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Senate

The Senate met at 9:30 a.m. and was called to order by the Honorable BENJAMIN L. CARDIN, a Senator from the State of Maryland.

PRAYER

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

Let us pray.

Eternal Lord God, before whose Eyes the ages pass, who knows our changing thoughts, help us to remember that You guide the planets and our times are in Your hands. Open our ears to hear Your voice as the heavens declare Your glory and the flowers speak of Your majesty. As You whisper in the wind, teach us to number our days and to seize the seasons You have given us to serve.

Strengthen our lawmakers for today's work. Give them priorities that honor You, patience to persevere, and humility to build new bridges of cooperation. Empower them, Lord, to do to others what they want done to themselves. Impart to them also the wisdom to live with gratitude to You, the author and finisher of our faith. We pray in Your sacred Name. Amen.

PLEDGE OF ALLEGIANCE

The Honorable BENJAMIN L. CARDIN 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 legislative clerk read the following letter:

U.S. SENATE,
PRESIDENT PRO TEMPORE,
Washington, DC, May 9, 2007.

To the Senate:

Under the provisions of rule I, paragraph 3, of the Standing Rules of the Senate, I hereby appoint the Honorable BENJAMIN L. CARDIN, a Senator from the State of Maryland, to perform the duties of the Chair.

ROBERT C. BYRD,
President pro tempore.

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

RECOGNITION OF THE MAJORITY LEADER

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

SCHEDULE

Mr. REID. Mr. President, this morning, there will be 60 minutes for morning business, with the Republicans controlling the first half, and the Democrats controlling the second half.

Following morning business, the Senate will resume consideration of the FDA legislation. Last night, due to the hard work of Senator ENZI and the staffs of Senators KENNEDY and ENZI, they were able to come to an agreement to complete action on this legislation today. I compliment the hard work of the many individuals who worked to accomplish this, especially Senator BROWN who, in the absence of the chairman, was here throughout the day to assist in moving the process along. In addition, I would like to single out Senator ENZI, who has worked so hard on this legislation in the committee and, of course, with it being on the floor. He has worked very well with Senator KENNEDY in the entire process of getting this legislation through the committee to the floor and now toward completion.

Through the hard work of these I have mentioned, we have only three amendments that are in order to the bill, and we have 60 minutes of debate time. Votes on the remaining amendments and passage of the bill will occur around 11:30 this morning.

Following final action on the FDA bill, the Senate will consider, for up to 3 hours, the nomination of Debra Ann Livingston to be a circuit court judge. Upon the use or yielding back of that time, then a vote on confirmation will occur.

Once the judge has been confirmed, I have every belief that the Senate will begin and complete the process of going to conference on the budget resolution. I have spoken to Senator CONRAD earlier this morning. He and Senator JUDD GREGG get along extremely well, and they will work out the time on the number of motions to instruct and how many motions to instruct the minority will require. So Members should be prepared to work into the evening on this most important item.

Finally, the cloture vote on the motion to proceed to the water resources legislation will not occur before tomorrow morning. Today will be a busy day, with votes occurring throughout the day, so Members should plan accordingly.

ORDER OF PROCEDURE

Mr. REID. Mr. President, on the FDA legislation, it is my understanding there will be three votes, and then final passage.

The ACTING PRESIDENT pro tempore. The Senator is correct.

Mr. REID. Mr. President, the votes occur all at one time?

The ACTING PRESIDENT pro tempore. There is 2 minutes between each vote.

Mr. REID. Mr. President, I ask unanimous consent that be the case, and I also ask consent that there be 10-minute votes after the first vote.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered as to each request.

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

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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 Missouri.

IRAQ

Mr. BOND. Mr. President, I am pleased to report to my colleagues on a trip, an Intelligence Committee trip, that I led to Iraq this past weekend, with Senators SNOWE and CHAMBLISS and Congressman ISSA. We found some very amazing things. We visited Tikrit, Baghdad, Ramadi, Balad. We talked to the commanding officers, sat down and talked with our troops, our soldiers, marines, and airmen.

In Ramadi—which only a month or so ago had been a denied area, an area so hostile that heavily armed U.S. units could not even successfully go in. It was extremely dangerous. On Sunday, as a result of changes that have happened in Ramadi in the last several weeks, the four of us Members of Congress, with the general in charge of the area, General Gaskin, and a driver, and two marines with M–16s, went down to downtown Baghdad. We had no phalanx of troops around us, no helicopters flying overhead. We got out and walked in downtown Baghdad at ''Firecracker Corner,'' so named, as one might guess, because of the tremendous number of rounds that perpetually were going off in that area.

It was quiet at the time. We went from there into the former Anbar college, which has become the security force headquarters for the area. That building is manned by Iraqi police units, Iraqi army units, and U.S. marines. They were living together, conducting missions together, and apparently they have been extremely successful because Ramadi has changed significantly.

In the last 3 months, attacks in Ramadi have decreased by some 74 percent. I have a chart in the Chamber. You probably cannot see it too well. But the first part shows weekly attacks going from a high of 127, in February, down to 24 in the week of April 20 to 26.

Indirect fire attacks went from 129 per week down to about 10. Improvised explosive device attacks—this is per month—went from over 320 last July, down to, in March, 67 per month; and in April to 28 per month.

Now, what is going on here? Well, it is quite simply that the surge and clear-and-hold counterinsurgency strategy is beginning to work. The mistake we made previously is we would go in and take out al-Qaida and leave. Well, al-Qaida would come right back. And anybody who had cooperated with the coalition forces would be subjected to death or other severe penalties.

Now, with significant new numbers of Iraqi police and army, backed up by the U.S. military, we are able to go in and clear and hold. That is why the marines, the Iraqi police, and army are stationed in downtown Baghdad. This is becoming—it is not yet a denied zone for al-Qaida.

Now, one of the most important and amazing things that has happened is the tribal sheiks, the Sunnis in that area—if you have been following the Al Anbar progress, the Sunni sheiks run that country. They have concluded—having dealt with al-Qaida, and having had their family members killed, businesses disrupted—they have decided that the coalition forces—American, Australian, British—in cooperation with the Iraqi Army and police are far better hopes for security.

By our making a commitment to go in there, they have made a commitment as well. Now they are volunteering large numbers of men to serve in the Iraqi police and the Iraqi Army.

In just a couple weeks, 1,200 Iraqi young men signed up for the army. There are now over 10,000 Iraqi policemen. They are being trained, and they are taking over the area.

As you look at the entire scope of Ramadi, there are 23 tribal areas. Last year, in one or two of the tribal areas, the sheiks were working with us. Now all 23 have joined with us to fight al-Qaida. There are no uncooperative tribes left. They are joining the military and the police force to help keep the area clear.

In downtown Ramadi, the U.S. military has gone in and been able to repair and help reopen the largest, most important mosque in Ramadi, the mosque that is central for the Sunnis in Al Anbar. It had been closed since the start of the war. Now, this past Friday, hundreds of Iraqis were able to attend services. The U.S. military has supplied and set up mosque speakers in Ramadi to broadcast security messages in addition to messages from the local Imams.

This is just one example we saw. In Baghdad, we learned the clear-and-hold strategy is working. Areas which had been highly dangerous, with a high number of attacks daily, now, because of the presence of the joint security forces—Iraqi, U.S., and coalition forces—have seen the incidents decline by more than two-thirds.

What does this mean? Well, it means al-Qaida is being significantly degraded. Significant numbers of al-Qaida have been killed and detained, and others have been forced out of Baghdad and Al Anbar. Our coalition forces, with the help of the Iraqi military, are, I understand, doing a very good job tracking them down and eliminating them.

Now, this is not conclusive. This is only the first results of the surge and the effective counterinsurgency strategy. It was recommended by the Baker-Hamilton commission last year, and it is being implemented by General Petraeus, who is an expert on counterinsurgency.

I would say that Marine General Gaskin, who is running Al Anbar, is doing a magnificent job. I was impressed with what we heard from General Odierno and General McCrystal and others who are working to make sure they complete their job.

We also met with the most influential leader of the Shia in Iraq, Ayatollah Abdul Aziz al-Hakim. He is the influential leader of the Supreme Council for Islamic Revolution in Iraq. We talked with him about the need for the Iraqis to find political solutions and to bring together a unity government of Sunnis, Kurds, and Shias to ensure the safety and stability of their country so they would have an opportunity to go back to normal lives and prosper. We have given them that opportunity, and they need to take that opportunity. We need to do a better job of telling people the difference, and our military is doing that. But at the same time, when we met with our troops, they kept asking us why we aren't getting the money. They know they are doing the job, and they asked us a question which is rather difficult to answer: You sent us over here to do a military mission. We are accomplishing that mission. Why are we not getting the money we need? Where are the Mine Resistant Ambush Protection vehicles that can reduce injuries and deaths so significantly? There was no answer, other than it has been delayed.

Let me conclude by saying we are making great progress, and we cannot afford to tell our troops we are not going to support them by sending in a bifurcated budget, funding a month at a time, a month at a time, because they have a several months' long game plan. When they hear people say that the war is lost, they say: We are risking our lives every day, because the war is not lost. What are people in Congress thinking? We cannot tell the Iraqis and our troops that we are going to cut out of here in a couple of months because we will lose the cooperation of the tribal sheiks and the others who are helping us against al-Qaida if they think we are about ready to leave and leave them at the mercy of al-Qaida, which will come back in if we leave prior to establishing strength in the Iraqi security forces that will enable them to prevent al-Qaida from taking over their country.

Make no mistake about it, that is the goal of al-Qaida. Our intelligence community unanimously says it. Ayman al-Zawahiri has said it, Osama bin Laden has said it. If we don't believe them, at least we ought to believe our intelligence community.

We must pass this supplemental for the full rest of the year without timelines and provide the troops the support and the weapons systems they need.

I thank the Chair, and I yield the floor.

Mr. CORNYN. Mr. President, may I inquire how much time is remaining in morning business on this side?

The ACTING PRESIDENT pro tempore. There is 18½ minutes.

Mr. CORNYN. I thank the Chair. I will take 9 minutes of that and then Senator THOMAS will take the remainder.

RISING GAS PRICES

Mr. CORNYN. Mr. President, yesterday I came to the floor with the Senator from Arizona and the senior Senator from Texas to talk about rising gas prices. The sticker shock at the pump is something all Americans are noticing. We can talk in esoteric sorts of ways about national energy policy, but when people drive up and have to fill up their tank to be able to drive their kids to school or be able to drive to work, that is when they begin to understand the consequences of Congress's failure to act in a number of respects.

Last year about this time, our friends on the other side of the aisle held a press conference over on Massachusetts Avenue and were decrying the lack of action on the part of the then majority of Congress to bring down gasoline prices, but since that time, the average retail price of gasoline has gone up by 13 cents. I saw in today's day book for the Associated Press that the new majority, the Democratic majority is now going to have another press conference over at the same gas station talking about high gas prices.

I would suggest the responsibilities of being in the majority are to act, not just to hold press conferences. I think our friends haven't quite recognized the fact that they are in charge now. They have a responsibility to act instead of using the same old shop-worn tactics of holding a press conference and launching new investigations.

In fact, the Federal Trade Commission and the Department of Justice have held extensive investigations already and basically concluded the problem is we don't have adequate supply, and we don't have adequate refinery capacity to keep up with the demand. As I noted yesterday, Congress can pass a lot of laws. We could even repeal some laws, but we can't repeal the laws of supply and demand. We know that in a booming world economy, where there is competition in India and China, countries with more than a billion people each, as the economies of other countries become more developed, they are going to demand more and more of the same limited supply of oil, and that is why we have seen the price of oil and gasoline go up. Rather than hold press conferences, my hope is our colleagues on the other side of the aisle, the new majority who is in charge, would work with us to pass legislation which would actually have an impact and bring down gasoline prices, bring down oil prices, and enhance our national security at the same time.

It is no secret to any of us that most—or not most but a lot of the oil that we import comes from troubled regions of the world. It comes from Hugo Chavez and Venezuela, it comes from the Middle East, and I don't need to say more about that and how much that supply is threatened at times by the bellicose actions of countries such as Iran, a rising, they hope, nuclear power. I hope they do not acquire nuclear capacity because they are a State sponsor of international terrorism. But my point is we need to develop more of our domestic resources. We need to look for alternative forms of energy that are clean. We need to continue our scientific research into things such as clean coal-burning technology. We have about 300 years' supply of coal in this country, and we all know that coal can burn dirty, but the fact is that by using the technological advantages that we have in this country, we can conduct the kind of research that will allow us to use this coal in a way that does not pollute and does not endanger the environment. The fact is we simply can't turn a blind eye to any source of energy and remain competitive in the world economy. But the fact is also that we are simply not going to solve these problems by holding press conferences, as our colleagues are going to do, apparently, this afternoon, I think at 2:30 or 3:30. I can't remember when. They did that last year when they were in the minority. They have not quite yet, I guess, accepted the fact that on November 7 they won the election and they are now responsible. It means more than holding press conferences; it means action.

I tell my colleagues the Republicans are willing, ready, and able to work with them to try to solve the energy crisis, the gasoline price crisis in this country. It is not going to be easy, but for sure, none of us can do it in a partisan way. The only way we are going to be able to do it is by working together in the best interests of the American people. I think the American people are more than a little tired of some of the hollow rhetoric when people talk about problems, but when you are in a position to actually do something about it, that nothing gets done.

As our leader on this side of the aisle, Senator MCCONNELL, has noted, divided Government actually provides an opportunity for us to take on some of these big problems, some of these big challenges that are harder to tackle when there is a single party in charge, but it takes a spirit of cooperation. It takes a desire to actually work together to try to solve these problems the best we can. The energy problem is just one of them. I would say the spiraling debt being accumulated by growth and entitlement programs is another one of them.

I am very disappointed that this new budget that is going to come to the floor later this week does nothing about passing the buck on entitlement spending. As a matter of fact, it imposes additional debt and burden on our children and grandchildren when we have the responsibility to pay our own bills, not use Social Security to pay for the general debt, which we are doing now, and other bookkeeping tactics that if we were in the private sector would probably mean that somebody would end up in jail. But the Federal Government plays those sorts of budget gimmicks, and they need to end.

So let me end by saying that this is an opportunity for us to work together but not if we are going to have press conferences and do nothing, talk tough but fail to use the tools that are available to us in Congress as representatives of our respective States to work together in a bipartisan way to try to solve them. I think that is what the American people want. That is why I came to the Senate. I wanted to do something. I wanted to actually make a difference. I think all of us feel roughly the same way, but somehow we have fallen into these bad habits of partisanship and avoiding the solutions that are readily at hand.

I thank the Chair and yield the floor.

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

Mr. THOMAS. Mr. President, I wish to join my friend from Texas in talking about the interest in energy. I don't think there is anything, frankly, when we look at it, that impacts our future and our jobs and our families anymore than energy and its availability. Think about it for a moment, what we actually use, each of us, every day. We drove here in our cars: energy; the lights up here: energy; air-conditioning or heat: energy; then, of course, in the whole economy. So I wanted to talk about some of it in the context of high gas prices and, of course, Americans are experiencing that right now.

I am on the Energy Committee, and we have passed good energy policy in the last couple years. We have already begun to see some of the benefits of that passage, there is no question about that, but there is much more that can be done. Unfortunately, we have gone along a good deal of the time this year and haven't done much about it, so we need to accomplish some things. The high price of gas, of course, touches all of us, but it is particularly important in a State such as mine, where people have to travel so far for school or work or other obligations.

Yesterday, the Energy Committee, of which I am a member, scheduled a hearing on short-term energy outlook for oil and gas. This hearing will be held next week, but that is not enough. Having hearings is not enough, as having press conferences is not enough. We need to move forward.

What is the answer to high gas prices? Of course, the simple economics of it is supply: Supply and demand. One option is to drive less, of course, and we can do some of this. We can have more efficient cars and those kinds of things. But we must drive to work. We must drive. We have to have energy. So there are some things we can do. But the other issue, and the one we can deal with, is increasing supply. My friend from Texas makes a good point. We get so wrapped up in bills and amendments sometimes, but we have to ask ourselves: What can we add? What can we regulate? What needs to be repealed? We cannot repeal the law of supply and demand. That is where the impact is on the price. That economic fact must inform this debate. We certainly can consume our energy in more efficient ways, and we should do that. I support those efforts. I am glad to be a cosponsor of a bill, S. 992, that does that. But we also have to pass alternative fuels, and I am for that. But I think we have to be honest on alternative fuels as to what kind of an impact that is going to have in a relatively short time. I am all for these kinds of things, whether it is wind or Sun or whatever, but it is years down the road before it will be able to do the kinds of volume that is necessary for energy.

So I think my real point is that in the meantime, as we look for alternatives, as we look for various things, there are things we can do now, and that is what we need to do to deal with our needs in the interim while these other things are being decided.

So I am hopeful the majority will bring legislation to the floor that allows us to provide Americans with secure, affordable, and responsible sources of energy. I am convinced that unless we move forward, the majority is not moving in this direction, and I think we must.

Last week, we marked up a biofuels bill in the Energy Committee. The bill focused on ethanol from corn and feed stuffs, and that is a good thing.

However, these fuels raise the cost of corn. They raise the cost of livestock feed and, subsequently, meat and other groceries. They cannot be transported in our existing system. You cannot put ethanol into pipelines and move it. The advanced technologies are not commercialized anywhere yet in the world.

Along with Senator BUNNING, I offered an amendment to add coal-to-liquids, and coal-to-liquids don't suffer from the same shortcomings as ethanol. It will have no impact on the affordability of food. It can be delivered through existing pipelines.

Coal is available as one of our most abundant resources, as a matter of fact. It is the most plentiful supply of fossil fuels we have in this country. Coal has the potential to be converted to liquids and fluids and to electricity on the spot. These are the things which need to be done.

We spent most of 2 hours talking about this amendment, and it received a great deal of support. However, when it came down to it, it was a party-line vote of 12 to 11, and it was defeated. So I will bring it to the floor when the Energy bill comes.

I think we need to look at the short-term impact. Here is one—conversion of coal to liquids—that can work. We are doing some of it now to a small degree. In Wyoming, we are developing a refinery that will take coal and turn it into diesel fuel. Interestingly enough, we had support from a number of agencies or organizations that you would not necessarily imagine in that, including the AFL–CIO building construction trades, AFL–CIO Industrial Union Council, Air Transportation Association. All these people know how important it is to have energy and to have it available. There is a list of about 15 groups of this kind that are supportive. They are not oil supporters necessarily; they are businesspeople who know that to meet our needs, we have to have energy.

Let me read from the letter they wrote:

> In this century, America cannot be secure unless its energy supplies are secure. Fostering greater reliance on domestic energy is a national security imperative. The Nation's abundant and affordable coal reserves, matched with the proven technology, can put America on the path to energy independence by dramatically reducing our growing dependence on imported oil and reducing our burgeoning trade deficit. Domestic production of coal-to-liquids fuels will see billions of dollars invested in new investments made in the United States and create thousands of new jobs.

That is not the end of the letter, but that is the message from groups that are not directly involved in energy but know the impacts of the shortage of energy. I could not agree more with the role these folks see in the future.

Senator BUNNING and I have been asked to refrain from offering our amendment, but we did not wait. We believe strongly in the purpose of the Energy Committee to develop the best possible approach we can in dealing with the energy problem and dealing with it not only in the long-term but in the shorter term until we reach the longer term goals that may be there. So we didn't achieve our goal there. That is why we want to move forward with this and see if we can't get coal-to-liquids in our energy policy and get some incentives to move forward. I want to work in a bipartisan way to address the current concerns our Members have. I hope we have the opportunity to revisit this issue.

Americans are suffering from high fuel prices. We should do everything we can to remedy that situation. We have to do more than just talk about it; we need to make a move to take our largest fossil fuel resource and make it available for domestic production.

Mr. President, I yield the floor and 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.

Ms. CANTWELL. 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. CANTWELL. Madam President, I ask unanimous consent to speak as in morning business for 5 minutes.

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

ENERGY INDEPENDENCE

Ms. CANTWELL. Madam President, I come to the floor this morning with a lot of enthusiasm for the progress we are making in various committees toward an energy policy we can discuss on the Senate floor which will eventually lead us to greater energy independence. I am very excited about this prospect; especially since I participated in the 2005 energy legislation, which was passed with great bipartisan support. We worked together to enact this groundbreaking energy bill in 2005, which greatly benefitted my State by giving tax credits to alternative energy technologies—wind and solar—and aided in the further development and broadened use of biodiesel and including the construction of a 100 million-gallon biodiesel facility in Washington State.

There were many great things about the 2005 Energy bill but the fact that stood out to me the most was that it was a bipartisan effort. I do wish that there had been a much more aggressive effort on energy independence then, but I think today we are on the cusp of achieving this important goal.

Senator REID has been very specific since the beginning of this legislative year that he wants energy independence to be a key priority. In fact, there are six different committees that are working on energy legislation today: the Agriculture, Nutrition, and Forestry Committee, the Finance Committee, the Commerce, Science, and Transportation Committee, the Environment and Public Works Committee, the Homeland Security and Governmental Affairs Committee, and the Energy and Natural Resources Committee. All of these committees are working hard on legislation, and more importantly, they are working on legislation in a bipartisan fashion. In fact, two of these committees have reported out significant energy legislation, working across the aisle ensure that we are getting the best ideas onto the Senate floor and continuing to discuss those ideas on which we have not yet been able to reach consensus.

Yesterday was undoubtedly a historic day because it marked the first time in 20 years, that we have been able to, in a very bipartisan way, put a CAFE bill on the Senate floor—which I hope we will be discussing soon—that actually increases the fuel efficiency standards of automobiles and hopefully lowers our consumption of foreign oil. If we can move from the current miles-per-

gallon standard of 25 miles today to 35 miles in a 10-year period, this would unquestionably be a great accomplishment.

Attached to this legislation is also very important consumer protection legislation that provides the Federal Trade Commission the tools it needs to protect consumers against price gouging. With our current statutes, the FTC has the ability to investigate certain cases on the basis of antitrust laws, which are based on whether we think oil companies are colluding to set prices. What we really have to question is whether the companies may be conducting activities that actually take supply offline and thereby decrease the supply, leading to shortages at the pump. Therefore we need to give the FTC the authority it needs through this legislation and make sure consumers are protected.

This legislation, as part of a package, was passed unanimously out of the Commerce, Science, and Transportation Committee yesterday. It was the result of a bipartisan effort, led by the work of the chairman, Senator INOUYE, and the ranking member, Senator STEVENS. Unfortunately certain provision did not make it into the final version of this bill, however I firmly believe that it is a historic and important piece of bipartisan legislation that will come to the Senate floor for all of us to discuss.

Just recently, the Energy and Natural Resources Committee passed another very positive landmark legislation which relates to setting a higher mandate on biofuels. In the last Energy bill we were able to pass, we stipulated that we should have a goal of producing 7½ billion gallons of biofuel a year by 2012. Both the President and the Congress are trying to achieve a higher goal. In this legislation, that sets the goal that by 2022, we would actually have a mandate of having 36 billion gallons of alternative fuel produced in this country. I firmly believe that this is a realistic goal and an achievable mandate for us, and that it will aid in starting mass-production of alternative fuels in this country.

In addition, that legislation had money for what we call a biofuels infrastructure—how we do actually get this product out to the consumer and to the corridors of transportation so the public does not have to worry about where they can fill up their cars. Thanks in part to this legislation we will have the infrastructure to do that.

In the Commerce Committee, we also produced legislation focusing on flex-fuel cars so that, by 2015, 80 percent of the cars being driven on our roads will be flex-fueled. These are vehicles that could either use gasoline or an alternative fuel.

We have also passed legislation now for studying plug-in hybrids and making sure the plug-in hybrid research continues to move ahead.

In the Energy bill, we also included language about carbon sequestration, making sure we move ahead so carbon sequestration becomes a reality. Again, this is an important issue and it is a very important bill to my colleagues in various parts of the country in which we have an ample supply of coal. I commend Senators DOMENICI and BINGAMAN for working so closely together. That legislation also was passed in a bipartisan effort. It is a great compliment to those two distinguished Senators who worked so closely on the last Energy bill to yet produce another Energy bill.

We are in a position to make a very positive impact on what I think is one of the biggest challenges we face, getting off our overdependence on foreign oil and providing sources of cleaner energy. We are well poised to take up that debate here on the Senate floor with this landmark bipartisan legislation out of two different committees.

We will have a lot of work to do across the aisle. We still have great opportunities to see legislation out of those other four committees I mentioned that will contribute to this energy package. But we should embrace the opportunity the President laid out in his State of the Union Address when he said that he wanted to make sure we had a higher fuel efficiency standard and that we also set a higher renewable fuel standard, and that is exactly what we are doing now.

I personally think we should also set a renewable standard for the amount of electricity we use from our electricity grid to further reduce our dependence on fossil fuel. These are topics that will be debated. I am sure later in the year we will have an important debate about climate change. But for now we are making great progress. I hope my colleagues will focus on the fact that this energy bill gives us another opportunity to work together here on the Senate floor and put real energy solutions before the American public.

Right now, with gas prices reaching $4, Americans want to know we are going to have an aggressive policy, not only giving them consumer protections but better planning for the future so our economy can benefit from alternative sources of fuel.

I yield the floor.

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 bill 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.

Pending:

Brown (for Grassley) amendment No. 1039, to clarify the authority of the Office of Surveillance and Epidemiology with respect to postmarket drug safety pursuant to recommendations by the Institute of Medicine.

Brown (for Grassley) amendment No. 998, to provide for the application of stronger civil penalties for violations of approved risk evaluation and mitigation strategies.

Brown (for Durbin/Bingaman) amendment No. 1034, to reduce financial conflict of interest in FDA Advisory Panels.

The PRESIDING OFFICER. Under the previous order, there will be 60 minutes for debate currently on the bill and remaining amendments, with 10 minutes under the control of the Senator from Iowa, Mr. GRASSLEY or his designee, 5 minutes under the control of the Senator from Illinois, Mr. DURBIN or his designee, and the remaining time equally divided between the chairman and ranking member or their designees.

The Senator from Massachusetts is recognized.

Mr. KENNEDY. Madam President, I yield myself 6 minutes of our time.

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

Mr. KENNEDY. Madam President, we will see later this morning the successful conclusion of this legislation. We have some important matters to consider, which we will do in a very short period of time. But as we are coming into the closing time for this amendment, I think it is appropriate that we review very quickly what this legislation does and what it does not do.

I am a strong believer in this legislation, which has strong bipartisan support. I am enormously grateful to Senator ENZI and Members on our side of the aisle as well as those on the other side for all of their help and assistance in getting us to the point where we are ready to take final action on something that makes a major difference to families in America. We ensure the safety of our prescription drug system and also are making very important progress in the safety of our food supply.

This is, in an important way, breakthrough legislation. I will review quickly what this does and then come back to the amendments that are before the Senate and how we think the Senate should dispose of them; why this legislation is urgent, why it is extremely important, and why the American people deserve the best.

