioactive material;

Whereas, in July 2005, Singapore became a partner of the United States in the Strategic Framework Agreement for Closer Cooperation in Defense and Security, an agreement which will build upon the already strong military relations between the United States and Singapore and expand the scope of defense and security cooperation between the 2 countries;

Whereas Singapore selected the F–15SG Fighter, built in the United States, for use by the Air Force of Singapore, which will greatly enhance the interoperability of the Air Forces of Singapore and the United States;

Whereas Singapore responded quickly to provide generous humanitarian relief and financial assistance to the people affected by the tragic tsunami that struck Southeast Asia in December 2004;

Whereas Singapore responded quickly to provide logistical support and assistance to the relief efforts in the United States after Hurricane Katrina;

Whereas Singapore has joined the United States in the global struggle against terrorism, providing intelligence and offering political and diplomatic support;

Whereas Singapore is the 15th largest trading partner of the United States and the first free trade partner of the United States in the Asia-Pacific region, and the United States is the second largest trading partner of Singapore;

Whereas the relationship between the United States and Singapore extends beyond the current campaign against terrorism and is reinforced by strong ties of culture, commerce, and scientific and technical cooperation; and

Whereas the relationship between the United States and Singapore encompasses almost every field of international cooperation, including a common commitment to fostering a stronger and more open international trading system: Now, therefore, be it

Resolved, That the Senate—

(1) welcomes the Prime Minister of Singapore, His Excellency Lee Hsien Loong, to the United States;

(2) congratulates the Association of Southeast Asian Nations (ASEAN), and Singapore as one of its founding members, on the 40th anniversary of ASEAN;

(3) expresses profound gratitude to the Government of Singapore for promoting security and prosperity in Southeast Asia and cooperating with the United States in the global campaign against terrorism; and

(4) reaffirms the commitment of the United States to continue strengthening the friendship and cooperation between the United States, Singapore, and the other countries of the ASEAN region.

SENATE RESOLUTION 180—RECOGNIZING THE 70TH ANNIVERSARY OF THE IDAHO POTATO COMMISSION AND DESIGNATING MAY 2007 AS ''IDAHO POTATO MONTH''

Mr. CRAPO (for himself and Mr. CRAIG) submitted the following resolution; which was referred to the Committee on the Judiciary:

S. RES. 180

Whereas the State of Idaho produces roughly one-third of all the potatoes grown in the United States, harvesting an average of 12,000,000,000 to 14,000,000,000 pounds annually;

Whereas the State of Idaho's unique climate of warm days, cool nights, mountain-fed irrigation, and rich volcanic soil is conducive to growing world-renowned potatoes;

Whereas Idaho potatoes are top-selling and highly recognized potatoes in the United States due to their consistently great taste, versatility, and nutritional content;

Whereas the Idaho potato ''brand'' is recognized throughout the world for its high quality and is an identifying characteristic of the great State of Idaho;

Whereas May 2007 marks the 70th consecutive year that Idaho potatoes have been promoted by the Idaho Potato Commission, an Idaho potato industry group responsible for generating attention for the numerous attributes of Idaho potatoes;

Whereas the Idaho Potato Commission is recognized nationally and internationally as a top promotional authority for Idaho's potatoes and potato products;

Whereas the Idaho Potato Commission's requirement, since 1959, that only potatoes grown in the State of Idaho are allowed to wear the ''Grown in Idaho'' Federal certification mark contributed toward the creation of a distinctive, enduringly successful, and popular brand for the Russet Burbank potato variety; and

Whereas Idaho's potato industry contributes approximately $2,700,000,000 to the State economy and employs 39,000 residents: Now, therefore, be it

Resolved, That the Senate—

(1) recognizes the 70th anniversary of the Idaho Potato Commission; and

(2) designates May 2007 as ''Idaho Potato Month''.

SENATE RESOLUTION 181—HONORING AND RECOGNIZING THE ACHIEVEMENTS OF THE UNITED STATES AIR FORCE ACADEMY FOOTBALL PROGRAM OVER THE LAST 27 YEARS

Mr. ALLARD (for himself, Mr. PRYOR, and Mr. CRAIG) submitted the following resolution; which was considered and agreed to:

S. RES. 181

Whereas, Fisher DeBerry, originally of Cheraw, South Carolina, coached football at the United States Air Force Academy for 27 years, 23 of which as head coach;

Whereas, Fisher DeBerry is the winningest head coach of any United States service academy with a record of 169–109–1;

Whereas, Fisher DeBerry has amassed a 35–11 record against the United States Military Academy and the United States Naval Academy, and led the U.S. Air Force Academy to 14 of its 16 Commander-in-Chief Trophy titles;

Whereas, Fisher DeBerry led his Air Force teams to 3 conference championships and 12 bowl games;

Whereas, Fisher DeBerry has been recognized numerous times for his coaching success, including selection as National Coach of the Year for 1985; selection 3 times as Western Athletic Conference Coach of the Year; induction into the South Carolina Sports Hall of Fame; induction into the Colorado Springs Sports Hall of Fame; induction into the Independence Bowl Hall of Fame; the 2001 State Farm Coach of Distinction honor; an honorary doctorate of humanities from Wofford College; service as president of the American Football Coaches Association (AFCA); and service as Chairman of the AFCA ethics committee;

Whereas, Fisher DeBerry has acted as a pillar of the Colorado Springs, Colorado, community during the past 27 years through his active involvement and volunteerism with local church, charity, and community organizations;

Whereas, in 2004 Fisher DeBerry founded the Fisher DeBerry Foundation, which is dedicated to the support and education of single mothers and their children, as well as other charitable causes;

Whereas, Fisher DeBerry has served as a positive influence and role model to numerous future Air Force officers, including coaching 3,375 players; having a graduation success rate of 91.6 percent among his players; and producing 19 All-American players, 124 All-Conference players, 11 Academic All-Americans, and 9 Postgraduate Scholarship winners;

Whereas, Fisher DeBerry imparted to his players the core values of the United States Air Force: Integrity First, Service Before Self, and Excellence In All We Do; and

Whereas, the United States Air Force Academy football program under the leadership of Fisher DeBerry has served as an example of these values for its community and the entire Nation: Now, therefore, be it

Resolved, That the United States Senate honors and recognizes the numerous contributions made by the United States Air Force Academy football program over the last 27 years to Colorado Springs and the surrounding communities, the United States Air Force Academy, and the United States Air Force.

SENATE RESOLUTION 182—HONORING THE LIFE OF JACK VALENTI

Mrs. FEINSTEIN (for herself, Mr. SPECTER, Mr. LEAHY, Mr. HATCH, Mrs. BOXER, Mr. CORNYN, Mr. KENNEDY, Mr. DURBIN, Mr. DODD, Mr. KERRY, Ms. STABENOW, Ms. CANTWELL, Mr. HARKIN, Ms. LANDRIEU, Mr. MENENDEZ, and Mr. COLEMAN) submitted the following resolution; which was considered and agreed to:

S. RES. 182

Whereas Jack Valenti was born September 5, 1921, in Houston, Texas, the grandson of Sicilian immigrants, Joe and Josephine Valenti, and was the youngest high school graduate in the city at age 15;

Whereas Jack Valenti married his beloved Mary Margaret in 1962, with whom he had 3 children, John, Alexandra, and Courtenay;

Whereas Jack Valenti joined the United States Army Air Forces in 1942 and flew 51 combat missions as a pilot of a B–25 attack bomber with the 12th Air Force in Italy during World War II, obtained the rank of lieutenant, and received 4 decorations, including the Distinguished Flying Cross, the Air Medal with 4 clusters, the Distinguished Unit Citation with one cluster, and the European Theater Ribbon with 4 battle stars;

Whereas Jack Valenti received a B.A. degree from the University of Houston in 1946 after doing all of his undergraduate work at night and working during the day, and became the first University of Houston graduate to be admitted to Harvard Business School, receiving an M.B.A. degree in 1948;

Whereas, in 1952, Jack Valenti cofounded Weekley and Valenti, an advertising and political consulting agency that worked on Dwight D. Eisenhower's presidential campaign in Texas, Representative Albert Thomas's run for Congress, and John Connally's campaign for Governor of Texas;

Whereas Jack Valenti met then-Senate Majority Leader Lyndon B. Johnson in 1957, the two became close friends, and Valenti worked on Lyndon Johnson's presidential campaign during the primaries of 1960;

Whereas Weekley and Valenti handled press during President John F. Kennedy's and Vice President Lyndon Johnson's fateful trip to Dallas, Texas, in November 1963;

Whereas Jack Valenti became the first special assistant hired when Lyndon Johnson ascended to the Presidency;

Whereas Jack Valenti resigned his White House post in 1966 and went on to serve as the president of the Motion Picture Association of America (MPAA) for the next 38 years;

Whereas Jack Valenti, as president of the MPAA, created the voluntary film rating system that is still in place today, which provides parents with advance information they can use to determine which movies are appropriate for their children;

Whereas Jack Valenti's persona and skill combined to give the motion picture industry a strong and enduring presence in the Nation's capital, which grew year by year during his nearly 4 decade tenure at the MPAA;

Whereas Jack Valenti presided over a worldwide change in the motion picture industry, ushered movies into the digital era, championed artists' rights, and condemned intellectual property theft;

Whereas Jack Valenti authored 5 books, including ''A Very Human President'', ''Protect and Defend'', ''The Bitter Taste Of Glory'', ''Speak Up With Confidence'', and, his most recent, ''This Time, This Place: My Life in War, the White House, and Hollywood'', and wrote numerous essays for the New York Times, the Washington Post, the Los Angeles Times, Reader's Digest, Atlantic Monthly, Newsweek, Cox newspapers, and other publications;

Whereas Jack Valenti was awarded with France's highly-prized Legion d'Honneur, the French Legion of Honor, and has been honored with his own star on the Hollywood Walk of Fame; and

Whereas Jack Valenti will be remembered as a dedicated family man, a philanthropist, a voice for copyright owners, a true visionary whose devotion, intelligence, creativity, and wisdom transformed the film industry, and as Hollywood's ultimate leading man: Now, therefore, be it

Resolved, That the Senate honors the life of Jack Valenti, a pioneer in the fields of motion pictures and public service, a dedicated family man, and a legendary figure in the history of the United States.

SENATE RESOLUTION 183—SUPPORTING THE GOALS AND IDEALS OF NATIONAL CHARTER SCHOOLS WEEK, APRIL 30, 2007, THROUGH MAY 4, 2007

Ms. LANDRIEU (for herself, Mr. ALEXANDER, Mr. LIEBERMAN, Mr. CARPER, Mr. BURR, Mr. DEMINT, Mr. VITTER, Mrs. DOLE, and Mr. GREGG) submitted the following resolution; which was considered and agreed to:

S. RES. 183

Whereas charter schools deliver high-quality education and challenge students to reach their potential;

Whereas charter schools provide thousands of families with diverse and innovative educational options for their children;

Whereas charter schools are public schools authorized by designated public entities to respond to the needs of communities, families, and students, and to promote the principles of quality, choice, and innovation;

Whereas, in exchange for the flexibility and autonomy given to charter schools, charter schools are held accountable by their sponsors for improving student achievement and for their finances and other operations;

Whereas 40 States and the District of Columbia have passed laws authorizing charter schools;

Whereas more than 4,000 charter schools operating across the United States serve more than 1,140,000 students;

Whereas, over the last 13 years, Congress has provided more than $2,026,225,000 in support to the charter school movement by providing facilities, financing assistance, and grants for planning, startup, implementation, and dissemination of information;

Whereas many charter schools improve the achievement of students and stimulate improvement in traditional public schools;

Whereas charter schools must meet the student achievement accountability requirements under section 1111 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 6311) in the same manner as traditional public schools, and often set higher and additional individual goals to ensure that charter schools are of high quality and truly accountable to the public;

Whereas charter schools give parents new freedom to choose public schools, routinely measure parental satisfaction levels, and must prove their ongoing success to parents, policymakers, and communities;

Whereas nearly 56 percent of charter schools report having a waiting list, and the total number of students on all such waiting lists is enough to fill over 1,100 average-sized charter schools;

Whereas charter schools nationwide serve a higher percentage of low-income and minority students than the traditional public school system;

Whereas charter schools have enjoyed broad bipartisan support from the President, Congress, State governors and legislatures, educators, and parents across the United States; and

Whereas the eighth annual National Charter Schools Week, to be held April 30 through May 4, 2007, is an event sponsored by charter schools and grassroots charter school organizations across the United States to recognize the significant impacts, achievements, and innovations of charter schools: Now, therefore, be it

Resolved, That the Senate—

(1) acknowledges and commends charter schools and students, parents, teachers, and administrators of charter schools across the United States for their ongoing contributions to education and improving and strengthening the public school system;

(2) supports the goals and ideals of the eighth annual National Charter Schools Week; and

(3) encourages the people of the United States to conduct appropriate programs, ceremonies, and activities to demonstrate support for charter schools during this week-long celebration in communities throughout the United States.

SENATE RESOLUTION 184—EXPRESSING THE SENSE OF THE SENATE WITH RESPECT TO CHILDHOOD STROKE AND DESIGNATING MAY 5, 2007, AS ''NATIONAL CHILDHOOD STROKE AWARENESS DAY''

Mr. CHAMBLISS (for himself and Mr. CASEY) submitted the following resolution; which was considered and agreed to:

S. RES. 184

Whereas a stroke, also known as a ''cerebrovascular accident'', is an acute neurologic injury that occurs when the blood supply to a part of the brain is interrupted by a clot in the artery or a burst of the artery;

Whereas a stroke is a medical emergency that can cause permanent neurologic damage or even death if not promptly diagnosed and treated;

Whereas 26 out of every 100,000 newborns and almost 3 out of every 100,000 children have a stroke each year;

Whereas an individual can have a stroke before birth;

Whereas stroke is among the top 10 causes of death for children in the United States;

Whereas 12 percent of all children who experience a stroke die as a result;

Whereas the death rate for children who experience a stroke before the age of 1 year is the highest out of all age groups;

Whereas many children who experience a stroke will suffer serious, long-term neurological disabilities, including—

(1) hemiplegia, which is paralysis of 1 side of the body;

(2) seizures;

(3) speech and vision problems; and

(4) learning difficulties;

Whereas those disabilities may require ongoing physical therapy and surgeries;

Whereas the permanent health concerns and treatments resulting from strokes that occur during childhood and young adulthood have a considerable impact on children, families, and society;

Whereas very little is known about the cause, treatment, and prevention of childhood stroke;

Whereas medical research is the only means by which the citizens of the United States can identify and develop effective treatment and prevention strategies for childhood stroke;

Whereas early diagnosis and treatment of childhood stroke greatly improves the chances that the affected child will recover and not experience a recurrence; and

Whereas the Children's Hospital of Philadelphia should be commended for its initiative in creating the Nation's first program dedicated to pediatric stroke patients: Now, therefore, be it

Resolved, That the Senate—

(1) designates May 5, 2007 as ''National Childhood Stroke Awareness Day''; and

(2) urges the people of the United States to support the efforts, programs, services, and advocacy of organizations that work to enhance public awareness of childhood stroke.

AMENDMENTS SUBMITTED AND PROPOSED

SA 983. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table.

SA 984. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 985. Mr. BROWNBACK (for himself and Mr. BROWN) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 986. Ms. LANDRIEU submitted an amendment intended to be proposed by her to the bill S. 1082, supra; which was ordered to lie on the table.

SA 987. Mr. INHOFE submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 988. Mr. INHOFE submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 989. Mr. HARKIN submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 990. 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) submitted an amendment intended to be proposed by him to the bill S. 1082, supra.

SA 991. Mr. KOHL (for himself, Mr. GRASSLEY, Mr. LEAHY, and Mr. SCHUMER) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 992. Mr. KOHL submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 993. Mr. GREGG submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 994. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 995. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 996. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 997. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 998. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 999. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1000. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1001. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1002. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1003. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1004. Ms. LANDRIEU proposed an amendment to the bill S. 1082, supra.

SA 1005. Mr. LEVIN submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1006. Ms. MURKOWSKI submitted an amendment intended to be proposed by her to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1007. Mr. REID (for Mr. BUNNING) proposed an amendment to the resolution S. Res. 162, commemorating and acknowledging the dedication and sacrifice made by the men and women who have lost their lives while serving as law enforcement officers.

TEXT OF AMENDMENTS

SA 983. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of subtitle E of title II, insert the following:

SEC. ____. COUNTERFEIT-RESISTANT TECHNOLOGIES FOR PRESCRIPTION DRUGS.

(a) REQUIRED TECHNOLOGIES.—The Secretary of Health and Human Services shall require that the packaging of any prescription drug incorporate—

(1) radio frequency identification (RFID) tagging technology, or similar trace and track technologies that have an equivalent function;

(2) tamper-indicating technologies; and

(3) blister security packaging when possible.

(b) USE OF TECHNOLOGIES.—

(1) AUTHORIZED USES.—The Secretary shall require that technologies described in subsection (a)(1) be used exclusively to authenticate the pedigree of prescription drugs, including by—

(A) implementing inventory control;

(B) tracking and tracing prescription drugs;

(C) verifying shipment or receipt of prescription drugs;

(D) authenticating finished prescription drugs; and

(E) electronically authenticating the pedigree of prescription drugs.

(2) PRIVACY PROTECTION.—The Secretary shall prohibit technologies required by subsection (a)(1) from containing or transmitting any information that may be used to identify a health care practitioner or the prescription drug consumer.

(3) PROHIBITION AGAINST ADVERTISING.—The Secretary shall prohibit technologies required by subsection (a)(1) from containing or transmitting any advertisement or information about prescription drug indications or off-label prescription drug uses.

(c) RECOMMENDED TECHNOLOGIES.—The Secretary shall encourage the manufacturers and distributors of prescription drugs to incorporate into the packaging of such drugs, in addition to the technologies required under subsection (a), overt optically variable counterfeit-resistant technologies that—

(1) are visible to the naked eye, providing for visual identification of prescription drug authenticity without the need for readers, microscopes, lighting devices, or scanners;

(2) are similar to technologies used by the Bureau of Engraving and Printing to secure United States currency;

(3) are manufactured and distributed in a highly secure, tightly controlled environment; and

(4) incorporate additional layers of nonvisible covert security features up to and including forensic capability.

(d) STANDARDS FOR PACKAGING.—

(1) MULTIPLE ELEMENTS.—For the purpose of making it more difficult to counterfeit the packaging of prescription drugs, the Secretary shall require manufacturers of prescription drugs to incorporate the technologies described in paragraphs (1), (2), and (3) of subsection (a), and shall encourage manufacturers and distributors of prescription drugs to incorporate the technologies described in subsection (c), into multiple elements of the physical packaging of the drugs, including—

(A) blister packs, shrink wrap, package labels, package seals, bottles, and boxes; and

(B) at the item level.

(2) LABELING OF SHIPPING CONTAINER.—Shipments of prescription drugs shall include a label on the shipping container that incorporates the technologies described in subsection (a)(1), so that members of the supply chain inspecting the packages will be able to determine the authenticity of the shipment. Chain of custody procedures shall apply to such labels and shall include procedures applicable to contractual agreements for the use and distribution of the labels, methods to audit the use of the labels, and database access for the relevant governmental agencies for audit or verification of the use and distribution of the labels.

(e) PENALTY.—A prescription drug is deemed to be misbranded for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) if the packaging or labeling of the drug is in violation of a requirement or prohibition applicable to the drug under subsection (a), (b), or (d).

(f) TRANSITIONAL PROVISIONS; EFFECTIVE DATES.—

(1) NATIONAL SPECIFIED LIST OF SUSCEPTIBLE PRESCRIPTION DRUGS.—

(A) INITIAL PUBLICATION.—Not later than 180 days after the date of the enactment of

this Act, the Secretary shall publish in the Federal Register a list, to be known as the National Specified List of Susceptible Prescription Drugs, consisting of not less than 30 of the prescription drugs that are most frequently subject to counterfeiting in the United States (as determined by the Secretary).

(B) REVISION.—Not less than annually through the end of calendar year 2010, the Secretary shall review and, as appropriate, revise the National Specified List of Susceptible Prescription Drugs. The Secretary may not revise the List to include fewer than 30 prescription drugs.

(2) EFFECTIVE DATES.—The Secretary shall implement the requirements and prohibitions of subsections (a), (b), and (d)—

(A) with respect to prescription drugs on the National Specified List of Susceptible Prescription Drugs, beginning not later than the earlier of—

(i) 1 year after the initial publication of such List; or

(ii) December 31, 2008; and

(B) with respect to all prescription drugs, beginning not later than December 31, 2011.

(3) AUTHORIZED USES DURING TRANSITIONAL PERIOD.—In lieu of the requirements specified in subsection (b)(1), for the period beginning on the effective date applicable under paragraph (2)(A) and ending on the commencement of the effective date applicable under paragraph (2)(B), the Secretary shall require that technologies described in subsection (a)(1) be used exclusively to verify the authenticity of prescription drugs.

(g) DEFINITIONS.—In this Act:

(1) The term ''pedigree''—

(A) means the history of each prior sale, purchase, or trade of the prescription drug involved to a distributor or retailer of the drug (including the date of the transaction and the names and addresses of all parties to the transaction); and

(B) excludes information about the sale, purchase, or trade of the drug to the drug consumer.

(2) The term ''prescription drug'' means a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

(3) The term ''Secretary'' means the Secretary of Health and Human Services.

SA 984. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE—IMPORTATION OF PRESCRIPTION DRUGS

SEC. __01. SHORT TITLE.

This Act may be cited as the ''Pharmaceutical Market Access Act of 2007''.

SEC. __02. FINDINGS.

Congress finds as follows:

(1) Americans unjustly pay up to 1,000 percent more to fill their prescriptions than consumers in other countries.

(2) The United States is the world's largest market for pharmaceuticals yet consumers still pay the world's highest prices.

(3) An unaffordable drug is neither safe nor effective. Allowing and structuring the importation of prescription drugs ensures access to affordable drugs, thus providing a level of safety to American consumers they do not currently enjoy.

(4) Prescription drug costs are a leading cause of the growth in United States health care spending, which reached nearly $2,000,000,0000 in 2005, of which spending on prescription drugs amounted to $200,700,000,000.

(5) According to the Congressional Budget Office, American seniors alone will spend $1,800,000,000,000 on pharmaceuticals over the next 10 years.

(6) Allowing open pharmaceutical markets could save American consumers at least $635,000,000,000 of their own money.

SEC. __03. PURPOSES.

The purposes of this title are to—

(1) give all Americans immediate relief from the outrageously high cost of pharmaceuticals;

(2) reverse the perverse economics of the American pharmaceutical market;

(3) allow the importation of prescription drugs only if the drugs and facilities where such drugs are manufactured are approved by the Food and Drug Administration, and to exclude pharmaceutical narcotics;

(4) ensure continued integrity to the prescription drug supply of the United States by—

(A) requiring that imported prescription drugs be packaged and shipped using counterfeit-resistant technologies;

(B) requiring Internet pharmacies to register with the United States Government for Americans to verify authenticity before purchases over the Internet;

(C) requiring all foreign sellers to register with United States Government and submit to facility inspections by the Government without prior notice; and

(D) limiting the eligible countries from which prescription drugs may be imported to Canada, member countries of the European Union, and other highly industrialized nations with safe pharmaceutical infrastructures.

SEC. __04. AMENDMENTS TO SECTION 804 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) DEFINITIONS.—Section 804(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(a)) is amended to read as follows:

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer' means a pharmacy, group of pharmacies, pharmacist, or wholesaler.

''(2) PERMITTED COUNTRY.—The term 'permitted country' means Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, Netherlands, Portugal, Spain, Sweden, the United Kingdom, Iceland, Liechtenstein, and Norway, except that the Secretary—

''(A) may add a country, union, or economic area as a permitted country for purposes of this section if the Secretary determines that the country, union, or economic area has a pharmaceutical infrastructure that is substantially equivalent or superior to the pharmaceutical infrastructure of the United States, taking into consideration pharmacist qualifications, pharmacy storage procedures, the drug distribution system, the drug dispensing system, and market regulation; and

''(B) may remove a country, union, or economic area as a permitted country for purposes of this section if the Secretary determines that the country, union, or economic area does not have such a pharmaceutical infrastructure.

''(3) PHARMACIST.—The term 'pharmacist' means a person licensed by the relevant governmental authority to practice pharmacy, including the dispensing and selling of prescription drugs.

''(4) PHARMACY.—The term 'pharmacy' means a person that is licensed by the relevant governmental authority to engage in the business of selling prescription drugs that employs 1 or more pharmacists.

''(5) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

''(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

''(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

''(C) an infused drug (including a peritoneal dialysis solution);

''(D) an intravenously injected drug;

''(E) a drug that is inhaled during surgery; or

''(F) a drug which is a parenteral drug, the importation of which pursuant to subsection (b) is determined by the Secretary to pose a threat to the public health, in which case section 801(d)(1) shall continue to apply.

''(6) QUALIFYING DRUG.—The term 'qualifying drug' means a prescription drug that—

''(A) is approved pursuant to an application submitted under section 505(b)(1); and

''(B) is not—

''(i) a drug manufactured through 1 or more biotechnology processes;

''(ii) a drug that is required to be refrigerated; or

''(iii) a photoreactive drug.

''(7) QUALIFYING INTERNET PHARMACY.—The term 'qualifying Internet pharmacy' means a registered exporter that dispenses qualifying drugs to individuals over an Internet website.

''(8) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

''(9) REGISTERED EXPORTER.—The term 'registered exporter' means a person that is in the business of exporting a drug to persons in the United States (or that seeks to be in such business), for which a registration under this section has been approved and is in effect.

''(10) WHOLESALER.—

''(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

''(B) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 801(d)(1).''.

(b) REGULATIONS.—Section 804(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(b)) is amended to read as follows:

''(b) REGULATIONS.—Not later than 180 days after the date of enactment of the Pharmaceutical Market Access Act of 2007, the Secretary, after consultation with the United States Trade Representative and the Commissioner of the Bureau of Customs and Border Protection, shall promulgate regulations permitting pharmacists, pharmacies, and wholesalers to import qualifying drugs from permitted countries into the United States.''.

(c) LIMITATION.—Section 804(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(c)) is amended by striking ''prescription drug'' each place it appears and inserting ''qualifying drug''.

(d) INFORMATION AND RECORDS.—Section 804(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(d)(1)) is amended—

(1) by striking subparagraph (G) and redesignating subparagraphs (H) through (N) as subparagraphs (G) through (M), respectively;

(2) in subparagraph (H) (as so redesignated), by striking ''telephone number, and professional license number (if any)'' and inserting ''and telephone number''; and

(3) in subparagraph (L) (as so redesignated), by striking ''(J) and (L)'' and inserting ''(I) and (K)''.

(e) TESTING.—Section 804(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(e)) is amended to read as follows:

''(e) TESTING.—The regulations under subsection (b) shall require that the testing described under subparagraphs (I) and (K) of subsection (d)(1) be conducted by the importer of the qualifying drug, unless the qualifying drug is subject to the requirements under section 505C for counterfeit-resistant technologies.''.

(f) REGISTRATION OF EXPORTERS; INSPECTIONS.—Section 804(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(f)) is amended to read as follows:

''(f) REGISTRATION OF EXPORTERS; INSPECTIONS.—

''(1) IN GENERAL.—Any person that seeks to be a registered exporter (referred to in this subsection as the 'registrant') shall submit to the Secretary a registration that includes the following:

''(A) The name of the registrant and identification of all places of business of the registrant that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the registrant;

''(B) An agreement by the registrant to—

''(i) make its places of business that relate to qualifying drugs (including warehouses and other facilities owned or controlled by, or operated for, the exporter) and records available to the Secretary for on-site inspections, without prior notice, for the purpose of determining whether the registrant is in compliance with this Act's requirements;

''(ii) export only qualifying drugs;

''(iii) export only to persons authorized to import the drugs;

''(iv) notify the Secretary of a recall or withdrawal of a qualifying drug distributed in a permitted country to or from which the registrant has exported or imported, or intends to export or import, to the United States;

''(v) monitor compliance with registration conditions and report any noncompliance promptly;

''(vi) submit a compliance plan showing how the registrant will correct violations, if any; and

''(vii) promptly notify the Secretary of changes in the registration information of the registrant.

''(2) NOTICE OF APPROVAL OR DISAPPROVAL.—

''(A) IN GENERAL.—Not later than 90 days after receiving a completed registration from a registrant, the Secretary shall—

''(i) notify such registrant of receipt of the registration;

''(ii) assign such registrant a registration number; and

''(iii) approve or disapprove the application.

''(B) DISAPPROVAL OF APPLICATION.—

''(i) IN GENERAL.—The Secretary shall disapprove a registration, and notify the registrant of such disapproval, if the Secretary has reason to believe that such registrant is not in compliance with a registration condition.

''(ii) SUBSEQUENT APPROVAL.—The Secretary may subsequently approve a registration that was denied under clause (i) if the Secretary finds that the registrant is in compliance with all registration conditions.

''(3) LIST.—The Secretary shall—

''(A) maintain an up-to-date list of registered exporters (including qualifying Internet pharmacies that sell qualifying drugs to individuals);

''(B) make such list available to the public on the Internet site of the Food and Drug Administration and via a toll-free telephone number; and

''(C) update such list promptly after the approval of a registration under this subsection.

''(4) EDUCATION OF CONSUMERS.—The Secretary shall carry out activities, by use of the Internet website and toll-free telephone number under paragraph (3), that educate consumers with regard to the availability of qualifying drugs for import for personal use under this section, including information on how to verify whether an exporter is registered.

''(5) INSPECTION OF IMPORTERS AND REGISTERED EXPORTERS.—The Secretary shall inspect the warehouses, other facilities, and records of importers and registered exporters as often as the Secretary determines necessary to ensure that such importers and registered exporters are in compliance with this section.''.

(g) SUSPENSION OF IMPORTATION.—Section 804(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(g)) is amended by—

(1) striking ''and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b)''; and

(2) by adding after the period at the end the following: ''The Secretary shall reinstate the importation by a specific importer upon a determination by the Secretary that the violation has been corrected and that the importer has demonstrated that further violations will not occur. This subsection shall not apply to a prescription drug imported by an individual, or to a prescription drug shipped to an individual by a qualifying Internet pharmacy.''.

(h) WAIVER AUTHORITY FOR INDIVIDUALS.—Section 804(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(j)) is amended to read as follows:

''(j) IMPORTATION BY INDIVIDUALS.—

''(1) IN GENERAL.—Not later than 180 days after the enactment of the Pharmaceutical Market Access Act of 2007, the Secretary shall by regulation permit an individual to import a drug from a permitted country to the United States if the drug is—

''(A) a qualifying drug;

''(B) imported from a licensed pharmacy or qualifying Internet pharmacy;

''(C) for personal use by an individual, or family member of the individual, not for resale;

''(D) in a quantity that does not exceed a 90-day supply during any 90-day period; and

''(E) accompanied by a copy of a prescription for the drug, which—

''(i) is valid under applicable Federal and State laws; and

''(ii) was issued by a practitioner who is authorized to administer prescription drugs.

''(2) DRUGS DISPENSED OUTSIDE THE UNITED STATES.—An individual may import a drug from a country that is not a permitted country if—

''(A) the drug was dispensed to the individual while the individual was in such country, and the drug was dispensed in accordance with the laws and regulations of such country;

''(B) the individual is entering the United States and the drug accompanies the individual at the time of entry;

''(C) the drug is approved for commercial distribution in the country in which the drug was obtained;

''(D) the drug does not appear to be adulterated; and

''(E) the quantity of the drug does not exceed a 14-day supply.''.

(i) REPEAL OF CERTAIN PROVISIONS.—Section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384) is amended by striking subsections (l) and (m).

SEC. __05. REGISTRATION FEES.

Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 397f et seq.) is amended by adding at the end the following:

''PART 5—FEES RELATING TO PRESCRIPTION DRUG IMPORTATION

''SEC. 740A. FEES RELATING TO PRESCRIPTION DRUG IMPORTATION.

''(a) REGISTRATION FEE.—The Secretary shall establish a registration fee program under which a registered exporter under section 804 shall be required to pay an annual fee to the Secretary in accordance with this subsection.

''(b) COLLECTION.—

''(1) COLLECTION ON INITIAL REGISTRATION.—A fee under this section shall be payable for the fiscal year in which the registered exporter first submits a registration under section 804 (or reregisters under that section if that person has withdrawn its registration and subsequently reregisters) in a amount of $10,000, due on the date the exporter first submits a registration to the Secretary under section 804.

''(2) COLLECTION IN SUBSEQUENT YEARS.—After the fee is paid for the first fiscal year, the fee described under this subsection shall be payable on or before October 1 of each year.

''(3) ONE FEE PER FACILITY.—The fee shall be paid only once for each registered exporter for a fiscal year in which the fee is payable.

''(c) FEE AMOUNT.—

''(1) IN GENERAL.—Subject to subsection (b)(1), the amount of the fee shall be determined each year by the Secretary and shall be based on the anticipated costs to the Secretary of enforcing the amendments made by the Pharmaceutical Market Access Act of 2007 in the subsequent fiscal year.

''(2) LIMITATION.—

''(A) IN GENERAL.—The aggregate total of fees collected under this section shall not exceed 1 percent of the total price of drugs exported annually to the United States by registered exporters under this section.

''(B) REASONABLE ESTIMATE.—Subject to the limitation described in subparagraph (A), a fee under this subsection for an exporter shall be an amount that is a reasonable estimate by the Secretary of the annual share of the exporter of the volume of drugs exported by exporters under this section.

''(d) USE OF FEES.—The fees collected under this section shall be used for the sole purpose of administering this section with respect to registered exporters, including the costs associated with—

''(1) inspecting the facilities of registered exporters, and of other entities in the chain of custody of a qualifying drug;

''(2) developing, implementing, and maintaining a system to determine registered exporters' compliance with the registration conditions under the Pharmaceutical Market Access Act of 2007, including when shipments of qualifying drugs are offered for import into the United States; and

''(3) inspecting such shipments, as necessary, when offered for import into the United States to determine if any such shipment should be refused admission.

''(e) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, registration fees.

''(f) EFFECT OF FAILURE TO PAY FEES.—

''(1) DUE DATE.—A fee payable under this section shall be paid by the date that is 30 days after the date on which the fee is due.

''(2) FAILURE TO PAY.—If a registered exporter subject to a fee under this section fails to pay the fee, the Secretary shall not

permit the registered exporter to engage in exportation to the United States or offering for exportation prescription drugs under this Act until all such fees owed by that person are paid.

''(g) REPORTS.—

''(1) FEE ESTABLISHMENT.—Not later than 60 days before the beginning of each fiscal year, the Secretary shall—

''(A) publish registration fees under this section for that fiscal year;

''(B) hold a meeting at which the public may comment on the recommendations; and

''(C) provide for a period of 30 days for the public to provide written comments on the recommendations.

''(2) PERFORMANCE AND FISCAL REPORT.—Beginning with fiscal year 2007, not later than 60 days after the end of each fiscal year during which fees are collected under this section, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes—

''(A) implementation of the registration fee authority during the fiscal year; and

''(B) the use by the Secretary of the fees collected during the fiscal year for which the report is made.''.

SEC. __06. COUNTERFEIT-RESISTANT TECHNOLOGY.

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352; deeming drugs and devices to be misbranded) is amended by adding at the end the following:

''(z) If it is a drug subject to section 503(b), unless the packaging of such drug complies with the requirements of section 505C for counterfeit-resistant technologies.''.

(b) REQUIREMENTS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505B the following:

''SEC. 505C. COUNTERFEIT-RESISTANT TECHNOLOGIES.

''(a) INCORPORATION OF COUNTERFEIT-RESISTANT TECHNOLOGIES INTO PRESCRIPTION DRUG PACKAGING.—The Secretary shall require that the packaging of any drug subject to section 503(b) incorporate—

''(1) overt optically variable counterfeit-resistant technologies that are described in subsection (b) and comply with the standards of subsection (c); or

''(2) technologies that have an equivalent function of security, as determined by the Secretary.

''(b) ELIGIBLE TECHNOLOGIES.—Technologies described in this subsection—

''(1) shall be visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

''(2) shall be similar to that used by the Bureau of Engraving and Printing to secure United States currency;

''(3) shall be manufactured and distributed in a highly secure, tightly controlled environment; and

''(4) should incorporate additional layers of non-visible covert security features up to and including forensic capability.

''(c) STANDARDS FOR PACKAGING.—

''(1) MULTIPLE ELEMENTS.—For the purpose of making it more difficult to counterfeit the packaging of drugs subject to section 503(b), manufacturers of the drugs shall incorporate the technologies described in subsection (b) into multiple elements of the physical packaging of the drugs, including blister packs, shrink wrap, package labels, package seals, bottles, and boxes.

''(2) LABELING OF SHIPPING CONTAINER.—Shipments of drugs described in subsection (a) shall include a label on the shipping container that incorporates the technologies described in subsection (b), so that officials inspecting the packages will be able to determine the authenticity of the shipment. Chain of custody procedures shall apply to such labels and shall include procedures applicable to contractual agreements for the use and distribution of the labels, methods to audit the use of the labels, and database access for the relevant governmental agencies for audit or verification of the use and distribution of the labels.

''(d) EFFECTIVE DATE.—This section shall take effect 180 days after the date of enactment of the Pharmaceutical Market Access Act of 2007.''.

SEC. __07. PROHIBITED ACTS.

Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by inserting after subsection (k) the following:

''(l) The failure to register in accordance with section 804(f) or to import or offer to import a prescription drug in violation of a suspension order under section 804(g).''.

SEC. __08. PATENTS.

Section 271 of title 35, United States Code, is amended—

(1) by redesignating subsections (h) and (i) as subsections (i) and (j), respectively; and

(2) by inserting after subsection (g) the following:

''(h) It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under section 804 (21 U.S.C. 384) of the Federal Food, Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.''.

SEC. __09. OTHER ENFORCEMENT ACTIONS.

(a) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act (as amended in section __04) is amended by adding at the end the following:

''(l) UNFAIR OR DISCRIMINATORY ACTS AND PRACTICES.—

''(1) IN GENERAL.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing or other agreement) to—

''(A) discriminate by charging a higher price for a prescription drug sold to a person in a permitted country that exports a prescription drug to the United States under this section than the price that is charged to another person that is in the same country and that does not export a prescription drug into the United States under this section;

''(B) discriminate by charging a higher price for a prescription drug sold to a person that distributes, sells, or uses a prescription drug imported into the United States under this section than the price that is charged to another person in the United States that does not import a prescription drug under this section, or that does not distribute, sell, or use such a drug;

''(C) discriminate by denying supplies of a prescription drug to a person in a permitted country that exports a prescription drug to the United States under this section or distributes, sells, or uses a prescription drug imported into the United States under this section;

''(D) discriminate by publicly, privately, or otherwise refusing to do business with a person in a permitted country that exports a prescription drug to the United States under this section or distributes, sells, or uses a prescription drug imported into the United States under this section;

''(E) discriminate by specifically restricting or delaying the supply of a prescription drug to a person in a permitted country that exports a prescription drug to the United States under this section or distributes, sells, or uses a prescription drug imported into the United States under this section;

''(F) cause there to be a difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and the drug for distribution in a permitted country for the purpose of restricting importation of the drug into the United States under this section;

''(G) refuse to allow an inspection authorized under this section of an establishment that manufactures a prescription drug that may be imported or offered for import under this section;

''(H) fail to conform to the methods used in, or the facilities used for, the manufacturing, processing, packing, or holding of a prescription drug that may be imported or offered for import under this section to good manufacturing practice under this Act;

''(I) become a party to a licensing or other agreement related to a prescription drug that fails to provide for compliance with all requirements of this section with respect to such prescription drug or that has the effect of prohibiting importation of the drug under this section; or

''(J) engage in any other action that the Federal Trade Commission determines to discriminate against a person that engages in, or to impede, delay, or block the process for, the importation of a prescription drug under this section.

''(2) AFFIRMATIVE DEFENSE.—It shall be an affirmative defense to a charge that a person has discriminated under subparagraph (A), (B), (C), (D), or (E) of paragraph (1) that the higher price charged for a prescription drug sold to a person, the denial of supplies of a prescription drug to a person, the refusal to do business with a person, or the specific restriction or delay of supplies to a person is not based, in whole or in part, on—

''(A) the person exporting or importing a prescription drug into the United States under this section; or

''(B) the person distributing, selling, or using a prescription drug imported into the United States under this section.

''(3) PRESUMPTION AND AFFIRMATIVE DEFENSE.—

''(A) PRESUMPTION.—A difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) created after January 1, 2007, between a prescription drug for distribution in the United States and the drug for distribution in a permitted country shall be presumed under paragraph (1)(H) to be for the purpose of restricting importation of the drug into the United States under this section.

''(B) AFFIRMATIVE DEFENSE.—It shall be an affirmative defense to the presumption under subparagraph (A) that—

''(i) the difference was required by the country in which the drug is distributed; or

''(ii) the Secretary has determined that the difference was necessary to improve the safety or effectiveness of the drug.

''(4) EFFECT OF SUBSECTION.—

''(A) SALES IN OTHER COUNTRIES.—This subsection applies only to the sale or distribution of a prescription drug in a country if the manufacturer of the drug chooses to sell or distribute the drug in the country. Nothing in this subsection shall be construed to compel the manufacturer of a drug to distribute or sell the drug in a country.

''(B) DISCOUNTS TO INSURERS, HEALTH PLANS, PHARMACY BENEFIT MANAGERS, AND COVERED ENTITIES.—Nothing in this subsection shall be construed to—

''(i) prevent or restrict a manufacturer of a prescription drug from providing discounts to an insurer, health plan, pharmacy benefit manager in the United States, or covered entity in the drug discount program under section 340B in return for inclusion of the drug on a formulary;

''(ii) require that such discounts be made available to other purchasers of the prescription drug; or

''(iii) prevent or restrict any other measures taken by an insurer, health plan, or pharmacy benefit manager to encourage consumption of such prescription drug.

''(C) CHARITABLE CONTRIBUTIONS.—Nothing in this subsection shall be construed to—

''(i) prevent a manufacturer from donating a prescription drug, or supplying a prescription drug at nominal cost, to a charitable or humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country; or

''(ii) apply to such donations or supplying of a prescription drug.

''(5) ENFORCEMENT.—

''(A) UNFAIR OR DECEPTIVE ACT OR PRACTICE.—A violation of this subsection shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under section 18(a)(1)(B) of the Federal Trade Commission Act.

''(B) ACTIONS BY THE COMMISSION.—The Federal Trade Commission—

''(i) shall enforce this subsection in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act were incorporated into and made a part of this section; and

''(ii) may seek monetary relief threefold the damages sustained.

''(6) ACTIONS BY STATES.—

''(A) IN GENERAL.—

''(i) CIVIL ACTIONS.—The attorney general of a State may bring a civil action on behalf of the residents of the State, and persons doing business in the State, in a district court of the United States of appropriate jurisdiction for a violation of paragraph (1) to—

''(I) enjoin that practice;

''(II) enforce compliance with this subsection;

''(III) obtain damages, restitution, or other compensation on behalf of residents of the State and persons doing business in the State, including threefold the damages; or

''(IV) obtain such other relief as the court may consider to be appropriate.

''(ii) NOTICE.—

''(I) IN GENERAL.—Before filing an action under clause (i), the attorney general of the State involved shall provide to the Federal Trade Commission—

''(aa) written notice of that action; and

''(bb) a copy of the complaint for that action.

''(II) EXEMPTION.—Subclause (I) shall not apply with respect to the filing of an action by an attorney general of a State under this paragraph, if the attorney general determines that it is not feasible to provide the notice described in that subclause before filing of the action. In such case, the attorney general of a State shall provide notice and a copy of the complaint to the Federal Trade Commission at the same time as the attorney general files the action.

''(B) INTERVENTION.—

''(i) IN GENERAL.—On receiving notice under subparagraph (A)(ii), the Commission shall have the right to intervene in the action that is the subject of the notice.

''(ii) EFFECT OF INTERVENTION.—If the Commission intervenes in an action under subparagraph (A), it shall have the right—

''(I) to be heard with respect to any matter that arises in that action; and

''(II) to file a petition for appeal.

''(C) CONSTRUCTION.—For purposes of bringing any civil action under subparagraph (A), nothing in this subsection shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State to—

''(i) conduct investigations;

''(ii) administer oaths or affirmations; or

''(iii) compel the attendance of witnesses or the production of documentary and other evidence.

''(D) ACTIONS BY THE COMMISSION.—

''(i) IN GENERAL.—In any case in which an action is instituted by or on behalf of the Commission for a violation of paragraph (1), a State may not, during the pendency of that action, institute an action under subparagraph (A) for the same violation against any defendant named in the complaint in that action.

''(ii) INTERVENTION.—An attorney general of a State may intervene, on behalf of the residents of that State, in an action instituted by the Commission.

''(iii) EFFECT OF INTERVENTION.—If an attorney general of a State intervenes in an action instituted by the Commission, such attorney general shall have the right—

''(I) to be heard with respect to any matter that arises in that action; and

''(II) to file a petition for appeal.

''(E) VENUE.—Any action brought under subparagraph (A) may be brought in the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code.

''(F) SERVICE OF PROCESS.—In an action brought under subparagraph (A), process may be served in any district in which the defendant—

''(i) is an inhabitant; or

''(ii) may be found.

''(G) LIMITATION OF ACTIONS.—Any action under this paragraph to enforce a cause of action under this subsection by the Federal Trade Commission or the attorney general of a State shall be forever barred unless commenced within 5 years after the Federal Trade Commission, or the attorney general, as the case may be, knew or should have known that the cause of action accrued. No cause of action barred under existing law on the effective date of the Pharmaceutical Market Access Act of 2007 shall be revived by such Act.

''(H) MEASUREMENT OF DAMAGES.—In any action under this paragraph to enforce a cause of action under this subsection in which there has been a determination that a defendant has violated a provision of this subsection, damages may be proved and assessed in the aggregate by statistical or sampling methods, by the computation of illegal overcharges or by such other reasonable system of estimating aggregate damages as the court in its discretion may permit without the necessity of separately proving the individual claim of, or amount of damage to, persons on whose behalf the suit was brought.

''(I) EXCLUSION ON DUPLICATIVE RELIEF.—The district court shall exclude from the amount of monetary relief awarded in an action under this paragraph brought by the attorney general of a State any amount of monetary relief which duplicates amounts which have been awarded for the same injury.

''(7) EFFECT ON ANTITRUST LAWS.—Nothing in this subsection shall be construed to modify, impair, or supersede the operation of the antitrust laws. For the purpose of this subsection, the term 'antitrust laws' has the meaning given it in the first section of the Clayton Act, except that it includes section 5 of the Federal Trade Commission Act to the extent that such section 5 applies to unfair methods of competition.

''(8) MANUFACTURER.—In this subsection, the term 'manufacturer' means any entity, including any affiliate or licensee of that entity, that is engaged in—

''(A) the production, preparation, propagation, compounding, conversion, or processing of a prescription drug, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

''(B) the packaging, repackaging, labeling, relabeling, or distribution of a prescription drug.''.

(b) REGULATIONS.—The Federal Trade Commission shall promulgate regulations to carry out the enforcement program under section 804(l) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

(c) SUSPENSION AND TERMINATION OF EXPORTERS.—Section 804(g) of the Federal Food, Drug, and Cosmetic Act (as amended by section __04(g)) (21 U.S.C. 384(g)) is amended by—

(1) striking ''SUSPENSION OF IMPORTATION.—The Secretary'' and inserting ''SUSPENSION OF IMPORTATION.—

''(1) IN GENERAL.—The Secretary''; and

(2) adding at the end the following:

''(2) SUSPENSION AND TERMINATION OF EXPORTERS.—

''(A) SUSPENSION.—With respect to the effectiveness of a registration submitted under subsection (f) by a registered exporter:

''(i) Subject to clause (ii), if the Secretary determines, after notice and opportunity for a hearing, that the registered exporter has failed to maintain substantial compliance with all registration conditions, the Secretary may suspend the registration.

''(ii) If the Secretary determines that, under color of the registration, the registered exporter has exported a drug that is not a qualifying drug, or a drug that does not meet the criteria under this section, or has exported a qualifying drug to an individual in violation of this section, the Secretary shall immediately suspend the registration. A suspension under the preceding sentence is not subject to the provision by the Secretary of prior notice, and the Secretary shall provide to the registered exporter involved an opportunity for a hearing not later than 10 days after the date on which the registration is suspended.

''(iii) The Secretary may reinstate the registration, whether suspended under clause (i) or (ii), if the Secretary determines that the registered exporter has demonstrated that further violations of registration conditions will not occur.

''(B) TERMINATION.—The Secretary, after notice and opportunity for a hearing, may terminate the registration under subsection (f) of a registered exporter if the Secretary determines that the registered exporter has engaged in a pattern or practice of violating 1 or more registration conditions, or if on 1 or more occasions the Secretary has under subparagraph (A)(ii) suspended the registration of the registered exporter. The Secretary may make the termination permanent, or for a fixed period of not less than 1 year. During the period in which the registration of a registered exporter is terminated, any registration submitted under subsection (f) by such exporter or a person who is a partner in the export enterprise or a principal officer in such enterprise, and any registration prepared with the assistance of such exporter or such a person, has no legal effect under this section.''.

SEC. __10. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated such sums as may be necessary to carry out this title (and the amendments made by this title).

SA 985. Mr. BROWNBACK (for himself and Mr. BROWN) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SEC. 524. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

''(a) DEFINITIONS.—In this section:

''(1) AIDS.—The term 'AIDS' means the acquired immune deficiency syndrome.

''(2) AIDS DRUG.—The term 'AIDS drug' means a drug indicated for treating HIV.

''(3) HIV.—The term 'HIV' means the human immunodeficiency virus, the pathogen that causes AIDS.

''(4) NEGLECTED OR TROPICAL DISEASE.—The term 'neglected or tropical disease' means—

''(A) HIV, malaria, tuberculosis, and related diseases; or

''(B) any other infectious disease that disproportionately affects poor and marginalized populations, including those diseases targeted by the Special Programme for Research and Training in Tropical Diseases cosponsored by the United Nations Development Program, UNICEF, the World Bank, and the World Health Organization.

''(5) PRIORITY REVIEW.—The term 'priority review', with respect to a new drug application described in paragraph (6), means review and action by the Secretary on such application not later than 180 days after receipt by the Secretary of such application, pursuant to the Manual of Policies and Procedures of the Food and Drug Administration.

''(6) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a tropical disease product that entitles such sponsor, or a person described under subsection (b)(2), to priority review of a new drug application submitted under section 505(b)(1) after the date of approval of the tropical disease product.

''(7) TROPICAL DISEASE PRODUCT.—The term 'tropical disease product' means a product that—

''(A) is a new drug, antibiotic drug, biological product, vaccine, device, diagnostic, or other tool for treatment of a neglected or tropical disease; and

''(B) is approved by the Secretary for use in the treatment of a neglected or tropical disease.

''(b) PRIORITY REVIEW VOUCHER.—

''(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a tropical disease product upon approval by the Secretary of such tropical disease product.

''(2) TRANSFERABILITY.—The sponsor of a tropical disease product that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a new drug for which an application under section 505(b)(1) will be submitted after the date of the approval of the tropical disease product.

''(3) LIMITATION.—A sponsor of a tropical disease product may not receive a priority review voucher under this section if the tropical disease product was approved by the Secretary prior to the date of enactment of this section.

''(c) PRIORITY REVIEW USER FEE.—

''(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a drug that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

''(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the anticipated costs to the Secretary of implementing this section.

''(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, the amount of the priority review user fee.

''(4) PAYMENT.—

''(A) IN GENERAL.—The fee required by this subsection shall be due upon the filing of the new drug application under section 505(b)(1) for which the voucher is used.

''(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection is not included in such application.''.

SA 986. Ms. LANDRIEU submitted an amendment intended to be proposed by her to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

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 the turtles for salmonella and maintain a safe pet.

SEC. ___. SALE OF BABY TURTLES.

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

(1) the turtle is raised, shipped, and sold using methods that are proven to keep the turtle free of salmonella, using salmonella safety standards that are comparable to such standards relating to other animals, including reptiles and amphibians, that are allowed for sale as pets, or animal products that are allowed for sale as food products;

(2) the Administration has approved a plan submitted by the turtle farmer or commercial retail seller involved relating to compliance with paragraph (1); and

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

(A) information regarding—

(i) 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;

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

(iii) 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) PLAN.—

(1) IN GENERAL.—A turtle farmer or other commercial seller that desires to sell a turtle as provided for under subsection (a) shall submit a plan to the Food and Drug Administration that details the manner in which the farmer or seller will ensure compliance with the requirements of subsection (a)(1) with respect to the turtles involved. The plan shall include use of non-antibiotic compounds that suppress or eliminate the presence of salmonella in turtle hatchlings.

(2) ACTION BY FDA.—Not later 30 days after the date on which the Food and Drug Administration receives a plan under paragraph (1), the Administration shall accept or reject such plan. If such plan is rejected, the Administration shall provide clear, specific guidance on the reasons for such rejection. The Administration may only reject such a plan if it is determined that the plan fails to achieve the same salmonella safety standards as such standards relating to other animals, including reptiles and amphibians, that are allowed for sale as pets, or animal products that are allowed for sale as food products.

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit the Food and Drug Administration to hold the sale of turtles less than 10.2 centimeters in

diameter as a pet to any greater salmonella safety standard applicable to other reptiles or amphibians sold as pets, animals sold as pets, or food products regulated by such Administration.

SA 987. Mr. INHOFE submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. HEAD START ACT AMENDMENT IMPOSING PARENTAL CONSENT REQUIREMENT FOR NONEMERGENCY INTRUSIVE PHYSICAL EXAMINATIONS.

The Head Start Act (42 U.S.C. 9831 et seq.) is amended by adding at the end the following:

"SEC. 657A. PARENTAL CONSENT REQUIREMENT FOR NONEMERGENCY INTRUSIVE PHYSICAL EXAMINATIONS.

''(a) IN GENERAL.—A Head Start agency shall obtain written parental consent before administration of any nonemergency intrusive physical examination of a child in connection with participation in a program under this subchapter.

''(b) DEFINITION.—The term 'nonemergency intrusive physical examination' means, with respect to a child, a physical examination that—

''(1) is not immediately necessary to protect the health or safety of the child involved or the health or safety of another individual; and

''(2) requires incision or is otherwise invasive, or involves exposure of private body parts.''.

SA 988. Mr. INHOFE submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. CHILD MEDICATION SAFETY.

(a) REQUIRED POLICIES AND PROCEDURES.—

(1) IN GENERAL.—As a condition of receiving funds under any program or activity administered by the Secretary of Education, not later than 1 year after the date of enactment of this section, each State shall develop and implement policies and procedures prohibiting school personnel from requiring a child to obtain a prescription for substances covered by section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) or a psychotropic drug as a condition of attending school or receiving services.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed to create a Federal prohibition against teachers and other school personnel consulting or sharing classroom-based observations with parents or guardians regarding a student's academic performance or behavior in the classroom or school, or regarding the need for evaluation for special education or related services under section 612(a)(3) of the Individuals with Disabilities Education Act (20 U.S.C. 1412(a)(3)).

(3) PROHIBITION OF PAYMENT OF FUNDS.—No Federal education funds may be paid to any local educational agency or other instrument of government that uses the refusal of a parent or legal guardian to provide a substance covered by section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) or a psychotropic drug for such individual's child as the basis of a charge of child abuse, child neglect, education neglect, or medical neglect until the agency or instrument demonstrates that it is no longer using such refusal as a basis of a child abuse, child neglect, education neglect, or medical neglect charge.

(b) DEFINITIONS.—In this section:

(1) CHILD.—The term ''child'' means any person within the age limits for which the State provides free public education.

(2) PSYCHOTROPIC DRUG.—The term ''psychotropic drug'' means a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is not a substance covered by section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) but is—

(A) used in the diagnosis, treatment, or prevention of a disease; and

(B) intended to have an altering effect on perception, emotion, or behavior.

(3) STATE.—The term ''State'' means each of the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.

(c) GAO STUDY AND REVIEW.—

(1) REVIEW.—The Comptroller General of the United States shall conduct a review of—

(A) the variation among States in definitions of psychotropic medications as used in regard to State jurisdiction over public education;

(B) the prescription rates of medications used in public schools to treat children diagnosed with attention deficit disorder, attention deficit hyperactivity disorder, and other disorders or illnesses;

(C) which medications used to treat such children in public schools are listed under the Controlled Substances Act; and

(D) which medications used to treat such children in public schools are not listed under the Controlled Substances Act, including the properties and effects of any such medications, including the incidence of hallucinations, psychosis, violence, suicide, heart problems, significant weight gain, or diabetes that students may experience while on these medications.

(2) REPORT.—Not later than 1 year after the date of enactment of this section, the Comptroller General of the United States shall prepare and submit a report that contains the results of the review under paragraph (1).

SA 989. Mr. HARKIN submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. REQUIRED INFORMATION IN DIRECT-TO-CONSUMER TELEVISION AND RADIO ADVERTISEMENTS.

Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by inserting after the first sentence the following: ''In addition to the requirements under the preceding sentence, in the case of an advertisement of a prescription drug presented directly to consumers in television or radio format that states the name of the drug and its medical indications, unless the audio portion of such advertisement includes a listing of all information in full about adverse reactions, contraindications, and precautions listed in the patient or professional labeling of the drug approved under this Act.''.

SA 990. 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) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

At the appropriate place, insert the following:

TITLE ____—IMPORTATION OF PRESCRIPTION DRUGS

SEC. __01. SHORT TITLE.

This title may be cited as the ''Pharmaceutical Market Access and Drug Safety Act of 2007''.

SEC. __02. FINDINGS.

Congress finds that—

(1) Americans unjustly pay up to 5 times more to fill their prescriptions than consumers in other countries;

(2) the United States is the largest market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand pharmaceuticals in the world;

(3) a prescription drug is neither safe nor effective to an individual who cannot afford it;

(4) allowing and structuring the importation of prescription drugs to ensure access to safe and affordable drugs approved by the Food and Drug Administration will provide a level of safety to American consumers that they do not currently enjoy;

(5) American spend more than $200,000,000,000 on prescription drugs every year;

(6) the Congressional Budget Office has found that the cost of prescription drugs are between 35 to 55 percent less in other highly-developed countries than in the United States; and

(7) promoting competitive market pricing would both contribute to health care savings and allow greater access to therapy, improving health and saving lives.

SEC. __03. REPEAL OF CERTAIN SECTION REGARDING IMPORTATION OF PRESCRIPTION DRUGS.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804.

SEC. __04. IMPORTATION OF PRESCRIPTION DRUGS; WAIVER OF CERTAIN IMPORT RESTRICTIONS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section __03, is further amended by inserting after section 803 the following:

"SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF PRESCRIPTION DRUGS.

''(a) IMPORTATION OF PRESCRIPTION DRUGS.—

''(1) IN GENERAL.—In the case of qualifying drugs imported or offered for import into the United States from registered exporters or by registered importers—

''(A) the limitation on importation that is established in section 801(d)(1) is waived; and

''(B) the standards referred to in section 801(a) regarding admission of the drugs are subject to subsection (g) of this section (including with respect to qualifying drugs to which section 801(d)(1) does not apply).

''(2) IMPORTERS.—A qualifying drug may not be imported under paragraph (1) unless—

''(A) the drug is imported by a pharmacy, group of pharmacies, or a wholesaler that is a registered importer; or

''(B) the drug is imported by an individual for personal use or for the use of a family

member of the individual (not for resale) from a registered exporter.

''(3) RULE OF CONSTRUCTION.—This section shall apply only with respect to a drug that is imported or offered for import into the United States—

''(A) by a registered importer; or

''(B) from a registered exporter to an individual.

''(4) DEFINITIONS.—

''(A) REGISTERED EXPORTER; REGISTERED IMPORTER.—For purposes of this section:

''(i) The term 'registered exporter' means an exporter for which a registration under subsection (b) has been approved and is in effect.

''(ii) The term 'registered importer' means a pharmacy, group of pharmacies, or a wholesaler for which a registration under subsection (b) has been approved and is in effect.

''(iii) The term 'registration condition' means a condition that must exist for a registration under subsection (b) to be approved.

''(B) QUALIFYING DRUG.—For purposes of this section, the term 'qualifying drug' means a drug for which there is a corresponding U.S. label drug.

''(C) U.S. LABEL DRUG.—For purposes of this section, the term 'U.S. label drug' means a prescription drug that—

''(i) with respect to a qualifying drug, has the same active ingredient or ingredients, route of administration, dosage form, and strength as the qualifying drug;

''(ii) with respect to the qualifying drug, is manufactured by or for the person that manufactures the qualifying drug;

''(iii) is approved under section 505(c); and

''(iv) is not—

''(I) a controlled substance, as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802);

''(II) a biological product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262), including—

''(aa) a therapeutic DNA plasmid product;

''(bb) a therapeutic synthetic peptide product;

''(cc) a monoclonal antibody product for in vivo use; and

''(dd) a therapeutic recombinant DNA-derived product;

''(III) an infused drug, including a peritoneal dialysis solution;

''(IV) an injected drug;

''(V) a drug that is inhaled during surgery;

''(VI) a drug that is the listed drug referred to in 2 or more abbreviated new drug applications under which the drug is commercially marketed; or

''(VII) a sterile opthlamic drug intended for topical use on or in the eye.

''(D) OTHER DEFINITIONS.—For purposes of this section:

''(i)(I) The term 'exporter' means a person that is in the business of exporting a drug to individuals in the United States from Canada or from a permitted country designated by the Secretary under subclause (II), or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

''(II) The Secretary shall designate a permitted country under subparagraph (E) (other than Canada) as a country from which an exporter may export a drug to individuals in the United States if the Secretary determines that—

''(aa) the country has statutory or regulatory standards that are equivalent to the standards in the United States and Canada with respect to—

''(AA) the training of pharmacists;

''(BB) the practice of pharmacy; and

''(CC) the protection of the privacy of personal medical information; and

''(bb) the importation of drugs to individuals in the United States from the country will not adversely affect public health.

''(ii) The term 'importer' means a pharmacy, a group of pharmacies, or a wholesaler that is in the business of importing a drug into the United States or that, pursuant to submitting a registration under subsection (b), seeks to be in such business.

''(iii) The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(iv) The term 'pharmacy' means a person that—

''(I) is licensed by a State to engage in the business of selling prescription drugs at retail; and

''(II) employs 1 or more pharmacists.

''(v) The term 'prescription drug' means a drug that is described in section 503(b)(1).

''(vi) The term 'wholesaler'—

''(I) means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A); and

''(II) does not include a person authorized to import drugs under section 801(d)(1).

''(E) PERMITTED COUNTRY.—The term 'permitted country' means—

''(i) Australia;

''(ii) Canada;

''(iii) a member country of the European Union, but does not include a member country with respect to which—

''(I) the country's Annex to the Treaty of Accession to the European Union 2003 includes a transitional measure for the regulation of human pharmaceutical products that has not expired; or

''(II) the Secretary determines that the requirements described in subclauses (I) and (II) of clause (vii) will not be met by the date on which such transitional measure for the regulation of human pharmaceutical products expires;

''(iv) Japan;

''(v) New Zealand;

''(vi) Switzerland; and

''(vii) a country in which the Secretary determines the following requirements are met:

''(I) The country has statutory or regulatory requirements—

''(aa) that require the review of drugs for safety and effectiveness by an entity of the government of the country;

''(bb) that authorize the approval of only those drugs that have been determined to be safe and effective by experts employed by or acting on behalf of such entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs;

''(cc) that require the methods used in, and the facilities and controls used for the manufacture, processing, and packing of drugs in the country to be adequate to preserve their identity, quality, purity, and strength;

''(dd) for the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective; and

''(ee) that require the labeling and promotion of drugs to be in accordance with the approval of the drug.

''(II) The valid marketing authorization system in the country is equivalent to the systems in the countries described in clauses (i) through (vi).

''(III) The importation of drugs to the United States from the country will not adversely affect public health.

''(b) REGISTRATION OF IMPORTERS AND EXPORTERS.—

''(1) REGISTRATION OF IMPORTERS AND EXPORTERS.—A registration condition is that the importer or exporter involved (referred to in this subsection as a 'registrant') submits to the Secretary a registration containing the following:

''(A)(i) In the case of an exporter, the name of the exporter and an identification of all places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter.

''(ii) In the case of an importer, the name of the importer and an identification of the places of business of the importer at which the importer initially receives a qualifying drug after importation (which shall not exceed 3 places of business except by permission of the Secretary).

''(B) Such information as the Secretary determines to be necessary to demonstrate that the registrant is in compliance with registration conditions under—

''(i) in the case of an importer, subsections (c), (d), (e), (g), and (j) (relating to the sources of imported qualifying drugs; the inspection of facilities of the importer; the payment of fees; compliance with the standards referred to in section 801(a); and maintenance of records and samples); or

''(ii) in the case of an exporter, subsections (c), (d), (f), (g), (h), (i), and (j) (relating to the sources of exported qualifying drugs; the inspection of facilities of the exporter and the marking of compliant shipments; the payment of fees; and compliance with the standards referred to in section 801(a); being licensed as a pharmacist; conditions for individual importation; and maintenance of records and samples).

''(C) An agreement by the registrant that the registrant will not under subsection (a) import or export any drug that is not a qualifying drug.

''(D) An agreement by the registrant to—

''(i) notify the Secretary of a recall or withdrawal of a qualifying drug distributed in a permitted country that the registrant has exported or imported, or intends to export or import, to the United States under subsection (a);

''(ii) provide for the return to the registrant of such drug; and

''(iii) cease, or not begin, the exportation or importation of such drug unless the Secretary has notified the registrant that exportation or importation of such drug may proceed.

''(E) An agreement by the registrant to ensure and monitor compliance with each registration condition, to promptly correct any noncompliance with such a condition, and to promptly report to the Secretary any such noncompliance.

''(F) A plan describing the manner in which the registrant will comply with the agreement under subparagraph (E).

''(G) An agreement by the registrant to enforce a contract under subsection (c)(3)(B) against a party in the chain of custody of a qualifying drug with respect to the authority of the Secretary under clauses (ii) and (iii) of that subsection.

''(H) An agreement by the registrant to notify the Secretary not more than 30 days before the registrant intends to make the change, of—

''(i) any change that the registrant intends to make regarding information provided under subparagraph (A) or (B); and

''(ii) any change that the registrant intends to make in the compliance plan under subparagraph (F).