Very quickly, again, there is strong emphasis on safer food and safer medicines for families in this country. We spelled out at the earlier part of our presentations the effective systems we have supported to make sure we are going to have the safest prescription drug program in the world, using different kinds of modern technologies and also modern surveillance systems for monitoring postmarketing safety. This will ensure in the future we are going to have the safest prescription drug program in the world. We will have safer medicines.

We will also have safer food for families and pets. I think all Americans have been alarmed, as they should have

been, by what has been reported in the news in the last few weeks. Many families have lost their pets because the agency lacked the authorities provided in this bill.

We will have earlier warnings on drug safety problems using extremely elaborate systems of postmarketing surveillance. These systems will use both public and private centers to collect information that the FDA will use to find early warnings of possible harm. In these cases, the agency will be able to take expeditious action. That has never been done before.

We are going to have better medicines for children. We are enormously appreciative of the excellent work that has been done by Senator DODD and Senator CLINTON. This was done in a bipartisan way with Senator DeWine, who is not here. We all realize that children are not little people; children are children, and therefore their bodies react differently to various kinds of prescription drugs. This legislation provides mechanisms to get information on safe and effective use of medications in children as well as to promote studies of drugs in pediatric populations. In the past few years, we have made enormous progress and we believe this legislation will help to an even greater extent.

We are going to have more transparency and stronger science at the FDA because of the wonderful work done by Senator MIKULSKI. She and others worked to assure that we have greater awareness by the public of what is happening at the agency.

There is greater focus and attention on making sure the agency is going to have the best in terms of the new sciences. We are in the life science century at the present time. This has been impressed on the country with the extraordinary convention on biosciences that took place in Boston in the last few days. There I listened and read about the potential the life sciences have, not only in terms of energy and agriculture but also in terms of medicines. The United States is absolutely poised to continue to be the world leader in these fields, with all of its implications of healthier families here and around the world.

We need to make sure we are going to have the best kind of science at the FDA. We do that in the way we have given greater authority over the development of the science function at FDA. We also provided a rather unique foundation that will be able to use public and private funding. This foundation will seek out the best and the newest modalities to help speed the review of various prescription drugs. That is going to be enormously important because time means cost. If we are able to resolve these issues more quickly the costs will be more understandable and reasonable to consumers and we will get them faster.

Briefly to comment on some of the amendments, we have taken a position in our proposal that both the safety and efficacy of particular prescription drugs is a function that ought to be considered in tandem. I know there are those who think we ought to separate those functions. We can imagine a circumstance, for example, where the side reaction of a particular drug is that individuals lose all of their hair and they become nauseated. Clearly I am describing the impact of methotrexate. That can happen to an individual on many anticancer drugs. You wouldn't prescribe that for athlete's foot because the side effects are so dramatic, but you would approve that for another kind of regime to try to treat cancer.

We also have items on civil penalties for the first time. There is a question of what those civil penalties should be. I want them to be higher, but I am mindful as well that this is the first time we are going to have those civil penalties. We are going to be working on those matters with the House. I basically think they should be a little higher, but I listened to my colleague on this issue and we are going to try to make sure we get something that is going to be fair and can do the job.

I am also mindful of the concern we have in terms of the potential of conflicts of interest. I will reserve my time to be able to deal with this issue.

This is a very important issue. We want to make sure, on the one hand, as we have these breakthroughs in science, that we are going to have the best experts participating in these review groups. We also have to be sensitive to the issues of conflicts of interests. I know the Senator from Illinois has a proposal on this.

I will reserve the rest of my time to be able to discuss that later.

ELEMENTS TO ASSURE SAFE USE

Ms. MURKOWSKI. Madam President I rise to engage in a colloquy with the Senator from Wyoming and ranking member of the Senate Health, Education, Labor, and Pensions Committee, Senator ENZI.

First, I would like to thank the chairman and the ranking member of the HELP Committee for their efforts to address the issue of access to health care in frontier areas. Much of Alaska is a frontier area and it is not an easy task to access health care in general, let alone find a specialist to obtain needed medications.

Toward that end, I am pleased that the bill before us today recognizes the problem of access and provides a willing provider in a frontier area with the ability to receive the training and certification necessary to prescribe a drug that has potential serious risks. For clarification purposes, I would like to ask the Senator from Wyoming if it is the intent of Congress that section 202 of S. 1082, the FDA Revitalization Act, allows all physician and nonphysician health care providers in frontier areas to be able to receive ''training or certification'' so that the provider can prescribe or dispense a particular drug without the need for an additional degree or medical specialty?

Mr. ENZI. Yes. This is the intent.

Ms. MURKOWSKI. And under the provisions of section 202, would the willing health care provider be able to receive this training or certification through remote learning methods so that a provider would not need to travel vast distances in order to get the requisite training?

Mr. ENZI. Yes. The language in the bill recognizes that travel in frontier areas, particularly in remote places such as Alaska, can be time-consuming and expensive, so it specifically notes that the training or certification should be available in a widely available training or certification method, such as an online course or through the mail. This is intended to reduce the amount of travel and expense a willing provider in a frontier area must undertake in order to be able to prescribe or dispense needed medicines to their

Ms. MURKOWSKI. I thank the Senator. And since the provider would not be required to obtain an additional degree or medical specialty, and the training or certification would hopefully be through an online course or through the mail, is there any indication of how long such training would take for the provider to be deemed sufficiently trained to prescribe a specific drug?

Mr. ENZI. While I cannot give the Senator a guaranteed time frame, I would point out that the training and certification is specifically for the drug the provider is seeking to prescribe or dispense—not for a range of drugs. Thus, the time frame should not be a lengthy one, particularly if the training can be conducted online.

Ms. MURKOWSKI. Now, I understand that many physicians around the country are invited to attend conferences or training seminars in order to be certified to prescribe certain drugs. Given the low volume of the high risk drugs we are talking about that are likely to be dispensed in frontier areas, how can we ensure that a willing provider will be able to access this training? What is the incentive for a drug manufacturer or the FDA to include frontier area among the areas where training and certification would be available?

Mr. ENZI. I thank the Senator for that question. The language in the bill specifically says that the training or certification shall be available to any willing provider from a frontier area. Shall be available—not may be available, but shall. It is the intent of Congress in this section to direct the FDA to guarantee that a willing provider will have access to the training and certification needed to prescribe a particular drug. And again, the language that encourages the availability of an online course or course through the mail is one way to provide for that training or certification at minimal cost.

Ms. MURKOWSKI. I thank the Senator for that clarification. I bring this colloquy to the Senate floor today because I want to ensure that every

American has access to prescription drugs regardless of whether they live in a large urban city like New York, or a frontier community like Bethel, AK. I believe that with the modifications that have been made to this bill, we will be able to achieve that.

Mr. FEINGOLD. Madam President, I am pleased to support S. 1082, the Food and Drug Administration Revitalization Act of 2007. This much-needed legislation improves our country's prescription drug and medical device safety, and responds to problems that Congress is long overdue in addressing. This legislation strengthens the Food and Drug Administration, a body that has been continually underfunded and weakened by political and corporate interests. While I would like to see an even stronger bill passed, this legislation drastically improves our current policies that regulate the FDA.

My constituents in Wisconsin largely trust that their food, medications, and medical devices are safe. I generally trust that they are as well. We all depend on the FDA to ensure that our lives are not jeopardized by faulty products or contaminated food. However, recently a steady stream of dangerous drugs, food, and devices have made their way into Americans' homes. Vioxx, antidepressant drugs for children, salmonella poisoning in food, pet food contaminations—these are just a few of the most publicized instances that have harmed and even killed people in our country.

Numerous investigations have been conducted in order to better understand why these events have occurred. The conclusions to these studies have found that we need a better FDA. We need to provide the agency with the legal authority necessary to ensure our safety, and we need to provide the FDA with the necessary funding to do its job. It is clear that the agency's authority has been watered down over the years as a result of corporate influence, and our citizens have suffered the consequences. This bill takes important steps to put safety over profit margins, and it has been long awaited.

I commend the immense bipartisan effort that has been put into crafting this legislation. This is not an easy topic to tackle. It is a complex topic rife with political infighting, but today we have legislation that both parties and even many companies are fine with. Granted, the bill may be too far-reaching for some, and for others like me, it doesn't necessarily go far enough, but this is something that will pass that is a vast improvement from current law.

I was glad to support Senator DURBIN's amendment to improve the FDA's oversight and ability to respond to contaminated pet food. Like the bill as a whole, I think we need to do more to ensure that the ingredients used in both pet and human food are free from contamination, but this amendment was an important step in the right direction. The amendment strengthens the standards for pet food processing and ingredients and at the same time improves the FDA's ability to react to a problem through better detection, an adulterated food registry, and improved communication with the public. I hope this will be a platform for improving Federal oversight of the human food supply, which has been shown many times over the last year to be at risk.

In my home State of Wisconsin, the outbreak of E.coli last summer, later linked to bagged spinach, killed an elderly woman and sickened at least fifty others. The spinach was traced back to four fields on four ranches in California. The FDA itself admits that ''There has been a long history of E. coli O157:H7 outbreaks involving leafy greens from the central California region'', and yet mostly depends on the industry to self-regulate. In fact, on the FDA Web site about this particular outbreak, it says, ''[the] FDA and the State of California expect the industry to develop a comprehensive plan which is designed to minimize the risk of another outbreak.'' I am concerned that all too often the FDA is allowing the food industry to dictate the rules and whether to implement food safety protections. This bill is a step in the right direction, but more steps are likely needed and I look forward to working with my colleagues on these.

Along these lines, I was glad to offer an amendment and have it accepted in the bill that would require the FDA to resume annual reports on the level of pesticide residues in domestic and imported food and agricultural products. Moreover, my amendment requires the FDA to make the report more useful for Congress and the public. Specifically the amendment requires the FDA to work with other agencies to include similar data collected by other government agencies, conduct more advanced statistical analysis, report on efforts to prevent smuggling through mislabeling one product as another, and target future testing on products or countries, in the case of exports, that show relatively more prohibited pesticides. The recent headlines about contaminated Chinese wheat gluten clearly show a need to get a better handle on food safety. So it clearly wasn't the time for the FDA to end reporting on pesticide residues and this amendment follows the larger theme of the bill in improving our food safety oversight.

While this pesticide residue amendment is important to improve consumers' confidence in the food they eat, it also can be important for U.S. farmers. For example, Wisconsin's ginseng growers have suffered a double insult over the past few years—facing unfair competition from imported ginseng that was treated with chemicals illegal in the U.S. and then often having that ginseng misbranded as the superior quality Wisconsin ginseng. My amendment and the improved pesticide residue data and ability to focus on certain products should help FDA identify and seize unsafe products such as contaminated ginseng imports.

On another note, I am disappointed that the bill does not actually allow importing lower cost prescription drugs. While the Dorgan-Snowe amendment was accepted in the bill, it was modified and effectively nullified by the Cochran amendment, which I strongly opposed

A competitive marketplace for prescription drugs will help in containing the skyrocketing costs of prescription drugs. Over the past 4 years, I have worked in a bipartisan fashion to allow the safe importation of prescription drugs from abroad. I am a proud cosponsor of the Pharmaceutical Market Access and Drug Safety Act, which the provisions in the Dorgan-Snowe amendment were based on. This legislation would have allowed the importation of FDA-approved drugs from countries with FDA-comparable regulations, such as Canada. This legislation will finally allow the importation of safe and affordable prescriptions drugs to the United States.

As I travel around Wisconsin listening to people's concerns, the high cost of health care continues to be at the top of the list, and this includes prescription drugs. The strong bipartisan support for reimportation makes clear that Americans of all political backgrounds want the Federal Government to support consumers, rather than the interests of drug companies, and make safe and affordable prescription drugs available to those who need them. The failure to include strong reimportation legislation in this bill is unfortunate, but we are getting closer to enacting reimportation with each vote. I fully expect this to pass in the near future, and I urge my colleagues to join me in supporting efforts to legalize reimportation. As I stated earlier, I will support the final FDA Revitalization Act, but I am disappointed that strong reimportation language is not included.

Mr. COBURN. Madam President, I appreciate the attention to drug safety on the part of Senators KENNEDY and ENZI. The drug safety problems our nation experienced surrounding Vioxx and the SSRIs demanded that we take a serious look at the FDA.

I appreciate the hundreds and hundreds of staff hours that have gone into working on this legislation both before and after the HELP Committee markup.

When the Health, Education, Labor, and Pensions Committee marked up this legislation, I strongly opposed it. I appreciate the willingness of Senators KENNEDY and ENZI to listen to my concerns and take action to address them. Many of the changes I requested are included in the final product that we vote on today.

This bill has come a very long ways since its consideration in the HELP Committee. Instead of requiring a risk evaluation and mitigation strategy, REMS, for every drug, a REMS may

only be requested when there is a scientific reason for one. In giving new regulatory authority to the FDA, we must be extremely cautious that we do not hurt access to new and innovative prescription drugs.

I appreciate that the concept, introduced by Senators GREGG, BURR, and myself, to establish a surveillance system for adverse prescription drug events has been included in this legislation. This will now allow cooperation with academic institutions that have the expertise to evaluate the signals from that surveillance system and ensure that both patients and doctors have the information they need to make decisions about the risks and benefits of medical drugs.

As a practicing physician, I know that it is impossible to ever completely eliminate drug risks. The right approach is to provide accurate risk information and preserve the doctor-patient relationship. I appreciate the progress made in the bill towards this end.

I appreciate the willingness of Senators KENNEDY and ENZI to work with me on preserving the doctor-patient relationship. The FDA's job is to approve drugs as safe and effective—not to dictate which doctors can prescribe which drugs to which patients. Medicine is not just a science; it is also an art.

This legislation will ensure that patients have access to potentially lifesaving drugs that might not otherwise be approved because of known adverse events caused by the drug. This legislation establishes that the agency will not limit or restrict distribution or use unless a drug has been shown to actually cause an adverse event.

I also appreciate the efforts of my colleague Senator ROBERTS in preserving the right to commercial free speech, as intended by the Constitution, in direct-to-consumer, DTC, advertising. While I am not a big fan of DTC, I am a big fan of the Constitution. I am pleased that a compromise was reached to remove the ban on DTC from this bill and instead ensure that drug companies are held accountable if their advertisements are false or misleading.

I appreciate the willingness of Senators KENNEDY and ENZI to accept an amendment that will provide a date certain for a safety evaluation of the drug RU–486.

The two user fee agreements for prescription drugs and medical devices, PDUFA and MDUFMA, have been negotiated between industry representatives and the FDA. The industry indicates what it will pay for faster drug approvals and the FDA commits to achievable performance goals.

I appreciate the work of FDA Commissioner Dr. Andrew von Eschenbach in crafting fair and reasonable proposals for both prescription drug and medical device companies. It is critical that we focus on public health and safety, and also hold the FDA accountable for improved agency performance goals. Maintaining timely and efficient patient access to lifesaving and life-enhancing medical drugs and devices is a win for the industry, doctors, and patients. I look forward to seeing how the new performance goals in both the PDUFA and MDUFMA agreements will both help keep the pipeline of innovation moving forward and improve communication and understanding between agency staff and manufacturers.

I can vote in favor of this legislation today because of the enormous progress made. However, there are some workability issues with both the Best Pharmaceuticals for Children Act and the Pediatric Research Improvement Act. These issues need to be resolved so that the FDA has the authority to do its job quickly and effectively.

The Best Pharmaceuticals for Children Act, BPCA, has generated more clinical information for the pediatric population than any other legislative or regulatory effort to date. I am concerned about this reauthorization of the Best Pharmaceuticals for Children Act because chips away at incentives that have been getting real results for kids.

I am also concerned that part of the bill, pediatric medical devices, would authorize $30 million in demonstration grants for improving the availability of pediatric devices. While this has a worthy goal, more accountability is needed for this program to ensure that such grants are used for helping save the lives of children. Additionally, the bill's sponsors failed to do their homework in examining existing Federal programs. The fact is, the National Institutes of Health already has a program for this purpose. In order to preserve a heritage for our grandchildren, Congress needs to do the hard work of taking an inventory of existing programs before we authorize new ones.

Again, I appreciate the enormous amount of work that has gone into improving this legislation. It is critical that in addressing drug safety that we do not harm access to new and lifesaving medical technologies.

Mr. DODD. Madam President, I rise to support passage of the committee substitute to S. 1082, the Food and Drug Administration Revitalization Act, FDARA. This legislation contains tremendous advances for children and their families through the reauthorization of the Best Pharmaceuticals for Children Act, BPCA, and the Pediatric Medical Device Safety and Improvement Act, which I authored, as well as the reauthorization of the Pediatric Research Equity Act, PREA, which was introduced by my colleague, Senator CLINTON.

I congratulate Chairman KENNEDY and Ranking Member ENZI for their efforts in putting this complex bill together and thank them both for working with me to ensure these vital programs for children can thrive well into the future.

We have had good debate on this legislation. I want to thank my friend from Colorado, Senator ALLARD, for the floor debate we had on BPCA. I want to assure him and those that voted for his amendment that this bill is about increasing pediatric clinical trials and improving our knowledge about products being used in children where previously we have had no information. BPCA is and has always been about striking an appropriate balance between the cost to consumers and benefits to children.

Ten years ago when Senator Mike DeWine and I undertook this effort, only 11 drugs on the market that were being used in children had actually been tested and studied for their use. Prior to the enactment of BPCA 10 years ago, pediatricians were essentially flying blind because they lacked information regarding the safety and effectiveness of drugs they were prescribing for children. But it was children who suffered the most from taking drugs where so little was known about their effects.

What we have learned over the past 10 years of experience is that children have been exposed to ineffective drugs, ineffective dosing, overdosing, or side effects from drugs that were previously unknown. In 10 years, nearly 800 studies involving more than 45,000 children in clinical trials have been completed. Useful new pediatric information is now part of product labeling for more than 119 drugs. In sum, there has been a twentyfold increase in the number of drugs studied in infants, children, and adolescents as a result of BPCA since its enactment.

Children with a wide range of diseases such as HIV/AIDS, cancer, allergies, asthma, neurological and psychiatric disorders, and obesity can now lead healthier, more productive lives as a result of new information about the safety and efficacy of drugs they use to treat and manage their diseases where previously there was none.

This successful program for children will expire on September 30 unless we act to reauthorize it.

The reauthorization of BPCA contained within S. 1082, makes several important improvements to this program which I have spent many months developing. It is my belief that these improvements will help ensure that this program continues to thrive well into the future. I strongly support the 5-year authorization of this program so that we can closely monitor how the program is working and make improvements as they are needed in the future.

S. 1082 will increase the amount and quality of pediatric information by streamlining BPCA and PREA at the Food and Drug Administration, FDA, and ensuring that labeling changes as a result of BPCA are communicated to physicians. S. 1082 will improve transparency and accountability by making market exclusivity determinations and written requests for pediatric studies public within 30 days of exclusivity being awarded. It also will improve the accuracy and speed of labeling changes

by requiring such changes to be made within the FDA's timeline and ensuring that labeling reflects the results of the BPCA study that was conducted.

S. 1082 will ensure that BPCA continues to yield more and better drug studies in children, while addressing the minority of cases where the incentive of 6 months additional market exclusivity has far exceeded the ''carrot'' it was intended to provide to drug sponsors. It improves market certainty by not allowing pediatric exclusivity to be granted within nine months of the end of the drug's patent and increases data about the use and applicability of BPCA through reports conducted by the Institute of Medicine, IOM, and the Government Accountability Office to review the program and assess the impact of the changes made within the legislation.

BPCA has shown us that it is unsafe to simply treat children as smaller versions of adults. Children face a similar inequity with respect to medical devices. Far too few medical devices are specifically designed for children's small and growing bodies. Experts say that the development of children's medical devices lags 5 to 10 years behind that of adults. That is largely due to the limited size of the market for pediatric devices.

When a medical device suitable for a child is needed to save that child's life but it does not exist, doctors are often forced to ''jury-rig'' adult versions of the device or, in some cases, perform a riskier surgery on the child. Ventilator masks, for instance, are far too large to fit over a baby's mouth. Often, the only alternative is to run an invasive tube down the baby's throat.

Because of what we witnessed over the past ten years with the market incentives provided under BPCA, I introduced an initiative called the Pediatric Medical Device Safety and Improvement Act to create similar incentives for device manufacturers. This legislation also streamlines the approval process for cutting-edge technology and establishes grants for matchmaking between inventors and manufacturers and the Federal Government.

Balancing incentives with safety, the legislation closely mirrors recommendations made by the IOM in its 2005 report on pediatric medical device safety to improve the serious flaws in the current postmarket safety surveillance of these devices. Specifically, the IOM called for and the legislation allows the FDA to require postmarket studies as a condition of clearance or approval for certain categories of devices and it gives the FDA the ability to require studies longer than 3 years with respect to a device that is to have significant use in pediatric populations if such studies would be necessary to address longer term pediatric questions, such as the impact on growth and development.

Some in the medical device industry continue to offer proposals to chip away at the authorities in the legislation intended to ensure the FDA can request manufacturers to conduct postmarket safety surveillances and ensure devices used in children are safe. I am disheartened by anyone who would attempt to deprive children and physicians of information that pertains to device safety and I will strongly oppose attempts to weaken the postmarket safety standards contained within the legislation as the bill heads to conference.

The faster we can get new, safe pediatric devices to market, the fewer parents have to stake their children's lives on improvisation and guesswork.

I have previously mentioned the broad-ranging support for these important initiatives for children but it is worth restating that the level of support from pediatricians, patient advocacy organizations, drug and device companies, and many others indicates that this important legislation will greatly benefit children and their families.

I want to thank the tremendous work of the staff on this bill. They have devoted countless hours and many weekends to working on this legislation. Specifically, I want to thank David Bowen and David Dorsey with Senator KENNEDY and Shana Christrup, Keith Flanagan and Amy Muhlberg with Senator ENZI who worked so closely with my office on the pediatrics initiatives in title IV of this legislation. I also want to thank Kate Leone with Senator HARRY REID whose terrific leadership helped guide this legislation to passage.

I also want to acknowledge the leadership of the American Academy of Pediatrics and the Elizabeth Glaser Pediatric AIDS Foundation whose staff, Mark Del Monte, Jeanne Ireland and Elaine Vining, have provided tremendous technical assistance on the pediatrics initiatives in S. 1082.

Before I close I want to address the other provision in this legislation which reauthorizes vital user fee programs at the FDA for drugs and devices and addresses the important issue of drug safety at the FDA, an agency that regulates 25 percent of the products consumed by Americans. In recent years, we have witnessed a public crisis of confidence in the FDA's ability to ensure that the drugs taken by millions of Americans are safe and effective once they are on the market. My colleagues and I on the Health, Education, Labor and Pensions, HELP, Committee heard testimony about the internal crisis within the scientific community at the FDA about inappropriate influences on decisionmaking.

I was deeply troubled by the recent Union of Concerned Scientists study showing that of nearly 1,000 FDA scientists questioned, 420 reported that they knew of cases in which the Department of Health and Human Services or FDA political appointees have inappropriately injected themselves into FDA determinations or actions. The same study also found that 378 FDA scientists disagreed or strongly disagreed that the FDA is acting effectively to protect public health. With Vioxx, antidepressants in children, and now Ketek, the FDA has repeatedly been accused of suppressing internal safety concerns and ignoring repeated warnings of safety concerns from the FDA's own scientists.

We need to restore the public trust in this vital agency, rid it of undue influences that benefit a political, rather than a public health, agenda, and, above all, we need to adequately fund the FDA through the appropriations process so that the agency is less reliant on user fees collected from private industry. Congress must act swiftly to give the FDA more resources. That, I believe, is how we maintain the FDA as the world's gold standard in drug and device safety.

Senator GRASSLEY and I authored one of the first drug safety and clinical trials bills in the Senate in the wake of the Vioxx scandal that would have given FDA's office of postmarket drug surveillance the independence, stature and funding to take action when a safety problem arises. We reintroduced the bill this congress with several colleagues on the HELP Committee including Senators MIKULSKI and BINGAMAN and I thank them for their support. While I do not agree with some of my colleagues who have argued that this authority would create a bigger bureaucracy at the FDA, our experience showed us that the support to move such a proposal simply wasn't there.

However, I believe that my colleagues and I were able to make significant improvements to S. 1082 with respect to drug safety. I believe those improvements will strengthen science at the FDA, improve transparency of decisionmaking so that dissenting views can be heard, and improve safety of drugs once they are on the market.

The drug safety and clinical trials components of S. 1082 are by no means perfect. In fact, I have serious concerns about what I view as inadequate enforcement authority in the bill and am particularly concerned about whether the bill will prevent companies from withholding information about clinical trials which were negative or were trials that companies abandoned because initial results were negative. As demonstrated by Ketek, I am also concerned about whether this bill does enough to capture clinical trials conducted overseas. I hope we can improve on these provisions when this bill goes to conference with the House.

Today the Senate voted on an important issue dealing with conflicts of interest on FDA advisory committees. As demonstrated by the FDA advisory committee considering Vioxx, it is clear that the FDA's policy with respect to financial conflicts of interest wasn't working. The FDA has made modifications to its policy and the underlying legislation makes several additional improvements. I believe the

amendment offered by Senators DURBIN and BINGAMAN would have made great improvements to the recruitment of qualified advisory committee members. The amendment would have required the FDA to conduct aggressive outreach to professional medical and scientific societies to help with recruitment for advisory committees, especially ones with the greatest number of vacancies. Those are important policy goals and ones that I fully support.

However, I voted against the amendment because I was concerned about the impact a hard and fast limit of one waiver per committee meeting would have on timely access to drugs and new drug information. Specifically, the Pediatric Advisory Committee, a standing FDA advisory committee which relies on experts with specific expertise in pediatric issues, is an important component of the Best Pharmaceuticals for Children Act program. I was concerned that setting an arbitrary limit on the number of waivers per committee meeting would further complicate an already small pool of qualified individuals in fields such as pediatrics.

I am disappointed that an agreement on the amendment was not reached between the bill managers and sponsors of the amendment so that the Senate bill could contain the important provisions dealing with recruitment and outreach. It is my hope that we can find a way to address these issues in the conference with the House.

Taken as a whole, the underlying legislation is vital to our nation's children as well as consumers needing timely access to safe and effective drugs. Therefore, it is essential that the House act quickly so that we can send a conference report to the President in the coming months. I urge the House to pass all of the major provisions contained in S. 1082. I support this legislation and look forward to continuing to work with my colleagues on both sides of the aisle and in both Chambers so that we can send this legislation to the President for his signature.

Mr. KENNEDY. Madam President, I would like to take some time to talk about some issues that I haven't spent a great deal of time describing to the Senate about S. 1082, the Food and Drug Administration Revitalization Act.

First, I thank Senator ROBERTS and Senator HARKIN for working with Senator ENZI and me and with many members of the committee on the important issue of direct-to-consumer, or DTC, advertising.

We have worked together to accomplish our common goal—a constitutionally sound, effective, workable way to see that DTC ads provide accurate information to patients about the drugs they are taking.

Some have advocated a ban on such advertising altogether, but Senator ENZI and I rejected that approach since it failed to meet the constitutional test. Instead, we included a more measured provision in our legislation that allows FDA to impose a moratorium in extraordinary circumstances where needed to protect public health.