''(I) In the case of an exporter—

''(i) An agreement by the exporter that a qualifying drug will not under subsection (a)

be exported to any individual not authorized pursuant to subsection (a)(2)(B) to be an importer of such drug.

''(ii) An agreement to post a bond, payable to the Treasury of the United States that is equal in value to the lesser of—

''(I) the value of drugs exported by the exporter to the United States in a typical 4-week period over the course of a year under this section; or

''(II) $1,000,000;

''(iii) An agreement by the exporter to comply with applicable provisions of Canadian law, or the law of the permitted country designated under subsection (a)(4)(D)(i)(II) in which the exporter is located, that protect the privacy of personal information with respect to each individual importing a prescription drug from the exporter under subsection (a)(2)(B).

''(iv) An agreement by the exporter to report to the Secretary—

''(I) not later than August 1 of each fiscal year, the total price and the total volume of drugs exported to the United States by the exporter during the 6-month period from January 1 through June 30 of that year; and

''(II) not later than January 1 of each fiscal year, the total price and the total volume of drugs exported to the United States by the exporter during the previous fiscal year.

''(J) In the case of an importer, an agreement by the importer to report to the Secretary—

''(i) not later than August 1 of each fiscal year, the total price and the total volume of drugs imported to the United States by the importer during the 6-month period from January 1 through June 30 of that fiscal year; and

''(ii) not later than January 1 of each fiscal year, the total price and the total volume of drugs imported to the United States by the importer during the previous fiscal year.

''(K) Such other provisions as the Secretary may require by regulation to protect the public health while permitting—

''(i) the importation by pharmacies, groups of pharmacies, and wholesalers as registered importers of qualifying drugs under subsection (a); and

''(ii) importation by individuals of qualifying drugs under subsection (a).

''(2) APPROVAL OR DISAPPROVAL OF REGISTRATION.—

''(A) IN GENERAL.—Not later than 90 days after the date on which a registrant submits to the Secretary a registration under paragraph (1), the Secretary shall notify the registrant whether the registration is approved or is disapproved. The Secretary shall disapprove a registration if there is reason to believe that the registrant is not in compliance with one or more registration conditions, and shall notify the registrant of such reason. In the case of a disapproved registration, the Secretary shall subsequently notify the registrant that the registration is approved if the Secretary determines that the registrant is in compliance with such conditions.

''(B) CHANGES IN REGISTRATION INFORMATION.—Not later than 30 days after receiving a notice under paragraph (1)(H) from a registrant, the Secretary shall determine whether the change involved affects the approval of the registration of the registrant under paragraph (1), and shall inform the registrant of the determination.

''(3) PUBLICATION OF CONTACT INFORMATION FOR REGISTERED EXPORTERS.—Through the Internet website of the Food and Drug Administration and a toll-free telephone number, the Secretary shall make readily available to the public a list of registered exporters, including contact information for the exporters. Promptly after the approval of a registration submitted under paragraph (1), the Secretary shall update the Internet website and the information provided through the toll-free telephone number accordingly.

''(4) SUSPENSION AND TERMINATION.—

''(A) SUSPENSION.—With respect to the effectiveness of a registration submitted under paragraph (1):

''(i) Subject to clause (ii), the Secretary may suspend the registration if the Secretary determines, after notice and opportunity for a hearing, that the registrant has failed to maintain substantial compliance with a registration condition.

''(ii) If the Secretary determines that, under color of the registration, the exporter has exported a drug or the importer has imported a drug that is not a qualifying drug, or a drug that does not comply with subsection (g)(2)(A) or (g)(4), or has exported a qualifying drug to an individual in violation of subsection (i)(2)(F), the Secretary shall immediately suspend the registration. A suspension under the preceding sentence is not subject to the provision by the Secretary of prior notice, and the Secretary shall provide to the registrant an opportunity for a hearing not later than 10 days after the date on which the registration is suspended.

''(iii) The Secretary may reinstate the registration, whether suspended under clause (i) or (ii), if the Secretary determines that the registrant has demonstrated that further violations of registration conditions will not occur.

''(B) TERMINATION.—The Secretary, after notice and opportunity for a hearing, may terminate the registration under paragraph (1) of a registrant if the Secretary determines that the registrant has engaged in a pattern or practice of violating 1 or more registration conditions, or if on 1 or more occasions the Secretary has under subparagraph (A)(ii) suspended the registration of the registrant. The Secretary may make the termination permanent, or for a fixed period of not less than 1 year. During the period in which the registration is terminated, any registration submitted under paragraph (1) by the registrant, or a person that is a partner in the export or import enterprise, or a principal officer in such enterprise, and any registration prepared with the assistance of the registrant or such a person, has no legal effect under this section.

''(5) DEFAULT OF BOND.—A bond required to be posted by an exporter under paragraph (1)(I)(ii) shall be defaulted and paid to the Treasury of the United States if, after opportunity for an informal hearing, the Secretary determines that the exporter has—

''(A) exported a drug to the United States that is not a qualifying drug or that is not in compliance with subsection (g)(2)(A), (g)(4), or (i); or

''(B) failed to permit the Secretary to conduct an inspection described under subsection (d).

''(c) SOURCES OF QUALIFYING DRUGS.—A registration condition is that the exporter or importer involved agrees that a qualifying drug will under subsection (a) be exported or imported into the United States only if there is compliance with the following:

''(1) The drug was manufactured in an establishment—

''(A) required to register under subsection (h) or (i) of section 510; and

''(B)(i) inspected by the Secretary; or

''(ii) for which the Secretary has elected to rely on a satisfactory report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent under a mutual recognition agreement, as provided for under section 510(i)(3), section 803, or part 26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regulation).

''(2) The establishment is located in any country, and the establishment manufactured the drug for distribution in the United States or for distribution in 1 or more of the permitted countries (without regard to whether in addition the drug is manufactured for distribution in a foreign country that is not a permitted country).

''(3) The exporter or importer obtained the drug—

''(A) directly from the establishment; or

''(B) directly from an entity that, by contract with the exporter or importer—

''(i) provides to the exporter or importer a statement (in such form and containing such information as the Secretary may require) that, for the chain of custody from the establishment, identifies each prior sale, purchase, or trade of the drug (including the date of the transaction and the names and addresses of all parties to the transaction);

''(ii) agrees to permit the Secretary to inspect such statements and related records to determine their accuracy;

''(iii) agrees, with respect to the qualifying drugs involved, to permit the Secretary to inspect warehouses and other facilities, including records, of the entity for purposes of determining whether the facilities are in compliance with any standards under this Act that are applicable to facilities of that type in the United States; and

''(iv) has ensured, through such contractual relationships as may be necessary, that the Secretary has the same authority regarding other parties in the chain of custody from the establishment that the Secretary has under clauses (ii) and (iii) regarding such entity.

''(4)(A) The foreign country from which the importer will import the drug is a permitted country; or

''(B) The foreign country from which the exporter will export the drug is the permitted country in which the exporter is located.

''(5) During any period in which the drug was not in the control of the manufacturer of the drug, the drug did not enter any country that is not a permitted country.

''(6) The exporter or importer retains a sample of each lot of the drug for testing by the Secretary.

''(d) INSPECTION OF FACILITIES; MARKING OF SHIPMENTS.—

''(1) INSPECTION OF FACILITIES.—A registration condition is that, for the purpose of assisting the Secretary in determining whether the exporter involved is in compliance with all other registration conditions—

''(A) the exporter agrees to permit the Secretary—

''(i) to conduct onsite inspections, including monitoring on a day-to-day basis, of places of business of the exporter that relate to qualifying drugs, including each warehouse or other facility owned or controlled by, or operated for, the exporter;

''(ii) to have access, including on a day-to-day basis, to—

''(I) records of the exporter that relate to the export of such drugs, including financial records; and

''(II) samples of such drugs;

''(iii) to carry out the duties described in paragraph (3); and

''(iv) to carry out any other functions determined by the Secretary to be necessary regarding the compliance of the exporter; and

''(B) the Secretary has assigned 1 or more employees of the Secretary to carry out the functions described in this subsection for the Secretary randomly, but not less than 12 times annually, on the premises of places of businesses referred to in subparagraph (A)(i),

and such an assignment remains in effect on a continuous basis.

''(2) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the exporter involved agrees to affix to each shipping container of qualifying drugs exported under subsection (a) such markings as the Secretary determines to be necessary to identify the shipment as being in compliance with all registration conditions. Markings under the preceding sentence shall—

''(A) be designed to prevent affixation of the markings to any shipping container that is not authorized to bear the markings; and

''(B) include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies.

''(3) CERTAIN DUTIES RELATING TO EXPORTERS.—Duties of the Secretary with respect to an exporter include the following:

''(A) Inspecting, randomly, but not less than 12 times annually, the places of business of the exporter at which qualifying drugs are stored and from which qualifying drugs are shipped.

''(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the exporter, which shall be accomplished or supplemented by the use of anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an exporter.

''(C) Randomly reviewing records of exports to individuals for the purpose of determining whether the drugs are being imported by the individuals in accordance with the conditions under subsection (i). Such reviews shall be conducted in a manner that will result in a statistically significant determination of compliance with all such conditions.

''(D) Monitoring the affixing of markings under paragraph (2).

''(E) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records, of other parties in the chain of custody of qualifying drugs.

''(F) Determining whether the exporter is in compliance with all other registration conditions.

''(4) PRIOR NOTICE OF SHIPMENTS.—A registration condition is that, not less than 8 hours and not more than 5 days in advance of the time of the importation of a shipment of qualifying drugs, the importer involved agrees to submit to the Secretary a notice with respect to the shipment of drugs to be imported or offered for import into the United States under subsection (a). A notice under the preceding sentence shall include—

''(A) the name and complete contact information of the person submitting the notice;

''(B) the name and complete contact information of the importer involved;

''(C) the identity of the drug, including the established name of the drug, the quantity of the drug, and the lot number assigned by the manufacturer;

''(D) the identity of the manufacturer of the drug, including the identity of the establishment at which the drug was manufactured;

''(E) the country from which the drug is shipped;

''(F) the name and complete contact information for the shipper of the drug;

''(G) anticipated arrival information, including the port of arrival and crossing location within that port, and the date and time;

''(H) a summary of the chain of custody of the drug from the establishment in which the drug was manufactured to the importer;

''(I) a declaration as to whether the Secretary has ordered that importation of the drug from the permitted country cease under subsection (g)(2)(C) or (D); and

''(J) such other information as the Secretary may require by regulation.

''(5) MARKING OF COMPLIANT SHIPMENTS.—A registration condition is that the importer involved agrees, before wholesale distribution (as defined in section 503(e)) of a qualifying drug that has been imported under subsection (a), to affix to each container of such drug such markings or other technology as the Secretary determines necessary to identify the shipment as being in compliance with all registration conditions, except that the markings or other technology shall not be required on a drug that bears comparable, compatible markings or technology from the manufacturer of the drug. Markings or other technology under the preceding sentence shall—

''(A) be designed to prevent affixation of the markings or other technology to any container that is not authorized to bear the markings; and

''(B) shall include anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of such technologies.

''(6) CERTAIN DUTIES RELATING TO IMPORTERS.—Duties of the Secretary with respect to an importer include the following:

''(A) Inspecting, randomly, but not less than 12 times annually, the places of business of the importer at which a qualifying drug is initially received after importation.

''(B) During the inspections under subparagraph (A), verifying the chain of custody of a statistically significant sample of qualifying drugs from the establishment in which the drug was manufactured to the importer, which shall be accomplished or supplemented by the use of anticounterfeiting or track-and-trace technologies, taking into account the economic and technical feasibility of those technologies, except that a drug that lacks such technologies from the point of manufacture shall not for that reason be excluded from importation by an importer.

''(C) Reviewing notices under paragraph (4).

''(D) Inspecting as the Secretary determines is necessary the warehouses and other facilities, including records of other parties in the chain of custody of qualifying drugs.

''(E) Determining whether the importer is in compliance with all other registration conditions.

''(e) IMPORTER FEES.—

''(1) REGISTRATION FEE.—A registration condition is that the importer involved pays to the Secretary a fee of $10,000 due on the date on which the importer first submits the registration to the Secretary under subsection (b).

''(2) INSPECTION FEE.—A registration condition is that the importer involved pays a fee to the Secretary in accordance with this subsection. Such fee shall be paid not later than October 1 and April 1 of each fiscal year in the amount provided for under paragraph (3).

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—Not later than 30 days before the start of each fiscal year, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for importers for that fiscal year that is sufficient, and not more than necessary, to pay the costs for that fiscal year of administering this section with respect to registered importers, including the costs associated with—

''(i) inspecting the facilities of registered importers, and of other entities in the chain of custody of a qualifying drug as necessary, under subsection (d)(6);

''(ii) developing, implementing, and operating under such subsection an electronic system for submission and review of the notices required under subsection (d)(4) with respect to shipments of qualifying drugs under subsection (a) to assess compliance with all registration conditions when such shipments are offered for import into the United States; and

''(iii) inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

''(B) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered importers under subsection (a).

''(C) TOTAL PRICE OF DRUGS.—

''(i) ESTIMATE.—For the purposes of complying with the limitation described in subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during the 6-month period from January 1 through June 30 of the previous fiscal year, as reported to the Secretary by each registered importer under subsection (b)(1)(J).

''(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered importers during that fiscal year by adding the total price of qualifying drugs imported by each registered importer during that fiscal year, as reported to the Secretary by each registered importer under subsection (b)(1)(J).

''(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered importers during a fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered importer on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.

''(D) INDIVIDUAL IMPORTER FEE.—Subject to the limitation described in subparagraph (B), the fee under paragraph (2) to be paid on October 1 and April 1 by an importer shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the importer of the volume of qualifying drugs imported by importers under subsection (a).

''(4) USE OF FEES.—

''(A) IN GENERAL.—Subject to appropriations Acts, fees collected by the Secretary under paragraphs (1) and (2) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration until expended (without fiscal year limitation), and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer some proportion of such fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended (without fiscal year limitation).

''(B) SOLE PURPOSE.—Fees collected by the Secretary under paragraphs (1) and (2) are

only available to the Secretary and, if transferred, to the Secretary of Homeland Security, and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

''(5) COLLECTION OF FEES.—In any case where the Secretary does not receive payment of a fee assessed under paragraph (1) or (2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(f) EXPORTER FEES.—

''(1) REGISTRATION FEE.—A registration condition is that the exporter involved pays to the Secretary a fee of $10,000 due on the date on which the exporter first submits that registration to the Secretary under subsection (b).

''(2) INSPECTION FEE.—A registration condition is that the exporter involved pays a fee to the Secretary in accordance with this subsection. Such fee shall be paid not later than October 1 and April 1 of each fiscal year in the amount provided for under paragraph (3).

''(3) AMOUNT OF INSPECTION FEE.—

''(A) AGGREGATE TOTAL OF FEES.—Not later than 30 days before the start of each fiscal year, the Secretary, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, shall establish an aggregate total of fees to be collected under paragraph (2) for exporters for that fiscal year that is sufficient, and not more than necessary, to pay the costs for that fiscal year of administering this section with respect to registered exporters, including the costs associated with—

''(i) inspecting the facilities of registered exporters, and of other entities in the chain of custody of a qualifying drug as necessary, under subsection (d)(3);

''(ii) developing, implementing, and operating under such subsection a system to screen marks on shipments of qualifying drugs under subsection (a) that indicate compliance with all registration conditions, when such shipments are offered for import into the United States; and

''(iii) screening such markings, and inspecting such shipments as necessary, when offered for import into the United States to determine if such a shipment should be refused admission under subsection (g)(5).

''(B) LIMITATION.—Subject to subparagraph (C), the aggregate total of fees collected under paragraph (2) for a fiscal year shall not exceed 2.5 percent of the total price of qualifying drugs imported during that fiscal year into the United States by registered exporters under subsection (a).

''(C) TOTAL PRICE OF DRUGS.—

''(i) ESTIMATE.—For the purposes of complying with the limitation described in subparagraph (B) when establishing under subparagraph (A) the aggregate total of fees to be collected under paragraph (2) for a fiscal year, the Secretary shall estimate the total price of qualifying drugs imported into the United States by registered exporters during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during the 6-month period from January 1 through June 30 of the previous fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

''(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered exporters during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during that fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

''(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered exporters during a fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered exporter on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.

''(D) INDIVIDUAL EXPORTER FEE.—Subject to the limitation described in subparagraph (B), the fee under paragraph (2) to be paid on October 1 and April 1 by an exporter shall be an amount that is proportional to a reasonable estimate by the Secretary of the semiannual share of the exporter of the volume of qualifying drugs exported by exporters under subsection (a).

''(4) USE OF FEES.—

''(A) IN GENERAL.—Subject to appropriations Acts, fees collected by the Secretary under paragraphs (1) and (2) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration until expended (without fiscal year limitation), and the Secretary may, in consultation with the Secretary of Homeland Security and the Secretary of the Treasury, transfer some proportion of such fees to the appropriation account for salaries and expenses of the Bureau of Customs and Border Protection until expended (without fiscal year limitation).

''(B) SOLE PURPOSE.—Fees collected by the Secretary under paragraphs (1) and (2) are only available to the Secretary and, if transferred, to the Secretary of Homeland Security, and are for the sole purpose of paying the costs referred to in paragraph (3)(A).

''(5) COLLECTION OF FEES.—In any case where the Secretary does not receive payment of a fee assessed under paragraph (1) or (2) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(g) COMPLIANCE WITH SECTION 801(a).—

''(1) IN GENERAL.—A registration condition is that each qualifying drug exported under subsection (a) by the registered exporter involved or imported under subsection (a) by the registered importer involved is in compliance with the standards referred to in section 801(a) regarding admission of the drug into the United States, subject to paragraphs (2), (3), and (4).

''(2) SECTION 505; APPROVAL STATUS.—

''(A) IN GENERAL.—A qualifying drug that is imported or offered for import under subsection (a) shall comply with the conditions established in the approved application under section 505(b) for the U.S. label drug as described under this subsection.

''(B) NOTICE BY MANUFACTURER; GENERAL PROVISIONS.—

''(i) IN GENERAL.—The person that manufactures a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country shall in accordance with this paragraph submit to the Secretary a notice that—

''(I) includes each difference in the qualifying drug from a condition established in the approved application for the U.S. label drug beyond—

''(aa) the variations provided for in the application; and

''(bb) any difference in labeling (except ingredient labeling); or

''(II) states that there is no difference in the qualifying drug from a condition established in the approved application for the U.S. label drug beyond—

''(aa) the variations provided for in the application; and

''(bb) any difference in labeling (except ingredient labeling).

''(ii) INFORMATION IN NOTICE.—A notice under clause (i)(I) shall include the information that the Secretary may require under section 506A, any additional information the Secretary may require (which may include data on bioequivalence if such data are not required under section 506A), and, with respect to the permitted country that approved the qualifying drug for commercial distribution, or with respect to which such approval is sought, include the following:

''(I) The date on which the qualifying drug with such difference was, or will be, introduced for commercial distribution in the permitted country.

''(II) Information demonstrating that the person submitting the notice has also notified the government of the permitted country in writing that the person is submitting to the Secretary a notice under clause (i)(I), which notice describes the difference in the qualifying drug from a condition established in the approved application for the U.S. label drug.

''(III) The information that the person submitted or will submit to the government of the permitted country for purposes of obtaining approval for commercial distribution of the drug in the country which, if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation.

''(iii) CERTIFICATIONS.—The chief executive officer and the chief medical officer of the manufacturer involved shall each certify in the notice under clause (i) that—

''(I) the information provided in the notice is complete and true; and

''(II) a copy of the notice has been provided to the Federal Trade Commission and to the State attorneys general.

''(iv) FEE.—If a notice submitted under clause (i) includes a difference that would, under section 506A, require the submission of a supplemental application if made as a change to the U.S. label drug, the person that submits the notice shall pay to the Secretary a fee in the same amount as would apply if the person were paying a fee pursuant to section 736(a)(1)(A)(ii). Subject to appropriations Acts, fees collected by the Secretary under the preceding sentence are available only to the Secretary and are for the sole purpose of paying the costs of reviewing notices submitted under clause (i).

''(v) TIMING OF SUBMISSION OF NOTICES.—

''(I) PRIOR APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (C) applies shall be submitted to the Secretary not later than 120 days before the qualifying drug with the difference is introduced for commercial distribution in a permitted country, unless the country requires that distribution of the qualifying drug with the difference begin less than 120 days after the country requires the difference.

''(II) OTHER APPROVAL NOTICES.—A notice under clause (i) to which subparagraph (D) applies shall be submitted to the Secretary not later than the day on which the qualifying drug with the difference is introduced for commercial distribution in a permitted country.

''(III) OTHER NOTICES.—A notice under clause (i) to which subparagraph (E) applies shall be submitted to the Secretary on the date that the qualifying drug is first introduced for commercial distribution in a permitted country and annually thereafter.

''(vi) REVIEW BY SECRETARY.—

''(I) IN GENERAL.—In this paragraph, the difference in a qualifying drug that is submitted in a notice under clause (i) from the

U.S. label drug shall be treated by the Secretary as if it were a manufacturing change to the U.S. label drug under section 506A.

''(II) STANDARD OF REVIEW.—Except as provided in subclause (III), the Secretary shall review and approve or disapprove the difference in a notice submitted under clause (i), if required under section 506A, using the safe and effective standard for approving or disapproving a manufacturing change under section 506A.

''(III) BIOEQUIVALENCE.—If the Secretary would approve the difference in a notice submitted under clause (i) using the safe and effective standard under section 506A and if the Secretary determines that the qualifying drug is not bioequivalent to the U.S. label drug, the Secretary shall—

''(aa) include in the labeling provided under paragraph (3) a prominent advisory that the qualifying drug is safe and effective but is not bioequivalent to the U.S. label drug if the Secretary determines that such an advisory is necessary for health care practitioners and patients to use the qualifying drug safely and effectively; or

''(bb) decline to approve the difference if the Secretary determines that the availability of both the qualifying drug and the U.S. label drug would pose a threat to the public health.

''(IV) REVIEW BY THE SECRETARY.—The Secretary shall review and approve or disapprove the difference in a notice submitted under clause (i), if required under section 506A, not later than 120 days after the date on which the notice is submitted.

''(V) ESTABLISHMENT INSPECTION.—If review of such difference would require an inspection of the establishment in which the qualifying drug is manufactured—

''(aa) such inspection by the Secretary shall be authorized; and

''(bb) the Secretary may rely on a satisfactory report of a good manufacturing practice inspection of the establishment from a permitted country whose regulatory system the Secretary recognizes as equivalent under a mutual recognition agreement, as provided under section 510(i)(3), section 803, or part 26 of title 21, Code of Federal Regulations (or any corresponding successor rule or regulation).

''(vii) PUBLICATION OF INFORMATION ON NOTICES.—

''(I) IN GENERAL.—Through the Internet website of the Food and Drug Administration and a toll-free telephone number, the Secretary shall readily make available to the public a list of notices submitted under clause (i).

''(II) CONTENTS.—The list under subclause (I) shall include the date on which a notice is submitted and whether—

''(aa) a notice is under review;

''(bb) the Secretary has ordered that importation of the qualifying drug from a permitted country cease; or

''(cc) the importation of the drug is permitted under subsection (a).

''(III) UPDATE.—The Secretary shall promptly update the Internet website with any changes to the list.

''(C) NOTICE; DRUG DIFFERENCE REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under section 506A(c) or (d)(3)(B)(i), require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

''(i) Promptly after the notice is submitted, the Secretary shall notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general that the notice has been submitted with respect to the qualifying drug involved.

''(ii) If the Secretary has not made a determination whether such a supplemental application regarding the U.S. label drug would be approved or disapproved by the date on which the qualifying drug involved is to be introduced for commercial distribution in a permitted country, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country not begin until the Secretary completes review of the notice; and

''(II) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the order.

''(iii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would not be approved, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country cease, or provide that an order under clause (ii), if any, remains in effect;

''(II) notify the permitted country that approved the qualifying drug for commercial distribution of the determination; and

''(III) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(iv) If the Secretary determines that such a supplemental application regarding the U.S. label drug would be approved, the Secretary shall—

''(I) vacate the order under clause (ii), if any;

''(II) consider the difference to be a variation provided for in the approved application for the U.S. label drug;

''(III) permit importation of the qualifying drug under subsection (a); and

''(IV) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(D) NOTICE; DRUG DIFFERENCE NOT REQUIRING PRIOR APPROVAL.—In the case of a notice under subparagraph (B)(i) that includes a difference that would, under section 506A(d)(3)(B)(ii), not require the approval of a supplemental application before the difference could be made to the U.S. label drug the following shall occur:

''(i) During the period in which the notice is being reviewed by the Secretary, the authority under this subsection to import the qualifying drug involved continues in effect.

''(ii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would not be approved, the Secretary shall—

''(I) order that the importation of the qualifying drug involved from the permitted country cease;

''(II) notify the permitted country that approved the qualifying drug for commercial distribution of the determination; and

''(III) promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of the determination.

''(iii) If the Secretary determines that such a supplemental application regarding the U.S. label drug would be approved, the difference shall be considered to be a variation provided for in the approved application for the U.S. label drug.

''(E) NOTICE; DRUG DIFFERENCE NOT REQUIRING APPROVAL; NO DIFFERENCE.—In the case of a notice under subparagraph (B)(i) that includes a difference for which, under section 506A(d)(1)(A), a supplemental application would not be required for the difference to be made to the U.S. label drug, or that states that there is no difference, the Secretary—

''(i) shall consider such difference to be a variation provided for in the approved application for the U.S. label drug;

''(ii) may not order that the importation of the qualifying drug involved cease; and

''(iii) shall promptly notify registered exporters and registered importers.

''(F) DIFFERENCES IN ACTIVE INGREDIENT, ROUTE OF ADMINISTRATION, DOSAGE FORM, OR STRENGTH.—

''(i) IN GENERAL.—A person who manufactures a drug approved under section 505(b) shall submit an application under section 505(b) for approval of another drug that is manufactured for distribution in a permitted country by or for the person that manufactures the drug approved under section 505(b) if—

''(I) there is no qualifying drug in commercial distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries with the same active ingredient or ingredients, route of administration, dosage form, and strength as the drug approved under section 505(b); and

''(II) each active ingredient of the other drug is related to an active ingredient of the drug approved under section 505(b), as defined in clause (v).

''(ii) APPLICATION UNDER SECTION 505(b).—The application under section 505(b) required under clause (i) shall—

''(I) request approval of the other drug for the indication or indications for which the drug approved under section 505(b) is labeled;

''(II) include the information that the person submitted to the government of the permitted country for purposes of obtaining approval for commercial distribution of the other drug in that country, which if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation;

''(III) include a right of reference to the application for the drug approved under section 505(b); and

''(IV) include such additional information as the Secretary may require.

''(iii) TIMING OF SUBMISSION OF APPLICATION.—An application under section 505(b) required under clause (i) shall be submitted to the Secretary not later than the day on which the information referred to in clause (ii)(II) is submitted to the government of the permitted country.

''(iv) NOTICE OF DECISION ON APPLICATION.—The Secretary shall promptly notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general of a determination to approve or to disapprove an application under section 505(b) required under clause (i).

''(v) RELATED ACTIVE INGREDIENTS.—For purposes of clause (i)(II), 2 active ingredients are related if they are—

''(I) the same; or

''(II) different salts, esters, or complexes of the same moiety.

''(3) SECTION 502; LABELING.—

''(A) IMPORTATION BY REGISTERED IMPORTER.—

''(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered importer, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the qualifying drug bears—

''(I) a copy of the labeling approved for the U.S. label drug under section 505, without regard to whether the copy bears any trademark involved;

''(II) the name of the manufacturer and location of the manufacturer;

''(III) the lot number assigned by the manufacturer;

''(IV) the name, location, and registration number of the importer; and

''(V) the National Drug Code number assigned to the qualifying drug by the Secretary.

''(ii) REQUEST FOR COPY OF THE LABELING.—The Secretary shall provide such copy to the registered importer involved, upon request of the importer.

''(iii) REQUESTED LABELING.—The labeling provided by the Secretary under clause (ii) shall—

''(I) include the established name, as defined in section 502(e)(3), for each active ingredient in the qualifying drug;

''(II) not include the proprietary name of the U.S. label drug or any active ingredient thereof;

''(III) if required under paragraph (2)(B)(vi)(III), a prominent advisory that the qualifying drug is safe and effective but not bioequivalent to the U.S. label drug; and

''(IV) if the inactive ingredients of the qualifying drug are different from the inactive ingredients for the U.S. label drug, include—

''(aa) a prominent notice that the ingredients of the qualifying drug differ from the ingredients of the U.S. label drug and that the qualifying drug must be dispensed with an advisory to people with allergies about this difference and a list of ingredients; and

''(bb) a list of the ingredients of the qualifying drug as would be required under section 502(e).

''(B) IMPORTATION BY INDIVIDUAL.—

''(i) IN GENERAL.—In the case of a qualifying drug that is imported or offered for import by a registered exporter to an individual, such drug shall be considered to be in compliance with section 502 and the labeling requirements under the approved application for the U.S. label drug if the packaging and labeling of the qualifying drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) and the labeling of the qualifying drug includes—

''(I) directions for use by the consumer;

''(II) the lot number assigned by the manufacturer;

''(III) the name and registration number of the exporter;

''(IV) if required under paragraph (2)(B)(vi)(III), a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug;

''(V) if the inactive ingredients of the drug are different from the inactive ingredients for the U.S. label drug—

''(aa) a prominent advisory that persons with an allergy should check the ingredient list of the drug because the ingredients of the drug differ from the ingredients of the U.S. label drug; and

''(bb) a list of the ingredients of the drug as would be required under section 502(e); and

''(VI) a copy of any special labeling that would be required by the Secretary had the U.S. label drug been dispensed by a pharmacist in the United States, without regard to whether the special labeling bears any trademark involved.

''(ii) PACKAGING.—A qualifying drug offered for import to an individual by an exporter under this section that is packaged in a unit-of-use container (as those items are defined in the United States Pharmacopeia and National Formulary) shall not be repackaged, provided that—

''(I) the packaging complies with all applicable regulations under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.); or

''(II) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply with such Act and that the exporter will provide the drug in packaging that is compliant at no additional cost.

''(iii) REQUEST FOR COPY OF SPECIAL LABELING AND INGREDIENT LIST.—The Secretary shall provide to the registered exporter involved a copy of the special labeling, the advisory, and the ingredient list described under clause (i), upon request of the exporter.

''(iv) REQUESTED LABELING AND INGREDIENT LIST.—The labeling and ingredient list provided by the Secretary under clause (iii) shall—

''(I) include the established name, as defined in section 502(e)(3), for each active ingredient in the drug; and

''(II) not include the proprietary name of the U.S. label drug or any active ingredient thereof.

''(4) SECTION 501; ADULTERATION.—A qualifying drug that is imported or offered for import under subsection (a) shall be considered to be in compliance with section 501 if the drug is in compliance with subsection (c).

''(5) STANDARDS FOR REFUSING ADMISSION.—A drug exported under subsection (a) from a registered exporter or imported by a registered importer may be refused admission into the United States if 1 or more of the following applies:

''(A) The drug is not a qualifying drug.

''(B) A notice for the drug required under paragraph (2)(B) has not been submitted to the Secretary.

''(C) The Secretary has ordered that importation of the drug from the permitted country cease under paragraph (2) (C) or (D).

''(D) The drug does not comply with paragraph (3) or (4).

''(E) The shipping container appears damaged in a way that may affect the strength, quality, or purity of the drug.

''(F) The Secretary becomes aware that—

''(i) the drug may be counterfeit;

''(ii) the drug may have been prepared, packed, or held under insanitary conditions; or

''(iii) the methods used in, or the facilities or controls used for, the manufacturing, processing, packing, or holding of the drug do not conform to good manufacturing practice.

''(G) The Secretary has obtained an injunction under section 302 that prohibits the distribution of the drug in interstate commerce.

''(H) The Secretary has under section 505(e) withdrawn approval of the drug.

''(I) The manufacturer of the drug has instituted a recall of the drug.

''(J) If the drug is imported or offered for import by a registered importer without submission of a notice in accordance with subsection (d)(4).

''(K) If the drug is imported or offered for import from a registered exporter to an individual and 1 or more of the following applies:

''(i) The shipping container for such drug does not bear the markings required under subsection (d)(2).

''(ii) The markings on the shipping container appear to be counterfeit.

''(iii) The shipping container or markings appear to have been tampered with.

''(h) EXPORTER LICENSURE IN PERMITTED COUNTRY.—A registration condition is that the exporter involved agrees that a qualifying drug will be exported to an individual only if the Secretary has verified that—

''(1) the exporter is authorized under the law of the permitted country in which the exporter is located to dispense prescription drugs; and

''(2) the exporter employs persons that are licensed under the law of the permitted country in which the exporter is located to dispense prescription drugs in sufficient number to dispense safely the drugs exported by the exporter to individuals, and the exporter assigns to those persons responsibility for dispensing such drugs to individuals.