During our committee's consideration of this issue, Senator ROBERTS brought up his concerns that even this limited provision fell afoul of recent Supreme Court decisions on free speech. Senator HARKIN raised his strong interest in seeing that these DTC ads include strong, effective safety information that is clearly and prominently presented to consumers in a way that does not gloss over important information. Senator ENZI and I committed to work with Senator ROBERTS to see that any provision on DTC met the constitutional threshold, and we agreed to work with Senator HARKIN to make certain that it provided strong safety information to consumers. The result of our discussions is an amendment that our two colleagues offered. It is a true bipartisan compromise, worked out by two Senators committed to making real progress on an important issue, and I am pleased to support the amendment.

Instead of the moratorium included in our original bill, the Roberts-Harkin amendment puts in place strong safety disclosures for DTC ads, coupled with effective enforcement. Under current law, safety disclosures can be an afterthought—a rushed disclaimer read by an announcer at the conclusion of a TV ad while distracting images help gloss over the important information provided. Our proposal requires safety announcements to be presented in a manner that is clear and conspicuous without distracting imagery.

We also give FDA the authority to require safety disclosures in DTC ads if the risk profile of the drug requires them. Senator ROBERTS had a concern that this authority not be used indiscriminately, so we have made clear that the required disclosure must pertain to a specific identified risk.

We have made important improvements in FDA's ability to enforce the requirement to provide clear and accurate information to consumers.

For advertisements, as in so many other areas, FDA's enforcement tools are now limited. Although FDA does have the capacity under current law to remove a drug from the market for misleading ads, that authority is not often used and rightly so, since it punishes patients for the transgressions of the manufacturers. Since removing a drug from the market is an empty threat, FDA is often left with little option but to make polite requests to companies to change their ads. Under the Roberts-Harkin amendment, FDA will have the ability to levy fines of up to $150,000 for false or misleading ads.

It is unacceptable for patients to be put at risk by inaccurate ads. The Roberts-Harkin amendment makes certain that FDA will have the ability to see that this does not occur, in a way that is clearly consistent with the Constitution.

The amendment is a victory for bipartisan common sense on a difficult issue.

I would also like to address the affect of title II of this bill. Generally speaking, title II grants the FDA new authority to conduct postapproval safety surveillance activity in order to improve drug safety.

In enacting title II, we do not intend to alter existing State law duties imposed on the holder of an approved drug application to obtain and disclose information regarding drug safety hazards either before or after the drug receives FDA approval or labeling. Nor are we expressing a belief that the regulatory scheme embodied in the bill is comprehensive enough to preempt the field or every aspect of State law. FDA's approved label has always been understood to be the minimum requirement necessary for approval. In providing the FDA with new tools and enhanced authority to determine drug safety, we do not intend to convert this minimum requirement into a maximum.

As the Institute of Medicine and others have found, the FDA's past performance has been inadequate. While we fully expect substantial improvement as a result of the enactment of this bill, we cannot and do not expect the FDA or this new process to identify every drug-specific safety concern before a drug manufacturer becomes aware or should have become aware of such concerns. Nor are the bill's requirements that holders disclose certain safety information to the Government intended to substitute for the disclosure requirements that may be required under State law.

I would also like to focus on another aspect of our legislation, the Reagan-Udall Foundation.

During the discussions that led to consideration of this bill, we heard time and again that there was a major need for better research tools to aid FDA in evaluating the safety of drugs and help researchers move through the long process of developing drugs more effectively. Every day that a new medicine is needlessly delayed is another day that a patient does not receive a treatment that could well mean the difference between health and continued illness. If new research tools and better ways to evaluate the safety and effectiveness of drugs could be developed, patients will benefit from quicker drug development. If current procedures can be made more effective, then the cost of developing new drugs will drop.

One area where scientists can make real progress is developing new cell lines and new genetic techniques for testing drugs that reduce the need for costly forms of testing.

The Reagan-Udall Foundation sets up a way to develop these new tools—not so they can help just one researcher or one company, but so they can help the entire research enterprise. New ways to test drugs for effectiveness and safety

will bring new advances to patients quicker and more smoothly. Through the Reagan-Udall Foundation, they will be available to the FDA and to the entire research enterprise. This new foundation is not many pages in a long bill, but it is an important component to help get needed medicines to patients as quickly as safety will allow.

I also wish to mention another critical aspect of our legislation—its registry of clinical trials.

This provision serves two essential purposes. First, it allows patients who want to enroll in those trials an accessible and central Internet site to find out which trials are being conducted and whether they might be eligible.

This provision builds on an existing provision of law to create a clinical trials site, but report after report has shown that the requirement to list trials has not been complied with. Our legislation puts more force in the requirement to list trials so that patients will benefit.

Listing trials is important for patient access—but reporting results is critical for safety. Our legislation requires that the results of trials be reported. No longer will companies be able to hide the outcome of a trial that did not turn out the way they hoped.

Examples of this kind of abuse are shocking. The manufacturer of the antidepressant drug Paxil conducted five clinical trials of the drug in adolescents and children, yet published only one study whose mixed results it deemed positive. The company sat on two major studies for up to 4 years, although the results of one were divulged by a whistleblower and all of the studies were submitted to the FDA when the company sought approval for new uses of Paxil. At that time it became apparent that Paxil was no more effective than a placebo in treating adolescent depression.

Under the bill, these kinds of abuses will not be permitted, since clinical trials will have to be reported—no matter what the result.

Senator ENZI, Senator DODD and many others in the committee worked hard to get this provision right. We require immediate listing of all publicly available data and require a negotiated rulemaking, backed by the full authority of statute to develop the precise requirements for other results information to be included.

I would like to thank my colleagues for considering these comments as they relate to S. 1082, and I urge my colleagues to support the bill.

Mr. COBURN. Madam President, as we debate the important issue of drug safety, I want to address the safety of one drug in particular: RU–486 or mifepristone. This drug was approved in 2000 under a special pathway, subpart H drug approval that is reserved for drugs that treat severe or life-threatening illnesses. Subpart H approvals generally require a special ''restricted distribution'' approval process. Unfortunately some drugs, RU–486 for example, approved under subpart H have caused serious adverse health events in women.

Every drug approved under Subpart H is listed on the Food and Drug Administration's Web site. The vast majority of drugs listed combat HIV or specific types of cancer. One governs the use of thalidomide in treating leprosy. These drugs are supposed to relate to the treatment of life-threatening illnesses.

One example of a subpart H approval makes a mockery of the regulatory process by an expedited approval of two extremely risky drugs for abortions. Pregnancy is not an illness and certainly not one that is life-threatening in the first 7 weeks, unless it is a tubal or ectopic pregnancy in which case RU–486 abortions are absolutely contraindicated.

RU–486 was inappropriately approved in 2000. RU–486 was approved using special ''subpart H'' regulations to address problems for ''certain new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses . . .'' and under restricted distribution conditions due to serious hazards presented by the drug; for example, severe hemorrhage and ectopic pregnancies. This was an inappropriate approval of RU–486 as pregnancy is not normally a life-threatening condition. Today many health care providers do not follow the limited distribution requirements of RU–486's approval.

RU–486 has put women's lives at risk. To date there have been six North American deaths related to the use of the RU–486 abortion regimen: five Americans and one Canadian have died from septic shock stemming from infection by the anaerobic bacteria Clostridium sordellii. Five other international deaths have been related to RU–486.

RU–486 causes serious safety issues. More than 1,000 adverse event reports—232 hospitalizations, 116 blood transfusions, and 88 cases of infection—have been submitted regarding RU–486 and are significant because they confirm that large numbers of mifepristone patients require surgical intervention for infection, hemorrhage, complications from ectopic pregnancy, and incomplete abortions. While lives have been lost from the use of RU–486, not a single case has been documented where RU–486 has been used to save a woman's life.

RU–486 is not always effective and when it is not the consequences are dire. I recently learned of a woman who was given RU–486 after she had a seizure. Her physicians assumed that the seizure was life-threatening to the baby she was carrying and gave her RU–486 for a therapeutic abortion.

RU–486 was not effective in her case and the woman carried the baby to term. When the baby was born at a low birth weight, it also suffered from failure to thrive. That baby has had three subsequent brain surgeries due to hydrocephalus. The baby also suffers from idiopathic lymphocytocholitis—an inflammatory disease of the colon, which is extremely rare in children. It is clear that RU–486 not only is unsafe in women, but it is also not completely effective. And when it is not effective, the results are devastating.

I appreciate the desire to effect safer drugs through this bill. Senator KENNEDY and Senator ENZI have done a great deal of work in designing the REMS scheme for certain drugs to ensure that they can be safely and effectively used.

Under the risk evaluation and mitigation system, REMS, provisions of this drug safety bill, a drug that has previously been approved under subpart H is deemed to have a REMS. Every REMS is subject to a periodic review. Therefore, RU–486 is deemed to have a REMS and is subject to periodic review.

I am pleased that the amendment offered by Senator DEMINT was accepted by the full Senate. Senator DEMINT's amendment sets a ''date certain'' REMS assessment for RU–486 to properly evaluate its drug safety risks in women. Women in this country deserve to know the safety risks associated with RU–486.

The PRESIDING OFFICER. Who yields time? The Senator from Illinois.

AMENDMENT NO. 1034

Mr. DURBIN. Madam President, I have an amendment pending and scheduled for a vote this morning on the conflict of interest provision. I believe I have 5 minutes to speak to it.

The PRESIDING OFFICER. The Senator does have 5 minutes.

Mr. DURBIN. I ask the chairman and ranking member if this a convenient time to raise the issue?

Thank you very much.

Yesterday I proposed this amendment with Senator BINGAMAN. The Food and Drug Administration Advisory Committees make important decisions, life-and-death decisions. They decide whether the drugs and medical devices which are going to be used in America are safe and effective. In other words, if a person in America has a prescription from a doctor and takes this drug, is it going to be good for their health, or bad?

This is a critical situation. If they make the wrong decision, if the advisory committee turns a dangerous drug loose on the market, it can have terrible consequences, so these committees literally have life-and-death decisions in their hands on approving drugs, on deciding what the warning labels say, deciding what you have to say in advertising. There might be a danger in these drugs. These advisory committees are the juries of scientific experts who have to make these calls. That is one of the most important decisions of our Government.

They are not just life-and-death decisions, they are decisions involving millions and millions of dollars. Drug companies spend a fortune over a long period of time trying to bring a drug to

market. They would hope this will be a drug very popular and profitable for them and their shareholders. That is a natural inclination of a business. So the advisory committee not only decides the safety and efficacy of the product, it makes a decision which has a direct impact worth millions of dollars to the drug companies involved.

Do you know what we found out? We found out over the last 10 years many people sitting on these advisory committees, those who are actually sitting on the so-called juries and deciding the fate of these drugs, have a conflict of interest. Some of them were already receiving, from the companies that make the drugs, tens of thousands of dollars in consulting fees and speaking fees. It turns out they are on the payroll, some of them, of the very companies on which they are being asked to stand in judgment. That is a conflict of interest which people cannot accept and I cannot accept.

The Food and Drug Administration argues that there are so few experts that we have to sometimes turn to those who have a conflict of interest; there is no place else to go. So occasionally we have to put a waiver in and allow someone to sit on an advisory committee panel who frankly has a financial interest in the company they are making a decision about.

That worries me. Because if you are going to have truly objective jurisdictions, that are right for the consumers of America, that approve drugs or disapprove them on the merits, not because of some inclination or prejudice which you might bring to the table, you don't need these conflicts of interest.

So basically what Senator BINGAMAN and I have said is: Let's strengthen the conflict-of-interest provisions on advisory committees. Let's make certain that there is confidence in the process. We know what happened with Vioxx. There were 10 people sitting on the advisory committee who had a financial conflict of interest. Had they been removed from the deliberation, the panel would not have recommended they go back on the market, endangering the health of thousands of Americans.

How can you ever justify that kind of conflict of interest? Our language tightens it. What we are trying to do is to make sure the Food and Drug Administration, with this amendment, limits the number of waivers to one per each advisory committee meeting, allows advisory committees to receive information from guest experts who have a financial conflict but prevents those experts from participating in the deliberations.

They can come in and express their point of view and then leave the room before the deliberation and the vote take place. And also strengthen the provisions to increase the outreach for new experts. The Food and Drug Administration has to do a better job of cultivating this new cadre of trustworthy experts who can serve on these advisory committees.

We have 125 medical schools in this country, 90 schools of pharmacy, 40 schools of public health. If the FDA is more aggressive in filling the slots on the advisory committees, we can remove this shadow of doubt which is over this process.

Now, some will argue: Well, the FDA has come forward with draft guidance to improve this. This is draft guidance. They are suggestions. This is law. This tells them they will have to follow the law to avoid these conflicts of interest. This is not an idea that Senator BINGAMAN and I bring to the table without support.

I ask unanimous consent, Madam President, to have printed in the RECORD with my remarks letters from the Consumers Union, the Union of Concerned Scientists, and a broader letter from 11 different organization that support this amendment, that would reduce and eliminate the conflicts of interest when it comes to approving new drugs and medical devices. What is at stake is the integrity of the Food and Drug Administration, the integrity of the process, and making certain we can say, with a straight face to American consumers, the products that are coming to the market, the life-and-death decisions that are being made that bring them to the market are being made by people who do not have a financial conflict of interest with these devices. I urge my colleagues to support the Durbin-Bingaman amendment.

I ask unanimous consent these letters be printed in the RECORD after my remarks.

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

CONSUMERS UNION,
May 8, 2007.

DEAR SENATOR, Consumers Union, the nonprofit, independent publisher of Consumer Reports, urges you to support the Durbin-Bingaman amendment to S. 1082, the Food and Drug Administration Revitalization Act. This amendment will help ensure that FDA advisory committees responsible for assessing a drug's safety are not inappropriately influenced by scientists or others with financial ties to the affected drug company.

A recent national survey by Consumer Reports National Research Center found that Americans are extremely concerned about the pharmaceutical industry's influence on the drug safety process, as well as financial conflicts on FDA advisory boards.

Sixty percent of those surveyed disapproved of allowing doctors and scientists with a conflicting financial interest to participate on advisory boards. And 84 percent of consumers agree that drug companies have too much influence over the government officials who regulate them.

This amendment would make it more difficult for the FDA to issue financial conflicts of interest waivers to the scientific experts who serve on its advisory committees. The Durbin-Bingaman amendment would: limit the number of waivers to one per advisory committee meeting; establish a specific process to allow experts with a financial conflict to present information to an advisory committee, while not permitting them to deliberate or vote with the committee; and enhance the FDA's outreach activities for identifying non-conflicted experts to participate in advisory committees.

The integrity of the FDA advisory process is vital to ensuring that decisions by federal policymakers benefit the public, and not the agendas of any special interest.

Please support the Durbin-Bingaman amendment to S. 1082. If you have any questions, please contact Bill Vaughan.

Sincerely,

BILL VAUGHAN,
Senior Policy Analyst.

MAY 8, 2007.

DEAR SENATOR: The Union of Concerned Scientists strongly urges you to support the Durbin-Bingaman amendment to the FDA Revitalization Act, S. 1082. This amendment will help ensure that the Food and Drug Agency's assessment of the safety and efficacy of drugs is not inappropriately influenced by scientists with ties to the drug companies affected by an FDA approval decision.

This amendment would make it more difficult for the FDA to issue financial conflicts of interest waivers to the scientific experts who serve on its 30-plus advisory committees.

Conflicts of interest can have serious consequences for drug safety. For example, ten of the 32 scientists on the February 2005 advisory committee that considered the safety of Cox-2 inhibitors, including Vioxx, had ties to the drug companies that made the products. The scientists voted to permit the companies to continue marketing the drugs, even though Vioxx had already been withdrawn from the market and had been implicated in tens of thousands of deaths.

The Durbin-Bingaman amendment would: limit the number of waivers to one per advisory committee meeting; establish a specific process to allow experts with a financial conflict to present information to an advisory committee, while not permitting them to deliberate or vote with the committee; and enhance the FDA's outreach activities for identifying non-conflicted experts to participate in advisory committees.

The integrity of science is vital to ensuring that decisions by federal policymakers benefit the public, and not the agendas of any special interest. We at the Union of Concerned Scientists are working to ensure that federal scientists, and those who advise federal agencies, are free to do their work without interference. This amendment will be a constructive step in addressing the pervasive problem of political interference in government science.

For all these reasons, we believe that the Durbin-Bingaman amendment merits your support. Please call our Washington Representative Celia Wexler if you'd like more information on either S. 1082 or the amendment.

Sincerely,

DR. FRANCESCA GRIFO,
Director, Scientific Integrity Program,
Union of Concerned Scientists.

APRIL 30, 2007.

Senator JEFF BINGAMAN,
Washington, DC.

DEAR SENATOR BINGAMAN: We, the undersigned organizations, give our wholehearted support to the amendment to S. 1082 that you plan to offer next week that would limit the number of conflict of interest waivers allowed on Food and Drug Administration advisory committees. This amendment would end the vast majority of conflicts of interest while insuring that the FDA has access to the best advice that this nation has to offer.

The amendment would: require the FDA to engage in greater efforts to find experts without conflicts of interest to serve on its

advisory committees; limit the number of waivers that can be granted to one per committee per year; and authorize the FDA to hire experts who have conflicts of interest to make presentations and answer questions at an advisory committee meeting if the FDA believes their expertise is crucial. However, these experts will not be allowed to vote or otherwise participate in the discussions leading up to committee vote.

The FDA advisory committee process has been severely compromised in recent years. According to the agency's most recent report, one in four experts advising the FDA received waivers because they have financial ties to companies with a stake in the outcome of advisory committee meetings. At the February 2005 meeting which voted to allow continued marketing of Vioxx and Bextra, nearly a third of the advisers had ties to Cox-2 manufacturers and had their votes not been counted, the vote would have been reversed.

The status quo is undermining the public's faith in the ability of the FDA to protect it from unsafe or ineffective drugs. We believe passing this amendment will help rebuild the public's confidence in the integrity of the scientific process at the FDA. Please circulate this letter among your colleagues and encourage them to vote yes on the Bingaman amendment.

Sincerely,

Center for Medical Consumers, Center for Science in the Public Interest, Consumers Union, Government Accountability Project, National Research Center for Women & Families, National Women's Health Network, Reproductive Health Technologies Project, Title II Community AIDS National Network, Union of Concerned Scientists, U.S. PIRG, Woody Matters.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Madam President, I wish to thank the Senator from Massachusetts, Mr. KENNEDY, for the statement he made a little bit earlier but mostly for the 2½ years' worth of effort he and I have put into this bill. It has been a very cooperative process between he and I and between the Members on both sides of the aisle on the committee.

There have been a lot of points raised about food and drug safety, particularly drug safety. It has been a cooperative process, as I mentioned. We have had a lot of questions. We have had some disagreements. But what that has resulted in is going back and getting more information and finding a way that we can come up with a solution that will provide more assurance to Americans that their drugs will be safe.

I also wish to thank the people at the Food and Drug Administration for their participation in this lengthy process and providing answers. It has been a long road for this bill. I do strongly urge my colleagues to vote ''yes'' on final passage and endorse the most comprehensive drug safety overhaul in more than a decade.

Completion of this bill marks yet another significant step in the process, but there is more work to be done. The House needs to pass their version of the legislation, and then the two bodies need to work out differences in the conference committee. My hope and expectation is that the House will act in a reasonable manner and soon because this is widely considered to be must-pass legislation.

This key FDA package includes four reauthorizations that must be done this year, along with the essential new authorities for the FDA to be able to react in a timely way to safety problems that arise after a drug has been brought to the market.

I would like to take a couple minutes to recap for my colleagues the path this legislation has taken thus far. The Senate Committee on Health, Education, Labor, and Pensions conducted a top-to-bottom review of the FDA's drug safety and approval processes over 2 years ago. We did that at the same time the Finance Committee was doing a review of the FDA's safety approval processes.

We used this information plus information from other Senators to do this bill. The bill is a culmination of that review and our continued evaluation and analysis of the FDA. The changes made in the drug safety components of this legislation are critical to restoring peace of mind to Americans who want to be assured the drugs they purchase to treat illnesses and chronic medical conditions can be relied upon and trusted.

Given the limitations we identified during our review of the FDA, I felt strongly it was necessary to correct those problems and ensure that the FDA has the right tools in the toolbox to address drug safety after the drug is on the market. That is why this bill creates the Risk Evaluation and Mitigation Strategy or REMS. The REMS give the FDA the full toolbox of options for dealing with potential safety problems, even if they are discovered after the drug is first marketed.

Our goal is to get the drugs to the market quicker and to discover problems faster and get them corrected. With this new toolbox, the FDA has the ability to identify side effects after the drug is marketed through active surveillance. FDA has the authority to request a separate study or clinical trial to learn more about a particular potential safety problem.

FDA can also obtain timely label changes for the first time under this Risk Evaluation and Mitigation Strategy System. Through the REMS process, the bill also makes several key improvements to how patients get their information through advertising and labeling.

I wish to thank my colleague, Senator ROBERTS, for his tireless efforts to provide an appropriate balance for direct-to-consumer advertising. It was not an easy task to reconcile some very different opinions. I am so pleased we were able to reach a resolution on this issue that we can all support.

I also thank my colleagues, Senator HARKIN and Senator KENNEDY, for their hard work on this issue. Senator ROBERTS had planned to vote for S. 1082 but cannot be here today because he is in Kansas showing the President the damage from the tornadoes. I wish him all the best in helping his State recover from that tragedy.

The FDA currently has very little authority to require labeling changes after a drug is brought to market. We have included provisions that ensure discussions between FDA and a drug manufacturer regarding the labeling changes come to a close quickly and effectively, rather than relying on FDA's nuclear option, which is pulling the drug completely off the market.

This legislation gives FDA the tools needed to get drugs to the market quickly and efficiently and to respond to potential problems the same way, especially when lives are on the line and people need new drugs and therapies.

FDA currently has no mechanism from active, routine surveillance of potential safety problems. It cannot easily detect safety problems after a drug has been put on the market. This legislation fixes that challenge and ensures that FDA has the right tools to address drug safety after the drug is on the market.

The legislation allows for routine, active safe monitoring using large linked databases, what I call health IT for drug safety. I wish to thank Senator GREGG for being the champion of this provision and ensuring that we crafted this provision properly.

Not every drug will need a REMS. However, every drug will need a very active FDA, an FDA with all the necessary tools to identify and quickly manage additional risks.

Title IV of the bill before us contains a number of critical provisions to improve children's health. Up to 75 percent of drugs used by kids have not been tested in kids. Without information from pediatric studies, kids are often overdosed, underdosed or receive ineffective treatment. They may suffer needlessly or even die. The Best Pharmaceuticals for Children Act makes drugs safer for kids by creating incentives to perform pediatric drug studies. The incentives have produced astonishing results. In the 7 years before BPCA incentives, a total of 11 pediatric studies were performed; 7 years, 11 studies.

In the 10 years since incentives were authorized, at least 132 studies have been completed and more are underway. As a grandfather, I am very happy that the law is in place. If my grandson Trey is sick, I want the drugs he needs to have been tested for kids. All of us want that for our children and grandchildren.

The bill also reauthorizes a companion study, the Pediatric Research Improvement Act, which enables FDA to require a pediatric study if it is not done under the incentive program or through the National Institutes of Health. These two laws work together as a carrot and a stick. I strongly support their reauthorization and continuing to keep them together.

Now, so far I have only talked about drugs for kids. The bill will also make medical devices safer for kids. Devices designed for adults might not fit in kids. A scaled-down device might fit at first, but a child can grow out of it, so doctors have to jury-rig adult devices, improvise or use more invasive treatments. In addition, the market for kids' devices is small, and the development costs are very high, so few kids' devices get made.

The bill before us creates new incentives to grow the market for kid's medical devices. I am hopeful these new incentives will be as helpful as the kids' drug incentive. I would like to thank Senator ALEXANDER, Senator ALLARD, Senator BOND, Senator DODD, Senator CLINTON, and others for their leadership on behalf of kids.

A number of other FDA issues were also addressed during debate of this legislation. The legislation was improved when the Senate adopted a food safety amendment by a vote of 94 to 0. This amendment adds additional food safety provisions to better protect our pet food supply and track when food is adulterated. My colleagues and I also reached consensus that the issue of follow-on biologics will be addressed in the Help Committee early this summer.

As my colleagues know, I have some concerns with the Dorgan amendment on drug importation that was adopted last week. I supported the Cochran safety amendment that was also adopted. I did not support the Dorgan approach to foreign drug importation because I do not believe it adequately ensures the safety of the prescription drug supply.

I was pleased to work with my colleague, Senator DORGAN, to add some very significant anticounterfeiting language to the bill in the managers' amendment. But a lot of work still remains. I support the process moving forward, and I will continue to work with my colleagues and Senator DORGAN and Senator SNOWE to improve this language during the conference process.

Finally, I would like to thank Senator HATCH for his work on the antibiotics and other Hatch-Waxman issues and the follow-on biologics. Senator HATCH was responsible for the first FDA Revitalization Act in 1990, before I was even elected a Member of the Senate. I would like to thank him for helping me to bring that full circle and for the mentoring he has done as a former chairman of the committee.

I will have a lot more thank-yous to deliver after the votes, but right now we have a bit of business left to conduct.

I yield the floor and retain the remainder of my time.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Madam President, how much time remains?

The PRESIDING OFFICER. The managers have 14 minutes.

Mr. KENNEDY. Madam President, I yield myself 4 minutes.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized for 4 minutes.

Mr. KENNEDY. Madam President, I commend my colleague from Illinois and my colleague from New Mexico for their amendment on the conflicts of interest and for working with us to address these issues in appropriations bills during the past year.

Their amendment includes many thoughtful proposals I support: including the right to call for the FDA to improve its outreach to experts who have no conflicts of interest and their right to call for greater transparency in the process of waivers.

But where I disagree with my friend from Illinois and New Mexico is that there should be an inflexible cap on the number of waivers for conflicts of interests an advisory committee can grant, no matter what the expertise of the scientists involved.

The amendment would impose a one-size-fits all, one waiver per conflict, per committee, relegating any additional members with conflicts to a secondary guest status on the committee.

The FDA has recently issued a policy not to grant a waiver for a financial interest that exceeds $50,000 and will allow those who receive a waiver for a lesser conflict to serve only as members who can participate in committee discussions but not vote.

The hallmark of this proposal is the flexibility it gives to ensure the committees will have the adequate expertise. If one or more experts with financial conflicts in excess of $50,000 have expertise that is essential to a committee, the Commissioner can grant the needed waivers. This is expected to be rare, but it can happen if needed.

Under the Durbin amendment, by contrast, the FDA can grant only one waiver per meeting. There is no flexibility on this point.

The FDA is already experiencing difficulty in filling vacancies on advisory committees. The Durbin amendment, no matter how well-intentioned, would worsen the problems, making it harder to fill critical vacancies and slowing the process of reviewing new medicines.