''(i) INDIVIDUALS; CONDITIONS FOR IMPORTATION.—

''(1) IN GENERAL.—For purposes of subsection (a)(2)(B), the importation of a qualifying drug by an individual is in accordance with this subsection if the following conditions are met:

''(A) The drug is accompanied by a copy of a prescription for the drug, which prescription—

''(i) is valid under applicable Federal and State laws; and

''(ii) was issued by a practitioner who, under the law of a State of which the individual is a resident, or in which the individual receives care from the practitioner who issues the prescription, is authorized to administer prescription drugs.

''(B) The drug is accompanied by a copy of the documentation that was required under the law or regulations of the permitted country in which the exporter is located, as a condition of dispensing the drug to the individual.

''(C) The copies referred to in subparagraphs (A)(i) and (B) are marked in a manner sufficient—

''(i) to indicate that the prescription, and the equivalent document in the permitted country in which the exporter is located, have been filled; and

''(ii) to prevent a duplicative filling by another pharmacist.

''(D) The individual has provided to the registered exporter a complete list of all drugs used by the individual for review by the individuals who dispense the drug.

''(E) The quantity of the drug does not exceed a 90-day supply.

''(F) The drug is not an ineligible subpart H drug. For purposes of this section, a prescription drug is an 'ineligible subpart H drug' if the drug was approved by the Secretary under subpart H of part 314 of title 21, Code of Federal Regulations (relating to accelerated approval), with restrictions under section 520 of such part to assure safe use, and the Secretary has published in the Federal Register a notice that the Secretary has determined that good cause exists to prohibit the drug from being imported pursuant to this subsection.

''(2) NOTICE REGARDING DRUG REFUSED ADMISSION.—If a registered exporter ships a drug to an individual pursuant to subsection (a)(2)(B) and the drug is refused admission to the United States, a written notice shall be sent to the individual and to the exporter that informs the individual and the exporter of such refusal and the reason for the refusal.

''(j) MAINTENANCE OF RECORDS AND SAMPLES.—

''(1) IN GENERAL.—A registration condition is that the importer or exporter involved shall—

''(A) maintain records required under this section for not less than 2 years; and

''(B) maintain samples of each lot of a qualifying drug required under this section for not more than 2 years.

''(2) PLACE OF RECORD MAINTENANCE.—The records described under paragraph (1) shall be maintained—

''(A) in the case of an importer, at the place of business of the importer at which the importer initially receives the qualifying drug after importation; or

''(B) in the case of an exporter, at the facility from which the exporter ships the qualifying drug to the United States.

''(k) DRUG RECALLS.—

''(1) MANUFACTURERS.—A person that manufactures a qualifying drug imported from a

permitted country under this section shall promptly inform the Secretary—

''(A) if the drug is recalled or withdrawn from the market in a permitted country;

''(B) how the drug may be identified, including lot number; and

''(C) the reason for the recall or withdrawal.

''(2) SECRETARY.—With respect to each permitted country, the Secretary shall—

''(A) enter into an agreement with the government of the country to receive information about recalls and withdrawals of qualifying drugs in the country; or

''(B) monitor recalls and withdrawals of qualifying drugs in the country using any information that is available to the public in any media.

''(3) NOTICE.—The Secretary may notify, as appropriate, registered exporters, registered importers, wholesalers, pharmacies, or the public of a recall or withdrawal of a qualifying drug in a permitted country.

''(l) DRUG LABELING AND PACKAGING.—

''(1) IN GENERAL.—When a qualifying drug that is imported into the United States by an importer under subsection (a) is dispensed by a pharmacist to an individual, the pharmacist shall provide that the packaging and labeling of the drug complies with all applicable regulations promulgated under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.) and shall include with any other labeling provided to the individual the following:

''(A) The lot number assigned by the manufacturer.

''(B) The name and registration number of the importer.

''(C) If required under paragraph (2)(B)(vi)(III) of subsection (g), a prominent advisory that the drug is safe and effective but not bioequivalent to the U.S. label drug.

''(D) If the inactive ingredients of the drug are different from the inactive ingredients for the U.S. label drug—

''(i) a prominent advisory that persons with allergies should check the ingredient list of the drug because the ingredients of the drug differ from the ingredients of the U.S. label drug; and

''(ii) a list of the ingredients of the drug as would be required under section 502(e).

''(2) PACKAGING.—A qualifying drug that is packaged in a unit-of-use container (as those terms are defined in the United States Pharmacopeia and National Formulary) shall not be repackaged, provided that—

''(A) the packaging complies with all applicable regulations under sections 3 and 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.); or

''(B) the consumer consents to waive the requirements of such Act, after being informed that the packaging does not comply with such Act and that the pharmacist will provide the drug in packaging that is compliant at no additional cost.

''(m) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, this section does not authorize the importation into the United States of a qualifying drug donated or otherwise supplied for free or at nominal cost by the manufacturer of the drug to a charitable or humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country.

''(n) UNFAIR AND DISCRIMINATORY ACTS AND PRACTICES.—

''(1) IN GENERAL.—It is unlawful for a manufacturer, directly or indirectly (including by being a party to a licensing agreement or other agreement), to—

''(A) discriminate by charging a higher price for a prescription drug sold to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section than the price that is charged, inclusive of rebates or other incentives to the permitted country or other person, to another person that is in the same country and that does not export a qualifying drug into the United States under this section;

''(B) discriminate by charging a higher price for a prescription drug sold to a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section than the price that is charged to another person in the United States that does not import a qualifying drug under this section, or that does not distribute, sell, or use such a drug;

''(C) discriminate by denying, restricting, or delaying supplies of a prescription drug to a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or to a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

''(D) discriminate by publicly, privately, or otherwise refusing to do business with a registered exporter or other person in a permitted country that exports a qualifying drug to the United States under this section or with a registered importer or other person that distributes, sells, or uses a qualifying drug imported into the United States under this section;

''(E) knowingly fail to submit a notice under subsection (g)(2)(B)(i), knowingly fail to submit such a notice on or before the date specified in subsection (g)(2)(B)(v) or as otherwise required under subsection (e) (3), (4), and (5) of section 4 of the Pharmaceutical Market Access and Drug Safety Act of 2007, knowingly submit such a notice that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information requested by the Secretary to review such a notice;

''(F) knowingly fail to submit an application required under subsection (g)(2)(F), knowingly fail to submit such an application on or before the date specified in subsection (g)(2)(F)(ii), knowingly submit such an application that makes a materially false, fictitious, or fraudulent statement, or knowingly fail to provide promptly any information requested by the Secretary to review such an application;

''(G) cause there to be a difference (including a difference in active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or person that manufactures the drug) between a prescription drug for distribution in the United States and the drug for distribution in a permitted country;

''(H) refuse to allow an inspection authorized under this section of an establishment that manufactures a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country;

''(I) fail to conform to the methods used in, or the facilities used for, the manufacturing, processing, packing, or holding of a qualifying drug that is, or will be, introduced for commercial distribution in a permitted country to good manufacturing practice under this Act;

''(J) become a party to a licensing agreement or other agreement related to a qualifying drug that fails to provide for compliance with all requirements of this section with respect to such drug;

''(K) enter into a contract that restricts, prohibits, or delays the importation of a qualifying drug under this section;

''(L) engage in any other action to restrict, prohibit, or delay the importation of a qualifying drug under this section; or

''(M) engage in any other action that the Federal Trade Commission determines to discriminate against a person that engages or attempts to engage in the importation of a qualifying drug under this section.

''(2) REFERRAL OF POTENTIAL VIOLATIONS.—The Secretary shall promptly refer to the Federal Trade Commission each potential violation of subparagraph (E), (F), (G), (H), or (I) of paragraph (1) that becomes known to the Secretary.

''(3) AFFIRMATIVE DEFENSE.—

''(A) DISCRIMINATION.—It shall be an affirmative defense to a charge that a manufacturer has discriminated under subparagraph (A), (B), (C), (D), or (M) of paragraph (1) that the higher price charged for a prescription drug sold to a person, the denial, restriction, or delay of supplies of a prescription drug to a person, the refusal to do business with a person, or other discriminatory activity against a person, is not based, in whole or in part, on—

''(i) the person exporting or importing a qualifying drug into the United States under this section; or

''(ii) the person distributing, selling, or using a qualifying drug imported into the United States under this section.

''(B) DRUG DIFFERENCES.—It shall be an affirmative defense to a charge that a manufacturer has caused there to be a difference described in subparagraph (G) of paragraph (1) that—

''(i) the difference was required by the country in which the drug is distributed;

''(ii) the Secretary has determined that the difference was necessary to improve the safety or effectiveness of the drug;

''(iii) the person manufacturing the drug for distribution in the United States has given notice to the Secretary under subsection (g)(2)(B)(i) that the drug for distribution in the United States is not different from a drug for distribution in permitted countries whose combined population represents at least 50 percent of the total population of all permitted countries; or

''(iv) the difference was not caused, in whole or in part, for the purpose of restricting importation of the drug into the United States under this section.

''(4) EFFECT OF SUBSECTION.—

''(A) SALES IN OTHER COUNTRIES.—This subsection applies only to the sale or distribution of a prescription drug in a country if the manufacturer of the drug chooses to sell or distribute the drug in the country. Nothing in this subsection shall be construed to compel the manufacturer of a drug to distribute or sell the drug in a country.

''(B) DISCOUNTS TO INSURERS, HEALTH PLANS, PHARMACY BENEFIT MANAGERS, AND COVERED ENTITIES.—Nothing in this subsection shall be construed to—

''(i) prevent or restrict a manufacturer of a prescription drug from providing discounts to an insurer, health plan, pharmacy benefit manager in the United States, or covered entity in the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 256b) in return for inclusion of the drug on a formulary;

''(ii) require that such discounts be made available to other purchasers of the prescription drug; or

''(iii) prevent or restrict any other measures taken by an insurer, health plan, or pharmacy benefit manager to encourage consumption of such prescription drug.

''(C) CHARITABLE CONTRIBUTIONS.—Nothing in this subsection shall be construed to—

''(i) prevent a manufacturer from donating a prescription drug, or supplying a prescription drug at nominal cost, to a charitable or

humanitarian organization, including the United Nations and affiliates, or to a government of a foreign country; or

''(ii) apply to such donations or supplying of a prescription drug.

''(5) ENFORCEMENT.—

''(A) UNFAIR OR DECEPTIVE ACT OR PRACTICE.—A violation of this subsection shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

''(B) ACTIONS BY THE COMMISSION.—The Federal Trade Commission—

''(i) shall enforce this subsection in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section; and

''(ii) may seek monetary relief threefold the damages sustained, in addition to any other remedy available to the Federal Trade Commission under the Federal Trade Commission Act (15 U.S.C. 41 et seq.).

''(6) ACTIONS BY STATES.—

''(A) IN GENERAL.—

''(i) CIVIL ACTIONS.—In any case in which the attorney general of a State has reason to believe that an interest of the residents of that State have been adversely affected by any manufacturer that violates paragraph (1), the attorney general of a State may bring a civil action on behalf of the residents of the State, and persons doing business in the State, in a district court of the United States of appropriate jurisdiction to—

''(I) enjoin that practice;

''(II) enforce compliance with this subsection;

''(III) obtain damages, restitution, or other compensation on behalf of residents of the State and persons doing business in the State, including threefold the damages; or

''(IV) obtain such other relief as the court may consider to be appropriate.

''(ii) NOTICE.—

''(I) IN GENERAL.—Before filing an action under clause (i), the attorney general of the State involved shall provide to the Federal Trade Commission—

''(aa) written notice of that action; and

''(bb) a copy of the complaint for that action.

''(II) EXEMPTION.—Subclause (I) shall not apply with respect to the filing of an action by an attorney general of a State under this paragraph, if the attorney general determines that it is not feasible to provide the notice described in that subclause before filing of the action. In such case, the attorney general of a State shall provide notice and a copy of the complaint to the Federal Trade Commission at the same time as the attorney general files the action.

''(B) INTERVENTION.—

''(i) IN GENERAL.—On receiving notice under subparagraph (A)(ii), the Federal Trade Commission shall have the right to intervene in the action that is the subject of the notice.

''(ii) EFFECT OF INTERVENTION.—If the Federal Trade Commission intervenes in an action under subparagraph (A), it shall have the right—

''(I) to be heard with respect to any matter that arises in that action; and

''(II) to file a petition for appeal.

''(C) CONSTRUCTION.—For purposes of bringing any civil action under subparagraph (A), nothing in this subsection shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State to—

''(i) conduct investigations;

''(ii) administer oaths or affirmations; or

''(iii) compel the attendance of witnesses or the production of documentary and other evidence.

''(D) ACTIONS BY THE COMMISSION.—In any case in which an action is instituted by or on behalf of the Federal Trade Commission for a violation of paragraph (1), a State may not, during the pendency of that action, institute an action under subparagraph (A) for the same violation against any defendant named in the complaint in that action.

''(E) VENUE.—Any action brought under subparagraph (A) may be brought in the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code.

''(F) SERVICE OF PROCESS.—In an action brought under subparagraph (A), process may be served in any district in which the defendant—

''(i) is an inhabitant; or

''(ii) may be found.

''(G) MEASUREMENT OF DAMAGES.—In any action under this paragraph to enforce a cause of action under this subsection in which there has been a determination that a defendant has violated a provision of this subsection, damages may be proved and assessed in the aggregate by statistical or sampling methods, by the computation of illegal overcharges or by such other reasonable system of estimating aggregate damages as the court in its discretion may permit without the necessity of separately proving the individual claim of, or amount of damage to, persons on whose behalf the suit was brought.

''(H) EXCLUSION ON DUPLICATIVE RELIEF.—The district court shall exclude from the amount of monetary relief awarded in an action under this paragraph brought by the attorney general of a State any amount of monetary relief which duplicates amounts which have been awarded for the same injury.

''(7) EFFECT ON ANTITRUST LAWS.—Nothing in this subsection shall be construed to modify, impair, or supersede the operation of the antitrust laws. For the purpose of this subsection, the term 'antitrust laws' has the meaning given it in the first section of the Clayton Act, except that it includes section 5 of the Federal Trade Commission Act to the extent that such section 5 applies to unfair methods of competition.

''(8) MANUFACTURER.—In this subsection, the term 'manufacturer' means any entity, including any affiliate or licensee of that entity, that is engaged in—

''(A) the production, preparation, propagation, compounding, conversion, or processing of a prescription drug, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

''(B) the packaging, repackaging, labeling, relabeling, or distribution of a prescription drug.''.

(b) PROHIBITED ACTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301 (21 U.S.C. 331), by striking paragraph (aa) and inserting the following:

''(aa)(1) The sale or trade by a pharmacist, or by a business organization of which the pharmacist is a part, of a qualifying drug that under section 804(a)(2)(A) was imported by the pharmacist, other than—

''(A) a sale at retail made pursuant to dispensing the drug to a customer of the pharmacist or organization; or

''(B) a sale or trade of the drug to a pharmacy or a wholesaler registered to import drugs under section 804.

''(2) The sale or trade by an individual of a qualifying drug that under section 804(a)(2)(B) was imported by the individual.

''(3) The making of a materially false, fictitious, or fraudulent statement or representation, or a material omission, in a notice under clause (i) of section 804(g)(2)(B) or in an application required under section 804(g)(2)(F), or the failure to submit such a notice or application.

''(4) The importation of a drug in violation of a registration condition or other requirement under section 804, the falsification of any record required to be maintained, or provided to the Secretary, under such section, or the violation of any registration condition or other requirement under such section.''; and

(2) in section 303(a) (21 U.S.C. 333(a)), by striking paragraph (6) and inserting the following:

''(6) Notwithstanding subsection (a), any person that knowingly violates section 301(i)(2) or (3) or section 301(aa)(4) shall be imprisoned not more than 10 years, or fined in accordance with title 18, United States Code, or both.''.

(c) AMENDMENT OF CERTAIN PROVISIONS.—

(1) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by striking subsection (g) and inserting the following:

''(g) With respect to a prescription drug that is imported or offered for import into the United States by an individual who is not in the business of such importation, that is not shipped by a registered exporter under section 804, and that is refused admission under subsection (a), the Secretary shall notify the individual that—

''(1) the drug has been refused admission because the drug was not a lawful import under section 804;

''(2) the drug is not otherwise subject to a waiver of the requirements of subsection (a);

''(3) the individual may under section 804 lawfully import certain prescription drugs from exporters registered with the Secretary under section 804; and

''(4) the individual can find information about such importation, including a list of registered exporters, on the Internet website of the Food and Drug Administration or through a toll-free telephone number required under section 804.''.

(2) ESTABLISHMENT REGISTRATION.—Section 510(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) is amended in paragraph (1) by inserting after ''import into the United States'' the following: '', including a drug that is, or may be, imported or offered for import into the United States under section 804,''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date that is 90 days after the date of enactment of this title.

(d) EXHAUSTION.—

(1) IN GENERAL.—Section 271 of title 35, United States Code, is amended—

(A) by redesignating subsections (h) and (i) as (i) and (j), respectively; and

(B) by inserting after subsection (g) the following:

''(h) It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under section 804 of the Federal Food, Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.''.

(2) RULE OF CONSTRUCTION.—Nothing in the amendment made by paragraph (1) shall be construed to affect the ability of a patent owner or licensee to enforce their patent, subject to such amendment.

(e) EFFECT OF SECTION 804.—

(1) IN GENERAL.—Section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall permit the importation

of qualifying drugs (as defined in such section 804) into the United States without regard to the status of the issuance of implementing regulations—

(A) from exporters registered under such section 804 on the date that is 90 days after the date of enactment of this title; and

(B) from permitted countries, as defined in such section 804, by importers registered under such section 804 on the date that is 1 year after the date of enactment of this title.

(2) REVIEW OF REGISTRATION BY CERTAIN EXPORTERS.—

(A) REVIEW PRIORITY.—In the review of registrations submitted under subsection (b) of such section 804, registrations submitted by entities in Canada that are significant exporters of prescription drugs to individuals in the United States as of the date of enactment of this title will have priority during the 90 day period that begins on such date of enactment.

(B) PERIOD FOR REVIEW.—During such 90-day period, the reference in subsection (b)(2)(A) of such section 804 to 90 days (relating to approval or disapproval of registrations) is, as applied to such entities, deemed to be 30 days.

(C) LIMITATION.—That an exporter in Canada exports, or has exported, prescription drugs to individuals in the United States on or before the date that is 90 days after the date of enactment of this title shall not serve as a basis, in whole or in part, for disapproving a registration under such section 804 from the exporter.

(D) FIRST YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date of enactment of this title, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may limit the number of registered exporters under such section 804 to not less than 50, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(E) SECOND YEAR LIMIT ON NUMBER OF EXPORTERS.—During the 1-year period beginning on the date that is 1 year after the date of enactment of this title, the Secretary may limit the number of registered exporters under such section 804 to not less than 100, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(F) FURTHER LIMIT ON NUMBER OF EXPORTERS.—During any 1-year period beginning on a date that is 2 or more years after the date of enactment of this title, the Secretary may limit the number of registered exporters under such section 804 to not less than 25 more than the number of such exporters during the previous 1-year period, so long as the Secretary gives priority to those exporters with demonstrated ability to process a high volume of shipments of drugs to individuals in the United States.

(3) LIMITS ON NUMBER OF IMPORTERS.—

(A) FIRST YEAR LIMIT ON NUMBER OF IMPORTERS.—During the 1-year period beginning on the date that is 1 year after the date of enactment of this title, the Secretary may limit the number of registered importers under such section 804 to not less than 100 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs imported into the United States.

(B) SECOND YEAR LIMIT ON NUMBER OF IMPORTERS.—During the 1-year period beginning on the date that is 2 years after the date of enactment of this title, the Secretary may limit the number of registered importers under such section 804 to not less than 200 (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups), so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs into the United States.

(C) FURTHER LIMIT ON NUMBER OF IMPORTERS.—During any 1-year period beginning on a date that is 3 or more years after the date of enactment of this title, the Secretary may limit the number of registered importers under such section 804 to not less than 50 more (of which at least a significant number shall be groups of pharmacies, to the extent feasible given the applications submitted by such groups) than the number of such importers during the previous 1-year period, so long as the Secretary gives priority to those importers with demonstrated ability to process a high volume of shipments of drugs to the United States.

(4) NOTICES FOR DRUGS FOR IMPORT FROM CANADA.—The notice with respect to a qualifying drug introduced for commercial distribution in Canada as of the date of enactment of this title that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 30 days after the date of enactment of this title if—

(A) the U.S. label drug (as defined in such section 804) for the qualifying drug is 1 of the 100 prescription drugs with the highest dollar volume of sales in the United States based on the 12 calendar month period most recently completed before the date of enactment of this Act; or

(B) the notice is a notice under subsection (g)(2)(B)(i)(II) of such section 804.

(5) NOTICE FOR DRUGS FOR IMPORT FROM OTHER COUNTRIES.—The notice with respect to a qualifying drug introduced for commercial distribution in a permitted country other than Canada as of the date of enactment of this title that is required under subsection (g)(2)(B)(i) of such section 804 shall be submitted to the Secretary not later than 180 days after the date of enactment of this title if—

(A) the U.S. label drug for the qualifying drug is 1 of the 100 prescription drugs with the highest dollar volume of sales in the United States based on the 12 calendar month period that is first completed on the date that is 120 days after the date of enactment of this title; or

(B) the notice is a notice under subsection (g)(2)(B)(i)(II) of such section 804.

(6) NOTICE FOR OTHER DRUGS FOR IMPORT.—

(A) GUIDANCE ON SUBMISSION DATES.—The Secretary shall by guidance establish a series of submission dates for the notices under subsection (g)(2)(B)(i) of such section 804 with respect to qualifying drugs introduced for commercial distribution as of the date of enactment of this title and that are not required to be submitted under paragraph (4) or (5).

(B) CONSISTENT AND EFFICIENT USE OF RESOURCES.—The Secretary shall establish the dates described under subparagraph (A) so that such notices described under subparagraph (A) are submitted and reviewed at a rate that allows consistent and efficient use of the resources and staff available to the Secretary for such reviews. The Secretary may condition the requirement to submit such a notice, and the review of such a notice, on the submission by a registered exporter or a registered importer to the Secretary of a notice that such exporter or importer intends to import such qualifying drug to the United States under such section 804.

(C) PRIORITY FOR DRUGS WITH HIGHER SALES.—The Secretary shall establish the dates described under subparagraph (A) so that the Secretary reviews the notices described under such subparagraph with respect to qualifying drugs with higher dollar volume of sales in the United States before the notices with respect to drugs with lower sales in the United States.

(7) NOTICES FOR DRUGS APPROVED AFTER EFFECTIVE DATE.—The notice required under subsection (g)(2)(B)(i) of such section 804 for a qualifying drug first introduced for commercial distribution in a permitted country (as defined in such section 804) after the date of enactment of this title shall be submitted to and reviewed by the Secretary as provided under subsection (g)(2)(B) of such section 804, without regard to paragraph (4), (5), or (6).

(8) REPORT.—Beginning with the first full fiscal year after the date of enactment of this title, not later than 90 days after the end of each fiscal year during which the Secretary reviews a notice referred to in paragraph (4), (5), or (6), the Secretary shall submit a report to Congress concerning the progress of the Food and Drug Administration in reviewing the notices referred to in paragraphs (4), (5), and (6).

(9) USER FEES.—

(A) EXPORTERS.—When establishing an aggregate total of fees to be collected from exporters under subsection (f)(2) of such section 804, the Secretary shall, under subsection (f)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered exporters during the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of days in such fiscal year during which this title is effective bears to 365.

(B) IMPORTERS.—When establishing an aggregate total of fees to be collected from importers under subsection (e)(2) of such section 804, the Secretary shall, under subsection (e)(3)(C)(i) of such section 804, estimate the total price of drugs imported under subsection (a) of such section 804 into the United States by registered importers during—

(i) the first fiscal year in which this title takes effect to be an amount equal to the amount which bears the same ratio to $1,000,000,000 as the number of days in such fiscal year during which this title is effective bears to 365; and

(ii) the second fiscal year in which this title is in effect to be $3,000,000,000.

(C) SECOND YEAR ADJUSTMENT.—

(i) REPORTS.—Not later than February 20 of the second fiscal year in which this title is in effect, registered importers shall report to the Secretary the total price and the total volume of drugs imported to the United States by the importer during the 4-month period from October 1 through January 31 of such fiscal year.

(ii) REESTIMATE.—Notwithstanding subsection (e)(3)(C)(ii) of such section 804 or subparagraph (B), the Secretary shall reestimate the total price of qualifying drugs imported under subsection (a) of such section 804 into the United States by registered importers during the second fiscal year in which this title is in effect. Such reestimate shall be equal to—

(I) the total price of qualifying drugs imported by each importer as reported under clause (i); multiplied by

(II) 3.

(iii) ADJUSTMENT.—The Secretary shall adjust the fee due on April 1 of the second fiscal year in which this title is in effect, from each importer so that the aggregate total of fees collected under subsection (e)(2) for such fiscal year does not exceed the total price of

qualifying drugs imported under subsection (a) of such section 804 into the United States by registered importers during such fiscal year as reestimated under clause (ii).

(D) FAILURE TO PAY FEES.—Notwithstanding any other provision of this section, the Secretary may prohibit a registered importer or exporter that is required to pay user fees under subsection (e) or (f) of such section 804 and that fails to pay such fees within 30 days after the date on which it is due, from importing or offering for importation a qualifying drug under such section 804 until such fee is paid.

(E) ANNUAL REPORT.—

(i) FOOD AND DRUG ADMINISTRATION.—Not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e), (f), or (g)(2)(B)(iv) of such section 804, the Secretary shall prepare and submit to the House of Representatives and the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for the fiscal year for which the report is made and credited to the Food and Drug Administration.

(ii) CUSTOMS AND BORDER CONTROL.—Not later than 180 days after the end of each fiscal year during which fees are collected under subsection (e) or (f) of such section 804, the Secretary of Homeland Security, in consultation with the Secretary of the Treasury, shall prepare and submit to the House of Representatives and the Senate a report on the use, by the Bureau of Customs and Border Protection, of the fees, if any, transferred by the Secretary to the Bureau of Customs and Border Protection for the fiscal year for which the report is made.

(10) SPECIAL RULE REGARDING IMPORTATION BY INDIVIDUALS.—

(A) IN GENERAL.—Notwithstanding any provision of this title (or an amendment made by this title), the Secretary shall expedite the designation of any additional countries from which an individual may import a qualifying drug into the United States under such section 804 if any action implemented by the Government of Canada has the effect of limiting or prohibiting the importation of qualifying drugs into the United States from Canada.

(B) TIMING AND CRITERIA.—The Secretary shall designate such additional countries under subparagraph (A)—

(i) not later than 6 months after the date of the action by the Government of Canada described under such subparagraph; and

(ii) using the criteria described under subsection (a)(4)(D)(i)(II) of such section 804.

(f) IMPLEMENTATION OF SECTION 804.—

(1) INTERIM RULE.—The Secretary may promulgate an interim rule for implementing section 804 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) of this section.

(2) NO NOTICE OF PROPOSED RULEMAKING.—The interim rule described under paragraph (1) may be developed and promulgated by the Secretary without providing general notice of proposed rulemaking.

(3) FINAL RULE.—Not later than 1 year after the date on which the Secretary promulgates an interim rule under paragraph (1), the Secretary shall, in accordance with procedures under section 553 of title 5, United States Code, promulgate a final rule for implementing such section 804, which may incorporate by reference provisions of the interim rule provided for under paragraph (1), to the extent that such provisions are not modified.

(g) CONSUMER EDUCATION.—The Secretary shall carry out activities that educate consumers—

(1) with regard to the availability of qualifying drugs for import for personal use from an exporter registered with and approved by the Food and Drug Administration under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by this section, including information on how to verify whether an exporter is registered and approved by use of the Internet website of the Food and Drug Administration and the toll-free telephone number required by this title;

(2) that drugs that consumers attempt to import from an exporter that is not registered with and approved by the Food and Drug Administration can be seized by the United States Customs Service and destroyed, and that such drugs may be counterfeit, unapproved, unsafe, or ineffective;

(3) with regard to the suspension and termination of any registration of a registered importer or exporter under such section 804; and

(4) with regard to the availability at domestic retail pharmacies of qualifying drugs imported under such section 804 by domestic wholesalers and pharmacies registered with and approved by the Food and Drug Administration.

(h) EFFECT ON ADMINISTRATION PRACTICES.—Notwithstanding any provision of this title (and the amendments made by this title), the practices and policies of the Food and Drug Administration and Bureau of Customs and Border Protection, in effect on January 1, 2004, with respect to the importation of prescription drugs into the United States by an individual, on the person of such individual, for personal use, shall remain in effect.

(i) REPORT TO CONGRESS.—The Federal Trade Commission shall, on an annual basis, submit to Congress a report that describes any action taken during the period for which the report is being prepared to enforce the provisions of section 804(n) of the Federal Food, Drug, and Cosmetic Act (as added by this title), including any pending investigations or civil actions under such section.

SEC. __05. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION INTO UNITED STATES.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section __04, is further amended by adding at the end the following section:

"SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED ADMISSION.

''(a) IN GENERAL.—The Secretary of Homeland Security shall deliver to the Secretary a shipment of drugs that is imported or offered for import into the United States if—

''(1) the shipment has a declared value of less than $10,000; and

''(2)(A) the shipping container for such drugs does not bear the markings required under section 804(d)(2); or

''(B) the Secretary has requested delivery of such shipment of drugs.

''(b) NO BOND OR EXPORT.—Section 801(b) does not authorize the delivery to the owner or consignee of drugs delivered to the Secretary under subsection (a) pursuant to the execution of a bond, and such drugs may not be exported.

''(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The Secretary shall destroy a shipment of drugs delivered by the Secretary of Homeland Security to the Secretary under subsection (a) if—

''(1) in the case of drugs that are imported or offered for import from a registered exporter under section 804, the drugs are in violation of any standard described in section 804(g)(5); or

''(2) in the case of drugs that are not imported or offered for import from a registered exporter under section 804, the drugs are in violation of a standard referred to in section 801(a) or 801(d)(1).

''(d) CERTAIN PROCEDURES.—

''(1) IN GENERAL.—The delivery and destruction of drugs under this section may be carried out without notice to the importer, owner, or consignee of the drugs except as required by section 801(g) or section 804(i)(2). The issuance of receipts for the drugs, and recordkeeping activities regarding the drugs, may be carried out on a summary basis.

''(2) OBJECTIVE OF PROCEDURES.—Procedures promulgated under paragraph (1) shall be designed toward the objective of ensuring that, with respect to efficiently utilizing Federal resources available for carrying out this section, a substantial majority of shipments of drugs subject to described in subsection (c) are identified and destroyed.

''(e) EVIDENCE EXCEPTION.—Drugs may not be destroyed under subsection (c) to the extent that the Attorney General of the United States determines that the drugs should be preserved as evidence or potential evidence with respect to an offense against the United States.

''(f) RULE OF CONSTRUCTION.—This section may not be construed as having any legal effect on applicable law with respect to a shipment of drugs that is imported or offered for import into the United States and has a declared value equal to or greater than $10,000.''.

(b) PROCEDURES.—Procedures for carrying out section 805 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall be established not later than 90 days after the date of the enactment of this title.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 90 days after the date of enactment of this title.

SEC. __06. WHOLESALE DISTRIBUTION OF DRUGS; STATEMENTS REGARDING PRIOR SALE, PURCHASE, OR TRADE.

(a) STRIKING OF EXEMPTIONS; APPLICABILITY TO REGISTERED EXPORTERS.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended—

(1) in paragraph (1)—

(A) by striking ''and who is not the manufacturer or an authorized distributor of record of such drug'';

(B) by striking ''to an authorized distributor of record or''; and

(C) by striking subparagraph (B) and inserting the following:

''(B) The fact that a drug subject to subsection (b) is exported from the United States does not with respect to such drug exempt any person that is engaged in the business of the wholesale distribution of the drug from providing the statement described in subparagraph (A) to the person that receives the drug pursuant to the export of the drug.

''(C)(i) The Secretary shall by regulation establish requirements that supersede subparagraph (A) (referred to in this subparagraph as 'alternative requirements') to identify the chain of custody of a drug subject to subsection (b) from the manufacturer of the drug throughout the wholesale distribution of the drug to a pharmacist who intends to sell the drug at retail if the Secretary determines that the alternative requirements, which may include standardized anti-counterfeiting or track-and-trace technologies, will identify such chain of custody or the identity of the discrete package of the drug from which the drug is dispensed with equal or greater certainty to the requirements of subparagraph (A), and that the alternative requirements are economically and technically feasible.

''(ii) When the Secretary promulgates a final rule to establish such alternative requirements, the final rule in addition shall, with respect to the registration condition established in clause (i) of section 804(c)(3)(B),

establish a condition equivalent to the alternative requirements, and such equivalent condition may be met in lieu of the registration condition established in such clause (i).'';

(2) in paragraph (2)(A), by adding at the end the following: ''The preceding sentence may not be construed as having any applicability with respect to a registered exporter under section 804.''; and

(3) in paragraph (3), by striking ''and subsection (d)—'' in the matter preceding subparagraph (A) and all that follows through ''the term 'wholesale distribution' means'' in subparagraph (B) and inserting the following: ''and subsection (d), the term 'wholesale distribution' means''.

(b) CONFORMING AMENDMENT.—Section 503(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(d)) is amended by adding at the end the following:

''(4) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

''(5) For purposes of this subsection, the term 'authorized distributors of record' means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.''.