Let's look at the problem FDA is facing now. The Antiviral Drugs Advisory Committee needs six experts with specialized knowledge in the fields of clinical pharmacology, internal medicine, infectious diseases, microbiology, virology, immunology, pediatrics, and other specialties. These experts are needed to review the safety and effectiveness of new medicines for pandemic flu, HIV/AIDS, and other serious infections. The Anesthesiology and Respiratory Therapy Devices Panel has nine vacancies. The Ophthalmology Panel is in need of nine experts. The Advisory Committee on Peripheral and Central Nervous System Drugs needs six members—on and on down the list, the story is the same, critical vacancies, missed opportunities, and missed expertise. I am not for conflicts of interest. I am against them. But they are a fact of life.

We need policies that reflect the current reality of research in the life sciences. We have increased transparency in this legislation so there will be wide understanding of exactly how decisions are made. This is the most important. In the time of life sciences, we are talking about cross-fertilization of different ideas. Visit the Institute of Medicine. They are talking about the life sciences and work that is taking place. Flip a molecule and it could be relevant to alternative fuels. Flip it again and it can be relevant to agriculture. Flip it again and it can be relevant to the health sciences. We need all of these disciplines working together. To take one particular requirement and exclude the possibility of getting the best in terms of future scientists, we need integrity in the FDA, integrity in decisionmaking, integrity when they grant waivers. The public ought to have the right to know. We have a balance in here. Hopefully, we will retain it.

I withhold the remainder of my time.

AMENDMENT NO. 1039

The PRESIDING OFFICER. The Senator from Iowa.

Mr. GRASSLEY. Madam President, I yield myself 5 minutes out of the 10 allotted to me.

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

Mr. GRASSLEY. I am going to speak about amendment No. 1039. I ask unanimous consent that Senators MIKULSKI, BROWN, SNOWE, and BINGAMAN be added as cosponsors.

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

Mr. GRASSLEY. This amendment is important because S. 1082 does not sufficiently address the underlying problems I have found existing at the Food and Drug Administration during my tenure as chairman of the Senate Finance Committee looking into the problems of the Food and Drug Administration, with the goal in mind that the Federal Government should only be paying for drugs that are safe. That problem is the lack of equality between the Office of New Drugs, which reviews drug applications and decides whether to approve a drug for marketing, and the Office of Surveillance and Epidemiology, the office which monitors and assesses the safety of drugs postmarketing.

Many times I quote the Institute of Medicine as justification for my amendment. They recognize this problem. The Institute of Medicine recognizes joint authority between these two offices for postapproval regulatory action related to safety. Even the Consumers Union supports this amendment.

Having equality between preapproval and postapproval offices at the FDA is fundamental to real reform. Concentrating on the entire life cycle of drugs

is critical. After all, the vast majority of a drug's life cycle is spent post-approval. In essence, the bill before us promotes the status quo when it comes to the specific role played by the Office of Surveillance. That means the Office of Surveillance and Epidemiology will remain nothing more than a mere consultant to the Office of New Drugs. This is not acceptable.

Amendment 1039 gives the Office of Surveillance sign-off authority. They are experts in postmarketing safety. Even the Institute of Medicine recognized that through their recommendations. Let me be clear: This is not the amendment Senator DODD and I originally proposed. I still believe an independent postmarketing safety center would be best to solve the problem. But under the process, that is not going to happen. Through this amendment, at least joint postmarketing decisionmaking between the Office of Surveillance and the Office of New Drugs will allow the office with the postmarketing safety expertise to have a say in what drug safety action will be taken by the FDA.

The problem is not only the FDA having enough tools—this bill gives additional tools—it is about FDA managers disregarding concerns raised by its own scientists in the Office of Surveillance and not taking prompt action. This amendment makes common sense when you weigh the evidence I presented over the last 3 years about these problems at the FDA.

Opponents of this amendment say it is unnecessary because the bill includes a dispute resolution process with strict deadlines. But that process is for disputes between the FDA and the drug company, not internal disagreements between FDA offices.

Getting down to brass tacks, when the office that looks at postmarketing surveillance is under the thumb of the Office of New Drugs, and the Office of New Drugs says: This drug is safe, they aren't going to want to get egg on their faces by listening to the advice of the Office of Postmarketing Surveillance. If that had been the case, Dr. Graham, in the case of Vioxx, and Dr. Mosholder, in the case of antidepressant drugs, when kids were committing suicide, would have been listened to, but they weren't until they came as whistleblowers to the Congress.

We have to have it so that we have enough independent decisionmaking within the FDA to make sure these drugs are safe.

This amendment provides an approach with checks and balances between the office that approves a drug for marketing and the office that watches a drug once it is on the market.

The PRESIDING OFFICER. The Senator has used 5 minutes.

Who yields time?

The Senator from Wyoming.

Mr. ENZI. Madam President, I yield myself such time as I need.

I rise in opposition to the amendment offered by my colleague from Iowa, Senator GRASSLEY, No. 1039, regarding the joint signing authority under the Office of New Drugs and the Office of Surveillance and Epidemiology. This amendment would add an unnecessary layer of bureaucracy into an agency that we have designed to be nimble and responsive in their process to deal with emerging drug safety issues.

Before the bill is passed, the option after market is to suggest changes or pull the drug off the market, kind of a nuclear option. The underlying bill has surveillance and techniques to notice problems quicker. That is why we will be able to get drugs on to the market faster. The underlying bill does have a dispute resolution process with firm and tight deadlines. There is both one with companies and with staff disputes. It requires by its very nature close collaboration between the two offices. This amendment only serves to separate what should be a together process and delay what should be a rapid process.

I urge my colleagues to oppose the amendment. The tools we have put in the toolbox will do what the Senator from Iowa wants to have done, which is quick response when there is a problem. I hope we don't add this extra layer of bureaucracy. We looked at this problem through a number of hearings and a number of concerns by members on the committee from both sides and came up with this third way for being able to do it that had not been polarized and that had some agreement. I hope people will stick with what is in the bill.

I yield the floor and reserve the remainder of my time.

The PRESIDING OFFICER. The Senator from Iowa.

AMENDMENT NO. 998

Mr. GRASSLEY. Madam President, I yield myself such time as I consume on amendment No. 998. I ask unanimous consent that Senators DODD, SNOWE, and BINGAMAN be added as cosponsors.

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

Mr. GRASSLEY. This amendment provides for the application of stronger civil monetary penalties for violations of approved risk evaluation and mitigation strategies. Currently, the bill before us contains penalties, but those penalties won't mean much to large global corporations. In fact, the penalties amount to the cost of doing business. This amendment is intended, then, to give the Food and Drug Administration, the watchdog, some bite along with its bark.

There is opposition to having strong civil monetary penalties, but that does not make sense to this Senator. Even the Consumers Union supports this amendment. The reality is, drug companies provide lifesaving pharmaceuticals throughout the world. The pharmaceutical companies make miracles happen. Before a drug is approved, a drug company has an incentive to provide evidence of a drug's effectiveness to the Food and Drug Administration. Without it, they can't sell drugs in this country. However, once a drug is already being sold in the marketplace, drug companies have almost no incentive to look for and evaluate safety issues. The bottom line is, sometimes market forces guide businesses in a way that may be contrary to the public interest.

We have seen this happen many times. For the Food and Drug Administration's new authorities to be meaningful in this legislation, there must be stronger civil monetary penalties in the underlying bill; hence, my amendment. Fines are nothing more than the cost of doing business, and we can't change behavior. More importantly, we can't even deter bad behavior. If a company does what it is supposed to do, a drug company doesn't need to fear any penalties. It is that simple.

I ask Members of the Senate to support this amendment because it adds real teeth to the FDA's bite.

I thank Senators KENNEDY and ENZI for the tremendous efforts they went to in bringing this bill to the Senate floor. Again, I want to make this bill even better. They have already included several ideas Senator DODD and I have shared with them.

I reserve the remainder of my time.

The PRESIDING OFFICER. Who yields time?

Mr. ENZI. Madam President, I yield myself such time as I need.

I thank the Senator from Iowa, Mr. GRASSLEY, for his participation in this bill. It has been tremendous. I mentioned the hearings he held, as we were holding hearings, as there were some crises with food and drugs. The valuable information he shared with us, as well as amendments, as he has correctly stated, are already a part of the bill.

With respect to amendment No. 998, I also have to oppose this amendment regarding the level of civil monetary penalties that can be assessed for violations of the drug safety plan.

I appreciate Senator KENNEDY's earlier comments. The level of civil penalties in the underlying bill was carefully crafted to reflect existing FDA policies for other regulated products. This is the first time we have had civil penalties in this portion covering the area of food and drugs. It was no small feat to get a consensus position so that we could have civil penalties in the bill, and I think that is necessary.

There is a precedent for the levels that we have selected, the current levels. Medical devices has the same levels. I reiterate that has never before been available to the FDA as a tool on drug safety issues, but we are providing it as a tool. Furthermore, I believe the very threat of a civil penalty is sufficient to deter bad behavior. This is the name-and-shame principle. The fine may be affordable to the company, but the loss of reputation is not.

I urge my colleagues to oppose this amendment as well. This is not the end of the process. I suspect the House will have something to say on it, as I have mentioned to the Senator from Iowa before. There will be additional negotiations, I am certain, on civil penalties. I hope we will stick with the civil penalties that have a basis in the medical devices as some basis from which to negotiate and would hope that the Senate position will be the one that is in the bill. I ask people to oppose the amendment.

I yield the floor and reserve the remainder of my time.

The PRESIDING OFFICER (Mr. CASEY). The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, how much time do I have?

The PRESIDING OFFICER. The Senator has 10 minutes remaining.

Mr. KENNEDY. Mr. President, I yield myself 5 minutes.

I support the comments Senator ENZI has made about the fines. We are going to have to look at this in conference, and it is clear the House is going to raise the fines, it seems to me, as Senator ENZI pointed out. So we will have a chance to look at it in conference. I think that is probably the best way to do it.

Let me point out two other items—something I think most Americans have been concerned about in recent times. It was reported today that China has detained managers from two companies linked to contaminated foods. As a first step, we need to determine the extent of the contamination and see how far into the food supply this internal adulteration has gone.

Yesterday's report from the FDA that contaminated wheat flour from China was fed to fish raised for human consumption is another example of the need for a comprehensive examination of our food safety system. We also found out yesterday that what we thought was contaminated highly processed wheat gluten was actually unprocessed wheat flour spiked with melamine to make it appear to be higher quality.

A month ago, the FDA warned that certain types of pet food were suspected of being contaminated. Then, there were more kinds of pet food. Then it was hogs being fed the contaminated food, but those had been caught before human consumption. Then we found out that tens of millions of chickens eaten by people had been fed the tainted food. Yesterday, we were informed that fish raised for human consumption had been fed contaminated food.

The incremental expansion of this crisis raises serious concerns about the FDA's ability to rapidly identify the source of food-related problems and bring to bear the effective tools. We know the issue of food safety is divided into different kinds of committees, but it has to be of concern to American families.

We have included strong new protections to allow FDA to better ensure the safety of human and pet foods, but this is a first step. Senator ENZI and Senator DURBIN have joined with me and others and we are committed to taking a comprehensive look at the safety of our food supply and we are committed to taking the actions, with our colleagues, needed to ensure that the foods our families and pets eat are as safe as possible.

As part of the managers' package adopted last night, we included important new provisions to allow the FDA to oversee the safety of farm-raised fish. We owe this—this is a story in the paper today—to Senators LINCOLN and PRYOR and SESSIONS on this important proposal.

This morning's newspaper talks about doctors reaping millions for the use of anemia drugs. People are going to wonder what we are doing in this bill, if anything, on this issue. Well, this is not what the FDA does exactly. It is safety and efficacy. But there are different agencies in what they call health research and quality. AHRQ has responsibility for this. We will be in touch with them to examine this issue and provide better guidance and recommendations to doctors and patients.

The FDA does not practice medicine. But this kind of action has to be of concern because it reflects itself in increased costs to the American consumer, and it does raise health issues as well.

So this is illustrative of the range of different areas of concerns the American families have. We believe we have made very important and substantial progress in trying to address those questions.

Mr. President, at this time I will withhold the remainder of my time.

The PRESIDING OFFICER. Who yields time?

The Senator from Wyoming.

AMENDMENT NO. 1034

Mr. ENZI. Mr. President, I have to make some comments in regard to the other amendment we will be voting on this morning, which I also hope people will oppose, and that is amendment No. 1034, offered by my colleague from Illinois, Senator DURBIN.

The FDA relies on 30 advisory committees to provide independent expert advice, which lends credibility to the product review process and informs consumers of trends and product development. Given the complex issues that are considered by the FDA, outside help is needed and beneficial, and it is advisory. The decisions are not made by the committees. They advise. But any scientist who is expert enough to merit interest by the FDA has almost certainly merited interest by other entities, such as granting agencies and companies involved in the field.

This amendment would seriously limit the FDA's ability to access the best experts in the field to assist the Agency with its decisionmaking process. It would restrict FDA to granting only one waiver per committee meeting.

How would the FDA decide who gets that one waiver? Who is more worthy, the toxicologist, the drug safety expert, the specialist in women's health? These are not easy answers.

The FDA, in March, released a guidance document outlining strict new limits on evaluating advisory personnel committee members for service. The comment period on this guidance has not even closed. It is premature to void that guidance before we even know whether and how it will work.

Let's take a step back and think about what might happen if we do not allow people who have worked with or for industry to be involved in an advisory committee meeting.

Louis Pasteur was a brilliant microbiologist who revolutionized human food and health safety. Every time you buy milk in the grocery store, you are benefiting from his contributions to society. But under the Durbin amendment, Pasteur would probably not have been able to serve on any advisory committee. You see, Pasteur's research was funded by the wine industry.

Now, do you want to prevent the FDA from benefiting from the advice of the best and the brightest they have to offer? We do want to move so there are not conflicts of interest. I think the guidelines that are out there, if finalized, will do that. The amendment almost gets into a position of not conflicts of interest but biases—much harder to determine. If we are going to do that, we will never be able to have anybody on any of the committees, particularly with the expertise we need.

So I ask we oppose that amendment as well.

I yield time to the Republican leader.

The PRESIDING OFFICER. The Republican leader is recognized.

Mr. MCCONNELL. Mr. President, I thank my friend from Wyoming.

I wish to take a moment to congratulate Senator ENZI on this wonderful, bipartisan effort he has been engaged in with our friend from Massachusetts, Senator KENNEDY. They have worked tirelessly for the past 3 weeks, through markup and floor consideration.

I also wish to commend Senator GREGG, who worked very hard with Senator ENZI to reach a bipartisan compromise on this important measure.

I particularly wish to note Senator ROBERTS was instrumental in working out the problems with direct-to-consumer advertising provisions. I know he would have liked to have been here today to support this bill, but he is out in Kansas with the President touring hurricane damage in his State.

Also, I wish to commend Senator COCHRAN. We appreciate his efforts to ensure that any proposal to bring drugs in from other countries must be certified by the Secretary of Health and Human Services as safe for the American people.

So again, I thank the Senator from Wyoming for his extraordinary accomplishment in moving this important, bipartisan legislation forward.

With that, I yield the floor.

The PRESIDING OFFICER. Who yields time?

The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I think we are about—I see my friend from Iowa on his feet so I will withhold. I will make a very brief comment at the very end, so I withhold.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. GRASSLEY. Mr. President, I yield myself such time as I might consume. I only have 2½ minutes.

AMENDMENT NO. 1039

On the very important amendment about making sure there is adequate cooperation and dialog between the Office of New Drugs and the Office of Postmarket Surveillance, I wish to make clear this amendment is not, as some have characterized it, about process. It seems to me this is the ultimate of insurance to do the right thing to protect the American people on the safety of drugs. It is based on so many examples I found over the last 3 years, where there was not the respect for the Office of Postmarketing Surveillance there ought to be from the Office of New Drugs.

A lot of safety issues would not have gotten out if we had not had a lot of red-blooded, patriotic whistleblowers who would come to Congress, such as Dr. Graham, for instance, in the case of Vioxx, such as Dr. Mosholder, in the case of depressants for children who were committing suicide. This ended up with Vioxx coming off the market. This ended up with black-box safety measures in the case of the antidepressants.

The Institute of Medicine has recognized the importance of these two groups within the FDA working very closely together on making a determination on postmarketing surveillance. That is what my amendment does. It makes sure this process works the way the Institute of Medicine indicated it should.

So as you consider voting on this amendment, I ask my colleagues—himself or herself—one basic question before voting: Since the Institute of Medicine recommends equality between the preapproval process—in other words, before a drug is marketed—and the postapproval process at the FDA, why not vote for this amendment and improve postmarketing safety for the American people?

I yield the floor.

The PRESIDING OFFICER. Who yields time?

The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, in a few minutes, we will be prepared to vote. I yield myself 3 or 4 minutes.

I will include in the RECORD, at the conclusion of this debate, the names of the staff on our committee who have done superb work. It has been extraordinary and on both sides of the aisle. We are enormously appreciative and grateful.

I am also personally appreciative of the work of my friend and colleague, the Senator from Ohio, Mr. BROWN, who was here yesterday and filled in. I had the opportunity to travel to Ireland, where they signed and put in place, after 400 years of struggle, the democratic institutions over there, in a very moving ceremony, which President Bush had supported—a very special day.

This legislation is a reflection of 2½ years of hearings under the leadership of Senator ENZI, when he was chair of the committee, and myself. It incorporates the Institute of Medicine's recommendations, by and large, after they had months and months of hearings. The American people ought to understand the legislation, which reflects bipartisan support in the Senate, is a reflection of the best judgments we could have as a result of months and years of working on this issue and of the membership on it. We are enormously grateful.

This legislation is going to make the prescription drugs our families take safer and our food safer. That is very important. It is going to ensure that the Agency has resources to do follow-on reviews to continue its important function to be the world leader, the gold standard, for safety for our people and the example for the rest of the world. So this is very important legislation.

We are reminded every day of the additional kinds of challenges we are facing in terms of safety for our families. We are very aware of it. Senator ENZI and I and the members of our committee are going to continue our study, our review, and continue our activity to ensure we are going to have the best in terms of a safe and secure food supply, pharmaceutical supply, and take advantage of this life science century so every American is going to have the best and, hopefully, at the most reasonable price, so they can have healthier and stronger families.

Mr. President, I yield back my remaining time.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Mr. President, I have a number of people I need to thank for their efforts on this bill, and I will do that following the vote so that we don't hold up the vote.

There has been tremendous cooperation, effort, knowledge, and capability that has been involved, not just of the Senators but also of the staffs. The staffs on both sides of the aisle have spent countless hours on this, even on weekends. In fact, I know of one day on one weekend they worked about 20 hours together to pull this thing together and get some of the final issues worked out. But they worked the entire weekend for at least the last three weekends. They will look forward to a little time to rest, and we will probably give them a day. That is because we have so many things happening in the committee, and Senator KENNEDY and I are determined to get a lot of that done to help the American people with their health and with their education and in the area of workplace safety and training and pensions.

But on this bill, I hope people will join us in supporting it. Of course I hope they will join us in maintaining a balance to take it to conference committee and to defeat the three amendments that are before us this morning.

I yield back the remainder of my time.

AMENDMENT NO. 1039

The PRESIDING OFFICER. Under the previous order, there will be 2 minutes for debate equally divided prior to a vote in relation to amendment No. 1039.

Who yields time?

Mr. GRASSLEY. Mr. President, I will speak in favor of 1039. I have 30 seconds, did you say, or 1 minute?

The PRESIDING OFFICER. The Senator has 1 minute.

Mr. GRASSLEY. Mr. President, one of the issues that has been very much a shortcoming within the FDA besides lack of respect for the scientific process, but it is involved in the issue of this amendment as well, is whether scientists in the FDA who have the responsibility of postmarketing surveillance get the respect they ought to from the Office of New Drugs that previously had approved the drug. We have found in the case of Vioxx, in the case of antidepressants for children, and in a lot of other areas as well that this has just not been the case.

My amendment will follow the Institute of Medicine recommendation and make sure there is adequate time and consideration given to postmarketing surveillance, the same as there is to the approval of the drug in the first place. So I ask for approval of this amendment. It is backed by the Institute of Medicine.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Mr. President, I oppose the amendment. I appreciate the thought that went into it, and I know that before we did this bill and put into place some of the processes we have in the toolbox for postapproval—which, nevertheless, existed before for the FDA—this amendment would have been necessary. But in light of the toolbox we provide and the dispute resolution we have, it would add an unnecessary layer of bureaucracy.

We have designed the bill to be a nimble and responsive process to deal with emerging drug safety issues. We want drugs on the market faster, we want to know about anything that goes wrong faster, and we think that is built into it. We do have a dispute resolution in the bill with tight guidelines that will result in rapid approvals. We don't need the additional process.

The amendment separates what should be together and delays what

should be rapid. So I urge my colleagues to oppose the amendment.

Mr. GRASSLEY. Mr. President, I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second? There appears to be a sufficient second.

Mr. KENNEDY. Mr. President, parliamentary inquiry: Could we ask unanimous consent that we have the yeas and nays on the other two amendments? I ask unanimous consent that it be in order now for the yeas and nays on the other two amendments and then on final passage.

The PRESIDING OFFICER. Is there objection? Without objection, it is so ordered.

Mr. KENNEDY. I thank the Chair.

The PRESIDING OFFICER. Is there a sufficient second on the remaining amendments? There appears to be a sufficient second. The yeas and nays are ordered on the remaining amendments as well.

The question is on agreeing to amendment No. 1039.

The clerk will call the roll.

The legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from Indiana (Mr. BAYH) and the Senator from South Dakota (Mr. JOHNSON) are necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from Idaho (Mr. CRAPO), the Senator from Arizona (Mr. MCCAIN), the Senator from Kansas (Mr. ROBERTS), and the Senator from Louisiana (Mr. VITTER).

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 46, nays 47, as follows:

[Rollcall Vote No. 154 Leg.]

YEAS—46

Baucus	Feingold	Nelson (FL)
Biden	Feinstein	Obama
Bingaman	Grassley	Pryor
Boxer	Harkin	Reed
Brown	Hutchison	Reid
Byrd	Klobuchar	Rockefeller
Cantwell	Kohl	Sanders
Cardin	Landrieu	Schumer
Carper	Lautenberg	Snowe
Casey	Leahy	Stabenow
Clinton	Levin	Tester
Conrad	Lieberman	Webb
Corker	Lincoln	Whitehouse
Dodd	Lugar	Wyden
Dorgan	Menendez	
Durbin	Mikulski	

NAYS—47

Akaka	Domenici	McConnell
Alexander	Ensign	Murkowski
Allard	Enzi	Murray
Bennett	Graham	Nelson (NE)
Bond	Gregg	Salazar
Bunning	Hagel	Sessions
Burr	Hatch	Shelby
Chambliss	Inhofe	Smith
Coburn	Inouye	Specter
Cochran	Isakson	Stevens
Coleman	Kennedy	Sununu
Collins	Kerry	Thomas
Cornyn	Kyl	Thune
Craig	Lott	Voinovich
DeMint	Martinez	Warner
Dole	McCaskill	

NOT VOTING—7

Bayh	Johnson	Vitter
Brownback	McCain	
Crapo	Roberts	

The amendment (No. 1039) was rejected.

Mr. ENZI. I move to reconsider the vote, and I move to lay that motion on the table.

The motion to lay on the table was agreed to.

AMENDMENT NO. 998

The PRESIDING OFFICER. Under the previous order, there will be 2 minutes for debate equally divided prior to a vote in relation to amendment No. 998.

The Senator from Iowa.

Mr. GRASSLEY. I have 1 minute?

The PRESIDING OFFICER. One minute.

Mr. GRASSLEY. Mr. President, the issue is the level of civil and monetary penalties. If the fines are nothing more than the cost of doing business, you can't change behavior and you can't deter bad behavior. My feeling is the levels in this underlying bill are not high enough to get the attention of the drug companies. After all, if a company does what it is supposed to do, a drug company doesn't need to fear any penalties. It is that simple.

I ask my colleagues to support my amendment so it has real teeth.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Mr. President, I have to oppose this amendment in keeping with having a balance in the bill that we have agreed on. This is the first time civil monetary penalties have been assessed for violations of the drug safety plan. That is what is in our bill. We do have civil penalties in the bill. The civil penalties are the same as the medical devices. That is how we decided at what level to do it.

We added civil penalties, and there will be more work done on this issue probably as we get to conference. I want to establish the fact that civil penalties are in the bill. I want to arrive at the level that the civil penalties are assessed with more consideration and with debate with the House. This amendment could burden small businesses and create problems there.

Civil penalties are part of the bill we put together with a compromise. I ask that my colleagues vote against the amendment.

The PRESIDING OFFICER. The question is on agreeing to amendment No. 998. The yeas and nays have been ordered. The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from South Dakota (Mr. JOHNSON) is necessarily absent

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from Idaho (Mr. CRAPO), the Senator from Arizona (Mr. MCCAIN), the Senator from Kansas (Mr. ROBERTS), and the Senator from Louisiana (Mr. VITTER).

The PRESIDING OFFICER (Mr. MENENDEZ). Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 64, nays 30, as follows:

[Rollcall Vote No. 155 Leg.]

YEAS—64

Akaka	Feinstein	Obama
Baucus	Graham	Pryor
Biden	Grassley	Reed
Bingaman	Harkin	Reid
Boxer	Hutchison	Rockefeller
Brown	Klobuchar	Salazar
Byrd	Kohl	Sanders
Cantwell	Landrieu	Schumer
Cardin	Lautenberg	Sessions
Carper	Leahy	Smith
Casey	Levin	Snowe
Clinton	Lieberman	Specter
Coleman	Lincoln	Stabenow
Collins	Lott	Sununu
Conrad	Lugar	Tester
Corker	Martinez	Thune
Cornyn	McCaskill	Warner
Dodd	Menendez	Webb
Dorgan	Mikulski	Whitehouse
Durbin	Murray	Wyden
Ensign	Nelson (FL)	
Feingold	Nelson (NE)	

NAYS—30

Alexander	Craig	Isakson
Allard	DeMint	Kennedy
Bayh	Dole	Kerry
Bennett	Domenici	Kyl
Bond	Enzi	McConnell
Bunning	Gregg	Murkowski
Burr	Hagel	Shelby
Chambliss	Hatch	Stevens
Coburn	Inhofe	Thomas
Cochran	Inouye	Voinovich

NOT VOTING—6

Brownback	Johnson	Roberts
Crapo	McCain	Vitter

The amendment (No. 998) was agreed to.

Mr. GRASSLEY. Mr. President, I move to reconsider the vote and to lay that motion on the table.

The motion to lay on the table was agreed to.

AMENDMENT NO. 1034

The PRESIDING OFFICER. Under the previous order, there will be 2 minutes of debate, equally divided, prior to a vote in relation to amendment No. 1034.

The Senator from Illinois is recognized.

Mr. DURBIN. Mr. President, 2 years ago, an advisory committee of the FDA sat down to judge painkiller drugs and whether they were safe to sell to America. They made the recommendation that selling Vioxx to America was safe. Ten of the members of that advisory committee had a financial conflict of interest when they made the decision. Had those 10 members with the conflict not been there, the panel would not have recommended keeping those drugs on the market.

This amendment Senator BINGAMAN and I offer will take the conflict of interest out of the advisory committees. We will allow one waiver for someone with a conflict of interest, and we will say that others who participate as guest experts have to leave the room before any deliberation or vote.

We will hear from the other side that the Food and Drug Administration has an idea of how they are going to change this rule at some future time.

This is not an idea we are proposing, it is a law—a law to protect the integrity of the advisory committees and the drugs and medical devices which are sold across America.

I urge my colleagues to support this amendment.

Mr. KENNEDY. Mr. President, the FDA has a new policy, a new procedure out there.

Basically, what the Durbin amendment says is, one size fits all. That concept has been rejected by the Europeans, rejected by the Canadians, and basically rejected by the Institute of Medicine. In this life science century, researchers who are looking at cancer drugs may be examining 15 different components. Are we going to say that if a conflict exists with one of those components that they meet the Durbin amendment standard. This would exclude some of the most knowledgeable people in this country from participating in the review of breakthrough drugs.

The FDA says they have adopted transparency. Everyone in the Senate is going to know who sits on the advisory committees. There is a financial limitation of $50,000 at the FDA now. Everyone is going to know the existence of any conflicts. It is a new day out there. We have now have transparency, but virtually everyone who understands that we are in the life science century says we have to have the best scientific minds at the table, and so the Institute of Medicine said: Don't go with a one-size-fits-all, which the Durbin amendment does.

The PRESIDING OFFICER. All time has expired.

The question is on agreeing to amendment No. 1034. The yeas and nays have been ordered.

The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from South Dakota (Mr. JOHNSON) is necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from Idaho (Mr. CRAPO), the Senator from Arizona (Mr. MCCAIN), the Senator from Kansas (Mr. ROBERTS), and the Senator from Louisiana (Mr. VITTER).

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 47, nays 47, as follows:

[Rollcall Vote No. 156 Leg.]

YEAS—47

Akaka	Collins	Lautenberg
Baucus	Conrad	Leahy
Bayh	Dorgan	Levin
Biden	Durbin	Lieberman
Bingaman	Feingold	Lincoln
Boxer	Feinstein	McCaskill
Brown	Grassley	Menendez
Cantwell	Harkin	Mikulski
Cardin	Inouye	Murray
Carper	Klobuchar	Nelson (FL)
Casey	Kohl	Obama
Clinton	Landrieu	Pryor
Reed	Schumer	Webb
Reid	Snowe	Whitehouse
Salazar	Stabenow	Wyden
Sanders	Tester	

NAYS—47

Alexander	Dole	Martinez
Allard	Domenici	McConnell
Bennett	Ensign	Murkowski
Bond	Enzi	Nelson (NE)
Bunning	Graham	Rockefeller
Burr	Gregg	Sessions
Byrd	Hagel	Shelby
Chambliss	Hatch	Smith
Coburn	Hutchison	Specter
Cochran	Inhofe	Stevens
Coleman	Isakson	Sununu
Corker	Kennedy	Thomas
Cornyn	Kerry	Thune
Craig	Kyl	Voinovich
DeMint	Lott	Warner
Dodd	Lugar	

NOT VOTING—6

Brownback	Johnson	Roberts
Crapo	McCain	Vitter

The amendment (No. 1034) was rejected.

The PRESIDING OFFICER. Under the previous order, the committee substitute amendment, as modified and amended, is agreed to, the motion to reconsider is considered made and laid upon the table, and the cloture motion on the bill is withdrawn.

Under the previous order, the clerk will read the bill for the third time.

The bill was ordered to be engrossed for a third reading and was read the third time.

The PRESIDING OFFICER. The bill having been read the third time, the question is, Shall the bill, as modified and amended, pass?

Mr. KENNEDY. I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second? There is a sufficient second.

The clerk will call the roll.

The legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from South Dakota (Mr. JOHNSON) is necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from Idaho (Mr. CRAPO), the Senator from Arizona (Mr. MCCAIN), the Senator from Kansas (Mr. ROBERTS), and the Senator from Louisiana (Mr. VITTER).

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 93, nays 1, as follows:

[Rollcall Vote No. 157 Leg.]

YEAS—93

Akaka	Casey	Ensign
Alexander	Chambliss	Enzi
Allard	Clinton	Feingold
Baucus	Coburn	Feinstein
Bayh	Cochran	Graham
Bennett	Coleman	Grassley
Biden	Collins	Gregg
Bingaman	Conrad	Hagel
Bond	Corker	Harkin
Boxer	Cornyn	Hatch
Brown	Craig	Hutchison
Bunning	DeMint	Inhofe
Burr	Dodd	Inouye
Byrd	Dole	Isakson
Cantwell	Domenici	Kennedy
Cardin	Dorgan	Kerry
Carper	Durbin	Klobuchar
Kohl	Mikulski	Smith
Kyl	Murkowski	Snowe
Landrieu	Murray	Specter
Lautenberg	Nelson (FL)	Stabenow
Leahy	Nelson (NE)	Stevens
Levin	Obama	Sununu
Lieberman	Pryor	Tester
Lincoln	Reed	Thomas
Lott	Reid	Thune
Lugar	Rockefeller	Voinovich
Martinez	Salazar	Warner
McCaskill	Schumer	Webb
McConnell	Sessions	Whitehouse
Menendez	Shelby	Wyden

NAYS—1

Sanders

NOT VOTING—6

Brownback	Johnson	Roberts
Crapo	McCain	Vitter

The bill (S. 1082) as modified and amended, was passed, as follows:

S. 1082

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 ''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 disclosure of a serious risk 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).

''(iv) REQUIRED SAFETY SURVEILLANCE.—If the approved risk evaluation and mitigation strategy for a drug requires the specific disclosure under clause (ii), the Secretary shall—

''(I) consider identifying and assessing all serious risks of using the drug to be a priority safety question under subsection (k)(3)(B);

''(II) not 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 priority drug safety question to determine whether serious risks that might occur among patients expected to be treated with the drug have been adequately identified and assessed;

''(III) remove such specific disclosure requirement as an element of such strategy if such serious risks have been adequately identified and assessed; and

''(IV) consider whether a specific disclosure under clause (i) should be required.

''(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 who prescribe the drug have particular training or experience, or are specially certified (which training or certification with respect to the drug shall be available to any willing provider from a frontier area in a widely available training or certification method (including an on-line course or via mail) as approved by the Secretary at minimal cost to the provider);

''(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. The Secretary shall promulgate regulations for how a physician may provide the drug under the mechanisms of section 561.

''(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.

''(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.''.

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) 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, is 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 excess amount in item (bb), provided that—

''(aa) the amount of the total appropriation for the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of the total appropriation for the Food and Drug Administration for fiscal year 2007 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under subsection (c)(1); and

''(bb) the amount of the total appropriations for the process of human drug review at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of appropriations for the process of human drug review at the Food and Drug Administration for 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), except with respect to the drug Mifeprex (mifepristone), such assessment shall be submitted 6 months after the applicant is so notified.

(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. 379l(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.

Subtitle F—Antibiotic Access and Innovation

SEC. 261. INCENTIVES FOR THE DEVELOPMENT OF, AND ACCESS TO, CERTAIN ANTIBIOTICS.

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

''(s) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997.—

''(1) ANTIBIOTIC DRUGS APPROVED BEFORE NOVEMBER 21, 1997.—

''(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

''(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

''(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

''(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

''(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997, BUT NOT APPROVED.—

''(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug—

''(i)(I) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

''(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

''(ii) a patent term extension under section 156 of title 35, United States Code, subject to the requirements of such section.

''(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

''(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

''(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 507 of this Act (as in effect before November 21, 1997), none of which was approved by the Secretary under such section.

''(3) LIMITATIONS.—

''(A) EXCLUSIVITIES AND EXTENSIONS.—Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an approved application described in subparagraphs (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

''(B) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applicable, was approved before the date of enactment of this subsection.

''(4) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A).''.

(b) TRANSITION RULE.—With respect to a patent issued on or before the date of enactment of this Act, any patent information required to be filed with the Secretary under subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to be listed on a drug to which subsection (s)(1) of such section 505 (as added by this section) applies shall be filed with such Secretary not later than 60 days after the date of enactment of this Act.

SEC. 262. ANTIBIOTICS AS ORPHAN PRODUCTS.

(a) PUBLIC MEETING.—The Commissioner of Food and Drugs shall convene a public meeting and, if appropriate, issue guidance, regarding which serious and life-threatening infectious diseases, such as diseases due to gram-negative bacteria and other diseases due to antibiotic-resistant bacteria, potentially qualify for available grants and contracts under subsection (a) of section 5 of the Orphan Drug Act (21 U.S.C. 360ee(a)) or other incentives for development.

(b) GRANTS AND CONTRACTS FOR THE DEVELOPMENT OF ORPHAN DRUGS.—Subsection (c) of section 5 of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended to read as follows:

''(c) For grants and contracts under subsection (a) there are authorized to be appropriated—

''(1) such sums as already have been appropriated for fiscal year 2007; and

''(2) $35,000,000 for each of fiscal years 2008 through 2012.''.

SEC. 263. IDENTIFICATION OF CLINICALLY SUSCEPTIBLE CONCENTRATIONS OF ANTIMICROBIALS.

(a) DEFINITION.—In this section, the term ''clinically susceptible concentrations'' means specific values which characterize bacteria as clinically susceptible, intermediate, or resistant to the drug (or drugs) tested.

(b) IDENTIFICATION.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), through the Commissioner of Food and Drugs, shall identify and periodically update clinically susceptible concentrations.

(c) PUBLIC AVAILABILITY.—The Secretary, through the Commissioner of Food and Drugs, shall make such clinically susceptible concentrations publicly available within 30 days of the date of identification and any update under this section.

(d) EFFECT.—Nothing in this section shall be construed to restrict, in any manner, the prescribing of antibiotics by physicians, or to limit the practice of medicine, including for diseases such as Lyme and tick-borne diseases.

SEC. 264. EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

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

''(t) CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.—

''(1) IN GENERAL.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active ingredient a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug, if—

''(A)(i) the single enantiomer has not been previously approved except in the approved racemic drug; and

''(ii) the application submitted under subsection (b) for such non-racemic drug—

''(I) includes full reports of new clinical investigations (other than bioavailability studies)—

''(aa) necessary for the approval of the application under subsections (c) and (d); and

''(bb) conducted or sponsored by the applicant; and

''(II) does not rely on any investigations that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

''(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use—

''(i) in a therapeutic category in which the approved racemic drug has been approved; or

''(ii) for which any other enantiomer of the racemic drug has been approved.

''(2) LIMITATION.—

''(A) NO APPROVAL IN CERTAIN THERAPEUTIC CATEGORIES.—Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

''(B) LABELING.—If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

''(3) DEFINITION.—

''(A) IN GENERAL.—For purposes of this subsection, the term 'therapeutic category' means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1860D–4(b)(3)(C)(ii) of the Social Security Act and as in effect on the date of enactment of this subsection.

''(B) PUBLICATION BY SECRETARY.—The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

''(4) AVAILABILITY.—The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after the date of enactment of this subsection and before October 1, 2012.''.

SEC. 265. REPORT.

Not later than January 1, 2012, the Comptroller General of the United States shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines whether and how this subtitle has—

(1) encouraged the development of new antibiotics and other drugs; and

(2) prevented or delayed timely generic drug entry into the market.

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) if the determination made under subsection (d)(3) is made less 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) if the determination made under subsection (d)(3) is made less 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, such as expertise in child and adolescent psychiatry, pertaining to the pediatric product under review.

''(vii) One or more experts from the Office of Pediatric Therapeutics, which may include an expert in pediatric ethics.

''(viii) Other individuals as designated by the Secretary.

''(C) ACTION BY COMMITTEE.—The committee established under this paragraph may perform a function under this section using appropriate members of the committee under subparagraph (B) and need not convene all members of the committee under subparagraph (B) in order to perform a function under this section.

''(D) DOCUMENTATION OF COMMITTEE ACTION.—The committee established under this paragraph shall document for each function under paragraphs (2) and (3), which members of the committee participated in such function.

''(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 make a recommendation to the Secretary 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);

''(G) information regarding reports submitted on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007; and

''(H) the number of times the committee established under paragraph (1) made a recommendation to the Secretary under paragraph (3), the number of times the Secretary

did not follow such a recommendation to accept reports under subsection (d)(3), and the number of times the Secretary did not follow such a recommendation to reject such reports under section (d)(3).

''(5) COMMITTEE.—The committee established under paragraph (1) is the committee established under section 505B(f)(1).'';

(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 written request under section 505A that was declined by the sponsor or holder, or a letter referencing such declined written request, 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, for the labeled indication or indications, 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, such as expertise in child and adolescent psychiatry, 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) ACTION BY THE COMMITTEE.—The committee established under paragraph (1) may perform a function under this section using appropriate members of the committee under paragraph (1) and need not convene all members of the committee under paragraph (1) in order to perform a function under this section.

''(3) DOCUMENTATION OF COMMITTEE ACTION.—For each drug or biological product, the committee established under this paragraph shall document for each function under paragraph (4) or (5), which members of the committee participated in such function.

''(4) 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).

''(5) 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.

''(6) 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).

''(7) COMMITTEE.—The committee established under paragraph (1) is the committee established under section 505A(f)(1).

''(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. POSTMARKET SURVEILLANCE.

(a) POSTMARKET SURVEILLANCE.—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—

''(I) implanted in the human body for more than 1 year; or

''(II) 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 or clearance of 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.

SEC. 504. SENSE OF THE SENATE WITH RESPECT TO FOLLOW-ON BIOLOGICS.

(a) FINDINGS.—The Senate finds the following:

(1) The Food and Drug Administration has stated that it requires legislative authority to review follow-on biologics.

(2) Business, consumer, and government purchasers require competition and choice to ensure more affordable prescription drug options.

(3) Well-constructed policies that balance the needs of innovation and affordability have broad bipartisan support.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that legislation should be enacted to—

(1) provide the Food and Drug Administration with the authority and flexibility to approve biopharmaceuticals subject to an abbreviated approval pathway;

(2) ensure that patient safety remains paramount in the system;

(3) establish a regulatory pathway that is efficient, effective, and scientifically-grounded and that also includes measures to ensure timely resolution of patent disputes; and

(4) provide appropriate incentives to facilitate the research and development of innovative biopharmaceuticals.

SEC. 505. 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.

''(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

''(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

''(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.''.

SEC. 506. CITIZENS PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

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

''(s) CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.—

''(1) IN GENERAL.—

''(A) NO DELAY OF CONSIDERATION OR APPROVAL.—

''(i) IN GENERAL.—With respect to a pending application submitted under subsection (b)(2) or (j), if a petition is submitted to the Secretary that seeks to have the Secretary take, or refrain from taking, any form of action relating to the approval of the application, including a delay in the effective date of the application, clauses (ii) and (iii) shall apply.

''(ii) NO DELAY OF CONSIDERATION OR APPROVAL.—Except as provided in clause (iii), the receipt and consideration of a petition described in clause (i) shall not delay consideration or approval of an application submitted under subsection (b)(2) or (j).

''(iii) NO DELAY OF APPROVAL WITHOUT DETERMINATION.—The Secretary shall not delay approval of an application submitted under subsection (b)(2) or (j) while a petition described in clause (i) is reviewed and considered unless the Secretary determines, not later than 25 business days after the submission of the petition, that a delay is necessary to protect the public health.

''(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A)(iii) that a delay is necessary to protect the public health the following shall apply:

''(i) Not later than 5 days after making such determination, the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement shall include a summary of the petition and comments and supplements, the specific substantive issues that the petition raises which

need to be considered prior to approving a pending application submitted under subsection (b)(2) or (j), and any clarifications and additional data that is needed by the Secretary to promptly review the petition.

''(ii) Not later than 10 days after making such determination, the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

''(2) TIMING OF FINAL AGENCY ACTION ON PETITIONS.—

''(A) IN GENERAL.—Notwithstanding a determination made by the Secretary under paragraph (1)(A)(iii), the Secretary shall take final agency action with respect to a petition not later than 180 days of submission of that petition unless the Secretary determines, prior to the date that is 180 days after the date of submission of the petition, that a delay is necessary to protect the public health.

''(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A) that a delay is necessary to protect the public health the following shall apply:

''(i) Not later than 5 days after making the determination under subparagraph (A), the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement should include the state of the review of the petition, the specific outstanding issues that still need to be resolved, a proposed timeframe to resolve the issues, and any additional information that has been requested by the Secretary of the petitioner or needed by the Secretary in order to resolve the petition and not further delay an application filed under subsection (b)(2) or (j).

''(ii) Not later than 10 days after making the determination under subparagraph (A), the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

''(3) VERIFICATIONS.—

''(A) PETITIONS FOR REVIEW.—The Secretary shall not accept a petition for review unless it is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) information upon which I have based the action requested herein first became known to the party on whose behalf this petition is filed on or about _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to file this petition: _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the filing of such petition and the signature of the petitioner inserted in the first and second blank space, respectively.

''(B) SUPPLEMENTAL INFORMATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and that the subject document is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to submit this information or its contents: _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the submission of such document and the signature of the petitioner inserted in the first and second blank space, respectively.

''(4) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITION.—The Secretary shall annually submit to the Congress a report that specifies—

''(A) the number of applications under subsection (b)(2) and (j) that were approved during the preceding 1-year period;

''(B) the number of petitions that were submitted during such period;

''(C) the number of applications whose effective dates were delayed by petitions during such period and the number of days by which the applications were so delayed; and

''(D) the number of petitions that were filed under this subsection that were deemed by the Secretary under paragraph (1)(A)(iii) to require delaying an application under subsection (b)(2) or (j) and the number of days by which the applications were so delayed.

''(5) EXCEPTION.—This subsection does not apply to a petition that is made by the sponsor of the application under subsection (b)(2) or (j) and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

''(6) REPORT BY INSPECTOR GENERAL.—The Office of Inspector General of the Department of Health and Human Services shall issue a report not later than 2 years after the date of enactment of this subsection evaluating evidence of the compliance of the Food and Drug Administration with the requirement that the consideration by the Secretary of petitions that do not raise public health concerns remain separate and apart from the review and approval of an application submitted under subsection (b)(2) or (j).

''(7) DEFINITION.—For purposes of this subsection, the term 'petition' includes any request for an action described in paragraph (1)(A)(i) to the Secretary, without regard to whether the request is characterized as a petition.''.

SEC. 507. PUBLICATION OF ANNUAL REPORTS.

(a) IN GENERAL.—The Commissioner on Food and Drugs shall annually submit to Congress and publish on the Internet website of the Food and Drug Administration, a report concerning the results of the Administration's pesticide residue monitoring program, that includes—

(1) information and analysis similar to that contained in the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'' as released in June of 2005;

(2) based on an analysis of previous samples, an identification of products or countries (for imports) that require special attention and additional study based on a comparison with equivalent products manufactured, distributed, or sold in the United States (including details on the plans for such additional studies), including in the initial report (and subsequent reports as determined necessary) the results and analysis of the Ginseng Dietary Supplements Special Survey as described on page 13 of the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'';

(3) information on the relative number of interstate and imported shipments of each tested commodity that were sampled, including recommendations on whether sampling is statistically significant, provides confidence intervals or other related statistical information, and whether the number of samples should be increased and the details of any plans to provide for such increase; and

(4) a description of whether certain commodities are being improperly imported as another commodity, including a description of additional steps that are being planned to prevent such smuggling.

(b) INITIAL REPORTS.—Annual reports under subsection (a) for fiscal years 2004 through 2006 may be combined into a single report, by not later than June 1, 2008, for purposes of publication under subsection (a). Thereafter such reports shall be completed by June 1 of each year for the data collected for the year that was 2-years prior to the year in which the report is published.

(c) MEMORANDUM OF UNDERSTANDING.—The Commissioner of Food and Drugs, the Administrator of the Food Safety and Inspection Service, the Department of Commerce, and the head of the Agricultural Marketing Service shall enter into a memorandum of understanding to permit inclusion of data in the reports under subsection (a) relating to testing carried out by the Food Safety and Inspection Service and the Agricultural Marketing Service on meat, poultry, eggs, and certain raw agricultural products, respectively.

SEC. 508. 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.

''(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit agencies from using established methods, for handling cases of suspected or known child abuse and neglect, that are in compliance with applicable Federal, State, or tribal law.''.

SEC. 509. 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 to preserve the appearance of fresh meat may create any health risks, or mislead consumers.

SEC. 510. IMPROVING GENETIC TEST SAFETY AND QUALITY.

Not later than 30 days after the date of enactment of this Act, the Secretary shall enter into a contract with the Institute of Medicine to conduct a study to assess the overall safety and quality of genetic tests and prepare a report that includes recommendations to improve Federal oversight and regulation of genetic tests. Such study shall take into consideration relevant reports by the Secretary's Advisory Committee on Genetic Testing and other groups and shall be completed not later than 1 year

after the date on which the Secretary entered into such contract.

SEC. 511. ORPHAN DISEASE TREATMENT IN CHILDREN.

(a) FINDING.—The Senate finds that parents of children suffering from rare genetic diseases known as orphan diseases face multiple obstacles in obtaining safe and effective treatment for their children due mainly to the fact that many Food and Drug Administration-approved drugs used in the treatment of orphan diseases in children may not be approved for pediatric indications.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that the Food and Drug Administration should enter into a contract with the Institute of Medicine for the conduct of a study concerning measures that may be taken to improve the likelihood that Food and Drug Administration-approved drugs that are safe and effective in treating children with orphan diseases are made available and affordable for pediatric indications.

SEC. 512. COLOR CERTIFICATION REPORTS.

Section 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e) is amended by adding at the end the following:

''(g) COLOR CERTIFICATION REPORTS.—Not later than—

''(1) 90 days after the close of a fiscal year in which color certification fees are collected, the Secretary shall submit to Congress a performance report for such fiscal year on the number of batches of color additives approved, the average turn around time for approval, and quantifiable goals for improving laboratory efficiencies; and

''(2) 120 days after the close of a fiscal year in which color certification fees are collected, the Secretary shall submit to Congress a financial report for such fiscal year that includes all fees and expenses of the color certification program, the balance remaining in the fund at the end of the fiscal year, and anticipated costs during the next fiscal year for equipment needs and laboratory improvements of such program.''.

SEC. 513. PROHIBITION ON IMPORTATION FROM A FOREIGN FOOD FACILITY THAT DENIES ACCESS TO FOOD INSPECTORS.

Notwithstanding any other provision of law, no food product may be imported into the United States that is the product of a foreign facility registered under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) that refuses to permit United States inspectors, upon request, to inspect such facility or that unduly delays access to United States inspectors.

SEC. 514. COUNTERFEIT-RESISTANT TECHNOLOGIES.

Notwithstanding any other provision of this Act, the requirement that the Secretary of Health and Human Services certify that the implementation of the title of this Act relating to the Importation of Prescription Drugs will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer shall not apply to the requirement that the Secretary require that the packaging of any prescription drug incorporates—

(1) not later than 18 months after the date of enactment of this Act, a standardized numerical identifier (which, to the extent practicable, shall be harmonized with international consensus standards for such an 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

(2) not later than 24 months after the date of enactment of this Act for the 50 prescription drugs with the highest dollar volume of sales in the United States, based on the calendar year that ends of December 31, 2007, and, not later than 30 months after the date of enactment of this Act for all other prescription drugs—

(A) overt optically variable counterfeit-resistant technologies that—

(i) are visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

(ii) are similar to that used by the Bureau of Engraving and Printing to secure United States currency;

(iii) are manufactured and distributed in a highly secure, tightly controlled environment; and

(iv) incorporate additional layers of nonvisible convert security features up to and including forensic capability; or

(B) technologies that have a function of security comparable to that described in subparagraph (A), as determined by the Secretary.

SEC. 515. ENHANCED AQUACULTURE AND SEAFOOD INSPECTION.

(a) FINDINGS.—Congress finds the following:

(1) In 2007, there has been an overwhelming increase in the volume of aquaculture and seafood that has been found to contain substances that are not approved for use in food in the United States.

(2) As of May 2007, inspection programs are not able to satisfactorily accomplish the goals of ensuring the food safety of the United States.

(3) To protect the health and safety of consumers in the United States, the ability of the Secretary of Health and Human Services to perform inspection functions must be enhanced.

(b) HEIGHTENED INSPECTIONS.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') is authorized to, by regulation, enhance, as necessary, the inspection regime of the Food and Drug Administration for aquaculture and seafood, consistent with obligations of the United States under international agreements and United States law.

(c) REPORT TO CONGRESS.—Not later than 90 days after the date of enactment of this Act, the Secretary shall submit to Congress a report that—

(1) describes the specifics of the aquaculture and seafood inspection program;

(2) describes the feasibility of developing a traceability system for all catfish and seafood products, both domestic and imported, for the purpose of identifying the processing plant of origin of such products; and

(3) provides for an assessment of the risks associated with particular contaminants and banned substances.

(d) PARTNERSHIPS WITH STATES.—Upon the request by any State, the Secretary may enter into partnership agreements, as soon as practicable after the request is made, to implement inspection programs regarding the importation of aquaculture and seafood.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

SEC. 516. SENSE OF THE SENATE REGARDING CERTAIN PATENT INFRINGEMENTS.

(a) FINDINGS.—The Senate makes the following findings:

(1) Innovation in developing life-saving prescription drugs saves millions of lives around the world each year.

(2) The responsible protection of intellectual property is vital to the continued development of new and life-saving drugs and future growth of the United States economy.

(3) In order to maintain the global competitiveness of the United States, the United States Trade Representative's Office of Intellectual Property and Innovation develops and implements trade policy in support of vital American innovations, including innovation in the pharmaceutical and medical technology industries.

(4) The United States Trade Representative also provides trade policy leadership and expertise across the full range of interagency initiatives to enhance protection and enforcement of intellectual property rights.

(5) Strong and fair intellectual property protection, including patent, copyright, trademark, and data protection plays an integral role in fostering economic growth and development and ensuring patient access to the most effective medicines around the world.

(6) There are concerns that certain countries have engaged in unfair price manipulation and abuse of compulsory licensing. Americans bear the majority of research and development costs for the world, which could undermine the value of existing United States pharmaceutical patents and could impede access to important therapies.

(7) There is a growing global threat of counterfeit medicines and increased need for the United States Trade Representative and other United States agencies to use available trade policy measures to strengthen laws and enforcement abroad to prevent harm to United States patients and patients around the world.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) the United States Trade Representative should use all the tools at the disposal of the Trade Representative to address violations and other concerns with intellectual property, including through—

(A) bilateral engagement with United States trading partners;

(B) transparency and balance of the annual ''Special 301'' review and reviews of compliance with the intellectual property requirements of countries with respect to which the United States grants trade preferences;

(C) negotiation of responsible and fair intellectual property provisions as part of bilateral and regional trade agreements; and

(D) multilateral engagement through the World Trade Organization (WTO); and

(2) the United States Trade Representative should develop and submit to Congress a strategic plan to address the problem of countries that infringe upon American pharmaceutical intellectual property rights and the problem of countries that engage in price manipulation.

SEC. 517. CONSULTATION REGARDING GENETICALLY ENGINEERED SEAFOOD PRODUCTS.

The Commissioner of Food and Drugs shall consult with the Assistant Administrator of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks.