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall take effect on January 1, 2010.

(2) DRUGS IMPORTED BY REGISTERED IMPORTERS UNDER SECTION 804.—Notwithstanding paragraph (1), the amendments made by paragraphs (1) and (3) of subsection (a) and by subsection (b) shall take effect on the date that is 90 days after the date of enactment of this title with respect to qualifying drugs imported under section 804 of the Federal Food, Drug, and Cosmetic Act, as added by section __04.

(3) EFFECT WITH RESPECT TO REGISTERED EXPORTERS.—The amendment made by subsection (a)(2) shall take effect on the date that is 90 days after the date of enactment of this title.

(4) ALTERNATIVE REQUIREMENTS.—The Secretary shall issue regulations to establish the alternative requirements, referred to in the amendment made by subsection (a)(1), that take effect not later than January 1, 2010.

(5) INTERMEDIATE REQUIREMENTS.—The Secretary shall by regulation require the use of standardized anti-counterfeiting or track-and-trace technologies on prescription drugs at the case and pallet level effective not later than 1 year after the date of enactment of this title.

(6) ADDITIONAL REQUIREMENTS.—

(A) IN GENERAL.—Notwithstanding any other provision of this section, the Secretary shall, not later than 18 months after the date of enactment of this title, require that the packaging of any prescription drug incorporates—

(i) a standardized numerical identifier unique to each package of such drug, applied at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing); and

(ii)(I) overt optically variable counterfeit-resistant technologies that—

(aa) are visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

(bb) are similar to that used by the Bureau of Engraving and Printing to secure United States currency;

(cc) are manufactured and distributed in a highly secure, tightly controlled environment; and

(dd) incorporate additional layers of nonvisible convert security features up to and including forensic capability, as described in subparagraph (B); or

(II) technologies that have a function of security comparable to that described in subclause (I), as determined by the Secretary.

(B) STANDARDS FOR PACKAGING.—For the purpose of making it more difficult to counterfeit the packaging of drugs subject to this paragraph, the manufacturers of such drugs shall incorporate the technologies described in subparagraph (A) into at least 1 additional element of the physical packaging of the drugs, including blister packs, shrink wrap, package labels, package seals, bottles, and boxes.

SEC. __07. INTERNET SALES OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503A the following:

''SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.

''(a) REQUIREMENTS REGARDING INFORMATION ON INTERNET SITE.—

''(1) IN GENERAL.—A person may not dispense a prescription drug pursuant to a sale of the drug by such person if—

''(A) the purchaser of the drug submitted the purchase order for the drug, or conducted any other part of the sales transaction for the drug, through an Internet site;

''(B) the person dispenses the drug to the purchaser by mailing or shipping the drug to the purchaser; and

''(C) such site, or any other Internet site used by such person for purposes of sales of a prescription drug, fails to meet each of the requirements specified in paragraph (2), other than a site or pages on a site that—

''(i) are not intended to be accessed by purchasers or prospective purchasers; or

''(ii) provide an Internet information location tool within the meaning of section 231(e)(5) of the Communications Act of 1934 (47 U.S.C. 231(e)(5)).

''(2) REQUIREMENTS.—With respect to an Internet site, the requirements referred to in subparagraph (C) of paragraph (1) for a person to whom such paragraph applies are as follows:

''(A) Each page of the site shall include either the following information or a link to a page that provides the following information:

''(i) The name of such person.

''(ii) Each State in which the person is authorized by law to dispense prescription drugs.

''(iii) The address and telephone number of each place of business of the person with respect to sales of prescription drugs through the Internet, other than a place of business that does not mail or ship prescription drugs to purchasers.

''(iv) The name of each individual who serves as a pharmacist for prescription drugs that are mailed or shipped pursuant to the site, and each State in which the individual is authorized by law to dispense prescription drugs.

''(v) If the person provides for medical consultations through the site for purposes of providing prescriptions, the name of each individual who provides such consultations; each State in which the individual is licensed or otherwise authorized by law to provide such consultations or practice medicine; and the type or types of health professions for which the individual holds such licenses or other authorizations.

''(B) A link to which paragraph (1) applies shall be displayed in a clear and prominent place and manner, and shall include in the caption for the link the words 'licensing and contact information'.

''(b) INTERNET SALES WITHOUT APPROPRIATE MEDICAL RELATIONSHIPS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), a person may not dispense a prescription drug, or sell such a drug, if—

''(A) for purposes of such dispensing or sale, the purchaser communicated with the person through the Internet;

''(B) the patient for whom the drug was dispensed or purchased did not, when such communications began, have a prescription for the drug that is valid in the United States;

''(C) pursuant to such communications, the person provided for the involvement of a practitioner, or an individual represented by the person as a practitioner, and the practitioner or such individual issued a prescription for the drug that was purchased;

''(D) the person knew, or had reason to know, that the practitioner or the individual referred to in subparagraph (C) did not, when issuing the prescription, have a qualifying medical relationship with the patient; and

''(E) the person received payment for the dispensing or sale of the drug.

For purposes of subparagraph (E), payment is received if money or other valuable consideration is received.

''(2) EXCEPTIONS.—Paragraph (1) does not apply to—

''(A) the dispensing or selling of a prescription drug pursuant to telemedicine practices sponsored by—

''(i) a hospital that has in effect a provider agreement under title XVIII of the Social Security Act (relating to the Medicare program); or

''(ii) a group practice that has not fewer than 100 physicians who have in effect provider agreements under such title; or

''(B) the dispensing or selling of a prescription drug pursuant to practices that promote the public health, as determined by the Secretary by regulation.

''(3) QUALIFYING MEDICAL RELATIONSHIP.—

''(A) IN GENERAL.—With respect to issuing a prescription for a drug for a patient, a practitioner has a qualifying medical relationship with the patient for purposes of this section if—

''(i) at least one in-person medical evaluation of the patient has been conducted by the practitioner; or

''(ii) the practitioner conducts a medical evaluation of the patient as a covering practitioner.

''(B) IN-PERSON MEDICAL EVALUATION.—A medical evaluation by a practitioner is an in-person medical evaluation for purposes of this section if the practitioner is in the physical presence of the patient as part of conducting the evaluation, without regard to whether portions of the evaluation are conducted by other health professionals.

''(C) COVERING PRACTITIONER.—With respect to a patient, a practitioner is a covering practitioner for purposes of this section if the practitioner conducts a medical evaluation of the patient at the request of a practitioner who has conducted at least one in-person medical evaluation of the patient and is temporarily unavailable to conduct the evaluation of the patient. A practitioner is a covering practitioner without regard to whether the practitioner has conducted any in-person medical evaluation of the patient involved.

''(4) RULES OF CONSTRUCTION.—

''(A) INDIVIDUALS REPRESENTED AS PRACTITIONERS.—A person who is not a practitioner (as defined in subsection (e)(1)) lacks legal capacity under this section to have a qualifying medical relationship with any patient.

''(B) STANDARD PRACTICE OF PHARMACY.—Paragraph (1) may not be construed as prohibiting any conduct that is a standard practice in the practice of pharmacy.

''(C) APPLICABILITY OF REQUIREMENTS.—Paragraph (3) may not be construed as having any applicability beyond this section, and does not affect any State law, or interpretation of State law, concerning the practice of medicine.

''(c) ACTIONS BY STATES.—

''(1) IN GENERAL.—Whenever an attorney general of any State has reason to believe that the interests of the residents of that State have been or are being threatened or adversely affected because any person has engaged or is engaging in a pattern or practice that violates section 301(l), the State may bring a civil action on behalf of its residents in an appropriate district court of the United States to enjoin such practice, to enforce compliance with such section (including a nationwide injunction), to obtain damages, restitution, or other compensation on behalf of residents of such State, to obtain reasonable attorneys fees and costs if the State prevails in the civil action, or to obtain such further and other relief as the court may deem appropriate.

''(2) NOTICE.—The State shall serve prior written notice of any civil action under paragraph (1) or (5)(B) upon the Secretary and provide the Secretary with a copy of its complaint, except that if it is not feasible for the State to provide such prior notice, the State shall serve such notice immediately upon instituting such action. Upon receiving a notice respecting a civil action, the Secretary shall have the right—

''(A) to intervene in such action;

''(B) upon so intervening, to be heard on all matters arising therein; and

''(C) to file petitions for appeal.

''(3) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in this chapter shall prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses or the production of documentary and other evidence.

''(4) VENUE; SERVICE OF PROCESS.—Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business or wherever venue is proper under section 1391 of title 28, United States Code. Process in such an action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

''(5) ACTIONS BY OTHER STATE OFFICIALS.—

''(A) Nothing contained in this section shall prohibit an authorized State official from proceeding in State court on the basis of an alleged violation of any civil or criminal statute of such State.

''(B) In addition to actions brought by an attorney general of a State under paragraph (1), such an action may be brought by officers of such State who are authorized by the State to bring actions in such State on behalf of its residents.

''(d) EFFECT OF SECTION.—This section shall not apply to a person that is a registered exporter under section 804.

''(e) GENERAL DEFINITIONS.—For purposes of this section:

''(1) The term 'practitioner' means a practitioner referred to in section 503(b)(1) with respect to issuing a written or oral prescription.

''(2) The term 'prescription drug' means a drug that is described in section 503(b)(1).

''(3) The term 'qualifying medical relationship', with respect to a practitioner and a patient, has the meaning indicated for such term in subsection (b).

''(f) INTERNET-RELATED DEFINITIONS.—

''(1) IN GENERAL.—For purposes of this section:

''(A) The term 'Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected world-wide network of networks that employ the transmission control protocol/internet protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire or radio.

''(B) The term 'link', with respect to the Internet, means one or more letters, words, numbers, symbols, or graphic items that appear on a page of an Internet site for the purpose of serving, when activated, as a method for executing an electronic command—

''(i) to move from viewing one portion of a page on such site to another portion of the page;

''(ii) to move from viewing one page on such site to another page on such site; or

''(iii) to move from viewing a page on one Internet site to a page on another Internet site.

''(C) The term 'page', with respect to the Internet, means a document or other file accessed at an Internet site.

''(D)(i) The terms 'site' and 'address', with respect to the Internet, mean a specific location on the Internet that is determined by Internet Protocol numbers. Such term includes the domain name, if any.

''(ii) The term 'domain name' means a method of representing an Internet address without direct reference to the Internet Protocol numbers for the address, including methods that use designations such as '.com', '.edu', '.gov', '.net', or '.org'.

''(iii) The term 'Internet Protocol numbers' includes any successor protocol for determining a specific location on the Internet.

''(2) AUTHORITY OF SECRETARY.—The Secretary may by regulation modify any definition under paragraph (1) to take into account changes in technology.

''(g) INTERACTIVE COMPUTER SERVICE; ADVERTISING.—No provider of an interactive computer service, as defined in section 230(f)(2) of the Communications Act of 1934 (47 U.S.C. 230(f)(2)), or of advertising services shall be liable under this section for dispensing or selling prescription drugs in violation of this section on account of another person's selling or dispensing such drugs, provided that the provider of the interactive computer service or of advertising services does not own or exercise corporate control over such person.''.

(b) INCLUSION AS PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by inserting after paragraph (k) the following:

''(l) The dispensing or selling of a prescription drug in violation of section 503B.''.

(c) INTERNET SALES OF PRESCRIPTION DRUGS; CONSIDERATION BY SECRETARY OF PRACTICES AND PROCEDURES FOR CERTIFICATION OF LEGITIMATE BUSINESSES.—In carrying out section 503B of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section), the Secretary of Health and Human Services shall take into consideration the practices and procedures of public or private entities that certify that businesses selling prescription drugs through Internet sites are legitimate businesses, including practices and procedures regarding disclosure formats and verification programs.

(d) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall, pursuant to the submission of an application meeting the criteria of the Secretary, make an award of a grant or contract to the National Clearinghouse on Internet Prescribing (operated by the Federation of State Medical Boards) for the purpose of—

(A) identifying Internet sites that appear to be in violation of Federal or State laws concerning the dispensing of drugs;

(B) reporting such sites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

(C) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken with respect to violations described in subparagraph (A).

(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out paragraph (1), there is authorized to be appropriated $100,000 for each of the first 3 fiscal years in which this section is in effect.

(e) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) take effect 90 days after the date of enactment of this title, without regard to whether a final rule to implement such amendments has been promulgated by the Secretary of Health and Human Services under section 701(a) of the Federal Food, Drug, and Cosmetic Act. The preceding sentence may not be construed as affecting the authority of such Secretary to promulgate such a final rule.

SEC. __08. PROHIBITING PAYMENTS TO UNREGISTERED FOREIGN PHARMACIES.

(a) IN GENERAL.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(g) RESTRICTED TRANSACTIONS.—

''(1) IN GENERAL.—The introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system is prohibited.

''(2) PAYMENT SYSTEM.—

''(A) IN GENERAL.—The term 'payment system' means a system used by a person described in subparagraph (B) to effect a credit transaction, electronic fund transfer, or money transmitting service that may be used in connection with, or to facilitate, a restricted transaction, and includes—

''(i) a credit card system;

''(ii) an international, national, regional, or local network used to effect a credit transaction, an electronic fund transfer, or a money transmitting service; and

''(iii) any other system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic fund transfers, or money transmitting services.

''(B) PERSONS DESCRIBED.—A person referred to in subparagraph (A) is—

''(i) a creditor;

''(ii) a credit card issuer;

''(iii) a financial institution;

''(iv) an operator of a terminal at which an electronic fund transfer may be initiated;

''(v) a money transmitting business; or

''(vi) a participant in an international, national, regional, or local network used to effect a credit transaction, electronic fund transfer, or money transmitting service.

''(3) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of an individual who places an unlawful drug importation request to any person engaged in the operation of an unregistered foreign pharmacy, of—

''(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful drug importation request (including credit extended through the use of a credit card);

''(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual for the purpose of the unlawful drug importation request;

''(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful drug importation request and is drawn on or payable at or through any financial institution; or

''(D) the proceeds of any other form of financial transaction (identified by the Board by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful drug importation request.

''(4) UNLAWFUL DRUG IMPORTATION REQUEST.—The term 'unlawful drug importation request' means the request, or transmittal of a request, made to an unregistered foreign pharmacy for a prescription drug by mail (including a private carrier), facsimile, phone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

''(5) UNREGISTERED FOREIGN PHARMACY.—The term 'unregistered foreign pharmacy' means a person in a country other than the United States that is not a registered exporter under section 804.

''(6) OTHER DEFINITIONS.—

''(A) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor', and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

''(B) ACCESS DEVICE; ELECTRONIC FUND TRANSFER.—The terms 'access device' and 'electronic fund transfer'—

''(i) have the meaning given the term in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a); and

''(ii) the term 'electronic fund transfer' also includes any fund transfer covered under Article 4A of the Uniform Commercial Code, as in effect in any State.

''(C) FINANCIAL INSTITUTION.—The term 'financial institution'—

''(i) has the meaning given the term in section 903 of the Electronic Transfer Fund Act (15 U.S.C. 1693a); and

''(ii) includes a financial institution (as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809)).

''(D) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meaning given the terms in section 5330(d) of title 31, United States Code.

''(E) BOARD.—The term 'Board' means the Board of Governors of the Federal Reserve System.

''(7) POLICIES AND PROCEDURES REQUIRED TO PREVENT RESTRICTED TRANSACTIONS.—

''(A) REGULATIONS.—The Board shall promulgate regulations requiring—

''(i) an operator of a credit card system;

''(ii) an operator of an international, national, regional, or local network used to effect a credit transaction, an electronic fund transfer, or a money transmitting service;

''(iii) an operator of any other payment system that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic transfers or money transmitting services where at least one party to the transaction or transfer is an individual; and

''(iv) any other person described in paragraph (2)(B) and specified by the Board in such regulations,

to establish policies and procedures that are reasonably designed to prevent the introduction of a restricted transaction into a payment system or the completion of a restricted transaction using a payment system

''(B) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under subparagraph (A), the Board shall—

''(i) identify types of policies and procedures, including nonexclusive examples, that shall be considered to be reasonably designed to prevent the introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system; and

''(ii) to the extent practicable, permit any payment system, or person described in paragraph (2)(B), as applicable, to choose among alternative means of preventing the introduction or completion of restricted transactions.

''(C) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—

''(i) IN GENERAL.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, and any participant in such payment system that prevents or otherwise refuses to honor transactions in an effort to implement the policies and procedures required under this subsection or to otherwise comply with this subsection shall not be liable to any party for such action.

''(ii) COMPLIANCE.—A person described in paragraph (2)(B) meets the requirements of this subsection if the person relies on and complies with the policies and procedures of a payment system of which the person is a member or in which the person is a participant, and such policies and procedures of the payment system comply with the requirements of the regulations promulgated under subparagraph (A).

''(D) ENFORCEMENT.—

''(i) IN GENERAL.—This section shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (15 U.S.C. 6805(a)).

''(ii) FACTORS TO BE CONSIDERED.—In considering any enforcement action under this subsection against a payment system or person described in paragraph (2)(B), the Federal functional regulators and the Federal Trade Commission shall consider the following factors:

''(I) The extent to which the payment system or person knowingly permits restricted transactions.

''(II) The history of the payment system or person in connection with permitting restricted transactions.

''(III) The extent to which the payment system or person has established and is maintaining policies and procedures in compliance with regulations prescribed under this subsection.

''(8) TRANSACTIONS PERMITTED.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, is authorized to engage in transactions with foreign pharmacies in connection with investigating violations or potential violations of any rule or requirement adopted by the payment system or person in connection with complying with paragraph (7). A payment system, or such a person, and its agents and employees shall not be found to be in violation of, or liable under, any Federal, State or other law by virtue of engaging in any such transaction.

''(9) RELATION TO STATE LAWS.—No requirement, prohibition, or liability may be imposed on a payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, under the laws of any state with respect to any payment transaction by an individual because the payment transaction involves a payment to a foreign pharmacy.

''(10) TIMING OF REQUIREMENTS.—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, must adopt policies and procedures reasonably designed to comply with any regulations required under paragraph (7) within 60 days after such regulations are issued in final form.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect on the day that is 90 days after the date of enactment of this Act.

(c) IMPLEMENTATION.—The Board of Governors of the Federal Reserve System shall promulgate regulations as required by subsection (g)(7) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as added by subsection (a), not later than 90 days after the date of enactment of this title.

SEC. __09. IMPORTATION EXEMPTION UNDER CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.

Section 1006(a)(2) of the Controlled Substances Import and Export Act (21 U.S.C. 956(a)(2)) is amended by striking ''not import the controlled substance into the United States in an amount that exceeds 50 dosage units of the controlled substance.'' and inserting ''import into the United States not more than 10 dosage units combined of all such controlled substances.''.

SEC. __10. SEVERABILITY.

If any provision of this title, an amendment by this title, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this title, the amendments made by this title, and the application of the provisions of such to any person or circumstance shall not affected thereby.

SA 991. Mr. KOHL (for himself, Mr. GRASSLEY, Mr. LEAHY, and Mr. SCHUMER) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the bill, insert the following:

TITLE ___ PRESERVE ACCESS TO AFFORDABLE GENERICS ACT

SEC. __01. SHORT TITLE.

This title may be cited as the ''Preserve Access to Affordable Generics Act''.

SEC. __02. CONGRESSIONAL FINDINGS AND DECLARATION OF PURPOSES.

(a) FINDINGS.—The Congress finds that—

(1) prescription drugs make up 11 percent of the national health care spending but are 1 of the largest and fastest growing health care expenditures;

(2) 56 percent of all prescriptions dispensed in the United States are generic drugs, yet they account for only 13percent of all expenditures;

(3) generic drugs, on average, cost 63 percent less than their brand-name counterparts;

(4) consumers and the health care system would benefit from free and open competition in the pharmaceutical market and the removal of obstacles to the introduction of generic drugs;

(5) full and free competition in the pharmaceutical industry, and the full enforcement of antitrust law to prevent anticompetitive practices in this industry, will lead to lower prices, greater innovation, and inure to the general benefit of consumers.

(6) the Federal Trade Commission has determined that some brand name pharmaceutical manufacturers collude with generic drug manufacturers to delay the marketing of competing, low-cost, generic drugs;

(7) collusion by the brand name pharmaceutical manufacturers is contrary to free competition, to the interests of consumers, and to the principles underlying antitrust law;

(8) in 2005, 2 appellate court decisions reversed the Federal Trade Commission's longstanding position, and upheld settlements that include pay-offs by brand name pharmaceutical manufacturers to generic manufacturers designed to keep generic competition off the market;

(9) in the 6 months following the March 2005 court decisions, the Federal Trade Commission found there were three settlement agreements in which the generic received compensation and agreed to a restriction on its ability to market the product;

(10) the FTC found that more than ⅔ of the approximately ten settlement agreements made in 2006 include a pay-off from the brand in exchange for a promise by the generic company to delay entry into the market; and

(11) settlements which include a payment from a brand name manufacturer to a generic manufacturer to delay entry by generic drugs are anti-competitive and contrary to the interests of consumers.

(b) PURPOSES.—The purposes of this title are—

(1) to enhance competition in the pharmaceutical market by prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market;

(2) to support the purpose and intent of antitrust law by prohibiting anticompetitive agreements and collusion in the pharmaceutical industry; and

(3) to clarify the law to prohibit payments from brand name to generic drug manufacturers with the purpose to prevent or delay the entry of competition from generic drugs.

SEC. 3. UNLAWFUL COMPENSATION FOR DELAY.

(a) IN GENERAL.—The Clayton Act (15 U.S.C. 12 et seq.) is amended by inserting after section 28 the following:

"SEC. 29. UNLAWFUL INTERFERENCE WITH GENERIC MARKETING.

''(a) It shall be unlawful under this Act for any person, in connection with the sale of a drug product, to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim which—

''(1) an ANDA filer receives anything of value; and

''(2) the ANDA filer agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time.

''(b) Nothing in this section shall prohibit a resolution or settlement of patent infringement claim in which the value paid by the NDA holder to the ANDA filer as a part of the resolution or settlement of the patent infringement claim includes no more than the right to market the ANDA product prior to the expiration of the patent that is the basis for the patent infringement claim.

''(c) In this section:

''(1) The term 'agreement' means anything that would constitute an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of the Federal Trade Commission Act (15 U.S.C. 45).

''(2) The term 'agreement resolving or settling a patent infringement claim' includes, any agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

''(3) The term 'ANDA' means an abbreviated new drug application, as defined under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

''(4) The term 'ANDA filer' means a party who has filed an ANDA with the Federal Drug Administration.

''(5) The term 'ANDA product' means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

''(6) The term 'drug product' means a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with 1 or more other ingredients, as defined in section 314.3(b) of title 21, Code of Federal Regulations.

''(7) The term 'NDA' means a new drug application, as defined under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

''(8) The term 'NDA holder' means—

''(A) the party that received FDA approval to market a drug product pursuant to an NDA;

''(B) a party owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the 'FDA Orange Book') in connection with the NDA; or

''(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subclauses (i) and (ii) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

''(9) The term 'patent infringement' means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

''(10) The term 'patent infringement claim' means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product may infringe any patent held by, or exclusively licensed to, the NDA holder of the drug product.''.

(b) REGULATIONS.—The Federal Trade Commission may, by rule promulgated under section 553 of title 5, United States Code, exempt certain agreements described in the section 29 of the Clayton Act, as added by subsection (a), if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers. Consistent with the authority of Commission, such rules may include interpretive rules and general statements of policy with respect to the practices prohibited under section 29 of the Clayton Act.

SEC. __04. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 1112(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 3155 note) is amended by—

(1) striking ''the Commission the'' and inserting ''the Commission (1) the''; and

(2) inserting before the period at the end the following: ''; and (2) a description of the subject matter of any other agreement the parties enter into within 30 days of an entering into an agreement covered by subsection (a) or (b)''.

(b) CERTIFICATION OF AGREEMENTS.—Section 1112 of such Act is amended by adding at the end the following:

''(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement required to be filed under subsection (a), (b), or (c) shall execute and file with the Assistant Attorney General and the Commission a certification as follows: 'I declare under penalty of perjury that the following is true and correct: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification: (1) represent the complete, final, and exclusive agreement between the parties; (2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and (3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.'.''.

SEC. __05. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

Section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by inserting ''section 28 of the Clayton Act or'' after ''that the agreement has violated''.

SEC. __06. STUDY BY THE FEDERAL TRADE COMMISSION.

(a) REQUIREMENT FOR A STUDY.—Not later than 180 days after the date of enactment of this Act and pursuant to its authority under section 6(a) of the Federal Trade Commission Act (15 U.S.C. 46(a)) and its jurisdiction to prevent unfair methods of competition, the Federal Trade Commission shall conduct a study regarding—

(1) the prevalence of agreements in patent infringement suits of the type described in section 29 of the Clayton Act, as added by this title, during the last 5 years;

(2) the impact of such agreements on competition in the pharmaceutical market; and

(3) the prevalence in the pharmaceutical industry of other anticompetitive agreements among competitors or other practices that are contrary to the antitrust laws, and the impact of such agreements or practices on competition in the pharmaceutical market during the last 5 years.

(b) CONSULTATION.—In conducting the study required under this section, the Federal Trade Commission shall consult with the Antitrust Division of the Department of Justice regarding the Justice Department's findings and investigations regarding anticompetitive practices in the pharmaceutical market, including criminal antitrust investigations completed by the Justice Department with respect to practices or conduct in the pharmaceutical market.

(c) REQUIREMENT FOR A REPORT.—Not later than 1 year after the date of enactment of this Act, the Federal Trade Commission shall submit a report to the Judiciary Committees of Senate and House of Representatives, and to the Department of Justice regarding the findings of the study conducted under subsection (a). This report shall contain the Federal Trade Commission's recommendation as to whether any amendment to the antitrust laws should be enacted to correct any substantial lessening of competition found during the study.

(d) FEDERAL AGENCY CONSIDERATION.—Upon receipt of the report required by subsection (c), the Attorney General or the Chairman of the Federal Trade Commission, as appropriate, shall consider whether any additional

enforcement action is required to restore competition or prevent a substantial lessening of competition occurring as a result of the conduct or practices that were the subject of the study conducted under subsection (b).

SEC. __07. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to the Federal Trade Commission such sums as may be necessary to carry out the provisions of this title.

SA 992. Mr. KOHL submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ____. CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended by adding at the end the following:

''(G)(i) Notwithstanding any other provision of law, any petition submitted under section 10.30 or section 10.35 of title 21, Code of Federal Regulations (or any successor regulation), shall include a statement that to the petitioner's best knowledge and belief, the petition—

''(I) includes all information and views on which the petitioner relies, including all representative data and information known to the petitioner that is favorable or unfavorable to the petition;

''(II) is well grounded in fact and is warranted by law;

''(III) is not submitted for an improper purpose, such as to harass or cause unnecessary delay (including unnecessary delay of competition or agency action); and

''(IV) does not contain a materially false, misleading, or fraudulent statement.

''(ii) The Secretary shall investigate, on receipt of a complaint, a request under clause (vi), or on its own initiative, any petition submitted under such section 10.30 or section 10.35 (or any successor regulation), that—

''(I) does not comply with the requirements of clause (i);

''(II) may have been submitted for an improper purpose as described in clause (i)(III); or

''(III) may contain a materially false, misleading, or fraudulent statement as described in clause (i)(IV).

''(iii) If the Secretary finds that the petitioner has knowingly and willingly submitted the petition for an improper purpose as described in clause (i)(III), or which contains a materially false, misleading, or fraudulent statement as described in clause (i)(IV), the Secretary may—

''(I) impose a civil penalty of not more than $1,000,000, plus attorneys fees and costs of reviewing the petition and any related proceedings;

''(II) suspend the authority of the petitioner to submit a petition under such section 10.30 or section 10.35 (or any successor regulation), for a period of not more than 10 years;

''(III) revoke permanently the authority of the petitioner to submit a petition under such section 10.30 or section 10.35 (or any successor regulation); or

''(IV) dismiss the petition at issue in its entirety.

''(iv) If the Secretary takes an enforcement action described in subclause (I), (II), (III), or (IV) of clause (iii) with respect to a petition, the Secretary shall refer that petition to the Federal Trade Commission for further action as the Federal Trade Commission finds appropriate.

''(v) In determining whether to take an enforcement action described in subclause (I), (II), (III), or (IV) of clause (iii) with respect to a petition, and in determining the amount of any civil penalty or the length of any suspension imposed under that clause, the Secretary shall consider the specific circumstances of the situation, such as the gravity and seriousness of the violation involved, the amount of resources expended in reviewing the petition at issue, the effect on marketing of competing drugs of the pendency of the improperly submitted petition, including whether the timing of the submission of the petition appears to have been calculated to cause delay in the marketing of any drug awaiting approval, and whether the petitioner has a history of submitting petitions in violation of this subparagraph.

''(vi)(I) Any person aggrieved by a petition filed under such section 10.30 or section 10.35 (or any successor regulation), including a person filing an application under subsection (b)(2) or (j) of this section to which such petition relates, may request that the Secretary initiate an investigation described under clause (ii) for an enforcement action described under clause (iii).

''(II) The aggrieved person shall specify the basis for its belief that the petition at issue is false, misleading, fraudulent, or submitted for an improper purpose. The aggrieved person shall certify that the request is submitted in good faith, is well grounded in fact, and not submitted for any improper purpose. Any aggrieved person who knowingly and intentionally violates the preceding sentence shall be subject to the civil penalty described under clause (iii)(I).

''(vii) The Secretary shall take final agency action with respect to a petition filed under such section 10.30 or section 10.35 (or any successor regulation) regarding an abbreviated new drug application within 6 months of receipt of such petition. The Secretary shall not extend such 6-month review period, even with consent of the petitioner, for any reason, including based upon the submission of comments relating to a petition or supplemental information supplied by the petitioner. If the Secretary has not taken final agency action on a petition regarding an abbreviated new drug application by the date that is 6 months after the date of receipt of the petition, such petition shall be deemed to have been denied on such date.

''(viii) The Secretary may promulgate regulations to carry out this subparagraph, including to determine whether petitions filed under such section 10.30 or section 10.35 (or any successor regulation) merit enforcement action by the Secretary under this subparagraph.''.

SA 993. Mr. GREGG submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE __—INTERNET PHARMACIES

SEC. __01. SHORT TITLE.

This title may be cited as the ''Safe Internet Pharmacy Act of 2007''.

SEC. __02. INTERNET PHARMACIES.

(a) INTERNET PHARMACIES.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 510 the following:

''SEC. 511. INTERNET PHARMACIES.

''(a) DEFINITIONS.—In this section:

''(1) ADVERTISING SERVICE PROVIDER.—The term 'advertising service provider' means an advertising company that contracts with a provider of an interactive computer service (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f)) to provide advertising on the Internet.

''(2) DESIGNATED PAYMENT SYSTEM.—

''(A) IN GENERAL.—The term 'designated payment system' means a system used by a person described in subparagraph (B) to effect a credit transaction, electronic fund transfer, or money transmitting service that the Board determines, by regulation or order, is regularly used in connection with, or to facilitate restricted transactions.

''(B) PERSONS DESCRIBED.—A person referred to in subparagraph (A) is—

''(i) a creditor;

''(ii) a credit card issuer;

''(iii) a financial institution;

''(iv) an operator of a terminal at which an electronic fund transfer may be initiated;

''(v) a money transmitting business; or

''(vi) a participant in an international, national, regional, or local network constructed primarily to effect a credit transaction, electronic fund transfer, or money transmitting service.

''(3) FEDERAL FUNCTIONAL REGULATOR.—The term 'Federal functional regulator' has the meaning given the term in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809).

''(4) INTERNET PHARMACY.—The term 'Internet pharmacy' means a person that offers to dispense or dispenses in the United States a prescription drug through an Internet website in interstate commerce, regardless of whether the physical location of the principal place of business of the Internet pharmacy is in the United States or in another country.

''(5) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug described in section 503(b) that is approved by the Secretary under section 505.

''(6) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of a individual who places an unlawful Internet pharmacy request to any person engaged in the operation of an unlicensed Internet pharmacy, of—

''(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful Internet request (including credit extended through the use of a credit card);

''(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual for the purpose of the unlawful Internet request;

''(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful Internet request and is drawn on or payable at or through any financial institution; or

''(D) the proceeds of any other form of financial transaction (identified by the Board by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful Internet request.

''(7) TREATING PROVIDER.—The term 'treating provider' means a health care provider licensed in the United States who is authorized to prescribe medications and who—

''(A)(i) performs a documented patient evaluation (including a patient history and physical examination) of an individual, portions of which may be conducted by other health professionals;

''(ii) discusses with the individual the treatment options of the individual and the risks and benefits of treatment; and

''(iii) maintains contemporaneous medical records concerning the individual; or

''(B) provides care to an individual as part of an on-call or cross-coverage arrangement with a health care provider described in subparagraph (A).

''(8) UNLAWFUL INTERNET PHARMACY REQUEST.—The term 'unlawful Internet pharmacy request' means the request, or transmittal of a request, made to an unlicensed Internet pharmacy for a prescription drug by mail (including a private carrier), facsimile, telephone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

''(9) UNLICENSED INTERNET PHARMACY.—The term 'unlicensed Internet pharmacy' means an Internet pharmacy that is not licensed under this section.