SEC. 518. REPORT ON THE MARKETING OF CERTAIN CRUSTACEANS.

Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Secretary of Commerce, shall submit to the Health, Education, Labor, and Pensions Committee and the Committee on Commerce, Science, and Transportation of the Senate, a report on the differences between taxonomy of species of lobster in the subfamily Nephropinae, and species of langostino, specifically from the infraorder Caridea or Anomura. This report shall also

describe the differences in consumer perception of such species, including such factors as taste, quality, and value of the species.

SEC. 519. CIVIL PENALTIES; DIRECT-TO-CONSUMER ADVERTISEMENT.

(a) CIVIL 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)(1) Any applicant (as such term is used in section 505(o)) who disseminates a direct-to-consumer advertisement for a prescription drug that is false or misleading and a violation of section 502(n) shall be liable to the United States for a civil penalty in an amount not to exceed $150,000 for the first such violation in any 3-year period, and not to exceed $300,000 for each subsequent violation committed after the applicant has been penalized under this paragraph any time in the preceding 3-year period. For the purposes of this paragraph, repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered as 1 violation.

''(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the applicant to be assessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and section 554 of title 5, United States Code. If upon receipt of the written notice, the applicant to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

''(3) Upon the request of the applicant to be assessed a civil penalty, the Secretary, in determining the amount of a civil penalty, shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

''(A) Whether the applicant submitted the advertisement or a similar advertisement for review under section 736A.

''(B) Whether the applicant submitted the advertisement for prereview if required under section 505(o)(5)(D).

''(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the applicant disseminated the advertisement before the end of the 45-day comment period.

''(D) Whether the applicant failed to incorporate any comments made by the Secretary with regard to the advertisement or a similar advertisement into the advertisement prior to its dissemination.

''(E) Whether the applicant ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

''(F) Whether the applicant had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

''(G) Whether the violations were material.

''(H) Whether the applicant who created the advertisement acted in good faith.

''(I) Whether the applicant who created the advertisement has been assessed a civil penalty under this provision within the previous 1-year period.

''(J) The scope and extent of any voluntary, subsequent remedial action by the applicant.

''(K) Such other matters, as justice may require.

''(4)(A) Subject to subparagraph (B), no applicant shall be required to pay a civil penalty under paragraph (1) if the applicant submitted the advertisement to the Secretary and disseminated such advertisement after incorporating any comment received from the Secretary.

''(B) The Secretary may retract or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary based on new information or changed circumstances, so long as the Secretary provides written notice to the applicant of the new views of the Secretary on the advertisement and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under paragraph (1).

''(5) The Secretary may compromise, modify, remit, with or without conditions, any civil penalty which may be assessed under paragraph (1). The amount of such penalty, when finally determined, or the amount charged upon in compromise, may be deducted from any sums owned by the United States to the applicant charged.

''(6) Any applicant who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such applicant resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessments was issued.

''(7) If any applicant fails to pay an assessment of a civil penalty—

''(A) after the order making the assessment becomes final, and if such applicant does not file a petition for judicial review of the order in accordance with paragraph (6); or

''(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.''.

(b) DIRECT-TO-CONSUMER ADVERTISEMENT.—

(1) IN GENERAL.—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 the case of an advertisement for a prescription drug presented directly to consumers in television or radio format that states the name of the drug and its conditions of use, the major statement relating to side effects, contraindications, and effectiveness referred to in the previous sentence shall be stated in a clear and conspicuous (neutral) manner.''.

(2) REGULATIONS TO DETERMINE NEUTRAL MANNER.—The Secretary of Health and Human Services shall by regulation establish standards for determining whether a major statement, relating to side effects, contraindications, and effectiveness of a drug, described in section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) (as amended by paragraph (1)) is presented in the manner required under such section.

SEC. 520. REPORT BY THE FOOD AND DRUG ADMINISTRATION REGARDING LABELING INFORMATION ON THE RELATIONSHIP BETWEEN THE USE OF INDOOR TANNING DEVICES AND DEVELOPMENT OF SKIN CANCER OR OTHER SKIN DAMAGE.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall determine—

(1) whether the labeling requirements for indoor tanning devices, including the positioning requirements, provide sufficient information to consumers regarding the risks that the use of such devices pose for the development of irreversible damage to the eyes and skin, including skin cancer; and

(2)(A) whether modifying the warning label required on tanning beds to read, ''Ultraviolet radiation can cause skin cancer'', or any other additional warning, would communicate the risks of indoor tanning more effectively; or

(B) whether there is no warning that would be capable of adequately communicating such risks.

(b) CONSUMER TESTING.—In making the determinations under subsection (a), the Secretary shall conduct appropriate consumer testing, using the best available methods for determining consumer understanding of label warnings.

(c) PUBLIC HEARINGS; PUBLIC COMMENT.—The Secretary shall hold public hearings and solicit comments from the public in making the determinations under subsection (a).

(d) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to the Congress a report that provides the determinations under subsection (a). In addition, the Secretary shall include in the report the measures being implemented by the Secretary to significantly reduce the risks associated with indoor tanning devices.

TITLE VI—FOOD SAFETY

SEC. 601. FINDINGS.

(a) FINDINGS.—Congress finds that—

(1) the safety and integrity of the United States food supply is vital to the public health, to public confidence in the food supply, and to the success of the food sector of the Nation's economy;

(2) illnesses and deaths of individuals and companion animals caused by contaminated food—

(A) have contributed to a loss of public confidence in food safety; and

(B) have caused significant economic losses to manufacturers and producers not responsible for contaminated food items;

(3) the task of preserving the safety of the food supply of the United States faces tremendous pressures with regard to—

(A) emerging pathogens and other contaminants and the ability to detect all forms of contamination; and

(B) an increasing volume of imported food from a wide variety of countries; and

(C) a shortage of adequate resources for monitoring and inspection;

(4) the United States is increasing the amount of food that it imports such that—

(A) from 2003 to the present, the value of food imports has increased from $45,600,000,000 to $64,000,000,000; and

(B) imported food accounts for 13 percent of the average Americans diet including 31 percent of fruits, juices, and nuts, 9.5 percent of red meat and 78.6 percent of fish and shellfish; and

(5) the number of full time equivalent Food and Drug Administration employees conducting inspections has decreased from 2003 to 2007.

SEC. 602. ENSURING THE SAFETY OF PET FOOD.

(a) PROCESSING AND INGREDIENT STANDARDS.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this title as the ''Secretary''), in consultation with the Association of American Feed Control Officials, and other relevant stakeholder groups, including veterinary medical

associations, animal health organizations, and pet food manufacturers, shall by regulation establish—

(1) processing and ingredient standards with respect to pet food, animal waste, and ingredient definitions; and

(2) updated standards for the labeling of pet food that includes nutritional information and ingredient information.

(b) EARLY WARNING SURVEILLANCE SYSTEMS AND NOTIFICATION DURING PET FOOD RECALLS.—Not later than 180 days after the date of enactment of this Act, the Secretary shall by regulation establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. In establishing such system, the Secretary shall—

(1) use surveillance and monitoring mechanisms similar to, or in coordination with, those mechanisms used by the Centers for Disease Control and Prevention to monitor human health, such as the Foodborne Diseases Active Surveillance Network (FoodNet) and PulseNet;

(2) consult with relevant professional associations and private sector veterinary hospitals; and

(3) work with the Health Alert Network and other notification networks to inform veterinarians and relevant stakeholders during any recall of pet food.

SEC. 603. ENSURING EFFICIENT AND EFFECTIVE COMMUNICATIONS DURING A RECALL.

The Secretary shall, during an ongoing recall of human or pet food—

(1) work with companies, relevant professional associations, and other organizations to collect and aggregate information pertaining to the recall;

(2) use existing networks of communication including electronic forms of information dissemination to enhance the quality and speed of communication with the public; and

(3) post information regarding recalled products on the Internet website of the Food and Drug Administration in a consolidated, searchable form that is easily accessed and understood by the public.

SEC. 604. STATE AND FEDERAL COOPERATION.

(a) IN GENERAL.—The Secretary shall work with the States in undertaking activities and programs that assist in improving the safety of fresh and processed produce so that State food safety programs involving the safety of fresh and processed produce and activities conducted by the Secretaries function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to—

(1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and

(2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of the State food safety programs is not unsafe for human consumption.

(b) ASSISTANCE.—The Secretary may provide to a State, for planning, developing, and implementing such a food safety program—

(1) advisory assistance;

(2) technical assistance, training, and laboratory assistance (including necessary materials and equipment); and

(3) financial and other assistance.

(c) SERVICE AGREEMENTS.—The Secretary may, under an agreement entered into with a Federal, State, or local agency, use, on a reimbursable basis or otherwise, the personnel, services, and facilities of the agency to carry out the responsibilities of the agency under this section. An agreement entered into with a State agency under this subsection may provide for training of State employees.

SEC. 605. ADULTERATED FOOD REGISTRY.

(a) FINDINGS.—Congress makes the following findings:

(1) In 1994, Congress passed the Dietary Supplement Health and Education Act (P.L. 103–417) to provide the Food and Drug Administration with the legal framework to ensure that dietary supplements are safe and properly labeled foods.

(2) In 2006, Congress passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act (P.L. 109–462) to establish a mandatory reporting system of serious adverse events for non-prescription drugs and dietary supplements sold and consumed in the United States.

(3) The adverse event reporting system created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act will serve as the early warning system for any potential public health issues associated with the use of these food products.

(4) A reliable mechanism to track patterns of adulteration in food would support efforts by the Food and Drug Administration to effectively target limited inspection resources to protect the public health.

(b) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

"SEC. 417. ADULTERATED FOOD REGISTRY.

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer', with respect to an article of food, means the person who submitted the notice with respect to such article of food under section 801(m).

''(2) RESPONSIBLE PARTY.—The term 'responsible party', with respect to an article of food, means any registered food facility under section 415(a), including those responsible for the manufacturing, processing, packaging or holding of such food for consumption in the United States.

''(3) REPORTABLE ADULTERATED FOOD.—The term 'reportable adulterated food' for purposes of this section means a food that is adulterated or—

''(A) presents a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death as defined in section 7.3(m)(1) of title, Code of Federal Regulations (or any successor regulations); or

''(B) meets the threshold established in section 304(h).

''(b) ESTABLISHMENT.—

''(1) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary shall establish within the Food and Drug Administration an Adulterated Food Registry to which instances of reportable adulterated food may be submitted by the Food and Drug Administration after receipt of reports of adulteration, via an electronic portal, from—

''(A) Federal, State, and local public health officials;

''(B) an importer;

''(C) a responsible party; or

''(D) a consumer or other individual.

''(2) REVIEW BY SECRETARY.—The Secretary shall review and determine the validity of the information submitted under paragraph (1) for the purposes of identifying adulterated food, submitting entries to the Adulterated Food Registry, acting under subsection (c), and exercising other existing food safety authorities under the Act to protect the public health.

''(c) ISSUANCE OF AN ALERT BY THE SECRETARY.—

''(1) IN GENERAL.—The Secretary shall issue an alert with respect to an adulterated food if the Adulterated Food Registry shows that the food—

''(A) has been associated with repeated and separate outbreaks of illness or has been repeatedly determined to be adulterated; or

''(B) is a reportable adulterated food.

''(2) SCOPE OF ALERT.—An alert under paragraph (1) may apply to a particular food or to food from a particular producer, manufacturer, shipper, growing area, or country, to the extent that elements in subparagraph (A) or (B) of paragraph (1) are associated with the particular food, producer, manufacturer, shipper, growing area, or country.

''(d) SUBMISSION BY A CONSUMER OR OTHER INDIVIDUAL.—A consumer or other individual may submit a report to the Food and Drug Administration using the electronic portal data elements described in subsection (e). Such reports shall be evaluated by the Secretary as specified in subsection (b)(2).

''(e) NOTIFICATION AND REPORTING OF ADULTERATION.—

''(1) DETERMINATION BY RESPONSIBLE PARTY OR IMPORTER.—If a responsible party or importer determines that an article of food it produced, processed, manufactured, distributed, or otherwise handled is a reportable adulterated food, the responsible party shall provide the notifications described under paragraph (2).

''(2) NOTIFICATION OF ADULTERATION.—

''(A) IN GENERAL.—Not later than 5 days after a responsible party or importer receives a notification, the responsible party or importer, as applicable, shall review whether the food referenced in the report described in paragraph (1) is a reportable adulterated food.

''(B) NOTIFICATION.—If a determination is made by such responsible party or importer that the food is a reportable adulterated food, such responsible party or importer shall, no later than 2 days after such determination is made, notify other responsible parties directly linked in the supply chain to which and from which the article of reportable adulterated food was transferred.

''(3) SUBMISSION OF REPORTS TO THE FOOD AND DRUG ADMINISTRATION BY A RESPONSIBLE PARTY OR IMPORTER.—The responsible party or importer, as applicable, shall submit a report to the Food and Drug Administration through the electronic portal using the data elements described in subsection (f) not later than 2 days after a responsible party or importer—

''(A) makes a notification under paragraph (2)(B); or

''(B) determines that an article of food it produced, processed, manufactured, distributed, imported, or otherwise handled is a reportable adulterated food, except that if such adulteration was initiated with such responsible party or importer, was detected prior to any transfer of such article of food, and was destroyed, no report is necessary.

''(f) DATA ELEMENTS IN THE REGISTRY.—A report submitted to the Food and Drug Administration electronic portal under subsection (e) shall include the following data elements:

''(1) Contact information for the individual or entity submitting the report.

''(2) The date on which an article of food was determined to be adulterated or suspected of being adulterated.

''(3) A description of the article of food including the quantity or amount.

''(4) The extent and nature of the adulteration.

''(5) The disposition of the article.

''(6) Product information typically found on packaging including product codes, use by dates, and names of manufactures or distributors.

''(7) Information about the place of purchase or process by which the consumer or

other individual acquired the article of adulterated food.

''(8) In the case of a responsible party or an importer, the elements required for the registration of food facilities under section 415(a).

''(9) The contact information for parties directly linked in the supply chain and notified under subsection (e)(2).

''(10) In the case of an importer, the elements required for the prior notice of imported food shipments under section 801(m).

''(g) MAINTENANCE AND INSPECTION OF RECORDS.—The responsible person or importer shall maintain records related to each report received, notification made, and report submitted to the Food and Drug Administration under this section and permit inspection of such records as provided for in section 414. Such records shall also be made available during an inspection under section 704.

''(h) REQUEST FOR INFORMATION.—Section 552 of title 5, United States Code, shall apply to any request for information regarding a record in the Adulterated Food Registry.

''(i) HOMELAND SECURITY NOTIFICATION.—If, after receiving a report under subsection (e), the Secretary suspects such food may have been deliberately adulterated, the Secretary shall immediately notify the Secretary of Homeland Security. The Secretary shall make the data in the Adulterated Imported Food Registry available to the Secretary of Homeland Security.''.

(c) DEFINITION.—Section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)) is amended by striking ''section 201(g)'' and inserting ''sections 201(g) and 417''.

(d) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by this Act, is further amended by adding at the end the following:

''(kk) The failure to provide a report as required under section 417(e)(3).

''(ll) The falsification a report as required under section 417(e)(3).''.

(e) SUSPECTED FOOD ADULTERATION REGULATIONS.—The Secretary shall, within 180 days of enactment of this Act, promulgate regulations that establish standards and thresholds by which importers and responsible parties shall be required and consumers may be able to, under section 417 of the Federal Food, Drug, and Cosmetic Act (as added by this section)—

(1) report instances of suspected reportable adulteration of food to the Food and Drug Administration for possible inclusion in the Adulterated Food Registry after evaluation of such report; and

(2) notify, in keeping with subsection (e)(2) of such section 417, other responsible parties directly linked in the supply chain, including establishments as defined in section 415(b) of such Act.

(f) EFFECTIVE DATE.—The requirements of section 417(e) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall become effective 180 days after the date of enactment of this Act.

SEC. 606. SENSE OF THE SENATE.

It is the sense of the Senate that—

(1) it is vital for Congress to provide the Food and Drug Administration with additional resources, authorities, and direction with respect to ensuring the safety of the food supply of the United States;

(2) additional inspectors are required to improve the Food and Drug Administration's ability to safeguard the food supply of the United States;

(3) because of the increasing volume of international trade in food products the Secretary of Health and Human Services should make it a priority to enter into agreements with the trading partners of the United States with respect to food safety; and

(4) the Senate should work to develop a comprehensive response to the issue of food safety.

SEC. 607. ANNUAL REPORT TO CONGRESS.

The Secretary shall, on an annual basis, 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 report that includes, with respect to the preceding 1-year period—

(1) the number and amount of food products regulated by the Food and Drug Administration imported into the United States, aggregated by country and type of food;

(2) a listing of the number of Food and Drug Administration inspectors of imported food products referenced in paragraph (1) and the number of Food and Drug Administration inspections performed on such products; and

(3) aggregated data on the findings of such inspections, including data related to violations of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.), and enforcement actions used to follow-up on such findings and violations.

SEC. 608. RULE OF CONSTRUCTION.

Nothing in this title (or an amendment made by this title) shall be construed to affect—

(1) the regulation of dietary supplements under the Dietary Supplement Health and Education Act; or

(2) the adverse event reporting system for dietary supplements created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act.

SEC. 609. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this title (and the amendments made by this title) such sums as may be necessary.

TITLE VII—DOMESTIC PET TURTLE MARKET ACCESS

SEC. 701. SHORT TITLE.

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

SEC. 702. 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. 703. SALE OF BABY TURTLES.

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 non-antibiotic method, 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.

SEC. 704. FDA REVIEW OF STATE PROTECTIONS.

The Commissioner of Food and Drugs 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 this title are insufficient to protect consumers against infectious diseases acquired from such turtle at the time of sale.

TITLE VIII—IMPORTATION OF PRESCRIPTION DRUGS

SEC. 801. SHORT TITLE.

This title may be cited as the ''Pharmaceutical Market Access and Drug Safety Act of 2007''.

SEC. 802. 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. 803. 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. 804. 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 803, 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. 805. 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 804, 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. 806. 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 804.

(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. 807. 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. 808. 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. 809. 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. 810. 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.

SEC. 811. PROTECTION OF HEALTH AND SAFETY.

This title, and the amendments made by this title, shall become effective only if the Secretary of Health and Human Services certifies to Congress that the implementation of this title (and amendments) will—

(1) pose no additional risk to the public's health and safety; and

(2) result in a significant reduction in the cost of covered products to the American consumer.

The PRESIDING OFFICER. Under the previous order, the motion to reconsider is considered made and laid upon the table, and the title amendment which is at the desk is agreed to, and the motion to reconsider is considered made and laid upon the table.

The title was amended 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.

The Senator from Wyoming.

Mr. ENZI. Mr. President, I ask unanimous consent that Senator KENNEDY and I have a few minutes here to thank some of the people involved. I have checked with the people who would be involved with the judges, and they have no objection.

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

Mr. ENZI. Mr. President, I do want to take a few minutes to thank the leaders, particularly the majority leader, who, after some difficulties last week, helped to smooth some things out and make it possible for us to move on a little bit on the bill. His coordination and leadership were indispensable.

I thank the Republican leader for the way he participated in the bill and, again, made sure we were working across the aisle and getting difficulties smoothed out.

I definitely wish to thank the chairman of the committee for the outstanding work he did through the entire process. As we mentioned a number of times, it has been a very lengthy process, but he has always been so forthright and knowledgeable and willing to work under all kinds of circumstances and difficulties. Because of his dedication and abilities, I have learned a lot about running the committee from him and I have learned a lot about getting a bill passed from him and have enjoyed working with him over the last 2 years on a number of bills.

I thank the staff people who have worked so hard. They have spent many evenings and even weekends away from their homes. They worked virtually through the night to get some of these issues worked out. The way we work a bill, it is a work in progress until it is finished. It is not finished yet; we have got to work with the House side yet, and we will do that.

This is such an important bill for the country. My HELP team worked overtime to get this bill to the floor and passed in the Senate.

I would first like to thank my health policy director, Shana Christrup. Shana was promoted to her leadership position in January of this year. She took ahold of the reins, has incredible knowledge, dedication, and negotiating experience and expertise that helped bring this bill to fruition.

I also want to greatly thank Amy Muhlberg, our crackerjack expert who knows all things FDA. Her knowledge and drafting skills were central to this bill.

I thank Keith Flanagan for his work on the children's statutes in this bill, and Dave Schmickel, who is our resident drug patent expert, for his ongoing work on follow-on biologics.

Others on the team I would like to thank include Todd Spangler and Brittany Moore, who provided the required backup that goes with moving a bill of this magnitude.

Finally, I thank my staff director, Katherine McGuire, whose steady hand in negotiating and communication skills and ability to juggle a number of issues at the same time and tap dance and do all sorts of things that make these bills possible provided the cement for the entire process.

I would also like to thank Ilyse Schuman, my chief counsel, for her precision and attention to detail.

I thank Amy Angelier Shank for her great work on the budget aspects of the bill; my press team, Craig Orfield and Mike Mahaffey; and my chief of staff, Flip McConnaughey, who was good at putting out brushfires throughout the process and kind of maintaining the core to our whole process.

On Senator KENNEDY's staff, I would like to thank Michael Myers, David Bowen, David Dorsey, Missy Rohrbach, Jeff Teitz, David Noll, and Tom Kraus. Senator KENNEDY's staffers were reasonable negotiators throughout the process and open and patient to hearing all sides of any issue.

As I mentioned before, Senator HATCH was responsible for the first FDA Revitalization Act, and I would like to thank him and his staff, Patty DeLoatche and Trish Knight, for helping me with the second FDA Revitalization Act.

With Senator GREGG's office, and for his assistance with the health IT for drug safety, I thank Dave Fisher and Liz Wroe.

Stephanie Carlton from Senator COBURN's staff and Jenny Ware with Senator BURR were also integral to many parts of the bill.

I would like to thank my colleague from Kansas, Senator ROBERTS, and his staff, Jennifer Swenson, Kate Anderson, and Mike Seyfert, for their incredible work on our direct-to-consumer advertising.

I also thank my colleague, Senator HARKIN, and his staffer, Mike Woody, for his hard work on the issue.

I thank Meghan Hauck, who is with Senator MCCONNELL, for her great assistance throughout the process and her tireless hours.

I thank Isaac Edwards, Amanda Makki, Tyler Thompson, Jennifer Claypool, and Mary-Sumpter Johnson.

Finally, there is a group of people without whom none of this would have happened. They work behind the scenes and make the rest of us look good. I am talking about the dedicated folks at legislative counsel, Stacy Kern-Scheerer, Bill Baird, Amy Gaynor, and the rest of the legislative counsel team. They have drafted forever on this, and redrafted, helped make this concept a reality. They did it with class, grace, patience, kindness, and I cannot thank them enough.

I yield the floor.

The PRESIDING OFFICER (Mr. BROWN). The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, one of the great joys of serving in the Senate has been working with my friend and colleague from Wyoming, Senator ENZI, on different legislation. He does it the old-fashioned way. He believes that what we ought to do is have the hearings on the problem and then listen to various alternatives and then try to work out a solution and carry the process forward. That is the old-fashioned way. Today people look at different issues, file bills, and try and ward off interventions. He has a deep-seated conservative philosophical commitment. He and I differ on some matters, but we always try to find common ground. We have been able to find it certainly on this legislation and many other pieces of legislation. I look forward to continuing this tradition. I am personally grateful to him for all his help in guiding us. You can see the closeness of these votes. This is enormously important legislation to bring the Food and Drug Administration into the 21st century. But there are strong feelings, strong opinions, strong arguments on different ways to do so. We have legislation. It is solid legislation. We are proud of it. I think the overwhelming, virtually unanimous vote of the Senate on both sides is a vindication of the efforts our committee has made. It starts with Senator ENZI. I am grateful to him.

I see SHERROD BROWN, the Senator from Ohio, was kind enough yesterday to stand in for me when I had the great honor to witness the coming together in Northern Ireland after 400 years of

conflict and the establishment of democratic institutions in a very momentous historical moment. When I left Monday night, there was a certain element of chaos surrounding this bill, and coming back early this morning, under the great work of Senator ENZI and Senator BROWN, we had an orderly path to proceed. He is knowledgeable about health issues and had a very distinguished record on health policy before he came to the Senate. He has not missed a beat in working through the issues. He has been invaluable to me personally and to our committee. I thank Senator BROWN for all of his good work.

Quickly: I would like to thank my friend, Senator DODD for his work on all of the issues that affect kids' drugs and devices; Senator CLINTON for her work on drugs and devices; Senator MIKULSKI for her work on the issues of transparency, enormously important provisions on which this legislation depends; Senator HATCH for his work on antibiotics; Senator GREGG for his work on the databases and Web portal; Senators ROBERTS and HARKIN for their work on the direct to consumer advertising issue, which involves a lot of different policy issues and a lot of emotion and feeling. They worked very hard with the staff, we had very solid recommendations on this; Senator STABENOW for her work on the citizens' petitions in order to help get product onto the markets in a quicker way. I would also like to thank Senator BROWN and Senator BROWNBACK, for their enormously creative innovative idea with regard to neglected diseases. This is something the United States should be doing more of, and they have been very creative in coming up with an idea; Senator COBURN on the doctor-patient relationship, a subject matter he feels intensely about and has been helpful to us on the legislation; Senator DURBIN on food safety provisions, very important and helpful; Senator ALEXANDER on the children's drugs; Senator ALLARD on food safety issues; Senator LINCOLN on food safety including the raised-fish issue.

These are some of the items. Again, we thank staff members: From my staff, Dave Bowen, David Dorsey, David Noll, and Caya Lewis, all who have spent a great deal of time and effort over these past weeks, Michael Myers and Carmel Martin and Missy Rohrbach, Tom Kraus, I thank them enormously.

I express appreciation to Senator ENZI's staff. If people try to find solutions, rather than perpetuate differences, it makes an enormous difference. That was certainly true of all the staffs on our committee. I thank Amy Muhlberg and David Schmickel and Keith Flanagan and Katherine McGuire, Shana Christrup; Senator BROWN's staff: Ellie Dehoney; Senator DODD: Tamar Magarik; Senator MIKULSKI: Ellen-Marie Whelan; Senator HATCH's staff: Patty DeLoatche, and Trisha Knight; Mike Woody from Senator HARKIN; Senator GREGG: Liz Wroe; Senator Roberts: Jennifer Swenson, Mike Seyfert, and Kate Anderson; Senator CLINTON's staff: Ann Gavaghan and Andrea Palm. I am sure I might have missed someone, but we will make sure they are included in the RECORD.

We thank all our colleagues and friends. We look forward to meeting with the House and reflecting the Senate's best judgment on the legislation.

Mr. President, over the past 10 days we have had a good debate about important issues affecting the safety of our Nation's citizens, about the drugs they use when they are ill, and about the food they eat every day.

S. 1082 will reauthorize two important user fee programs at the FDA. First among these is the prescription drug user fee program. In 2008, the program is projected to supply the FDA with nearly $400 million to help support new drug reviews and monitor the safety of drugs once they are approved and on the market. Additionally, the bill will reauthorize the medical device user fee program, which subsidizes the medical device review process. Both these programs speed new medical products to patients by enhancing the resources the FDA can devote to medical product review, without changing the standards that must be met for FDA approval or clearance.

These resources to enhance speedy access to drugs and biologics are balanced with several significant provisions that will improve postapproval drug safety. A public-private partnership involving the FDA will build a network of health care databases to gather far better information about the safety risks of prescription drugs. Expanded drug user fees would also be used to develop this active surveillance system for all FDA approved drugs.

The bill will create an additional risk-based method for approving and monitoring new drugs and biologics, called risk evaluation and mitigation strategies, or REMS. A REMS consists of a flexible collection of tools that the agency can apply to address the unique risks associated with a new drug. From labeling changes to postapproval safety studies to measures to assure safe use of a drug, the bill gives FDA important new authorities to address safety issues that arise after a drug is approved. For the first time, civil money penalties will deter noncompliance. The bill increases drug user fees to implement the REMS and enhance the postapproval drug safety system.

Furthermore, this legislation would improve transparency, strengthen the agency's science-based culture, and inspire the trust of the American public. For example, it would require the FDA to identify and disclose conflicts of interest among advisory committee members who provide the agency expert scientific recommendations.

It would also improve access to information for patients and health care providers by launching a pubic database with the results of clinical trials. A clinical trials registry would enhance patient enrollment and provide a mechanism to track the progress of clinical trials.

Finally, the legislation would establish the Reagan-Udall Foundation for the FDA to head collaborative research projects, among the FDA, academic institutions, and industry intended to improve medical product development and evaluation.

I appreciate Senator DODD and Senator CLINTON's leadership to promote the safety of drugs and devices used to treat children.

I thank Senator ROBERTS and Senator HARKIN for working with Senator ENZI and me to design constitutionally sound, effective, and feasible controls on DTC advertising. The amendment we produced will ensure the information that ads provide is accurate, clear, and conspicuous without imposing a moratorium.

I commend Senators STABENOW, BROWN, LOTT, THUNE, COBURN, and HATCH for coming to a solution on the issue of citizens' petitions. They were able to craft an amendment that ensures that only citizens' petitions with meritorious claims could delay approval of a generic drug and that frivolous petitions will not lead to unwarranted delays in the approval of new generic drugs.

I applaud Senator BROWNBACK and Senator BROWN for their novel proposal to encourage investment in new medicines for neglected tropical diseases. Their proposal entitles companies that develop new therapies or vaccines to a voucher allowing them a priority review at the FDA for a product of their choosing. It would provide pharmaceutical manufacturers a significant incentive without raising costs to consumers or relaxing the safety standards applied to the drug given priority review.

I would also like to draw attention to the essential amendment introduced by Senator HATCH, with important contributions from Senators BROWN, BURR, STABENOW, and others. The amendment would close a loophole that did away with the incentive to bring old but never approved antibiotics to market. It would also establish a public process to identify drug-resistant infections that are orphan diseases and that could be treated with orphan drugs. Additionally, the amendment would make certain molecules that are a part of old active ingredients eligible for recognition as new active ingredients, provided they will be used for a new indication. This provision includes limits that would prevent pharmaceutical manufacturers from abusing the process to extend the life of old active ingredient drugs.

Finally, I am grateful to my friend, Senator ENZI, for his leadership and commitment to addressing prescription drug safety. We have worked together for over 2½ years to develop this legislation, and I am proud of where we are today.

I have already thanked a number of people, and I would also like to thank, on Senator ENZI's staff, Ilyse Schuman, and on my own staff, Stacy Sachs, Molly Nicholson, Jeff Teitz, and Charlotte Burrows, and two of my interns, Ashley Bennett and Lara Mounir.

I would also like to thank the many other staff members, both on and off the committee, who did such great work on this bill: Carmen Green, Nancy Hardt, Paula Burg, Lisa German, Jessica Gerrity, Dora Hughes, Ed Ramos, Ben Klein, Jim Esquea, David Lazarus, Lisa Layman, Jenny Ware, Mary-Sumpter Johnson, Stephanie Carlton, and Jennifer Claypool.

I would also like to thank the legislative counsels Bill Baird, Amy Gaynor, and Stacey Kern-Scheerer for all of their hard work on this bill.

Mr. ROBERTS. Mr. President, today the Senate voted to approve S. 1082, the Food and Drug Administration Revitalization Act. I am very pleased the Senate took this action and I now look forward to its consideration in the House.

Unfortunately, I was not present to vote for the bill, but I would like the record to reflect that I had planned to vote in favor of this legislation. Just last weekend, Kansas experienced a horrible disaster when a tornado devastated an entire community and took the lives of several Kansans.

Late last Friday evening, the town of Greensburg, KS, was literally wiped off the map by an enormous tornado. As a result of this and storms associated with the system, 12 Kansans are confirmed dead, and all of the 1500 residents of Greensburg have been displaced. What we have experienced in Greensburg is unlike any other event in recent Kansas history. The hospital is gone, the schools are gone, every church is gone, virtually every business in the community is gone, including all of Main Street. Estimates are that fully 95 percent of the structures in the town are damaged or destroyed. Because of this devastation, I invited President Bush to come to Greensburg, KS, and view the damage from this unspeakable disaster. Today, President Bush is in Greensburg, and I, along with other members of the Kansas congressional delegation, are showing him the devastation this community has experienced, so I could not be present to vote for S. 1082.

However, I want my colleagues to know that I support this legislation and would have voted in favor of the bill if I were present. I believe S. 1082 will give FDA the tools to ensure drug safety and will renew some very important prescription drug and medical device programs. I am also pleased the bill includes an amendment I sponsored with Senators HARKIN, BURR, and COBURN to improve the drug advertisement provisions in the underlying bill. This amendment was accepted unanimously by the Senate.

Our amendment addresses the first amendment concerns with the advertising provisions in the original bill and gives the FDA the tools they need to protect the public from false or misleading prescription drug advertisements. We believe this amendment is a more commonsense approach to dealing with prescription drug advertisements and ensures the public will get truthful and accurate information about new prescription drugs.

I especially want to thank Chairman KENNEDY, Ranking Member ENZI, and Senator HARKIN for their leadership and hard work on this issue. I also thank Senators BURR and COBURN for their cooperation and cosponsorship of my amendment. This amendment represents the result of our efforts to achieve an outcome that is acceptable to all of us. The agreement that was accepted today is a fair compromise that addresses the concerns of all of the Members involved

Mr. BYRD. Mr. President, I voted against Senator DURBIN's amendment because it would have forced the removal of the best scientific minds from the oversight of the safety of our Nation's food and prescription drug approval process. Though well intentioned, the Durbin amendment would have limited the advice available to the Food and Drug Administration for critical decisions pertaining to consumer safety. I will support the efforts to ensure that conflicts of interest do not interfere with the safety of the American people, and I will work to ensure that the country's best experts continue to secure our medications and food supply.

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. LEAHY. I ask unanimous consent that the order for the quorum call be rescinded.

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

EXECUTIVE SESSION

NOMINATION OF DEBRA ANN LIVINGSTON TO BE UNITED STATES CIRCUIT JUDGE FOR THE SECOND CIRCUIT

The PRESIDING OFFICER. Under the previous order, the Senate will proceed to executive session to consider Executive Calendar No. 104, which the clerk will report.

The legislative clerk read the nomination of Debra Ann Livingston, of New York, to be United States Circuit Judge for the Second Circuit.

The PRESIDING OFFICER. Under the previous order, there will be 3 hours for debate equally divided between the chairman, Senator LEAHY, and the ranking member of the Judiciary Committee or their designees.

The Senator from Vermont is recognized.

JACK VALENTI

Mr. LEAHY. Mr. President, in the time allotted to me, I will talk about some other things. Later this afternoon, a wonderful American man who had a life that epitomizes what is best in our country will be buried in Arlington. I am speaking about Jack Valenti. Jack and his wife Mary Margaret first took my wife Marcel and I under their wings when I came here as an unknown 34-year-old Senator from Vermont. We had so many wonderful times with both of them. There would be times, obviously, as many of us did during Jack's years as president of the Motion Picture Association, when we would gather for a dinner at the MPAA, always with at least one Italian dish, and then watch a first-run movie. Jack would be greeting everybody by name. For those of us who sometimes have to remember the names of our own families, he was remarkable. But the remarkable thing was, he greeted everybody. He knew about you and was interested in what you were interested in, but also on the points that he wanted to get across, he would do so in a way with integrity, with brilliance, and with the respect of both Republicans and Democrats, as he would go through the halls of the Senate and the House.

On a personal basis, with he and Mary Margaret, we would sit sometimes having a quiet meal at their house or on one occasion at a favorite restaurant of theirs, on a soft summer evening, sitting outdoors and talking about kids and, in that case, their pending grandchild. I could not help but think about this man, who by all rights never should have made it through World War II. He was a highly decorated fighter bomber pilot. He went through battles where there were enormous casualties. He received the Distinguished Flying Cross and just about every other bravery medal one could, and he survived.

He came back to a career that ranged from being somber, as we all know, in Texas at the time of President Kennedy's death, to going on the plane with President Johnson, and sharing those Texas roots and working with him.

From a personal point of view, I think of the time he spent with my late mother who was an Italian American. They had that bond. He would single her out at national gatherings of Italian Americans. She loved it. She called me once and said: I saw that nice young man on television. I said: Mother, whom are you talking about? She said: Jack Valenti, that nice young man. I said: Mom, Jack is almost 20 years older than I am. She said: Really. Well, he doesn't look it. And then came the killing shot. She said: Patrick, you should take better care of yourself. When Jack had one of his many retirement parties—I will speak to that in a moment—I told that story.

I am afraid more than one person in the audience agrees with my mother.

I said ''one of his many retirements.'' He never retired. He continued to write books. He had one that he just finished before a stroke silenced him a few

weeks ago. I have a copy of his book in my desk on the Senate floor. I have a copy of all his books. They are well written. He had a command of the English language that all of us would like to think we could master with the best of all speechwriters, and we can't. He did it. He was his own speechwriter. Nobody else could begin to match what he did.

One of the things I think of—and I was thinking of this at his funeral, where I had the honor of being an honorary pallbearer—I spoke with Mary Margaret and his son John afterward, his daughter Courtney. I was speaking with others. I remembered an op-ed piece that my friend Matt Gerson wrote for the Saturday, April 28, Washington Post about Jack. Matt refers to the mentoring that he did of so many people. Matt refers to his own mentoring by Jack Valenti.

Well, I am one of those Senators—one of hundreds of Senators—on both sides of the aisle mentored by Jack. I, along with my wife, am among the thousands of people who will miss his phone calls, who will miss his conversations, who will miss his friendship, and we join in sending our condolences to Mary Margaret, and know she carries on great memories of her own, and memories we will continue to share.

Mr. President, I ask unanimous consent that the op-ed piece I referred to by Matt Gerson be printed in the RECORD.

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

[Saturday, April 28, 2007]

WHAT JACK VALENTI TAUGHT US ALL

(By Matt Gerson)

Jack Valenti lived a unique life between two of society's fascinations—politics and Hollywood. For Republicans and Democrats, for senators and young aides, for celebrities and the legions behind the cameras, interactions with him were graduate seminars in history, politics, human nature and common sense. This extraordinary communicator punctuated every conversation with a witticism linked to his beloved Texas, a quote from an obscure historical figure or a rule passed on to him by his mentor, Lyndon Johnson. In the weeks leading up to his death Thursday, all over town a simple "How's Jack?" almost always led to, "You know, I try to live by something I once heard him say."

I first noticed his reach when a lunch companion said, "I try to return every phone call the same day I receive it, and I try to treat an appointment secretary like a Cabinet secretary." That was followed by a senator who revealed: "Jack was the first one to contact me after my son died. I will never forget his concern and support. How can I reach his family?"

For those Jack mentored during the 38 years he dedicated to America's film industry, it became clear that character was defined by loyalty. In both Washington and Hollywood, people often desert "friends" at the first whiff of public disfavor. Not Jack—time and again he insisted that you never abandon a friend who was going through a rough time, and he always stood with a beleaguered colleague or public official who was receiving unwanted publicity.

He would tell his team to respect every elected official ("because you never even ran for dog catcher, and they were sent here by the people"). He admonished us that your adversary today might be your ally tomorrow. "In a political struggle, never get personal—else the dagger digs too deep."

Jack rejected the partisanship that gripped Washington and would warn that "nothing lasts—today's minority backbencher will be tomorrow's subcommittee chairman." On the day the Motion Picture Association of America headquarters was named the Jack Valenti Building, Sen. Ted Stevens observed, "Jack works across the aisle because he doesn't see an aisle. It is the root of his success and what others ought to emulate."

Each of the six studio chiefs who spoke at the dedication ceremony emphasized that Jack's word was his bond—if he made a promise, he never wavered. His rock-solid commitment gave him unusual credibility with leaders on both coasts and around the world.

Jack was a gifted public speaker who put incredible effort into making it all look effortless. He would rework his text behind closed doors, reciting it until the cadence was just right. Jack was ebullient when a president complimented him once on the "extemporaneous" remarks he had made at the Gridiron Club. "The president couldn't believe I didn't have a prepared text. I neglected to mention that I didn't need notes because I spent several days getting ready," he said.

It was especially fun to watch Washington's most accomplished professionals try to decipher one of his homilies. They eventually got the point and often adopted the line as their own. When a project was in trouble, it was time to "hunker down like a mule in a hailstorm." [Modified from the original Texas vernacular for a family newspaper.] When prospects got even worse, "The ox was in the ditch." But every problem could be addressed if you remembered "the three most important words in the English language: Wait a minute."

When someone from the MPAA left to take a new job, Jack would say, "I like to think I teach my people everything they know. But I know I didn't teach them everything I know." That line always got a laugh. I worked with Jack for six years and was friends with him for nearly two decades. In the past few years, frankly, I thought I had gleaned every lesson he had to offer. But then I picked up the galleys of his soon-to-be-published memoir, a book that tracks his "Greatest Generation" fable. This grandson of Sicilian immigrants, decorated combat pilot, Harvard MBA ("thanks to the greatest piece of social legislation ever devised by man—the G.I. Bill"), presidential adviser and confidant of America's business leaders has left a treatise with even more rules to live by.

One paragraph is a must-read for the BlackBerry-addicted. Jack quoted Emerson's observation that "for every gain, there is a loss. For every loss, there is a gain." While lamenting the number of nights he spent away from his family, he reminded us that attending one more reception meant missing a meal around the dinner table, and one extra night on a business trip would mean one less chance to help with homework or watch a soccer game.

I have recounted that quote many times over the past few weeks. And while this loss is devastating for many in Washington and Los Angeles, the life lessons that are his legacy are our gain.

NATIONAL GUARD EQUIPMENT STOCKS

Mr. LEAHY. Mr. President, earlier today, we had a meeting of the Senate Appropriations Committee. Defense Secretary Gates and Chairman of the Joint Chiefs of Staff General Pace were there. I was at that meeting. I had questions that I asked. I have been bothered since the meeting, not so much by what they said, but by what has happened in the last few days.

Every one of us, when we turn on our television set, sees the devastation in Kansas by a tornado—something we would not see in my State of Vermont. But even in a State where these are not unusual things, the devastation of this tornado was unique. I thought yesterday about how the President of the United States, through his spokesperson, blatantly dismissed the all too real concerns of the Governor of Kansas, Governor Sebelius, about the equipment levels available to our National Guard for dealing with such emergencies at home as this horrible disaster I spoke of that befell Greensburg, KS.

The White House spokesperson, sitting comfortably at the White House, said: Well, you know, there is no problem. The Guard has considerable equipment stocks still available.

Everybody who has studied the situation with our National Guard around this country knows that assertion is absurd on a number of levels. Maybe they felt they could make a political statement because the Governor is of another party. But the reality is, the Governor spoke the truth. She knows the Guard faces real, incontrovertible shortfalls in vital equipment.

Contrary to what the White House has said, the Governors—I am talking about the Governors; Republican, Democratic Governors alike—and their adjutant generals—those who are the heads of the National Guard in their respective States—are reporting something quite different than the blase attitude of the White House.

State after State reports missing humvees, medium-sized trucks, generators, dump trucks, communications systems. These are not claims from just any observer of Guard issues; these are the leaders who have been elected by the people to provide for their security and deal with these sometimes terrifying State emergencies.

As the Presiding Officer knows, the Governors command the Guard when operating in a State, and we have to give special credence to what they say. The idea that there is no problem—this kind of dismissive "there is no problem"—is equally ridiculous because it has been clearly documented there is a very real $24 billion equipment shortfall in Army National Guard equipment alone. Now, those are reports that do not take into consideration the shortfalls within the Air National Guard. But both the Active Army and the National Guard agree on this figure. It was developed together with the National Guard Bureau working closely with the Army staff.

To say there is no problem, on the one hand, and have an arm of the administration, on the other hand, say there is a $24 billion shortfall—to me, that is a problem.

What is a greater problem is there are no plans to address this shortfall in the long-range budget. There are no plans to buy the 18,000 needed humvees, no plans to obtain the 30,000 medium-sized trucks, no plans to purchase the 12,000 required generators, no plans to purchase the 62,000 communications sets—the list goes on and on.

Another reason the White House's assessment of Guard equipment issues is so flawed is that everyone—from the Guard leadership to the Army leadership to Members here on the Hill—knows that, very frequently, that equipment slated for the Guard never actually makes it to the Guard because it is diverted, transferred to the Active Force before it gets into Guard stocks.

Even when the Guard equipment makes it into the Guard stocks, it is often quickly turned around and sent right back off to Iraq, along with deploying Guard units, many of which now face their second Iraq deployment.

It is passing strange to me that while this administration asks for a blank check to resupply the Iraqi National Guard, they do not have 1 cent in their long-range budget to resupply the American National Guard. Now, whether someone is for or against the war in Iraq, you would think our own forces—our own American national guard—could be treated at least on par with the Iraqi national guard, especially as we see the brave men and women of our National Guard not only answering the call in Iraq and Afghanistan, but answering the call when there are dangers here at home. We do not see them, as we have seen in units of the Iraqi national guard, setting out to kill each other or forming death squads. So why do we write blank checks for the Iraqi national guard when we can't take care of our own? I wish the President and the White House would come to fully realize this reality. Here is the real situation when it comes to National Guard equipment: The Guard does not have adequate stocks to deal with emergencies where they can maximize their full potential. In a smaller scale disaster, they cannot respond as quickly to support first responders and local law enforcement.

That is what we saw recently in Kansas. Now, suppose you have another emergency in Kansas or a larger scale emergency or something like Hurricane Katrina or, God forbid, two simultaneous disasters. The Guard is going to be hard pressed to respond as well as it did along the gulf coast almost 2 years ago.

Let me show you some photographs. You can see from these photographs, these are things our Guard does. You see this capsized tanker, and helicopters trying to rescue the people. Those are National Guard helicopters.

Here we have a forest fire close to an urban area, where homes are in danger. You can see an airplane putting down a fire retardant. That is a National Guard airplane.

Here you see a little child being rescued, carried up to a helicopter in the arms—the embracing arms, the safety of the arms—of a National Guard member.

Here you see the rescue of somebody who was in an accident.

Here you see National Guard in armored personnel carriers in a flooded area. In case you are wondering where that area is, look at the sign in the background that says ''Welcome to New Orleans.'' Much of that sign is under water. First responders—the police, fire departments—in New Orleans were totally overwhelmed, figuratively and literally. The Guard responded.

Look at these firefighters, trudging through a forest, at risk to their own lives, to put out a forest fire. Who are they? National Guard members.

The Secretary of Defense maintained this morning in his appearance before the Defense Appropriations Subcommittee that the Guard has 56 percent of its equipment stocks available. Well, that figure contradicts everything I have heard from other responsible officials, who put the figure closer to 35 percent. Frankly, 35 percent or 56 percent is not adequate, by any means.

In the latest supplemental spending bill, which the President seemed happy to veto, I worked with my colleague on the National Guard Caucus, Senator BOND. We cochair the National Guard Caucus. We also serve on the Defense Appropriations Subcommittee. We added $1 billion for Army Guard equipment purchases. That $1 billion was not requested by the administration. We had virtually unanimous support, Republicans and Democrats, in this body for it. It would go directly for dealing with that $24 billion shortfall. Now, that has been vetoed. We are going to work together in a bipartisan fashion to get it back into whatever spending bill we pass.

We cannot do that unless we work together—unless we work together. This is a case where it almost becomes a cliche to say: We cannot afford to let our Guard down—but we cannot. We do not have tornadoes in Vermont, but we have had some pretty vicious floods—one that nearly wiped out my hometown of Montpelier, VT, the capital. We have had some pretty vicious ice storms—one that almost removed the agricultural sector of a major part of our State.

In each case—as hard working as the local responders were, and they were, the police and the fire departments—the first call of the Governor went to the Guard, the National Guard. And they came. They rescued people. They kept people going.

When you have an ice storm, and it is 10 degrees below zero in your State, you can't wait for them to say: Well, we have 56 percent or we have 35 percent of your equipment. The other equipment you need is in Los Angeles, and we will ship it to you as quickly as we can. That is the old ''check is in the mail.'' If it is 10 degrees below zero, and you have an ice storm, with all the power lines that come down, people are going to die—people are going to die—if they can't get power within a matter of, really, minutes. The Guard can do that.

We know what a fiasco it was with our still dysfunctional Department of Homeland Security after Katrina. We have seen how the Department of Homeland Security and its FEMA division have still not responded to that. But we did respond when the Governors called out the National Guard.

So I rarely ever respond to comments made by the White House and their press operation, even when they take gratuitous swipes at me, but this one, I couldn't pass up. They know what the numbers are. They know the Governor of Kansas was speaking the truth. They know the Guard is woefully undersupplied. They know they have been diverting money to pay for the Iraqi National Guard from our Guard. So I think it would be really helpful for the White House to stop showing contempt for the views of our Nation's elected Governors. Take and consider their input, respect their thoughts about the Guard given their places with the National Guard in their States.

Let's turn the situation around. Let's come up with a new plan to replenish depleted Guard equipment stocks. We can't afford to continue to let our Guard down.

Mr. President, I ask unanimous consent to have printed in the RECORD the appropriate charts on this matter.

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

FY08
ARNG TOP 25 EQUIPMENT MODERNIZATION SHORTFALL LIST

	Quantity Required	Quantity Shortage	Shortage $M	POM 08-13 $M	APPN	UFR 08-13 $M
HMMWV	48,715	18,611	$4,039	$1,647.0	OPA	$2,392.0
Family of Medium Tactical Vehicles	37,995	30,140	$7,267	$1,689.9	OPA	$5,577.1
HTV - HEMTT/LHS/PLS	21,180	14,796	$1,652	$1,059.3	OPA	$592.7
M916A3 Light Equipment Transporter	1,591	794	$180	$152.4	OPA	$27.6
Tactical Trailers	5,699	2,984	$177	$10.6	OPA	$166.4
M917A2 Dump Truck	544	334	$67	$0.0	OPA	$67.0
CH-47F Chinook	159	159	$6,678	$670.6	ACFT	$6,007.4
Comm Systems (JNN, SINCGARS, HF)	143,615	62,613	$3,997	$968.7	OPA	$3,028.3
UAV Systems (Shadow , Raven)	586	575	$462	$307.1	OPA	$154.9
Small Arms	209,098	99,129	$360	$240.0	OPA	$120.4
ABCS (Suite of Systems)	1,399	800	$166	$20.7	OPA	$145.3
Digital Enablers (Log Automation)	12,167	7,873	$196	$0.0	OPA	$196.0
Movement Tracking System	16,711	12,588	$302	$203.4	OPA	$98.6
Night Vision (AN/PAS-13, AN/VAS-5)	41,912	33,170	$640	$241.5	OPA	$398.5
Tactical Water Purification System	131	128	$61	$38.9	OPA	$22.1
Tactical Quiet Generators	19,611	12,748	$324	$118.1	OPA	$205.9
All Terrain Crane (ATEC)	174	29	$7	$0.0	OPA	$7.0
M9 ACE SLEP	114	90	$80	$0.0	OPA	$80.0
Route and Area Clearance Systems	138	138	$203	$167.8	OPA	$35.2
Horizontal Construction Systems	587	332	$141	$111.0	OPA	$30.0
How itzers (M777A1, M119A2)	498	342	$4,259	$477.4	WTCV	$3,781.6
Profiler	65	63	$57	$57.2	OPA	$0.0
LLDR	1,099	1,034	$362	$187.5	OPA	$174.5
Gun Laying Positioning System	455	208	$20	$0.0	OPA	$20.0
Chemical (Detectors, Decon & Shelters)	65,719	52,433	$669	$107.5	OPA	$561.5
TOTALS	629,962	352,111	$32,367	$8,476.5		$23,890.1

Quantity Required = Endstate FY08 ARNG Requirements (MTOE or like AC) to fully modernize the ARNG.
Quantity Shortage = Quantity Required – On-Hand – Programmed (2-year Equipment Distribution Plans).
Shortage ($M) = Quantity Shortage x Per Unit Cost.
POM 08-13 ($M) = Total procurement funding stream from FDIIS (dtd 10 JAN 07), by Army Program Element (APE) for respective equipment systems.
APPN = Type of Appropriation (OPA – Other Procurement Army, ACFT – Aircraft, WTCV – Weapons & Tracked Combat Vehicles.
UFR 08-13 ($M) = Shortage dollar amount – POM 08-13 dollar amount.