''(10) OTHER DEFINITIONS.—

''(A) BOARD.—The term 'Board' means the Board of Governors of the Federal Reserve System.

''(B) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor', and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

''(C) ELECTRONIC FUND TRANSFER.—The term 'electronic fund transfer'—

''(i) has the meaning given the term in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a); and

''(ii) includes any fund transfer covered under article 4A of the Uniform Commercial Code, as in effect in any State.

''(D) FINANCIAL INSTITUTION.—The term 'financial institution'—

''(i) has the meaning given the term in section 903 of the Electronic Transfer Fund Act (15 U.S.C. 1693a); and

''(ii) includes a financial institution (as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809)).

''(E) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meanings given the terms in section 5330(d) of title 31, United States Code.

''(b) IN GENERAL.—An Internet pharmacy may only dispense or offer to dispense a prescription drug to a person in the United States in accordance with this section.

''(c) LICENSING OF INTERNET PHARMACIES.—

''(1) IN GENERAL.—An Internet pharmacy shall be licensed by the Secretary in accordance with this section prior to offering to dispense or dispensing a prescription drug to an individual.

''(2) CONDITIONS FOR LICENSING.—

''(A) APPLICATION REQUIREMENTS.—An Internet pharmacy shall submit to the Secretary an application that includes—

''(i)(I) in the case of an Internet pharmacy located in the United States, verification that, in each State in which the Internet pharmacy engages in dispensing or offering to dispense prescription drugs, the Internet pharmacy, and all employees and agents of the Internet pharmacy, is in compliance with applicable Federal and State laws regarding—

''(aa) the practice of pharmacy, including licensing laws and inspection requirements; and

''(bb) the manufacturing and distribution of controlled substances, including with respect to mailing or shipping controlled substances to consumers; or

''(II) in the case of an Internet pharmacy whose principal place of business is located outside the United States, verification that—

''(aa) all employees and agents of the Internet pharmacy are in compliance with applicable Federal and State laws regarding the practice of pharmacy, including licensing laws and inspection requirements;

''(bb) the Internet pharmacy is in compliance with applicable Federal and State laws regarding the practice of pharmacy, including licensing laws and inspection requirements;

''(cc) the Internet pharmacy expressly and affirmatively agrees to provide and maintain an agent for service of process in the United States;

''(dd) the Internet pharmacy expressly and affirmatively agrees to be subject to the jurisdiction of the United States and any of its States or territories where it engages in commerce; and

''(ee) the Internet pharmacy agrees to affix to each shipping container of drugs to be shipped in the United States such markings as the Secretary determines to be necessary to identify that the shipment is from a licensed Internet pharmacy, which may include anticounterfeiting or track-and-trace technologies;

''(ii) verification that the person that owns the Internet pharmacy has not had a license for an Internet pharmacy terminated by the Secretary, and that no other Internet pharmacy owned by the person has had a license under this subsection that has been terminated by the Secretary;

''(iii) verification from the person that owns the Internet pharmacy that the person will permit inspection of the facilities and business practices of the Internet pharmacy by the Secretary to the extent necessary to determine whether the Internet pharmacy is in compliance with this subsection;

''(iv) in the case of an agreement between a patient and an Internet pharmacy that releases the Internet pharmacy, and any employee or agent of the Internet pharmacy, from liability for damages arising out of the negligence of the Internet pharmacy, an assurance that such a limitation of liability shall be null and void;

''(v) verification that the Internet pharmacy expressly and affirmatively agrees to provide the Secretary with the identity of any providers of interactive computer services that provide host services or advertising services for the Internet pharmacy; and

''(vi) assurance that the Internet pharmacy will comply with the requirements under subparagraphs (B) and (C).

''(B) IDENTIFICATION REQUIREMENTS.—An Internet pharmacy shall post in a clear and visible manner, on each page of the website of the Internet pharmacy or by a link to a separate page, the following information:

''(i) The street address, city, ZIP Code or comparable mail code, State (or comparable entity), country, and telephone number of—

''(I) each place of business of the Internet pharmacy; and

''(II) the name of the supervising pharmacist of the Internet pharmacy and each individual who serves as a pharmacist for purposes of the Internet pharmacy website.

''(ii) The names of all States in which the Internet pharmacy and the pharmacists employed by the Internet pharmacy are licensed or otherwise authorized to dispense prescription drugs.

''(iii) If the Internet pharmacy makes referrals to, or solicits on behalf of, a health care practitioner or group of practitioners in the United States for prescription services—

''(I) the name, street address, city, ZIP Code or comparable mail code, State, and telephone number of the practitioner or group; and

''(II) the name of each State in which each practitioner is licensed or otherwise authorized to prescribe drugs.

''(iv) A statement that the Internet pharmacy will dispense prescription drugs only after receipt of a valid prescription from a treating provider.

''(v) A distinctive tamper resistant seal to identify that the Internet pharmacy is licensed.

''(C) PROFESSIONAL SERVICES REQUIREMENTS.—An Internet pharmacy shall carry out the following:

''(i) Maintain patient medication profiles and other related data in a readily accessible format organized to facilitate consultation with treating providers, caregivers, and patients.

''(ii) Conduct prospective drug use reviews before dispensing medications or medical devices.

''(iii) Ensure patient confidentiality and the protection of patient identity and patient-specific information, in accordance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

''(iv) Offer interactive and meaningful consultation by a licensed pharmacist to the caregiver or patient before and after the time at which the Internet pharmacy dispenses the drug.

''(v)(I) Establish a mechanism for patients to report errors and suspected adverse drug reactions.

''(II) Document in the reporting mechanism the response of the Internet pharmacy to those reports.

''(III) Submit those reports within 3 days of receipt and the response of the Internet pharmacy to the Food and Drug Administration in a manner determined appropriate by the Secretary.

''(vi) Develop a system to inform caregivers and patients about drug recalls.

''(vii) Educate caregivers and patients about the appropriate means of disposing of expired, damaged, or unusable medications.

''(viii) Assure that the sale of a prescription drug is in accordance with a valid prescription from the treating provider of the individual.

''(ix)(I) Verify the validity of the prescription of an individual by using 1 of the following methods:

''(aa) If the prescription for any drug other than a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) is received from an individual or the treating provider of the individual by mail (including a private carrier), or from the treating provider of the individual by electronic mail, the validity of the prescription shall be confirmed in accordance with all applicable Federal and State laws.

''(bb) If the prescription is for a controlled substance (as defined in section 102 of the Controlled Substances Act), the validity of the prescription shall be confirmed with the treating provider as described in subclause (II).

''(II) When seeking verification of a prescription of an individual under subclause (I)(bb), an Internet pharmacy shall provide to the treating provider the following information:

''(aa) The full name and address of the individual.

''(bb) Identification of the prescription drug.

''(cc) The quantity of the prescription drug to be dispensed.

''(dd) The date on which the individual presented the prescription to the Internet pharmacy.

''(ee) The date and time of the verification request.

''(ff) The name of a contact person at the Internet pharmacy, including a voice telephone number, electronic mail address, and facsimile telephone number.

''(III) A prescription is verified under subclause (I)(bb) only if 1 of the following occurs:

''(aa) The treating provider confirms, by direct communication with the Internet pharmacy, that the prescription is accurate.

''(bb) The treating provider informs the Internet pharmacy that the prescription is inaccurate and provides the accurate prescription.

''(IV) An Internet pharmacy shall not fill a prescription if—

''(aa) a treating provider informs the Internet pharmacy within 72 hours after receipt of a communication under subclause (I)(bb) that the prescription is inaccurate or expired; or

''(bb) the treating provider does not respond within that time.

''(x) Maintain, for such period of time as the Secretary shall prescribe by regulation, a record of all direct communications with a treating provider regarding the dispensing of a prescription drug, including verification of the prescription.

''(3) LICENSURE PROCEDURE.—

''(A) ACTION BY SECRETARY.—On receipt of a complete licensing application from an Internet pharmacy under paragraph (2), the Secretary shall—

''(i) assign an identification number to the Internet pharmacy;

''(ii) notify the applicant of the receipt of the licensing application; and

''(iii) if the Internet pharmacy is in compliance with the conditions under paragraph (2), issue a license not later than 60 days after receipt of a licensing application from the Internet pharmacy.

''(B) ELECTRONIC FILING.—

''(i) IN GENERAL.—For the purpose of reducing paperwork and reporting burdens, the Secretary shall require the use of electronic methods of submitting to the Secretary a licensing application required under this section and provide for electronic methods of receiving the applications.

''(ii) AUTHENTICATION.—In providing for the electronic submission of such licensing applications under this section, the Secretary shall ensure that adequate authentication protocols are used to allow identification of the Internet pharmacy and validation of the data as appropriate.

''(4) DATABASE.—

''(A) IN GENERAL.—The Secretary shall compile, maintain, and periodically update a database of the Internet pharmacies licensed under this section.

''(B) AVAILABILITY.—The Secretary shall make the database described under subparagraph (A) and information submitted by the licensee under paragraph (2)(B) available to the public on an Internet website and through a toll-free telephone number.

''(5) FEES.—

''(A) IN GENERAL.—

''(i) LICENSING APPLICATION FEE.—The Secretary shall establish a licensing application fee to be paid by all applicants.

''(ii) RENEWAL FEE.—The Secretary shall establish a yearly renewal fee to be paid by all Internet pharmacies licensed under this section.

''(B) COLLECTION.—

''(i) COLLECTION OF LICENSING APPLICATION FEE.—A licensing application fee payable for the fiscal year in which the Internet pharmacy submits a licensing application, as established under subparagraph (C), shall be payable upon the submission to the Secretary of such licensing application.

''(ii) COLLECTION OF RENEWAL FEES.—After the licensing application fee is paid for the first fiscal year of licensure, the yearly renewal fee, as established under subparagraph (C), shall be payable on or before October 1 of each subsequent fiscal year.

''(iii) ONE FEE PER INTERNET PHARMACY.—The licensing application fee and yearly renewal fee shall be paid only once for each Internet pharmacy for a fiscal year in which the fee is payable.

''(C) FEE AMOUNT.—The amount of the licensing application fee and the yearly renewal fee for an Internet pharmacy shall be determined each year by the Secretary based on the anticipated costs to the Secretary of enforcing the requirements of this section in the subsequent fiscal year.

''(D) ANNUAL FEE DETERMINATION.—

''(i) IN GENERAL.—Not later than 60 days before the beginning of each fiscal year beginning after September 30, 2007, the Secretary shall determine the amount of the licensing application fee and the yearly renewal fee for that fiscal year.

''(ii) PUBLICATION OF FEE AMOUNT.—Not later than 60 days before each fiscal year, the Secretary shall publish the amount of the licensing application fee and the yearly renewal fee under this section for that fiscal year and provide for a period of 30 days for the public to provide written comments on the fees.

''(E) USE OF FEES.—The fees collected under this section shall be used, without further appropriation, to carry out this section.

''(F) FAILURE TO PAY FEE.—

''(i) DUE DATE.—A fee payable under this section shall be paid by the date that is 30 days after the date on which the fee is due.

''(ii) FAILURE TO PAY.—If an Internet pharmacy subject to a fee under this section fails to pay the fee by the date specified under clause (i), the Secretary shall not permit the Internet pharmacy to engage in the dispensing of drugs as described under this section until all such fees owed by the Internet pharmacy are paid.

''(G) REPORTS.—Beginning with fiscal year 2008, not later than 60 days after the end of each fiscal year during which licensing application fees are collected under this section, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes—

''(i) implementation of the licensing fee authority during the fiscal year; and

''(ii) the use by the Secretary of the licensing fees collected during the fiscal year for which the report is made.

''(6) SUSPENSION.—

''(A) IN GENERAL.—If the Secretary determines that an Internet pharmacy is engaged in a pattern of violations of any of the requirements of this Act, the Secretary may immediately order the suspension of the license of the Internet pharmacy.

''(B) APPEAL OF SUSPENSION ORDER.—An Internet pharmacy subject to a suspension order under subparagraph (A) may appeal the suspension order to the Secretary. Not later than 30 days after an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall affirm or terminate the order.

''(C) FAILURE TO ACT.—If, during the 30-day period specified in subparagraph (B), the Secretary fails to provide an opportunity for a hearing or to affirm or terminate the order, the order shall be deemed to be terminated.

''(D) NO JUDICIAL REVIEW.—An order under this paragraph shall not be subject to judicial review.

''(7) TERMINATION OF LICENSE.—The Secretary may terminate a license issued under this subsection, after notice to the Internet pharmacy and an opportunity for a hearing, and if the Secretary determines that the Internet pharmacy—

''(A) has demonstrated a pattern of noncompliance with this section;

''(B) has made an untrue statement of material fact in its licensing application; or

''(C) is in violation of any applicable Federal or State law relating to the dispensing of a prescription drug.

''(8) RENEWAL EVALUATION.—

''(A) IN GENERAL.—Before renewing a license of an Internet pharmacy under this subsection, the Secretary shall conduct an evaluation to determine whether the Internet pharmacy is in compliance with this section.

''(B) EVALUATION OF INTERNET PHARMACIES.—At the discretion of the Secretary and as applicable, an evaluation under subparagraph (A) may include testing of the Internet pharmacy website or other systems through which the Internet pharmacy communicates with consumers, and a physical inspection of the records and premises of the pharmacy.

''(9) CONTRACT FOR OPERATION OF PROGRAM.—

''(A) IN GENERAL.—The Secretary may award a contract under this subsection for the operation of the licensing program.

''(B) TERM.—The duration of a contract under subparagraph (A) shall not exceed 5 years and may be renewable.

''(C) PERFORMANCE REVIEW.—The Secretary shall annually review performance under a contract under subparagraph (A).

''(d) PROVIDERS OF INTERACTIVE COMPUTER SERVICES OR ADVERTISING SERVICES.—No provider of interactive computer services (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f)) or an advertising service provider shall be liable under this section on account of another person's selling or dispensing of a prescription drug, so long as the provider of the interactive computer service or the advertising service provider does not own or exercise corporate control over such person.

''(e) POLICIES AND PROCEDURES REQUIRED TO PREVENT PAYMENTS FOR UNLAWFUL INTERNET PHARMACY REQUESTS.—

''(1) REGULATIONS.—Not later than 180 days after designating a system under subsection (a)(2), the Board shall promulgate regulations that require—

''(A) an operator of a credit card system that is a designated payment system, an operator of an international, national, or local network used to effect a credit transaction, electronic fund transfer, or money transmitting service that is a designated payment system, and an operator of any other designated payment system specified by the Board that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic transfers, or money transmitting services where at least 1 party to the transaction or transfer is an individual; and

''(B) in the case of a designated payment system, other than a designated payment system described in subparagraph (A), a person described in subsection (a)(2)(B);

to establish policies and procedures that are reasonably designed to prevent the introduction of restricted transactions into a designated payment system or the completion of restricted transactions using a designated payment system.

''(2) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under paragraph (1), the Board shall—

''(A) identify types of policies and procedures, including nonexclusive examples, that shall be considered to be reasonably designed to identify and reasonably designed to prevent the introduction of a restricted transaction in a designated payment or the completion of restricted transactions using a designated payment system; and

''(B) to the extent practicable, permit any designated payment system, or person described in subsection (a)(2)(B), as applicable, to choose among alternative means of preventing the introduction or completion of restricted transactions.

''(3) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—

''(A) IN GENERAL.—A designated payment system, or a person described in subsection (a)(2)(B), that is subject to a regulation or an order issued under this subsection, and any participant in such payment system, that—

''(i) prevents or otherwise refuses to honor restricted transactions, in an effort to implement the policies and procedures required under this subsection or to otherwise comply with this section, shall not be liable to any party for such action; and

''(ii) prevents or otherwise refuses to honor a nonrestricted transaction in an effort to implement the policies and procedures under this subsection or to otherwise comply with this section, shall not be liable to any party for such action.

''(B) COMPLIANCE WITH THIS SUBSECTION.—A person described in subsection (a)(2)(B) meets the requirements of this subsection, if any, if the person relies on and complies with the policies and procedures of a designated payment system of which the person is a member or in which the person is a participant, and such policies and procedures of the designated payment system comply with the requirements of the regulations under paragraph (1)(B).

''(4) ENFORCEMENT.—

''(A) IN GENERAL.—This subsection shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (21 U.S.C. 6805(a)).

''(B) FACTORS TO BE CONSIDERED.—In considering any enforcement action under this subsection against a payment system or person described in subsection (a)(2)(B), the Federal functional regulators and the Federal Trade Commission shall consider the following factors:

''(i) The extent to which the payment system or person knowingly permits restricted transactions.

''(ii) The history of the payment system or person in connection with permitting restricted transactions.

''(iii) The extent to which the payment system or person has established and is maintaining policies and procedures in compliance with regulations prescribed under this subsection.

''(iv) The feasibility that any specific remedy prescribed can be implemented by the payment system or person without substantial deviation from normal business practice.

''(v) The costs and burdens the specific remedy will have on the payment system or person.

''(f) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—The Secretary shall, pursuant to the submission of an application meeting criteria prescribed by the Secretary, make an award of a grant or contract to an entity with experience in developing and maintaining systems for the purpose of—

''(1) identifying Internet pharmacy websites that are not licensed or that appear to be operating in violation of Federal or State laws concerning the dispensing of drugs;

''(2) reporting such Internet pharmacy websites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

''(3) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken with respect to violations described in paragraph (1).

''(g) TRANSACTIONS PERMITTED.—A designated payment system or person subject to a regulation or an order issued under subsection (e) may engage in transactions with licensed and unlicensed Internet pharmacies in connection with investigating violations or potential violations of any rule or requirement adopted by the payment system or person in connection with complying with subsection (e). A person subject to a regulation or an order issued under subsection (e) and the agents and employees of that person shall not be found to be in violation of, or liable under, any Federal, State, or other law for engaging in any such transaction.

''(h) RELATION TO STATE LAWS.—No requirement, prohibition, or liability may be imposed on a designated payment system or person subject to a regulation or an order issued under subsection (e) under the laws of any State with respect to any payment transaction by an individual because the payment transaction involves a payment to an Internet pharmacy.

''(i) TIMING OF REQUIREMENTS.—A designated payment system or a person subject to a regulation under subsection (e) shall adopt policies and procedures reasonably designed to comply with any regulations required under subsection (e) not later than 180 days after the date on which such final regulations are issued.''.

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh)(1) The sale, under section 511, of a drug that is not a prescription drug, the sale of such a prescription drug without a valid prescription from a treating provider, or the ownership or operation of an Internet pharmacy, in violation of section 511.

''(2) The representation by advertisement, sales presentation, direct communication (including telephone, facsimile, or electronic mail), or otherwise by an Internet pharmacy, that a prescription drug may be obtained from the Internet pharmacy without a prescription, in violation of section 511.

''(3) The advertisement related to a prescription drug through any media including sales presentation, direct communication (including telephone, facsimile, or electronic mail), by an unlicensed Internet pharmacy.

''(4) The provision of an untrue statement of material fact in the licensing application of an Internet pharmacy.

''(5) For purposes of this subsection, any term used in this subsection that is also used in section 511 shall have the meaning given that term in section 511.''.

(c) LINKS TO UNLICENSED INTERNET PHARMACIES.—Section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332) is amended by adding at the end the following:

''(c)(1) In the case of a violation of section 511 relating to an unlicensed Internet pharmacy (as defined in such section 511), the district courts of the United States and the United States courts of the territories shall have jurisdiction to order a provider of an interactive computer service to remove, or disable access to, links to a website violating that section that resides on a computer server that the provider controls or operates.

''(2) Relief under paragraph (1)—

''(A) shall be available only after provision to the provider of notice and an opportunity to appear;

''(B) shall not impose any obligation on the provider to monitor its service or to affirmatively seek facts indicating activity violating section 511;

''(C) shall specify the provider to which the relief applies; and

''(D) shall specifically identify the location of the website to be removed or to which access is to be disabled.''.

(d) REGULATIONS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this title, the Secretary of Health and Human Services shall promulgate interim final regulations to carry out the amendments made by this section.

(2) EFFECTIVE DATE.—The requirement of licensure under section 511 of the Federal Food, Drug, and Cosmetic Act (as added by this section) shall take effect on the date determined by the Secretary of Health and Human Services but in no event later than 90 days after the effective date of the interim final regulations under paragraph (1).

(e) PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(g) Notwithstanding subsection (a), any person who knowingly violates paragraph (1), (2), (3), or (4) of section 301(hh) shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.''.

SA 994. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ____. CENTER FOR POSTMARKET EVALUATION AND RESEARCH FOR DRUGS AND BIOLOGICS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506C the following:

''SEC. 507. DRUG SAFETY.

''(a) ESTABLISHMENT OF THE CENTER FOR POSTMARKET EVALUATION AND RESEARCH FOR DRUGS AND BIOLOGICS.—There is established within the Food and Drug Administration a Center for Postmarket Evaluation and Research for Drugs and Biologics (referred to in the section as the 'Center'). The Director of the Center shall report directly to the Commissioner of Food and Drugs.

''(b) DUTIES OF THE CENTER FOR POSTMARKET EVALUATION AND RESEARCH FOR DRUGS AND BIOLOGICS.—

''(1) RESPONSIBILITIES OF DIRECTOR.—The Director of the Center, in consultation with the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research, as appropriate, shall—

''(A) conduct postmarket risk assessment of drugs approved under section 505 of this Act and of biological products licensed under section 351 of the Public Health Service Act;

''(B) conduct and improve postmarket surveillance of approved drugs and licensed biological products using postmarket surveillance programs and activities (including MedWatch), risk-benefit analyses, adverse event reports, the scientific literature, any clinical or observational studies (including studies required under subsection (d) or (e)), and any other resources that the Director of the Center determines appropriate;

''(C) determine whether a study is required under subsection (d) or (e) and consult with the sponsors of drugs and biological products to ensure that such studies are completed by the date, and according to the terms, specified by the Director of the Center;

''(D) contract, or require the sponsor of an application or the holder of an approved application or license to contract, with the holders of domestic and international patient databases to conduct epidemiologic and other observational studies;

''(E) determine, based on postmarket surveillance programs and activities (including MedWatch), risk-benefit analyses, adverse event reports, the scientific literature, and any clinical or observational studies (including studies required under subsection (d) or (e)), and any other resources that the Director of the Center determines appropriate, whether a drug or biological product may present an unreasonable risk to the health of patients or the general public, and take corrective action if such an unreasonable risk may exist;

''(F) make information about the safety and effectiveness of approved drugs and licensed biological products available to the public and healthcare providers in a timely manner; and

''(G) conduct other activities as the Director of the Center determines appropriate to ensure the safety and effectiveness of all drugs approved under section 505 and all biological products licensed under section 351 of the Public Health Service Act.

''(2) DETERMINATION OF UNREASONABLE RISK.—In determining whether a drug or biological product may present an unreasonable risk to the health of patients or the general public, the Director of the Center, in consultation with the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research, as appropriate, shall consider the risk in relation to the known benefits of such drug or biological product.

''(c) SECRETARIAL AUTHORITY.—

''(1) IN GENERAL.—Approval of a drug under section 505 of this Act or issuance of a license for a biological product under section 351 of the Public Health Service Act may be subject to the requirement that the sponsor conduct 1 or more postmarket studies as described in subsection (d) or (e) of this section, or other postmarket studies as required by the Secretary, to validate the safety and effectiveness of the drug or biological product.

''(2) DEFINITION.—For purposes of this section, the term 'postmarket' means—

''(A) with respect to a drug, after approval of an application under section 505; and

''(B) with respect to a biological product, after licensure under section 351 of the Public Health Service Act.

''(d) PREAPPROVAL REVIEW.—

''(1) REVIEW OF APPLICATION.—

''(A) IN GENERAL.—

''(i) REVIEW.—At any time before a drug is approved under section 505 of this Act or a biological product is licensed under section 351 of the Public Health Service Act, the Director of the Center shall review the application (or supplement to the application), and any analyses associated with the application, of such drug or biological product.

''(ii) EFFECT OF APPROVAL OR LICENSURE.—The approval of a drug under section 505 or the licensure of a biological product under such section 351 shall not affect the continuation and completion of a review under clause (i).

''(B) LIMITATION.—In no case shall the review under subparagraph (A) delay a decision with respect to an application for a drug under section 505 of this Act or for a biological product under section 351 of the Public Health Service Act.

''(2) RESULT OF REVIEW.—The Director of the Center may, based on the review under paragraph (1)—

''(A) require that the sponsor of the application agree to conduct 1 or more postmarket studies to determine the safety or effectiveness of a drug or biological product, including such safety or effectiveness as compared to other drugs or biological products, to be completed by a date, and according to the terms, specified by the Director of the Center; or

''(B) contract, or require the sponsor of the application to contract, with a holder of a domestic or an international patient database to conduct 1 or more epidemiologic or other observational studies.

''(e) POSTMARKETING STUDIES OF DRUG SAFETY.—

''(1) IN GENERAL.—At any time after a drug is approved under section 505 of this Act or a biological product is licensed under section 351 of the Public Health Service Act, the Director of the Center, may—

''(A) require that the holder of an approved application or license conduct 1 or more studies to determine the safety or effectiveness of such drug or biological product, including such safety and effectiveness as compared to other drugs or biological products, to be completed by a date, and according to the terms, specified by such Director; or

''(B) contract, or require the holder of the approved application or license to contract, with a holder of a domestic or an international patient database to conduct 1 or more epidemiologic or other observational studies.

''(2) REVIEW OF OUTSTANDING STUDIES.—Not later than 90 days after the date of enactment of the Food and Drug Administration Safety Act of 2007, the Director of the Center shall—

''(A) review and publish a list in the Federal Register of any postmarketing studies outstanding on the date of enactment of the Food and Drug Administration Safety Act of 2007; and

''(B) as the Director determines appropriate, require the sponsor of a study described in subparagraph (A) to conduct such study under this subsection.

''(f) PUBLICATION OF PROGRESS REPORTS AND COMPLETED STUDIES.—

''(1) IN GENERAL.—The Director of the Center shall require that the sponsor of a study under subsection (d) or (e) submit to the Secretary—

''(A) not less frequently than every 90 days, an up-to-date report describing the progress of such study; and

''(B) upon the completion date of such study, the results of such study.

''(2) COMPLETION DATE.—For purposes of this section, the completion date of such study shall be determined by the Director of the Center.

''(g) DETERMINATIONS BY DIRECTOR.—

''(1) RESULTS OF STUDY.—The Director of the Center shall determine, upon receipt of the results of a study required under subsection (d) or (e)—

''(A) whether the drug or biological product studied may present an unreasonable risk to the health of patients or the general public; and

''(B) what, if any, corrective action under subsection (k) shall be taken to protect patients and the public health.

''(2) RESULTS OF EVIDENCE.—The Director of the Center may, at any time, based on the empirical evidence from postmarket surveillance programs and activities (including MedWatch), risk-benefit analyses, adverse event reports, the scientific literature, any clinical or observational studies (including studies required under subsection (d) or (e)), or any other resources that the Director of the Center determines appropriate—

''(A) make a determination that a drug or biological product may present an unreasonable risk to the health of patients or the general public; and

''(B) order a corrective action under subsection (k) be taken to protect patients and the public health.

''(3) REQUIRED CONSULTATION AND CONSIDERATIONS.—Before making a determination under paragraph (2), ordering a study under subsection (d) or (e), or taking a corrective action under subsection (k), the Director of the Center shall—

''(A) consult with the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research, as appropriate; and

''(B) consider—

''(i) the benefit-to-risk profile of the drug or biological product;

''(ii) the effect that a corrective action, or failure to take corrective action, will have on the patient population that relies on the drug or biological product; and

''(iii) the extent to which the drug or biological product presents a meaningful therapeutic benefit as compared to other available treatments.

''(h) PUBLIC INFORMATION.—Periodically, but not less often than every 90 days, the Secretary shall make available to the public, by publication in the Federal Register and posting on an Internet website, the following information:

''(1) Studies required under subsection (d) or (e) including—

''(A) the type of study;

''(B) the nature of the study;

''(C) the primary and secondary outcomes of the study;

''(D) the date the study was required under subsection (d) or (e) or was agreed to by the sponsor;

''(E) the deadline for completion of the study; and

''(F) if the study has not been completed by the deadline under subparagraph (E), a statement that explains why.

''(2) The periodic progress reports and results of completed studies described under subsection (f).

''(3) Any determinations made by the Director of the Center under subsection (g), including—

''(A) reasons for the determination, including factual basis for such determination;

''(B) reference to supporting empirical data; and

''(C) an explanation that describes why contrary data is insufficient.

''(i) DRUG ADVISORY COMMITTEE.—The Drug Safety and Risk Management Advisory Committee within the Center of the Food and Drug Administration shall—

''(1) meet not less frequently than every 180 days; and

''(2) make recommendations to the Director of the Center with respect to—

''(A) which drugs and biological products should be the subject of a study under subsection (d) or (e);

''(B) the design and duration for studies under subsection (d) or (e);

''(C) which drugs and biological products may present an unreasonable risk to the health of patients or the general public; and

''(D) appropriate corrective actions under subsection (k).

''(j) PENALTIES.—

''(1) IN GENERAL.—If the Secretary determines, after notice and opportunity for an informal hearing, that a sponsor of a drug or biological product or other entity has failed to complete a study required under subsection (d) or (e) by the date or to the terms specified by the Secretary under such subsection, the Secretary may order such sponsor or other entity to—

''(A) complete the study in a specified time;

''(B) revise the study to comply with the terms specified by the Secretary under subsection (d) or (e); or

''(C) pay a civil penalty.

''(2) AMOUNT OF PENALTIES.—

''(A) IN GENERAL.—The civil penalty ordered under paragraph (1) shall be $250,000 for the first 30-day period after the date specified by the Secretary that the study is not completed, and shall double in amount for every 30-day period thereafter that the study is not completed.

''(B) LIMITATION.—In no case shall a penalty under subparagraph (A) exceed $2,000,000 for any 30-day period.

''(3) NOTIFICATION OF PENALTY.—The Secretary shall publish in the Federal Register any civil penalty ordered under this subsection.

''(k) RESULT OF DETERMINATION.—

''(1) IN GENERAL.—If the Director of the Center makes a determination that a drug or biological product may present an unreasonable risk to the health of patients or the general public under subsection (g), such Director shall order a corrective action, as described under paragraph (2).

''(2) CORRECTIVE ACTIONS.—The corrective action described under subsection (g)—

''(A) may include—

''(i) requiring a change to the drug or biological product label by a date specified by the Director of the Center;

''(ii) modifying the approved indication of the drug or biological product to restrict use to certain patients;

''(iii) placing restriction on the distribution of the drug or biological product to ensure safe use;

''(iv) requiring the sponsor of the drug or biological product or license to establish a patient registry;

''(v) requiring patients to sign a consent form prior to receiving a prescription of the drug or biological product;

''(vi) requiring the sponsor to monitor sales and usage of the drug or biological product to detect unsafe use;

''(vii) requiring patient or physician education; and

''(viii) requiring the establishment of a risk management plan by the sponsor; and

''(B) shall include the requirements with respect to promotional material under subsection (l)(1).

''(3) PENALTIES.—

''(A) IN GENERAL.—If the Secretary determines, after notice and opportunity for an informal hearing, that a sponsor of a drug or biological product has failed to take the corrective action ordered by the Director of the Center under this subsection or has failed to comply with subsection (l)(2), the Secretary may order such sponsor to pay a civil penalty.

''(B) AMOUNT OF PENALTIES.—

''(i) IN GENERAL.—The civil penalty ordered under subparagraph (A) shall be $250,000 for the first 30-day period that the sponsor does not comply with the order under paragraph (1), and shall double in amount for every 30-day period thereafter that the order is not complied with.

''(ii) LIMITATION.—In no case shall a penalty under clause (i) exceed $2,000,000 for any 30-day period.

''(C) NOTIFICATION OF PENALTY.—The Secretary shall publish in the Federal Register any civil penalty ordered under this paragraph.

''(l) PROMOTION MATERIAL.—

''(1) SAFETY ISSUE.—If the Director of the Center makes a determination that a drug or biological product may present an unreasonable risk to the health of patients or the general public under subsection (g), such Director, in consultation with the Division of Drug Marketing, Advertising, and Communications of the Food and Drug Administration, shall—

''(A) notwithstanding section 502(n), require that the sponsor of such drug or biological product submit to the Director of the Center copies of all promotional material with respect to the drug or biological product not less than 30 days prior to the dissemination of such material; and

''(B) require that all promotional material with respect to the drug or biological product include certain disclosures, which shall be displayed prominently and in a manner easily understood by the general public, including—

''(i) a statement that describes the unreasonable risk to the health of patients or the general public as determined by the Director of the Center;

''(ii) a statement that encourages patients to discuss potential risks and benefits with their healthcare provider;

''(iii) a description of the corrective actions required under subsection (k);

''(iv) where appropriate, a statement explaining that there may be products available to treat the same disease or condition that present a more favorable benefit-to-risk profile, and that patients should talk to their healthcare provider about the risks and benefits of alternative treatments;

''(v) a description of any requirements of outstanding clinical and observational studies, including the purpose of each study; and

''(vi) contact information to report a suspected adverse reaction.

''(2) NEW PRODUCTS; OUTSTANDING STUDIES.—For the first 2-year period after a drug is approved under section 505 of this Act or a biological product is licensed under section 351 of the Public Health Service Act, and with respect to drugs and biological products for which there are outstanding study requirements under subsection (d) or (e), the Director of the Center, in consultation with the Division of Drug Marketing, Advertising, and Communications of the Food and Drug Administration, shall—

''(A) notwithstanding section 502(n), require that the sponsor of such drug or biological product submit to the Director of the Center copies of all promotional material with respect to the drug or biological product not less than 30 days prior to the dissemination of such material; and

''(B) require that all promotional material with respect to the drug or biological product include certain disclosures, which shall be displayed prominently and in a manner easily understood by the general public, including—

''(i) a statement explaining that the drug or biological product is newly approved or licensed or the subject of outstanding clinical or observational studies, as the case may be, and, as a result, not all side effects or drug interactions may be known;

''(ii) the number of people in which the drug or biological product has been studied and the duration of time during which the drug or biological product has been studied;

''(iii) a statement that encourages patients to discuss the potential risks and benefits of treatment with their healthcare provider;

''(iv) a description of any requirements of outstanding clinical and observational studies, including the purpose of each study; and

''(v) contact information to report a suspected adverse reaction.

''(3) EFFECT OF VOLUNTARY SUBMISSION.—Paragraphs (1)(A) and (2)(A) shall not apply to the sponsor of a drug or biological product if such sponsor has voluntarily submitted to the Division of Drug Marketing, Advertising, and Communications of the Food and Drug Administration all promotional material with respect to the drug or biological product prior to the dissemination of such material.

''(m) WITHDRAWAL OR SUSPENSION OF APPROVAL OR LICENSURE.—

''(1) IN GENERAL.—The Director of the Center, may withdraw or suspend approval of a drug or licensure of a biological product using expedited procedures (as prescribed by the Secretary in regulations promulgated not later than 1 year after the date of enactment of the Food and Drug Administration Safety Act of 2007, which shall include an opportunity for an informal hearing) after consultation with the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research, as appropriate, and any other person as determined appropriate by the Director of the Center, if—

''(A) the Director of the Center makes a determination that the drug or biological product may present an unreasonable risk to the health of patients or the general public, and that risk cannot be satisfactorily alleviated by a corrective action under subsection (k); or

''(B) the sponsor fails to comply with an order or requirement under this section.

''(2) PUBLIC INFORMATION.—The Secretary shall make available to the public, by publication in the Federal Register and posting on an Internet website, the details of the consultation described in paragraph (1), including—

''(A) the reason for the determination to withdraw, suspend, or failure to withdraw or suspend, approval for the drug or licensure for the biological product;

''(B) the factual basis for such determination;

''(C) reference to supporting empirical data;

''(D) an explanation that describes why contrary data is insufficient; and

''(E) the position taken by each individual consulted.

''(n) EFFECT OF SECTION.—The authorities conferred by this section shall be separate from and in addition to the authorities conferred by section 505B.

''(o) ADMINISTRATION OF SECTION.—The provisions of this section shall be carried out by the Secretary, acting through the Director of the Center.''.

(b) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by inserting after subsection (j) the following:

''(k) If it is a drug or biological product for which the sponsor of an application or holder of an approved application or license has not complied with an order or requirement under section 507.''.

(c) REPORT ON DEVICES.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Commissioner of Food and Drugs, the Director of the Center for Postmarket Evaluation and Research for Drugs and Biologics, and the Director of the Center for Devices and Radiological Health, shall submit to Congress a report that—

(1) identifies gaps in the current process of postmarket surveillance of devices approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.);

(2) includes recommendations on ways to improve gaps in postmarket surveillance of devices; and

(3) identifies the changes in authority needed to make those improvements, recognizing the legitimate differences between devices and other medical products regulated by the Food and Drug Administration.

(d) TRANSFER OF FUNCTIONS.—The functions and duties of the Office of Surveillance and Epidemiology, including the Drug Safety

and Risk Management Advisory Committee, of the Food and Drug Administration on the day before the date of enactment of this Act shall be transferred to the Center for Postmarket Evaluation and Research for Drugs and Biologics established under section 507 of the Federal Food, Drug, and Cosmetic Act (as added by this section). The Center for Postmarket Evaluation and Research for Drugs and Biologics shall be a separate entity within the Food and Drug Administration and shall not be an administrative office of the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section (and the amendments made by this section)—

(1) $50,000,000 for fiscal year 2008;

(2) $75,000,000 for fiscal year 2009;

(3) $100,000,000 for fiscal year 2010;

(4) $125,000,000 for fiscal year 2011; and

(5) $150,000,000 for fiscal year 2012.

SA 995. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of subtitle E of title II, insert the following:

SEC. 2__. AUTHORITY OF THE OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY; CHIEF SAFETY OFFICER.

(a) AUTHORITY.—With respect to all actions of the Food and Drug Administration related to postmarketing drug safety, including labeling changes, postapproval studies, and restrictions on distribution or use of drugs with serious risks, the Office of Surveillance and Epidemiology (or successor office) of such Administration and the Office of New Drugs (or successor office) of such Administration shall make decisions jointly. In the event of a disagreement with respect to an action related to postmarketing drug safety, including labeling changes, postapproval studies, and restrictions on distribution or use of drugs with serious risks, between such 2 offices, the Commissioner of Food and Drugs shall make the decision with respect to such action.

(b) CHIEF SAFETY OFFICER.—Notwithstanding any other provision of law, the Director of the Office of Surveillance and Epidemiology (or successor office) of the Food and Drug Administration shall serve as the Chief Postmarket Drug Safety Officer within the Food and Drug Administration. In such capacity, the Director shall serve as a liaison between the Office of the Commissioner of Food and Drugs and employees of the Food and Drug Administration. To ensure drug safety concerns are identified and promptly evaluated and resolved, any employee of the Center for Drug Evaluation and Research within the Food and Drug Administration who has drug safety concerns may report such concerns to the Chief Postmarket Drug Safety Officer.

SA 996. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by section 251 of the bill, add the following:

''(r) CERTIFICATION OF INFORMATION.—When submitting information in support of a new drug application or a supplemental new drug application, the sponsor shall certify, in writing, that all clinical trials, federally or privately funded, whether conducted within or outside the United States, related to the safety or efficacy of the drug under review, have been submitted to the Food and Drug Administration.''.

SA 997. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

Strike clause (i) of section 402(j)(3)(A) of the Public Health Service Act, as added by this bill, and insert the following:

''(i) IN GENERAL.—

''(I) REQUIREMENT.—Not later than 90 days after the date of enactment of the Food and Drug Administration Revitalization Act, for all clinical trials (except as provided in subclause (II)), whether federally or privately funded, conducted to test the safety or efficacy (including comparative efficacy), of any drug or device (including those drugs or devices approved or cleared by the Secretary), the Secretary shall ensure that the registry data bank includes links to results information for such clinical trial—

''(aa) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

''(bb) not later than 30 days after such information becomes publicly available, as applicable.

''(II) EXCEPTION.—The requirement of subclause (I) shall not apply to phase I clinical investigations conducted to test solely the safety of an unapproved drug or unlicensed biological product, or pilot or feasibility studies conducted to confirm the design and operating specifications of an unapproved or not yet cleared medical device.

''(III) VOLUNTARY SUBMISSION.—A responsible party for a clinical trial that is not an applicable drug clinical trial or an applicable device clinical trial may submit to the Secretary results information for a clinical trial described in subclause (II).

At the end section 402(j)(4) of the Public Health Service Act, as added by this bill, insert the following:

''(F) TRIALS CONDUCTED OUTSIDE OF THE UNITED STATES.—

''(i) IN GENERAL.—With respect to clinical trials described in clause (ii), the responsible party shall submit to the Secretary the information required under this subsection. The Secretary shall ensure that such information and the results of such clinical trials are made available to the public in a timely manner and as soon as practicable after receiving such information. Failure to comply with this paragraph shall be deemed to be a failure to submit information as required under this subsection, and the appropriate remedies and sanctions under this section shall apply.

''(ii) CLINICAL TRIAL DESCRIBED.—A clinical trial is described in this clause if—

''(I) such trial is conducted outside of the United States; and

''(II) the data from such trial is—

''(aa) submitted to the Secretary as part of an application, including a supplemental application, for a drug or device under section 505, 510, 515, or 520 of the Federal Food, Drug, and Cosmetic Act or for the biological product under section 351 of this Act; or

''(bb) used in advertising or labeling to make a claim about the drug or device involved.

SA 998. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place in section 505(o) of the Federal, Food, Drug, and Cosmetic, as added by section 202, insert the following:

''(9) CIVIL MONETARY PENALTY.—Notwithstanding any other provision of this Act, an applicant (as such term is defined for purposes of this section) that knowingly fails to comply with a requirement of an approved risk evaluation and mitigation strategy under this subsection shall be subject to a civil money penalty of $250,000 for the first 30-day period that the applicant is in noncompliance, and such amount shall double for every 30-day period thereafter that the requirement is not complied with, not to exceed $2,000,000.''.

SA 999. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by section 251 of the bill, add the following:

''(r) CERTIFICATION OF INFORMATION.—

''(1) CERTIFICATION.—

''(A) REQUIREMENT.—When submitting information in support of a new drug application or a supplemental new drug application, the sponsor shall certify, in writing, that the information submitted to the Food and Drug Administration complies with the requirements of this Act and that such information is not false or misleading.

''(B) FAILURE TO SUBMIT.—If the sponsor fails to provide a certification as required under subparagraph (A), the Secretary shall transmit to such sponsor a notice stating that such sponsor shall submit the certification by a date determined by the Secretary. If, by the date specified by the Secretary in the notice under this subparagraph, the Secretary has not received the certification, the Secretary, after providing the opportunity for a hearing, shall order such sponsor to pay a civil monetary penalty of $10,000 for each day after such date that such certification is not submitted.

''(C) ADDITIONAL CIVIL MONETARY PENALTY.—If the Secretary determines, after notice and opportunity for a hearing, that a sponsor knew or should have known that the information submitted in support of a new drug application or a supplemental new drug application was false or inaccurate, the Secretary shall order such sponsor to pay a civil monetary penalty of not less than $100,000, but not to exceed $2,000,000.

''(2) REQUIRED STATEMENT.—The certification under paragraph (1) shall include a statement that all clinical trials, federally or privately funded, whether conducted within or outside the United States, related to the safety or efficacy of the drug under review, have been submitted to the Food and Drug Administration.

''(3) CLINICAL COMPARISON STUDIES.—

''(A) IN GENERAL.—The Secretary shall deposit funds collected under paragraph (1)

into an account and use such funds shall be used, after consultation with the Director of the Agency for Healthcare Research and Quality, to fund studies that compare the clinical effectiveness of 2 or more treatments for similar diseases or conditions.

''(B) PRIORITY LIST.—The Secretary shall award funding under subparagraph (A) based on a priority list established, not later than 6 months after the date of enactment of this Act, by the Director of the Agency for Healthcare Research and Quality and periodically updated as determined appropriate by the Director.

''(4) DRUG CONSULTATIONS.—Not later than 90 days after the date of the completion of a written consultation on a drug concerning the drug's safety, as conducted by the Office of Surveillance and Epidemiology, regardless of whether such consultation was initiated by such Office or by an entity outside of the Office, the Commissioner of Food and Drugs shall make available to the public a full copy of such consultation.

''(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to alter or amend section 301(j) of this Act or section 1905 of title 18, United States Code.''.

SA 1000. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE____FDA EMPLOYEE PROTECTIONS

SEC. ____01. SHORT TITLE.

This title may be cited as the ''FDA Employee Rights Protection Act''.

SEC. ____02. EMPLOYEES' RIGHT TO PETITION CONGRESS.

The right of all employees of the Food and Drug Administration, individually or collectively, to petition Congress or a Member of Congress, or to furnish information to either House of Congress, or to a committee or Member thereof, shall not be interfered with or denied by any employee of the Food and Drug Administration, the Department of Health and Human Services, the Department of Justice, or any other employee of the Executive Branch of the Federal Government.

SEC. __03. PENALTIES.

Any individual who intentionally or willfully obstructs, impedes, or otherwise interferes with an employee's right to furnish information as described in section ____02 shall be subject to a fine of not less than $10,000 per violation, or imprisoned for not more than 1 year, or both.

SA 1001. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ____. SUBPOENA AUTHORITY OF THE COMMISSIONER OF FOOD AND DRUGS.

(a) IN GENERAL.—Section 310 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 337) is amended by adding at the end the following:

''(c) For the purpose of—

''(1) any hearing, investigation, or other proceeding respecting a violation of this Act,

''(2) any hearing, investigation, or other proceeding to determine if a person is in compliance with a standard or other requirement under this Act, or

''(3) any hearing, investigation, or other proceeding to establish a standard or other requirement under this Act,

the Commissioner may issue subpoenas requiring the attendance and testimony of witnesses and the production of documentary evidence. Such attendance of witnesses and production of evidence at the designated place of such hearing, investigation, or other proceeding may be required from any place in the United States or in any territory or possession of the United States. Subpoenas of the Commissioner shall be served by a person authorized by the Commissioner by delivering a copy thereof to the person named therein or by certified mail addressed to such person at such person's last known dwelling place or principal place of business. A verified return by the person so serving the subpoena setting forth the manner of service, or, in the case of service by certified mail, the return post office receipt therefor signed by the person so served, shall be proof of service. Witnesses so subpoenaed shall be paid the same fees and mileage as are paid witnesses in the district courts of the United States.

''(d) In case of a refusal to obey a subpoena duly served upon any person under subsection (c), any district court of the United States for the judicial district in which such person charged with refusal to obey is found, resides, or transacts business, upon application by the Commissioner, shall have jurisdiction to issue an order requiring such person to appear and give testimony or to appear and produce evidence, or both. The failure to obey such order of the court may be punished by the court as contempt thereof.''.

(b) ENFORCEMENT.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(jj) The failure or refusal to obey a subpoena issued by the Commissioner under section 310(c).''.

SA 1002. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ____. REQUIREMENT TO DOCUMENT CONTACT WITH DRUG SPONSORS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 251, is further amended by adding at the end the following:

''(r) REQUIREMENT TO DOCUMENT CONTACT WITH DRUG SPONSOR.—Each employee of the Food and Drug Administration shall document, in writing, each communication or contact, and the purpose of such communication or contact, that such official has with a sponsor of a drug for which an application is filled pursuant to subsection (b) or (j).''.

SA 1003. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

After section 211 of the bill, insert the following:

SEC. 211A. REQUIREMENT TO SUBMIT INFORMATION ELECTRONICALLY.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.), as amended by this Act, is further amended by adding at the end the following:

''SEC. 567. REQUIREMENT TO SUBMIT INFORMATION ELECTRONICALLY.

''Not later than 5 years after the date of enactment of the Food and Drug Administration Revitalization Act, the Secretary shall ensure that any information required to be submitted to the Food and Drug Administration under section 505, 505A, 505B, 506A, 506B, 510, 512, 513, 515, 519, 520, or 526 is submitted in electronic form that is interoperable with the Food and Drug Administration's information technology systems.''.

SA 1004. Ms. LANDRIEU proposed an amendment to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

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.

(a) Notwithstanding any other provision of law, the Food and Drug Administration shall not restrict the sale by a turtle farmer, wholesaler or 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 of State health protections described in subsection (a) are insufficient to protect consumers against infectious diseases acquired from such turtles at the time of sale.

SA 1005. Mr. LEVIN submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. SAFETY OF FOOD ADDITIVES.

Not later than 90 days after the date of enactment of this Act, the Food and Drug Administration shall issue a report on the question of whether substances used in fresh meat that are capable of artificially keeping such meat red beyond the point of spoilage of such meat, create a health risk or are misleading to consumers.

SA 1006. Ms. MURKOWSKI submitted an amendment intended to be proposed by her to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of section 505(o)(6) of the Federal Food, Drug, and Cosmetic Act, as added by section 202 of the bill, insert the following:

''(H) In a case where a drug may be prescribed only by a physician with particular training or experience, or who is specially certified, a health care provider who is not so certified or trained to prescribe the drug may enter into a cooperation plan with a physician who has particular training or experience, or is specially certified, in order to prescribe such drug with the informed consent of the patient. The Commissioner of Food and Drugs shall determine the requirements for such cooperation plan.

SA 1007. Mr. REID (for Mr. BUNNING) proposed an amendment to the resolution S. Res. 162, commemorating and acknowledging the dedication and sacrifice made by the men and women who have lost their lives while serving as law enforcement officers; as follows:

On page 2, strike the first whereas clause and insert:

Whereas peace officers are on the front lines in protecting the schools and schoolchildren of the United States;

AUTHORTIY FOR COMMITTEES TO MEET

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Agriculture, Nutrition and Forestry be authorized to conduct a hearing during the session of the Senate on Tuesday, May 1, 2007 at 2 p.m. in 328A, Senate Russell Office Building. The purpose of this Committee hearing will be to consider conservation policy recommendations for the farm bill.

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

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Commerce, Science, and Transportation be authorized to hold a hearing during the session of the Senate on Tuesday, May 1, 2007, at 2:30 p.m., in room 253 of the Russell Senate Office Building. The purpose of the hearing is to examine Electronic On-Board Recorders (EOBRs) and Truck Driver Fatigue, and related regulations to be issued by the Federal Motor Carrier Safety Administration.

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

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Finance be authorized to meet during the Session of the Senate on Tuesday, May 1, 2007, at 10 a.m., in 215 Dirksen Senate Office Building, to hear testimony on ''Advanced Technology Vehicles: The Road Ahead.''

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

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Committee on Homeland Security and Governmental Affairs be authorized to meet on Tuesday, May 1, 2007, at 9:30 a.m. to consider the nomination of Howard C. Weizmann to be Deputy Director of the Office of Personnel Management.

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

COMMITTEE ON THE JUDICIARY

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Senate Committee on the Judiciary be authorized to meet to conduct a hearing on Process Patents for Tuesday, May 1, 2007, at 2:30 p.m. in Dirksen Senate Office Building Room 226.

Witness list: Wayne Herrington, Assistant General Counsel, United States International Trade Commission, Washington, DC; John R. Thomas, Professor of Law, Georgetown University Law Center, Washington, DC; Mike Kirk, Executive Director, American Intellectual Property Law Association, Arlington, VA; and Christopher A. Cotropia, Professor of Law, Richmond School of Law, Richmond, VA.

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

SEAPOWER SUBCOMMITTEE

Mr. SCHUMER. Mr: President, I ask unanimous consent that the Seapower Subcommittee of the Committee on Armed Services be authorized to meet during the session of the Senate on Tuesday, May 1, 2007, at 2:30 p.m., in open session to receive testimony on Department of Defense Transportation programs in review of the defense authorization request for fiscal year 2008 and the future years defense program.

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

SELECT COMMITTEE ON INTELLIGENCE

Mr. SCHUMER. Mr. President, I ask unanimous consent that the Select Committee on Intelligence be authorized to meet during the session of the Senate on May 1, 2007 at 2:30 p.m. to hold a hearing.

The PRESIDING OFFICER. Without object it is so ordered.

PRIVILEGES OF THE FLOOR

Mr. REED. Mr. President, I ask unanimous consent that Jessica Gerrity, a fellow in my office, be accorded the privilege of the floor.

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

Mr. KENNEDY. Mr. President, I ask unanimous consent that Adam Solander, an intern on my staff, be granted floor privileges during the debate on the Food and Drug Administration Revitalization Act.

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

Mr. HATCH. Mr. President, I ask unanimous consent that Remy Yucel, a fellow in my staff, be granted the privilege of the floor for the pendency of the consideration of S. 1082, including any conference report.

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

NOTICE: PUBLIC FINANCIAL DISCLOSURE REPORTS

The filing date for 2006 Public Financial Disclosure reports is Tuesday, May 15, 2007. Senators, political fund designees and staff members whose salaries exceed 120% of the GS–15 pay scale must file reports.

Public Financial Disclosure reports should be submitted to the Senate Office of Public Records, 232 Hart Building, Washington, D.C. 20510–7116.

The Public Records office will be open from 9:00 a.m. to 6:00 p.m. on the filing date to accept these filings. For further information, please contact the Public Records office at (202) 224–0322.

APPOINTMENTS

The ACTING PRESIDENT pro tempore. The Chair, pursuant to Executive Order 12131, as amended and extended, reappoints and appoints the following Members to the President's Export Council: Reappointment: the Senator from North Dakota (Mr. DORGAN); Appointment: the Senator from Ohio (Mr. BROWN) and the Senator from Michigan (Ms. STABENOW).

MEASURE PLACED ON CALENDAR—H.R. 1332

Mr. REID. Mr. President, I understand that H.R. 1332 is at the desk and due for a second reading.

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

The clerk will report.

The legislative clerk read as follows:

A bill (H.R. 1332) to improve the access to capital programs of the Small Business Administration, and for other purposes.

Mr. REID. Mr. President, I object to any further proceedings at this time.

The ACTING PRESIDENT pro tempore. Objection is heard.

The bill will be placed on the calendar.

EXPRESSING THE SENSE OF THE SENATE ON EFFORTS TO CONTROL GUN VIOLENCE IN GUATEMALA

Mr. REID. Mr. President, I ask unanimous consent that the Foreign Relations Committee be discharged from consideration of S. Res. 155 and that the Senate proceed to its consideration.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered. The clerk will report the resolution by title.

The legislative clerk read as follows:

A resolution (S. Res. 155) expressing the sense of the Senate on efforts to control violence and strengthen the rule of law in Guatemala.

There being no objection, the Senate proceeded to consider the resolution.

Mr. REID. Mr. President, I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, the motion to reconsider be laid upon the table, and that any statements relating thereto be printed in the RECORD as if read.

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

The resolution (S. Res. 155) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 155

Whereas warring parties in Guatemala ended a 36-year internal armed conflict with a peace agreement in 1996, but the country has since faced alarming levels of violence, organized crime, and corruption;

Whereas the alleged involvement of senior officials of the National Civilian Police in the murder of three Salvadoran parliamentarians and their driver, and the subsequent killing of four of the police officers while in custody underscored the need to purge and strengthen law enforcement and judicial institutions in Guatemala;

Whereas high-level officials of the Government of Guatemala have acknowledged the infiltration of organized criminal networks into the state apparatus and the difficulty of combating these networks when they are deeply entrenched in public institutions;

Whereas, in its 2006 Country Report on Human Rights Practices in Guatemala, the Department of State noted that police corruption was a serious problem in Guatemala and that there were credible allegations of involvement by individual police officers in criminal activity, including rapes, killings, and kidnappings;

Whereas, in its most recent report on Guatemala, the United Nations High Commissioner for Human Rights notes that impunity continues to undermine the credibility of the justice system in Guatemala and that the justice system is still too weak to confront organized crime and its powerful structures; and

Whereas, the Government of Guatemala and the United Nations signed an agreement on December 12, 2006, to establish the International Commission against Impunity in Guatemala (Comisión Internacional Contra la Impunidad en Guatemala—CICIG), to assist local authorities in investigating and dismantling the illegal security groups and clandestine organizations that continue to operate in Guatemala: Now, therefore, be it

Resolved, That—

(1) it is the sense of the Senate that the International Commission against Impunity in Guatemala is an innovative mechanism to support local efforts to confront the entrenched and dangerous problem posed by illegal armed groups and clandestine security organizations in Guatemala and their infiltration into state institutions;

(2) the Senate commends the Government of Guatemala, local civil society organizations, and the United Nations for such a creative effort;

(3) the Senate encourages the Guatemalan Congress to enact necessary legislation required to implement the International Commission against Impunity in Guatemala and other pending legislation needed to fulfill the 1996 peace agreement;

(4) the Senate calls on the Government of Guatemala and all sectors of society in Guatemala to unreservedly support the investigation and prosecution of illegal armed groups and clandestine security organizations; and

(5) the Senate reiterates its commitment to support the Government of Guatemala in its efforts to strengthen the rule of law in that country, including the dismantling of the clandestine groups, the purging of the police and judicial institutions, and the implementation of key justice and police reforms.

RECOGNIZING THE ACHIEVEMENTS OF THE U.S. AIR FORCE ACADEMY FOOTBALL PROGRAM

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of S. Res. 181.

The ACTING PRESIDENT pro tempore. The clerk will report the resolution by title.

The legislative clerk read as follows:

A resolution (S. Res. 181) honoring and recognizing the achievements of the United States Air Force Academy football program over the last 27 years.

There being no objection, the Senate proceeded to consider the resolution.

Mr. REID. Mr. President, I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, and the motion to reconsider be laid upon the table.

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

The resolution (S. Res. 181) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 181

Whereas, Fisher DeBerry, originally of Cheraw, South Carolina, coached football at the United States Air Force Academy for 27 years, 23 of which as head coach;

Whereas, Fisher DeBerry is the winningest head coach of any United States service academy with a record of 169–109–1;

Whereas, Fisher DeBerry has amassed a 35–11 record against the United States Military Academy and the United States Naval Academy, and led the U.S. Air Force Academy to 14 of its 16 Commander-in-Chief Trophy titles;

Whereas, Fisher DeBerry led his Air Force teams to 3 conference championships and 12 bowl games;

Whereas, Fisher DeBerry has been recognized numerous times for his coaching success, including selection as National Coach of the Year for 1985; selection 3 times as Western Athletic Conference Coach of the Year; induction into the South Carolina Sports Hall of Fame; induction into the Colorado Springs Sports Hall of Fame; induction into the Independence Bowl Hall of Fame; the 2001 State Farm Coach of Distinction honor; an honorary doctorate of humanities from Wofford College; service as president of the American Football Coaches Association (AFCA); and service as Chairman of the AFCA ethics committee;

Whereas, Fisher DeBerry has acted as a pillar of the Colorado Springs, Colorado, community during the past 27 years through his active involvement and volunteerism with local church, charity, and community organizations;

Whereas, in 2004 Fisher DeBerry founded the Fisher DeBerry Foundation, which is dedicated to the support and education of single mothers and their children, as well as other charitable causes;

Whereas, Fisher DeBerry has served as a positive influence and role model to numerous future Air Force officers, including coaching 3,375 players; having a graduation success rate of 91.6 percent among his players; and producing 19 All-American players,

124 All-Conference players, 11 Academic All-Americans, and 9 Postgraduate Scholarship winners;

Whereas, Fisher DeBerry imparted to his players the core values of the United States Air Force: Integrity First, Service Before Self, and Excellence In All We Do; and

Whereas, the United States Air Force Academy football program under the leadership of Fisher DeBerry has served as an example of these values for its community and the entire Nation: Now, therefore, be it

Resolved, That the United States Senate honors and recognizes the numerous contributions made by the United States Air Force Academy football program over the last 27 years to Colorado Springs and the surrounding communities, the United States Air Force Academy, and the United States Air Force.

HONORING THE LIFE OF JACK VALENTI

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of S. Res. 182.

The ACTING PRESIDENT pro tempore. The clerk will report the resolution by title.

The legislative clerk read as follows:

A resolution (S. Res. 182) honoring the life of Jack Valenti.

There being no objection, the Senate proceeded to consider the resolution.

THE PASSING OF MR. JACK VALENTI

Mr. HATCH. Mr. President, I wish to honor my good friend Jack Valenti, who, passed away last week on April 26.

Throughout his life, Jack Valenti wore several hats, including that of a soldier, a devoted public servant, and a pioneer in the film industry.

Jack was born on September 5, 1921, in Houston, TX and was the grandson of Sicilian immigrants. At age 15, he became the youngest high school graduate in the history of the city of Houston and began a career as an office boy with Exxon Oil.

Jack served honorably in the Army Air Corps during World War II, flying in 51 separate combat missions as pilot of the B–25 attack bomber with the 12th Air Force in Italy. He obtained the rank of lieutenant and received multiple decorations, including the Distinguished Flying Cross, the Air Medal with four clusters, the Distinguished Unit Citation with one cluster, and the European Theater Ribbon with four battle stars.

After serving in the war, Jack attended college at the University of Houston, doing all his undergraduate work at night as he worked during the day. He earned a bachelor of arts degree in 1946 and later became the University of Houston's first graduate ever to be admitted to Harvard Business School. He received an MBA from Harvard in 1948.

In the intervening years, Jack held many positions in this town, but in 1966 Jack resigned from a top position in the White House to become only the third president of the Motion Picture Association of America, MPAA. He held this, his most famous position, for 38 years before retiring in 2004.

As president of MPAA, Jack arbitrated one of the most famous developments the film industry has ever come out with—the voluntary rating system. The ratings ''G,'' ''PG,'' ''PG–13'' and ''R'' have become staples, not only in the movie-going practices of every American but also in our Nation's cultural consciousness. However, more important than the societal notions and the clichéd images associated with these ratings is the real assistance that this system has provided to parents and families in evaluating the appropriateness of various movies. Indeed, the MPAA rating system pioneered by Jack Valenti has become a prime example of the effectiveness of industry self-regulation without government intervention, and I am very grateful for Jack's work in this area even when many in his industry fought him along the way.

In addition to pioneering the rating system, Jack Valenti also worked to advance the film industry into the 21st century. Indeed, during his tenure at the MPAA, he presided over unprecedented changes in the worldwide film industry, including the advancement of the digital era. I remember having several conversations with Jack as the film industry struggled to deal with the new challenges presented by digital distribution of their content. Together, Jack and I worked tirelessly to balance the competing demands of consumer's rights and the protection of one of America's largest exports—entertainment.

With Jack's help, we were able to refocus the Federal Government's resources to more effectively protect the creative genius of a great American industry—the film industry. We all know how blatantly some bad actors around the world pirate America's movies and rob the United States of jobs. Thanks to Jack's efforts, we have made great strides in this area and laid the groundwork to allow us to stamp out this criminal activity in the years ahead. Combating the theft and piracy of intellectual property was a real passion for Jack, and I was privileged to work with him in this endeavor.

Mr. President, those of us who knew Jack Valenti personally will always remember him as a charitable man who was devoted to his family. While his influence on the film industry has been famous and unmistakable, many of us will remember him more for the personal friendship we shared with him. I will miss him greatly.

Mr. REID. Mr. President, I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, the motion to reconsider be laid upon the table, and that any statements relating to the resolution be printed in the RECORD.

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

The resolution (S. Res. 182) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 182

Whereas Jack Valenti was born September 5, 1921, in Houston, Texas, the grandson of Sicilian immigrants, Joe and Josephine Valenti, and was the youngest high school graduate in the city at age 15;

Whereas Jack Valenti married his beloved Mary Margaret in 1962, with whom he had 3 children, John, Alexandra, and Courtenay;

Whereas Jack Valenti joined the United States Army Air Forces in 1942 and flew 51 combat missions as a pilot of a B-25 attack bomber with the 12th Air Force in Italy during World War II, obtained the rank of lieutenant, and received 4 decorations, including the Distinguished Flying Cross, the Air Medal with 4 clusters, the Distinguished Unit Citation with one cluster, and the European Theater Ribbon with 4 battle stars;

Whereas Jack Valenti received a B.A. degree from the University of Houston in 1946 after doing all of his undergraduate work at night and working during the day, and became the first University of Houston graduate to be admitted to Harvard Business School, receiving an M.B.A. degree in 1948;

Whereas, in 1952, Jack Valenti cofounded Weekley and Valenti, an advertising and political consulting agency that worked on Dwight D. Eisenhower's presidential campaign in Texas, Representative Albert Thomas's run for Congress, and John Connally's campaign for Governor of Texas;

Whereas Jack Valenti met then-Senate Majority Leader Lyndon B. Johnson in 1957, the two became close friends, and Valenti worked on Lyndon Johnson's presidential campaign during the primaries of 1960;

Whereas Weekley and Valenti handled press during President John F. Kennedy's and Vice President Lyndon Johnson's fateful trip to Dallas, Texas, in November 1963;

Whereas Jack Valenti became the first special assistant hired when Lyndon Johnson ascended to the Presidency;

Whereas Jack Valenti resigned his White House post in 1966 and went on to serve as the president of the Motion Picture Association of America (MPAA) for the next 38 years;

Whereas Jack Valenti, as president of the MPAA, created the voluntary film rating system that is still in place today, which provides parents with advance information they can use to determine which movies are appropriate for their children;

Whereas Jack Valenti's persona and skill combined to give the motion picture industry a strong and enduring presence in the Nation's capital, which grew year by year during his nearly 4 decade tenure at the MPAA;

Whereas Jack Valenti presided over a worldwide change in the motion picture industry, ushered movies into the digital era, championed artists' rights, and condemned intellectual property theft;

Whereas Jack Valenti authored 5 books, including ''A Very Human President'', ''Protect and Defend'', ''The Bitter Taste Of Glory'', ''Speak Up With Confidence'', and, his most recent, ''This Time, This Place: My Life in War, the White House, and Hollywood'', and wrote numerous essays for the New York Times, the Washington Post, the Los Angeles Times, Reader's Digest, Atlantic Monthly, Newsweek, Cox newspapers, and other publications;

Whereas Jack Valenti was awarded with France's highly-prized Legion d'Honneur, the

French Legion of Honor, and has been honored with his own star on the Hollywood Walk of Fame; and

Whereas Jack Valenti will be remembered as a dedicated family man, a philanthropist, a voice for copyright owners, a true visionary whose devotion, intelligence, creativity, and wisdom transformed the film industry, and as Hollywood's ultimate leading man: Now, therefore, be it

Resolved That the Senate honors the life of Jack Valenti, a pioneer in the fields of motion pictures and public service, a dedicated family man, and a legendary figure in the history of the United States.

NATIONAL CHARTER SCHOOLS WEEK

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of S. Res. 183.

The ACTING PRESIDENT pro tempore. The clerk will report the resolution by title.

The legislative clerk read as follows:

A resolution (S. Res. 183) supporting the goals and ideals of National Charter Schools Week, April 30, 2007, through May 4, 2007.

There being no objection, the Senate proceeded to consider the resolution.

Ms. LANDRIEU. Mr. President, today I wish to honor National Charter School Week. The role of charter schools has become increasingly important as these institutions have become one of the fastest growing innovative forces in education policy. The District of Columbia and 40 States have laws that allow charter schools. There are over 4,000 public charter schools serving more than 1.1 million students and there are many more students on waiting lists who want to attend.

As many of you know, I have been a part of that charter school growth, both here in Washington, DC, and in my home, Louisiana. Today, more than 30 percent of all DC public school students attend charter schools and are largely successful. These charter school projects are largely successful. These charter schools not only help to better educate students, but are also helping to build a better, stronger, more prosperous city.

In addition to having an impact in Washington, DC, charter schools are also helping to rebuild the school system in New Orleans. Hurricanes Katrina and Rita did not just wash away our levees—they also washed away our homes and schools. We must seize upon this opportunity and build a better, stronger school system for New Orleans and throughout Louisiana.

Charter schools are key players in this process by not only rebuilding our school system, but reinventing it. Every step in this process is based on what is best for our students, with the goal of delivering learning and achievement for all students. The new school system effectively eliminates the previous system of have and have-nots, allowing parents to choose from any school in the network, making quality school options available to all students and raising the bar for educators throughout the system.

The new Educational Network Model will organize schools, the majority of them charters, into small groups to provide support, foster collaboration and ensure accountability. This will shift the majority of money and decisionmaking to the school level, where it can be managed based on the needs of the students in each school. It will also create a lean district office focused on academic standards and performance monitoring, allowing more dollars to go to schools. Finally, it will migrate toward a single, aligned and highly-effective governing board that provides a stable leadership team with skills to oversee successful implementation of the plan.

Today, over 50 percent of our schools in New Orleans have reopened as charter schools. They have provided us with an expedient means to restart public education in New Orleans. It is my hope that we can continue this trend by utilizing the Educational Network Model for these schools and others nationwide by engaging community involvement and support through a shared services model.

Mr. REID. Mr. President, I ask unanimous consent that the resolution be agreed, the preamble be agreed to, the motion to reconsider be laid upon the table, and that any statements relating to the resolution be printed in the RECORD, with no intervening action or debate.

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

The resolution (S. Res. 183) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 183

Whereas charter schools deliver high-quality education and challenge students to reach their potential;

Whereas charter schools provide thousands of families with diverse and innovative educational options for their children;

Whereas charter schools are public schools authorized by designated public entities to respond to the needs of communities, families, and students, and to promote the principles of quality, choice, and innovation;

Whereas, in exchange for the flexibility and autonomy given to charter schools, charter schools are held accountable by their sponsors for improving student achievement and for their finances and other operations;

Whereas 40 States and the District of Columbia have passed laws authorizing charter schools;

Whereas more than 4,000 charter schools operating across the United States serve more than 1,140,000 students;

Whereas, over the last 13 years, Congress has provided more than $2,026,225,000 in support to the charter school movement by providing facilities, financing assistance, and grants for planning, startup, implementation, and dissemination of information;

Whereas many charter schools improve the achievement of students and stimulate improvement in traditional public schools;

Whereas charter schools must meet the student achievement accountability requirements under section 1111 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 6311) in the same manner as traditional public schools, and often set higher and additional individual goals to ensure that charter schools are of high quality and truly accountable to the public;

Whereas charter schools give parents new freedom to choose public schools, routinely measure parental satisfaction levels, and must prove their ongoing success to parents, policymakers, and communities;

Whereas nearly 56 percent of charter schools report having a waiting list, and the total number of students on all such waiting lists is enough to fill over 1,100 average-sized charter schools;

Whereas charter schools nationwide serve a higher percentage of low-income and minority students than the traditional public school system;

Whereas charter schools have enjoyed broad bipartisan support from the President, Congress, State governors and legislatures, educators, and parents across the United States; and

Whereas the eighth annual National Charter Schools Week, to be held April 30 through May 4, 2007, is an event sponsored by charter schools and grassroots charter school organizations across the United States to recognize the significant impacts, achievements, and innovations of charter schools: Now, therefore, be it

Resolved, That the Senate—

(1) acknowledges and commends charter schools and students, parents, teachers, and administrators of charter schools across the United States for their ongoing contributions to education and improving and strengthening the public school system;

(2) supports the goals and ideals of the eighth annual National Charter Schools Week; and

(3) encourages the people of the United States to conduct appropriate programs, ceremonies, and activities to demonstrate support for charter schools during this weeklong celebration in communities throughout the United States.

NATIONAL CHILDHOOD STROKE AWARENESS DAY

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of S. Res. 184.

The ACTING PRESIDENT pro tempore. The clerk will report the resolution by title.

The legislative clerk read as follows:

A resolution (S. Res. 184) expressing the sense of the Senate with respect to childhood stroke and designating May 5, 2007 as ''National Childhood Stroke Awareness Day.''

There being no objection, the Senate proceeded to consider the resolution.

Mr. REID. Mr. President, I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, and the motion to reconsider be laid upon the table.

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

The resolution (S. Res. 184) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S RES. 184

Whereas a stroke, also known as a ''cerebrovascular accident'', is an acute neurologic injury that occurs when the blood supply to a part of the brain is interrupted by a clot in the artery or a burst of the artery;

Whereas a stroke is a medical emergency that can cause permanent neurologic damage or even death if not promptly diagnosed and treated;

Whereas 26 out of every 100,000 newborns and almost 3 out of every 100,000 children have a stroke each year;

Whereas an individual can have a stroke before birth;

Whereas stroke is among the top 10 causes of death for children in the United States;

Whereas 12 percent of all children who experience a stroke die as a result;

Whereas the death rate for children who experience a stroke before the age of 1 year is the highest out of all age groups;

Whereas many children who experience a stroke will suffer serious, long-term neurological disabilities, including—

(1) hemiplegia, which is paralysis of 1 side of the body;

(2) seizures;

(3) speech and vision problems; and

(4) learning difficulties;

Whereas those disabilities may require ongoing physical therapy and surgeries;

Whereas the permanent health concerns and treatments resulting from strokes that occur during childhood and young adulthood have a considerable impact on children, families, and society;

Whereas very little is known about the cause, treatment, and prevention of childhood stroke;

Whereas medical research is the only means by which the citizens of the United States can identify and develop effective treatment and prevention strategies for childhood stroke;

Whereas early diagnosis and treatment of childhood stroke greatly improves the chances that the affected child will recover and not experience a recurrence; and

Whereas the Children's Hospital of Philadelphia should be commended for its initiative in creating the Nation's first program dedicated to pediatric stroke patients: Now, therefore, be it

Resolved, That the Senate—

(1) designates May 5, 2007 as ''National Childhood Stroke Awareness Day''; and

(2) urges the people of the United States to support the efforts, programs, services, and advocacy of organizations that work to enhance public awareness of childhood stroke.

URGING ALL MEMBER COUNTRIES OF THE INTERNATIONAL COMMISSION OF THE INTERNATIONAL TRACING SERVICE TO EXPEDITE THE RATIFICATION PROCESS

Mr. REID. Mr. President, I ask unanimous consent that the Foreign Relations Committee be discharged from further consideration of S. Res. 141.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered. The clerk will report the resolution by title.

The legislative clerk read as follows:

A resolution (S. Res. 141) urging all member countries of the International Commission of the International Tracing Service who have yet to ratify the May 2006 amendments to the 1955 Bonn Accords to expedite the ratification process to allow for open access to the Holocaust archives located at Bad Arolsen, Germany.

There being no objection, the Senate proceeded to consider the resolution.

Mr. REID. I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, the motion to reconsider be laid on the table, and any statements be printed in the RECORD.

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

The resolution (S. Res. 141) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 141

Whereas the International Tracing Service (ITS) archives located in Bad Arolsen, Germany, which are administered by the International Committee of the Red Cross, contain an estimated 50,000,000 records on the fates of some 17,500,000 individual victims of Nazi war crimes;

Whereas the ITS archives at Bad Arolsen remain the largest closed Holocaust-era archives in the world;

Whereas, although access to individual records can be requested by Holocaust survivors and their descendants, many who have requested information from the ITS archives have reported facing significant delays and even unresponsiveness;

Whereas the ITS archives remain inaccessible to researchers and research institutions;

Whereas the Agreement Constituting an International Commission for the International Tracing Service, signed at Bonn June 6, 1955 (6 UST 6186) (commonly known as the ''Bonn Accords'') established an international commission of 11 member countries (Belgium, France, Germany, Greece, Israel, Italy, Luxembourg, the Netherlands, Poland, the United Kingdom, and the United States) charged with overseeing the administration of the ITS Holocaust archives;

Whereas, following years of delay, in May 2006 in Luxembourg, the International Commission of the ITS agreed upon amendments to the Bonn Accords that would allow researchers to use the archives and would allow each member country of the International Commission to receive digitized copies of archive materials and make the records available to researchers under the respective national laws relating to archives and privacy;

Whereas the May 2006 amendments to the Bonn Accords require each of the 11 member countries of the International Commission to ratify the amendments before open access to the Holocaust archives is permitted;

Whereas, although the final signature was affixed to the amendments in October 2006, only 5 out of the 11 member countries of the International Commission, the United States, Israel, Poland, the Netherlands, and the United Kingdom, have ratified the amendments;

Whereas the United States Holocaust Memorial Museum has for years been working tirelessly to provide public access to the materials in the Bad Arolsen archives;

Whereas, on March 8, 2007, representatives from the 11 member countries of the International Commission of the ITS met in the Netherlands and reviewed the current ratification status of each country and the ratification process in its entirety;

Whereas it is a moral and humanitarian imperative to permit public access to the millions of Holocaust records housed at Bad Arolsen;

Whereas it is essential that researchers obtain access while Holocaust survivors are living, so that the researchers can benefit in their scholarly work from the insights of eyewitnesses;

Whereas, in the aftermath of the Holocaust, there have been far too many instances of survivors and heirs of Holocaust victims being refused their moral and legal right to information, for restitution purposes, slave labor compensation, and personal closure;

Whereas opening the historic records is a vital contribution to the world's collective memory and understanding of the Holocaust and efforts to ensure that the anti-Semitism that made such horrors possible is never again permitted to take hold;

Whereas anti-Semitism has seen a resurgence in recent years, and as recently as December 2006, the President of Iran, Mahmoud Ahmadinejad, held the second Holocaust denial conference in Tehran in one year; and

Whereas in light of this conference, the anti-Semitic rhetoric of President Ahmadinejad, and a resurgence of anti-Semitism in part of the world, the opening of the archives at Bad Arolsen could not be more urgent: Now, therefore, be it

Resolved, That the Senate—

(1) commends in the strongest terms all countries that have to date ratified the amendments to the Agreement Constituting an International Commission for the International Tracing Service, signed at Bonn June 6, 1955 (6 UST 6186) (commonly known as the ''Bonn Accords'') to allow for open access to the Holocaust archives of the International Tracing Service (ITS) located at Bad Arolsen, Germany;

(2) commends the countries that have committed to expedite the process of releasing the archives and expects those countries to abide by their commitments;

(3) strongly urges all countries that have to yet to ratify the amendments to abide by the treaty obligations made in May 2006 and to expedite the ratification of the amendments;

(4) strongly urges all member countries of the International Commission of the ITS to consider the short time left to Holocaust survivors and unanimously consent to open the ITS archives should all countries not ratify the amendments by May 2007;

(5) expresses the hope that bureaucratic and diplomatic processes will not further delay this process; and

(6) refuses to forget the murder of 6,000,000 Jews and more than 5,000,000 other victims during the Holocaust by Nazi perpetrators and their collaborators.

DESIGNATING APRIL 30, 2007, AS ''DIA DE LOS NIÑOS: CELEBRATING YOUNG AMERICANS''

Mr. REID. Mr. President, I ask unanimous consent that the Judiciary Committee be discharged from consideration of S. Res. 177.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered. The clerk will report the resolution by title.

The legislative clerk read as follows:

A resolution (S. Res. 177) designating April 30, 2007, as ''Dia de los Niños: Celebrating Young Americans,'' and for other purposes.

There being no objection, the Senate proceeded to consider the resolution.

Mr. REID. I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, the motion to reconsider be laid on the table, and any statements be printed in the RECORD with no intervening action or debate.

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

The resolution (S. Res. 177) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 177

Whereas many nations throughout the world, and especially within the Western hemisphere, celebrate ''Día de los Niños'', or ''Day of the Children'' on the 30th of April, in recognition and celebration of their country's future—their children;

Whereas children represent the hopes and dreams of the people of the United States;

Whereas children are the center of American families;

Whereas children should be nurtured and invested in to preserve and enhance economic prosperity, democracy, and the American spirit;

Whereas Hispanics in the United States, the youngest and fastest growing ethnic community in the Nation, continue the tradition of honoring their children on this day, and wish to share this custom with the rest of the Nation;

Whereas it is projected that by the year 2050, 1 in 4 Americans will be of Hispanic descent, and currently approximately 12,300,000 Hispanic children live in the United States;

Whereas traditional Hispanic family life centers largely on children;

Whereas the primary teachers of family values, morality, and culture are parents and family members, and we rely on children to pass on these family values, morals, and culture to future generations;

Whereas more than 500,000 children drop out of school each year, 138,000 of whom are Hispanic, and these dropout rates are unacceptably high;

Whereas the importance of literacy and education are most often communicated to children through family members;

Whereas families should be encouraged to engage in family and community activities that include extended and elderly family members and encourage children to explore, develop confidence, and pursue their dreams;

Whereas the designation of a day to honor the children of the United States will help affirm for the people of the United States the significance of family, education, and community;

Whereas the designation of a day of special recognition for the children of the United States will provide an opportunity for children to reflect on their future, to articulate their dreams and aspirations, and to find comfort and security in the support of their family members and communities;

Whereas the National Latino Children's Institute, serving as a voice for children, has worked with cities throughout the country to declare April 30 as ''Día de los Niños: Celebrating Young Americans''—a day to bring together Hispanics and other communities nationwide to celebrate and uplift children; and

Whereas the children of a nation are the responsibility of all its people, and people should be encouraged to celebrate the gifts of children to society—their curiosity, laughter, faith, energy, spirit, hopes, and dreams: Now, therefore, be it

Resolved, That the Senate—

(1) designates April 30, 2007, as ''Día de los Niños: Celebrating Young Americans''; and

(2) calls on the people of the United States to join with all children, families, organizations, communities, churches, cities, and States across the United States to observe the day with appropriate ceremonies, including activities that—

(A) center around children, and are free or minimal in cost so as to encourage and facilitate the participation of all our people;

(B) are positive and uplifting and that help children express their hopes and dreams;

(C) provide opportunities for children of all backgrounds to learn about one another's cultures and to share ideas;

(D) include all members of the family, especially extended and elderly family members, so as to promote greater communication among the generations within a family, enabling children to appreciate and benefit from the experiences and wisdom of their elderly family members;

(E) provide opportunities for families within a community to get acquainted; and

(F) provide children with the support they need to develop skills and confidence, and to find the inner strength—the will and fire of the human spirit—to make their dreams come true.

THE CALENDAR

Mr. REID. Mr. President, I ask unanimous consent that the Senate now proceed en bloc to the consideration of the following calendar items: Calendar No. 121, S. Res. 116; Calendar No. 122, S. Res. 125; Calendar No. 123, S. Res. 146; and Calendar No. 124, S. Res. 162.

There being no objection, the Senate proceeded to consider the resolutions en bloc.

Mr. REID. I ask unanimous consent that the resolutions be agreed to en bloc; the amendment to the preamble, where applicable, be agreed to; the preambles, as amended if amended, be agreed to en bloc; the motions to reconsider be laid upon the table en bloc; that the consideration of these items appear separately in the RECORD and any statements be printed in the RECORD.

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

DESIGNATING MAY 2007 AS ''NATIONAL AUTOIMMUNE DISEASES AWARENESS MONTH''

The resolution (S. Res. 116) designating May 2007 as ''National Autoimmune Diseases Awareness Month'' and supporting efforts to increase awareness of autoimmune diseases and increase funding for autoimmune disease research was agreed to; as follows:

S. RES. 116

Whereas autoimmune diseases are chronic, disabling diseases in which underlying defects in the immune system lead the body to attack its own organs and tissues;

Whereas autoimmune diseases can affect any part of the body, including the blood, blood vessels, muscles, nervous system, gastrointestinal tract, endocrine glands, and multiple-organ systems, and can be life-threatening;

Whereas researchers have identified over 80 different autoimmune diseases, and suspect at least 40 additional diseases of qualifying as autoimmune diseases;

Whereas researchers have identified a close genetic relationship and a common pathway of disease that exists among autoimmune diseases, explaining the clustering of autoimmune diseases in individuals and families;

Whereas the family of autoimmune diseases is under-recognized, and poses a major health care challenge to the United States;

Whereas the National Institutes of Health (NIH) estimates that autoimmune diseases afflict up to 23,500,000 people in the United States, 75 percent of the people affected are women, and the prevalence of autoimmune diseases is rising;

Whereas NIH estimates the annual direct health care costs associated with autoimmune diseases at more than $100,000,000,000 and there are over 250,000 new diagnoses each year;

Whereas autoimmune diseases are among the top 10 leading causes of death in female children and adult women;

Whereas autoimmune diseases most often affect children and young adults, leading to a lifetime of disability;

Whereas diagnostic tests for most autoimmune diseases are not standardized, making autoimmune diseases very difficult to diagnose;

Whereas, because autoimmune diseases are difficult to diagnose, treatment is often delayed, resulting in irreparable organ damage and unnecessary suffering;

Whereas the Institute of Medicine of the National Academies reported that the United States is behind other countries in research into immune system self-recognition, the cause of autoimmune diseases;

Whereas a study by the American Autoimmune Related Diseases Association revealed that it takes the average patient with an autoimmune disease more than 4 years, and costs more than $50,000, to get a correct diagnosis;

Whereas there is a significant need for more collaboration and cross-fertilization of basic autoimmune research;

Whereas there is a significant need for research focusing on the etiology of all autoimmune-related diseases, to increase understanding of the root causes of these diseases rather treating the symptoms after the disease has had its destructive effect;

Whereas the National Coalition of Autoimmune Patient Groups is a coalition of national organizations focused on autoimmune diseases working to consolidate the voices of patients with autoimmune diseases and to promote increased education, awareness, and research into all aspects of autoimmune diseases through a collaborative approach; and

Whereas designating May 2007 as ''National Autoimmune Diseases Awareness Month'' would help educate the public about autoimmune diseases and the need for research funding, accurate diagnosis, and effective treatments: Now, therefore, be it

Resolved, That the Senate—

(1) designates May 2007 as ''National Autoimmune Diseases Awareness Month'';

(2) supports the efforts of health care providers and autoimmune patient advocacy and education organizations to increase awareness of the causes of, and treatments for, autoimmune diseases; and

(3) supports the goal of increasing Federal funding for aggressive research to learn the root causes of autoimmune diseases, as well as the best diagnostic methods and treatments for people with autoimmune diseases.

ENDANGERED SPECIES DAY

The resolution (S. Res. 125) designating May 18, 2007, as ''Endangered Species Day,'' and encouraging the people of the United States to become educated about, and aware of, threats to species, success stories in species recovery, and the opportunity to promote species conservation worldwide, was agreed to. The preamble was agreed to. The resolution (S. Res. 125), with its preamble, reads as follows:

S. RES. 125

Whereas in the United States and around the world, more than 1,000 species are officially designated as at risk of extinction and thousands more also face a heightened risk of extinction;

Whereas the actual and potential benefits derived from many species have not yet been fully discovered and would be permanently lost if not for conservation efforts;

Whereas recovery efforts for species such as the whooping crane, Kirtland's warbler, the peregrine falcon, the gray wolf, the gray whale, the grizzly bear, and others have resulted in great improvements in the viability of such species;

Whereas saving a species requires a combination of sound research, careful coordination, and intensive management of conservation efforts, along with increased public awareness and education;

Whereas two-thirds of endangered or threatened species reside on private lands;

Whereas voluntary cooperative conservation programs have proven to be critical for habitat restoration and species recovery; and

Whereas education and increasing public awareness are the first steps in effectively informing the public about endangered species and species restoration efforts: Now, therefore, be it

Resolved, That the Senate—

(1) designates May 18, 2007, as ''Endangered Species Day''; and

(2) encourages—

(A) educational entities to spend at least 30 minutes on Endangered Species Day teaching and informing students about threats to, and the restoration of, endangered species around the world, including the essential role of private landowners and private stewardship to the protection and recovery of species;

(B) organizations, businesses, private landowners, and agencies with a shared interest in conserving endangered species to collaborate on educational information for use in schools; and

(C) the people of the United States to observe the day with appropriate ceremonies and activities.

DESIGNATING JUNE 20, 2007, AS ''AMERICAN EAGLE DAY''

The resolution (S. Res. 146) Designating June 20, 2007, as ''American Eagle Day,'' and celebrating the recovery and restoration of the American bald eagle, the national symbol of the United States, was agreed to; as follows:

S. RES. 146

Whereas, the bald eagle was designated as the national emblem of the United States on June 20, 1782, by our country's Founding Fathers at the Second Continental Congress;

Whereas, the bald eagle is the central image used in the Great Seal of the United States and the seals of the President and Vice President;

Whereas, the image of the bald eagle is displayed in the official seal of many branches and departments of the Federal Government, including—

(1) Congress;

(2) the Supreme Court;

(3) the Department of Defense;

(4) the Department of the Treasury;

(5) the Department of Justice;

(6) the Department of State;

(7) the Department of Commerce;

(8) the Department of Homeland Security;

(9) the Department of Veterans Affairs;

(10) the Department of Labor;

(11) the Department of Health and Human Services;

(12) the Department of Energy;

(13) the Department of Housing and Urban Development;

(14) the Central Intelligence Agency; and

(15) the United States Postal Service;

Whereas, the bald eagle is an inspiring symbol of the American spirit of freedom and democracy;

Whereas, the image, meaning, and symbolism of the bald eagle have played a significant role in American art, music, history, literature, architecture, and culture since the founding of our Nation;

Whereas, the bald eagle is featured prominently on United States stamps, currency, and coinage;

Whereas, the habitat of bald eagles exists only in North America;

Whereas, by 1963, the number of nesting pairs of bald eagles in the lower 48 States had dropped to about 417;

Whereas, the bald eagle was first listed as an endangered species in 1967 under the Endangered Species Preservation Act, the Federal law that preceded the Endangered Species Act of 1973;

Whereas, caring and concerned citizens of the United States in the private and public sectors banded together to save, and help ensure the protection of, bald eagles;

Whereas, in 1995, as a result of the efforts of those caring and concerned citizens, bald eagles were removed from the ''endangered'' species list and upgraded to the less imperiled ''threatened'' status under the Endangered Species Act of 1973;

Whereas, by 2006, the number of bald eagles in the lower 48 States had increased to approximately 7,000 to 8,000 nesting pairs;

Whereas, the administration is likely to officially delist the bald eagle from both the ''endangered'' and ''threatened'' species lists under the Endangered Species Act of 1973, with a final decision expected no later than June 29, 2007;

Whereas, if delisted under the Endangered Species Act of 1973, bald eagles should be provided strong protection under the Bald and Golden Eagle Protection Act and the Migratory Bird Treaty Act;

Whereas, bald eagles would have been permanently extinct if not for vigilant conservation efforts of concerned citizens and strict protection laws;

Whereas, the dramatic recovery of the bald eagle population is an endangered species success story and an inspirational example for other wildlife and natural resource conservation efforts around the world;

Whereas, the initial recovery of the bald eagle population was accomplished by the concerted efforts of numerous government agencies, corporations, organizations, and individuals; and

Whereas, the sustained recovery of the bald eagle population will require the continuation of recovery, management, education, and public awareness programs, to ensure that the population and habitat of bald eagles will remain healthy and secure for future generations: Now, therefore, be it

Resolved, That the Senate—

(1) designates June 20, 2007, as ''American Eagle Day''; and

(2) encourages—

(A) educational entities, organizations, businesses, conservation groups, and government agencies with a shared interest in conserving endangered species to collaborate on education information for use in schools; and

(B) the people of the United States to observe American Eagle Day with appropriate ceremonies and other activities.

Mr. LEAHY. Mr. President, I am pleased that today the Senate has agreed to S. Res. 146, a bipartisan resolution establishing a national American Eagle Day, on June 20, 2007, the day the bald eagle was selected as our national emblem during the Second Continental Congress in 1782. I am delighted that the bald eagle is scheduled to be ''delisted'' from the Endangered Species Act on June 20 of this year. I commend Senators ALEXANDER and BYRD for their work on this resolution.

The bald eagle has been protected under Federal law since Congress passed the Bald and Golden Eagle Protection Act in 1940. This law prohibits the taking, possessing, or commerce of both bald and golden eagles. The Endangered Species Act of 1973 reinforced protection of the bald eagle. I am a longtime supporter of the Endangered Species Act, a landmark environmental law that provides crucial protection to fish and wildlife on the verge of extinction.

Vermont is actually one of the only States in the continental United States without nesting bald eagles. Senator JEFFORDS funded a program about three years ago where orphaned or threatened nestlings were relocated from sites between Maryland and Maine to nests in the Dead Creek State wildlife management area in Addison County, VT, along Lake Champlain.

About 25 individual birds were successfully raised and released from nests there. While eagles usually return to nest in the general area where they were nestlings, it can take up to 4 years. Vermont fish and wildlife staff are closely monitoring the effort to see if Vermont will be successful in joining other states as a home to the bald eagle.

I support the passage of this resolution, which would allow all of us to celebrate the successful recovery of the bald eagle, and to remember the freedoms and ideals that the eagle represents as a symbol of our country.

SACRIFICE MADE BY THE MEN AND WOMEN WHO HAVE LOST THEIR LIVES WHILE SERVING AS LAW ENFORCEMENT OFFICERS

The Senate proceeded to consider the resolution (S. Res. 162) commemorating and acknowledging the dedication and sacrifice made by the men and women who have lost their lives while serving as law enforcement officers.

Mr. LEAHY. Mr. President, I am pleased the Senate is considering today a bipartisan resolution to designate May 15, 2007, as National Peace Officers Memorial Day that Senator SPECTER and I introduced along with the majority leader, and Senators BIDEN, GRASSLEY, CORNYN, STABENOW, MENENDEZ, DURBIN, KOHL, KENNEDY and BROWNBACK. Last week, the Judiciary Committee favorably reported this resolution unanimously. I thank all members of the Judiciary Committee and the cosponsors on this bipartisan resolution for their support in recognizing

the sacrifices that law enforcement officers make each day for the American people.

This is now the eleventh year running that I have been involved in this resolution to honor the sacrifice and commitment of those law enforcement officers who give their lives serving their communities. For many years I introduced this resolution with my friend Senator CAMPBELL, a former deputy sheriff. Both SENATOR CAMPBELL, and I, as a former prosecutor, witnessed firsthand the risks faced by law enforcement officers every day while they serve and protect our communities. I am pleased that Senator SPECTER, himself a former prosecutor, former chair of the Judiciary Committee, and now our ranking member, has become the lead Republican sponsor of this bipartisan measure.

Currently, more than 870,000 men and women who guard our communities do so at great risk. After the hijacked planes hit the World Trade Center in New York City on September 11, 2001, 72 peace officers died while trying to ensure that their fellow citizens in those buildings got to safety. That act of terrorism resulted in the highest number of peace officers ever killed in a single incident in the history of our country, and is a tragic reminder of how important it is for the Congress to provide all of the resources necessary to protect officers in the line of duty.

Since the first recorded police death in 1792, there have been more than 17,900 law enforcement officers who have made the ultimate sacrifice. We are fortunate in Vermont that we rank as the State with the fewest officer deaths in history. With 19 deaths, however, that is 19 deaths too many. In 2006, 147 law enforcement officers died while serving in the line of duty, well below the decade-long average of 165 deaths annually, and a drop from 2005 when 156 officers were killed. That is 147 officers too many. We need to continue our support for better equipment and the increased use of bullet-resistant vests, improved training, and advanced emergency medical care. I hope as the 110th Congress moves forward that all Senators can work together to ensure that all of our law enforcement officers and their families have the full support and the resources they need from the Federal Government.

I am proud of the work I have been involved in to help make it safer on the beat for our officers. Back in 1998, Senator Campbell and I authored the Bulletproof Vest Grant Partnership Act in response to the tragic Carl Drega shootout on the Vermont-New Hampshire border, in which two State troopers who lacked bulletproof vests were killed. Since then, we have successfully reauthorized this program three more times: In the Bulletproof Vest Partnership Grant Act of 2000, in the State Justice Institute Reauthorization Act of 2004, and most recently as part of the Violence Against Women and Department of Justice Reauthorization Act of 2005. It is now authorized at $50 million per year through fiscal year 2009 to help State, tribal and local jurisdictions purchase armor vests for use by law enforcement officers. I have already begun to work with my colleagues to make sure that the bulletproof vest partnership grant program is fully funded this year. Bulletproof vests have saved the lives of thousands of officers and are a fundamental line of defense that no officer should be without. I know I am not alone in calling for the Senate to fully fund the bulletproof vest partnership program and I hope the Congress agrees that it is crucially important that we provide the funding authorized for this program. Hundreds of thousands of police officers are counting on us.

I am also pleased to join with Senator REED and others to introduce the Equity in Law Enforcement Act, which will provide parity in Federal benefits for law enforcement officers working in private educational institutions and for our Nation's rail carriers. Among these benefits are access to grants under the bulletproof vest partnership, and survivor benefits. All of the men and women who serve our society as law enforcement officers should be equally entitled to all of the benefits the Federal Government provides, no matter where they serve.

I think we can all agree that the men and women in law enforcement who have sacrificed for our safety deserve our deep gratitude and respect. National Peace Officers Memorial Day will offer the people of the United States, in their communities, in their State capitals, and in the Nation's Capital, the opportunity to honor and reflect on the extraordinary service and sacrifice given year after year by our police forces.

Our Nation's law enforcement officers deserve our commitment to protect those who help keep us all safe. They are the real-life heroes; too many of whom too often make the ultimate sacrifice. It is important to support and respect our State and local police officers and all of our first responders, and to recognize their role in upholding the rule of law and keeping our Nation's citizens safe and secure. During the week of May 13, more than 20,000 peace officers are expected to gather in Washington to join with the families of their fallen comrades. I thank the Senate for joining in honoring their service and passing this bipartisan resolution.

The amendment (No. 1007) was agreed to, as follows:

AMENDMENT NO. 1007

On page 2, strike the first whereas clause and insert:

Whereas peace officers are on the front lines in protecting the schools and schoolchildren of the United States;

The resolution (S. Res. 162), as amended, was agreed to.

The preamble, as amended, was agreed to.

The resolution, with its preamble, as amended, reads as follows:

S. RES. 162

Whereas the well-being of all citizens of the United States is preserved and enhanced as a direct result of the vigilance and dedication of law enforcement personnel;

Whereas more than 900,000 men and women, at great risk to their personal safety, presently serve their fellow citizens as guardians of the peace;

Whereas peace officers are on the front lines in protecting the schools and schoolchildren of the United States;

Whereas 147 peace officers across the United States were killed in the line of duty during 2006, which is below the decade-long annual average of 167 deaths;

Whereas a number of factors contributed to this reduction in deaths, including—

(1) better equipment and increased use of bullet-resistant vests;

(2) improved training;

(3) longer prison terms for violent offenders; and

(4) advanced emergency medical care;

Whereas every other day, 1 out of every 16 peace officers is assaulted, 1 out of every 56 peace officers is injured, and 1 out of every 5,500 peace officers is killed in the line of duty somewhere in the United States; and

Whereas on May 15, 2007, more than 20,000 peace officers are expected to gather in Washington, D.C., to join with the families of their recently fallen comrades to honor those comrades and all others who went before them: Now, therefore, be it

Resolved, That the Senate—

(1) recognizes May 15, 2007, as ''Peace Officers Memorial Day'', in honor of the Federal, State, and local officers that have been killed or disabled in the line of duty; and

(2) calls on the people of the United States to observe that day with appropriate ceremonies and respect.

ORDERS FOR WEDNESDAY, MAY 2, 2007

Mr. REID. Mr. President, I ask unanimous consent that when the Senate completes its business today, it stand adjourned until 9:30 a.m., Wednesday, May 2; that on Wednesday, following the prayer and pledge, the Journal of proceedings be approved to date, the morning hour be deemed expired, and the time for the two leaders be reserved for their use later in the day; that there then be a period of morning business for 60 minutes, with the first half controlled by the majority and the final portion under the control of the Republicans; that at the close of morning business the Senate then resume consideration of S. 1082, and the mandatory quorum call under rule XXII be waived.

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

ADJOURNMENT UNTIL 9:30 A.M. TOMORROW

Mr. REID. Mr. President, if there is no further business to come before the Senate this evening, I now ask unanimous consent the Senate stand adjourned under the previous order.

There being no objection, the Senate, at 7:49 p.m., adjourned until Wednesday, May 2, 2007, at 9:30 a.m.