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31 JAN 07 ARO—Materiel Programs Division

ARNG Equipping Requirements versus Resources

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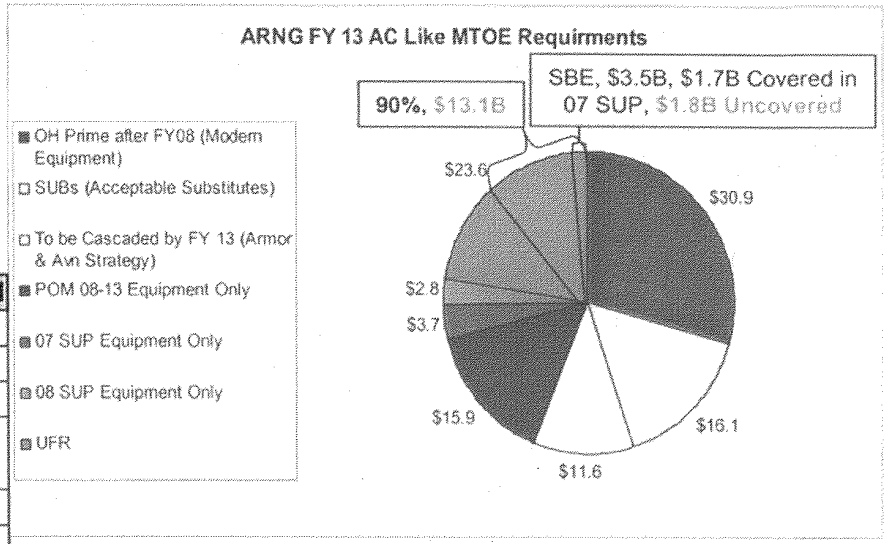
ARNG Equipping Requirements Overview

ARNG Total Requirement for FY13 AC Like MTOE & TDA: $104.6B

ARNG FY13 AC Like MTOE Rqmnts	$B	% OF Rqd
Total Required $B	$104.6	100%
OH Prime after FY08 (Modern Equipment)	$30.9	30%
SUB (Acceptable Substitues)	$16.1	15%
To be Cascaded from AC by FY 13 (Armor & Avn Strategy)	$11.6	11%
POM 08-13 Equipment Only	$15.9	15%
07 SUP Equipment Only	$3.7	4%
08 SUP Equipment Only	$2.8	3%
Value On Hand + Pgmd + Cascade	$81.0	77%
Total UFR	$23.6	23%
UFR to Reach 90%	$13.1	



FY13 ARNG AC Like MTOE Requirements

The ARNG has a **$23.6 UFR** after FY13

$13.1B against this equips ARNG to 90%

* "Equipment Only" Only includes funds that purchase new equipment.
* On Hand Equipment does not include Unacceptable Substitutes (Example- M35s and 800s)
* Does not Include "Grow the Army" and all costs are based in FY08 dollars

ARNG UFR to reach 90%: $13.1B

Equipment Category	Required Quantities (000)	On Hand Quantities (000)	Quantities Delivered FY 07-08 (000)	Shortfall Quantities before FY 08-13 (000)	Shortfall before FY 08-13 ($M)	Procurement Program FY 08-13 ($M)	Post FY 08-13 Shortfall ($M)	* UFR to S-1 Floor (90%)
Armor-Hvy T/W	15.04	8.58	0.59	5.87	$1,949.18	$2,312.76	$0.00	$0.00
AVN	60.58	29.84	0.36	30.38	$12,928.15	$3,596.72	$9,331.43	$5,528.87
C2	189.68	17.02	23.95	148.71	$1,917.63	$2,021.18	$0.00	$0.00
Communicate	589.81	336.90	15.52	237.39	$3,009.98	$1,512.38	$1,497.60	$891.07
Engineer	30.97	14.42	0.79	15.76	$1,655.52	$851.72	$803.80	$478.26
Force Protection	476.50	356.94	20.29	99.27	$996.37	$122.89	$873.48	$519.72
ISR	5.65	2.22	0.93	2.50	$381.96	$787.05	$0.00	$0.00
Logistics	588.11	137.45	3.07	447.59	$1,637.92	$648.38	$989.54	$588.78
Maintenance	19.25	3.25	2.29	13.71	$281.19	$36.50	$244.69	$145.59
Medical	25.14	10.24	6.19	8.71	$15.98	$101.67	$0.00	$0.00
Precision Strike	27.51	10.49	0.91	16.10	$1,975.81	$2,474.67	$0.00	$0.00
Security	1730.86	819.94	135.94	774.97	$3,561.81	$1,543.94	$2,017.87	$1,200.63
Transportation	179.61	51.20	17.61	110.80	$10,163.36	$5,178.90	$4,984.46	$2,965.76
Other	262.05	72.35	0.00	189.70	$1,451.32	$0.00	$1,451.32	$863.54
Totals	4,200.75	1,870.85	228.23	2101.46	$41,926.18	$21,188.76	$22,194.19	$13,182.22

*** In addition to the fall current funds programmed through FY13, an additional UFR of $13.18B is required to get the ARNG to 90% EOH (S-1). It will take approximately $24B to reach 100%. All figures are based on FY 08 Costs and don't include "Grow the Army" Costs.**

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Essential 10 Key Enablers: DSCA Prioritized Buy List

ITEM	PRIORITY 1	PRIORITY 2	PRIORITY 3	PRIORITY 4	RATIONALE/JUSTIFICATION
Joint Force Headquarters					
Miscellaneous Equipment	$5,000,066	$5,000,027	$5,000,126	$5,000,111	
Command and Control (C2)					
Joint Network Nodes (JNN)	$33,300,000	$16,650,000	$16,650,000	$16,650,000	Provides the tactical user with an interface to strategic data networks, and interoperability with commercial, joint, combined and coalition communications systems across multiple security levels.
Army Battle Command Systems (ABCS)	$7,808,500	$7,233,500	$5,638,100	$6,458,800	Provides enhanced situational awareness via a suite of systems that receive and transmit C4ISR information.
Standard Army Management Information System (STAMIS)	$25,727,920	$20,550,610	$21,595,610	$15,953,980	Provides logistics management/automation systems an electronic information exchange capability via both tactical and commercial networks.
Unmanned Aerial Vechicle - SHADOW	$15,000,000	$15,000,000	$15,000,000	$15,000,000	Without funding the ARNG will be unable to provide commanders superior situational awareness, information flow, and adequate Force Protection in urban and conventional tactical environments.
Communications					
HF Radios / Equipment	$16,288,475	$17,445,135	$15,435,815	$18,785,815	Provides secure, long-range voice and data capability.
Aviation					
Helicopters - Hoists/Mounts	$953,016	$1,191,270	$1,191,270	$1,191,270	Required to support HLD/HLS, state, domestic and other contingency operations.
Helicopters - NAVSTAR GPS Aviation Sets	$1,235,130	$1,235,130	$1,370,130	$1,370,130	Provides modern equipment and interoperability to ARNG aircraft.
Civil Support Teams and Force Protection					
NBC Shelters	$5,502,000	$6,288,000	$7,860,000	$7,860,000	Provides a contamination free and environmentally controlled work area for medical personnel.
NBC - Joint Services Transportable Decontamination System Small Scale (JSTDS-SS)	$990,000	$990,000	$1,155,000	$1,320,000	Without funding the ARNG will be cascaded outdated and no longer in production models of the M17 LDS from the Active Component.
NBC Radiation/Chemical Detectors	$682,160	$682,160	$816,990	$910,740	Provides the capability to monitor and record the exposure of individual personnel to gamma and neutron radiation.
Engineer					
Heavy Construction Equipment - Horizontal (Dumps, Graders, Excavators)	$16,151,889	$11,927,933	$12,579,096	$11,957,388	Replaces overaged systems that are in critical need of modernization and incapable of full mission support.
Heavy Construction Equipment - Vertical RTCH, ATLAS)	$19,004,075	$16,755,970	$19,505,970	$22,255,970	Primary container/material handling equipment required to support and sustain ARNG units.
Logistics					
Generators - Small/Medium	$5,348,830	$5,839,690	$5,839,690	$5,783,445	Critical requirement during natural disaster or state emegency. Provides electrical power as needed to support mission requirements.
Liquid Logistics - Water Purification	$6,451,500	$8,070,000	$8,047,500	$10,707,500	Replaces existing 600 GPH reverse osmosis water purification systems with a 1500 GPH capability.
Liquid Logistics - Tank Water	$4,840,000	$4,840,000	$4,840,000	$5,550,000	Provides a bulk water delivery/distribution/storage systems.
Maintenance					
STAMIS - Standard Army Maintenance System (SAMS)	$967,458	$942,780	$983,910	$1,557,590	Mission critical system required to support unit-level maintenance support requirements.
Medical					
HMMWV Ambulance	$13,455,000	$14,490,000	$14,490,000	$13,455,000	Provides patient transport/evacuation capability.
Security					
Small Arms - Shotgun	$264,610	$299,860	$332,525	$377,845	Critical for security operations in urban environments.
Night Vision - Driver's Vision Enhancers (DVE)	$4,926,825	$4,926,825	$5,038,310	$5,474,250	Provides a thermal night vision capability to drivers enabling continuous mission operations.
Transportation					
HMMWV - Un Armored	$101,590,000	$107,800,000	$107,800,000	$106,765,000	
HMMWV - Up Armored	$31,598,000	$38,003,000	$38,003,000	$35,868,000	Critical enabler for the ARNG to perform all mission and support requirements, domestic or combat.
FMTV - Trucks	$60,451,326	$61,580,790	$60,966,638	$60,451,326	Replaces obsolete, non-deployable trucks. Critical enabler for the ARNG to perform all mission and support requirements.
HTV - HEMTT Tanker / Wrecker / LHS	$42,833,720	$52,628,720	$51,203,720	$50,637,440	Provides line and local haul, resupply, and recovery capability to sustain operations.
HTV - PLS Truck / Trailer / Bed / CHU	$56,768,600	$56,768,600	$56,768,600	$56,768,600	Primary component of the maneuver-oriented ammunition distribution system. Also performs local-haul, line-haul, unit re-supply and other transportation missions.
MTV - M916A3 Light Equipment Transporter	$11,350,000	$11,350,000	$11,350,000	$11,350,000	Prime mover for pulling the M870 series trailer and heavy engineer equipment.
MTV - Tactical Trailers	$11,510,000	$11,510,000	$10,540,000	$10,540,000	Required for transport of heavy engineer equipment, ISO containers, and other cargo.
Total	$500,000,000	$500,000,000	$500,000,000	$500,000,000	

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Mr. LEAHY. Mr. President, I suggest the absence of a quorum, with the time to be charged to both sides.

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

The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. LEAHY. 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. LEAHY. Mr. President, I ask for the yeas and nays on the pending judicial nomination.

The PRESIDING OFFICER. Is there a sufficient second? There appears to be a sufficient second.

The yeas and nays are ordered.

Mr. LEAHY. Mr. President, the Senate continues to make significant progress today with another confirmation of another lifetime appointment to the Federal bench. The judicial nomination we consider is Debra Ann Livingston of New York, who has been nominated to the United States Court of Appeals for the Second Circuit. That is the circuit for New York, Connecticut and, of course, Vermont. Professor Livingston has the support of both her home State Senators. I thank Senator SCHUMER for chairing the confirmation hearing at which she appeared.

Professor Livingston is the Paul J. Kellner Professor of Law and vice dean of the Columbia Law School, where she has been a professor for 13 years, teaching criminal procedure, evidence, and national security law. She previously taught at the University of Michigan Law School. Prior to her academic career, Professor Livingston served as a Federal prosecutor and deputy chief of appeals for the U.S. Attorney's Office for the Southern District of New York and worked in private practice for the Wall Street law firm of Paul, Weiss, Rifkind, Wharton & Garrison. I congratulate Professor Livingston and her family on what I am sure will be her confirmation today.

Coincidentally, this is the anniversary of the date 6 years ago, in 2001, on which this President began his assault upon the courts by announcing his first list of nominees. With the help of Senate Republicans, this President has sought to pack the courts and tilt them decidedly in one direction. To a great extent, he has succeeded. After Republican Senators stalled President Clinton's nominees to the Fourth, Fifth, Sixth, D.C., and other circuits, the Senate proceeded to confirm this President's nominees to the very vacancies that had previously been maintained by pocket filibuster in the Senate.

In my time as chairman from mid-2001 to the end of 2002, I worked hard to reach out to this President and tried hard to change the tone and get the confirmation process back on track. We succeeded in confirming 100 nominees in 17 months, including 17 to the circuit courts. But I could not change the tone alone. This White House chose, instead, to use judicial nominations to divide and to seek political gain in the ensuing confrontations.

I have tried, again, this year to restore order and civility to the process. In spite of all our progress and all our efforts, we are still confronted by shrill complaints. More ominous are the signals and rumors that the White House is, again, gearing up to nominate more extreme nominees and more who do not have the support of their home State Senators. That is wrong. It may be the good politics to appeal to the Republican base, but it is wrong to use our courts in that way—just as it is wrong to corrupt the law enforcement responsibilities of the Department of Justice.

Some will undoubtedly repeat the current Republican ''talking point'' that the Senate must confirm 15 circuit judges this Congress, this year and next, because that is a ''statistical average'' of selected years. Well, during the 1996 session the Republican-led Senate refused to confirm a single circuit court nominee, not one. That meant that in the 104th Congress, in 1995 and 1996 combined, only 11 circuit nominees were confirmed.

It is true that during the last 2 years of this President's father's term, a Democratic-led Senate confirmed an extraordinary number of circuit nominees—20—in fact. That action was not reciprocated by the Republican majority during the Clinton years.

It is true that during the last 2 years of the Reagan administration, a Democratic-led Senate confirmed 17 circuit court nominees. That action was not reciprocated by the Republican majority during the Clinton years.

Instead, the last 2 years of President Clinton's two terms witnessed a Republican-led Senate confirming only 11 circuit nominees and then, with vacancies skyrocketing to historic highs, 15 circuit nominees in the 106th Congress.

Thus, to get to the supposed ''historical average'' that Republicans like to talk about, they take advantage of the high confirmation numbers during Democratic-led Senates and thereby inflate and excuse their own actions from the Clinton years.

There are three more factors that the Republican talking point ignores: The first is the number of vacancies. The second is adding additional judgeships by congressional action. The third is the number of qualified circuit nominees.

The last Congress of the Reagan administration, the one in which a Democratic-led Senate confirmed 17 circuit nominees, the circuit court vacancies went down from 13 to 8 during the course of the Congress. Seven circuit nominations were returned to the President without action. In fact, in addition to filling vacancies that were arising in the regular course, the Democratic-led Senate was working to fill many of the 24 additional circuit judgeships created in 1984. By the end of the Reagan Presidency all circuit vacancies, those from existing judgeships and those created during his Presidency, were reduced from a high of 25 down to 8.

During the last Congress of the first Bush administration, the one in which a Democratic-led Senate confirmed 20 circuit judges, the circuit vacancies again went down, from 18 to 16. Again, the Senate was filling both existing and newly created vacancies. In 1990, during President Bush's term, Congress authorized an additional 11 circuit judgeships. That was why vacancies at the beginning of the 102nd Congress rose to 18.

By contrast, during the last Congress of the Clinton administration, the one in which a Republican-led Senate confirmed 15 circuit judges, circuit court vacancies skyrocketed from 17 to 26. This rise in circuit vacancies had nothing to do with Congress creating additional circuit judgeships, however. Unlike during the Reagan administration and during the Bush administration, during the Clinton administration the Republican-led Congress refused to act in accordance with the previous 6-year cycle for reviewing needed judgeships. Not a single new circuit judgeship was created during the Clinton administration that I can recall. Instead, the Republican-led Senate engaged in strenuous efforts to keep circuit judgeships vacant in anticipation of a Republican President. Indeed, at the end of the 106th Congress, the last in the Clinton Presidency, 17 circuit court nominees were returned to President Clinton without action. More circuit nominees were returned without action that Congress than were acted upon by the Senate for the first time in modern history.

Likewise, during the last Congress of the first term of President Clinton, the one in which a Republican-led Senate confirmed only 11 circuit judges, circuit court vacancies went up, from 16 to 19. Again, this was without the addition of new circuit judgeships.

Despite the carping and the clamor, the vacancies on the circuit courts have gone from 26—where a Republican-led Senate forced the circuit vacancies at the end of the Clinton administration—steadily downward during the Bush administration. With the confirmation of Judge Livingston, circuit vacancies will be at half that amount today 13—and approaching a historic low.

Judge Livingston will be the third circuit court nomination confirmed this year. It is only May, but we have already equaled the total circuit nominees confirmed in the entire year of 1993. We have far surpassed the total confirmed during the entire 1996 session when the Republican majority would not consider or confirm a single circuit nomination of President Clinton's.

This will be the 20th circuit court nomination confirmed while I presided as Judiciary chairman. It is a little

known fact that during the more than 6 years of the Bush Presidency, more circuit judges, more district judges and more total judges have been confirmed while I served as Judiciary chairman than during either of the two Republican chairmen working with Republican Senate majorities.

This will be the 18th judicial confirmation this year. It is spring and we have already confirmed more judges than were confirmed during the entire 1996 session when President Clinton's nominees were being reviewed by a Republican Senate majority. This is the 118th judicial confirmation while I have served as Judiciary chairman. That exceeds by more than a dozen the confirmations Senator HATCH presided over during the more than 2 years he was Judiciary chairman.

The Administrative Office of the U.S. Courts lists 47 judicial vacancies, yet the President has sent us only 24 nominations for these vacancies. Twenty-three of these vacancies—almost half—have no nominee. Of the 15 vacancies deemed by the Administrative Office to be judicial emergencies, the President has yet to send us nominees for six of them. That means more than a third of the judicial emergency vacancies are without a nominee.

This is the third factor I mentioned above, the lack of nominees.

This President has shown that he would rather pick politic fights than good judges. I was encouraged at the beginning of this Congress that a few of the most controversial nominees from the last Congress were not renominated. That sensible approach seems to have ended, however, and this White House seems to be returning to its old, bad habits.

Despite the harping and the criticism, the Judiciary Committee has been working hard to make progress on those nominations the President has sent to us. Of course, when he sends nominees that he knows are unacceptable to home State Senators, it is not a formula for success. Sadly, that is what appears to be happening, again.

Before the consideration of the Second Circuit nominee today, we had already proceeded with committee and Senate consideration of the nominations of Randy Smith and Thomas Hardiman. They were confirmed to the Ninth and Third Circuits, respectively.

Some may recall that I had been working for more than a year to make progress on the Smith nomination. When the President finally renominated Judge Smith for an Idaho vacancy, we were able to make quick progress with that nomination.

Our circuit court confirmations so far this year are in addition to the 15 lifetime appointments to the Federal district courts we have proceeded to confirm. During the entire 1996 session only 17 judges were confirmed. We are doing pretty well with 18 confirmations before the middle of May.

With respect to circuit nominees, after this confirmation there will be only 13 vacancies. Eight of those are without a nomination. Of the five remaining current circuit nominees, one was only nominated a few weeks ago. Having consulted with the home State Senators from Mississippi, I have scheduled our next judicial confirmation hearing to be held tomorrow to include Judge Leslie Southwick of Mississippi.

All three of the other circuit nominations are renominations that were not considered last Congress with a Republican majority. Two are renominations that the White House made knowing full well that they did not yet have the support of their home State Senators. When I previously chaired the committee, I was able to break the blockade of Sixth Circuit nominations that was established by the Republican majority when it pocket filibustered several of President Clinton's outstanding nominations to the Sixth Circuit. Once we broke through with two Sixth Circuit confirmations in 2002, President Bush was left with seven appointments to the Sixth Circuit during his term in office. Given the White House's unwillingness to work with the home State Senators of the two current nominees, however, it will be very difficult to make more progress.

With respect to the nomination of Peter Keisler, that renomination is controversial. He was previously nominated in June of 2006 but was not considered by the Republican majority then in control. The Republican majority did not seek to proceed with this controversial nomination at that time. In fact, the President and the Republican Senate majority insisted, instead, to proceed over the last several years on other nominations to the important D.C. Circuit, which were, themselves, highly controversial. The nominations of Janice Rogers Brown, Thomas Griffith and Brett Kavanaugh were each apparently a higher priority for this White House and the Republican majority than the nomination of Mr. Keisler. The others have each been confirmed to lifetime appointments on this very important court. At the end of the last Congress, the Keisler nomination was returned to the President without action in accordance with Senate Rules.

The Republican Senate majority pocket filibustered more than 60 of President Clinton's qualified and moderate judicial nominees. I have proceeded on more judicial nominees far faster than Republicans did on President Clinton's nominees.

With the cooperation of the President, with his working with Senators from both parties in making his nominations, with the cooperation of the committee and the Senate, we can continue to make progress.

I will yield the floor and reserve the remainder of my time.

Mr. SPECTER. 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. CORNYN. 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.

Who yields time?

Mr. SPECTER. Mr. President, I yield the Senator from Texas 10 minutes.

The ACTING PRESIDENT pro tempore. The Senator from Texas is recognized for 10 minutes.

Mr. CORNYN. Mr. President, we are into the fifth month of the 110th Congress. Even before this Congress convened in January, observers were predicting that judicial nominations would be one of the most contentious issues that we face. But I think by taking a forward-looking approach, the Senate managed to avoid an unnecessary confrontation. I think, by and large, we have started off on the right foot.

Earlier this year, the Washington Post and the Los Angeles Times both applauded the President for the difficult concessions he made in not choosing to renominate certain previous nominees who generated intense opposition. While I thought some of that opposition was mostly unfair and unwarranted, I respect the President's decision to extend an olive branch to the new Democratic majority in the Senate. Those two newspapers also encouraged the new Democratic majority to reciprocate with cooperation and fairness.

In that spirit of cooperation, Senate Republicans received assurances earlier this year from the Democratic majority of a fair and reasonable pace for the confirmation of nominees to the U.S. courts of appeals. I was pleased to hear the majority leader pledge his cooperation and leadership to help this Congress ''at least meet the standards of Congresses similarly situated as ours.'' We saw progress in the first couple of months of this year, with the confirmation of two circuit court nominees.

Today, the Senate will vote to confirm a Third Circuit judge. I welcome today's vote and hope it will be an indication of the majority's intent to keep working with us on the pace necessary to meet the historical average that the majority leader has endorsed.

Yesterday, the distinguished chairman of the Judiciary Committee commented on how he views this progress. I would like to briefly discuss the historical analogy he cited. First, I should note I am proud to continue to closely work on several significant pieces of legislation with the senior Senator from Vermont, Mr. LEAHY. He and I have found common ground on, among other things, historic changes to the Freedom of Information Act and much needed reforms to the U.S. patent system. I look forward to working with the chairman to help make these important bills become law.

The chairman and I tend to part ways on some issues related to judges. I just want to take a moment to comment on the remarks he delivered yesterday on the pace of judicial confirmations. In particular, I am wondering why he chose the year 1996 as the appropriate measuring stick for progress on judges made by this Congress. Of course, there is one obvious parallel between 1996 and the present year, and that parallel is divided government.

In 1996, President Clinton, a Democrat, sat in the White House, and the Senate majority was held by Republicans. But I submit we ought to be in the business of comparing apples with apples. We must look at Congresses similarly situated to this Congress. Point in fact: Looking to ''similarly situated'' Congresses is the very comparison cited by the majority leader.

Mr. President, you will recall the majority leader's commitment to judicial nominations—in his own words—to ''at least meet the standards of Congresses similarly situated as ours.''

Mr. President, by any reasonable measure, the proper comparison—and the one the majority leader has apparently endorsed—is not with a single year but with an entire Congress; specifically, with a Congress the final 2 years of a Presidency and a Senate majority of the opposing party. In fact, we are fortunate to be able to look to historical parallels during the last three Presidencies, not just one.

The landscape we face in the 110th Congress was similarly faced by President Clinton in 1999 and 2000, during the 106th Congress. President Clinton worked with the Republican-controlled Senate during the final 2 years of his Presidency to confirm 15 circuit court judges.

In 1991 and 1992, the 102d Congress, President George Herbert Walker Bush worked with a Democrat-controlled Senate during the final 2 years of his Presidency. President Bush and the Democrat-controlled Senate confirmed 20 circuit court judges in 1991 and 1992.

Finally, in 1987 and 1988, President Reagan finished out his Presidency opposite a Democrat-controlled majority in the Senate. President Reagan and the Democrat-controlled Senate worked together to confirm 17 circuit court judges.

Again, I submit we have to compare apples to apples. When we do that, we see somewhere between 15 and 20 circuit court judges were confirmed during each of those final two years of our last three Presidents. That is the standard that is relevant to this discussion.

The facts are what they are. This Congress has confirmed two circuit court nominees. We will shortly confirm our third, and that is a good thing. But the fact is, we are not yet back on pace to reach the output of the last 2 years of the Clinton Presidency—when a 55-member Republican majority in the Senate confirmed 15 circuit court nominees.

There is no satisfactory reason I have heard as to why no circuit court nominees were confirmed in April, or even reported out of committee. The reasons that have been offered—the vacancy rate is not that bad, the President needs to nominate more circuit court judges, and President Clinton was treated worse—are all irrelevant to the majority leader's representations on the Senate floor that this Senate will ''at least'' hit the historical average.

I urge my colleagues on the other side of the aisle to work with us, as we must, and work with the President to get back on track. That is our constitutional duty.

I thank the Chair and yield the floor.

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

Mr. LEAHY. Mr. President, while the Senator is still on the floor, I wish he had heard my statement. I can assure him that neither the chairman of the Judiciary Committee nor the majority leader intends to emulate what the Republicans did, with a pocket filibuster of more than 60 of President Clinton's nominees. I know of nobody on this side of the aisle who expects the Democrats to do a pocket filibuster of 60 of President Bush's nominees, as the Republicans did of President Clinton's.

It is interesting, when I hear this talk about historical averages, they weren't only—when you bring up the number of times there was a Democratic majority with a Republican President, a Republican President was treated far better than the Republicans treated a Democratic President. At no time were the Democrats ever pocket-filibustering 60 of the President's nominees.

There has been talk about President Bush withdrawing some of these nominees he had last year. I point out he had a Republican majority throughout the year, and they didn't pass through many. One was opposed by organizations that had never taken a position on a judge before—the Wildlife Federation—and all the Native American councils. Another one was not only involved in running the torture memos, but after swearing under oath and telling us information, he broke that oath by never giving or bringing the information. That was a person who would not have gotten a majority under a Republican-controlled committee. He would not have gotten out of committee because both Republicans and Democrats would have opposed him. So no big deal withdrawing people who were not going to go forward. In fact, in one instance, because somebody was nominated in the wrong State for a circuit court, that person was withdrawn. We moved very quickly to put the next nominee in that came from the right State.

I remember once that I got criticism from the White House, Karl Rove, and Vice President CHENEY for holding up because a person asked about a nominee. I must admit, to their credit, they withdrew his name after he was indicted and pled guilty to fraud. They are probably kind of happy I didn't let him go forward.

The Senator from Texas says we should compare. I wish he would stay with me one more moment. If the Senator from Texas doesn't want to listen and we have closed minds, I can't do anything about it.

I will say this: I have been chairman for 21 months during President Bush's Presidency. During that time, counting today's, we have confirmed 20 circuit judges and 98 district judges. One of the other chairmen was there for 2 years, there were 18 circuit judges. They were there longer than I have been with less judges; 85 district judges compared to my 98 in less time. Another chairman, 16 circuit judges compared to my 20; 35 district judges compared to the 98 we put through.

What we have done, of course, is the distinguished ranking member, as chairman, put together strenuous debate on two Supreme Court nominees. I think he knows full well the Democrats cooperated with him, whether they supported the nominee or not, to get them through.

Frankly, I am tired of misstatements of the record, and I will take time—I probably will have to have time on every single judge that comes up—to correct that. So people understand, we will not do as the Republicans did and pocket filibuster 60 or more of President Bush's nominees and, secondly, obviously we know when the Republican rule, the Strom Thurmond rule, kicks in next April, that changes all the rules.

I will point out, the proof is in the pudding. In less than 2 years, with the Democrats in control, we have moved faster on the President's nominees than during comparable times with Republicans.

I yield the floor.

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

Mr. SPECTER. Mr. President, the subject matter at hand is the confirmation of Ms. Debra Ann Livingston for the U.S. Court of Appeals for the Second Circuit, and I urge my colleagues to confirm her. She has an excellent, outstanding academic and professional record.

She was a superb graduate of Princeton, magna cum laude, 1980, Phi Beta Kappa; a graduate of the Harvard Law School in 1984, again, magna cum laude. She was editor on the Harvard Law Review, a law clerk to Judge Lumbard of the Court of Appeals for the Second Circuit. She practiced law with the prestigious firm of Paul, Weiss, Rifkind, Wharton and Garrison. She was an assistant U.S. attorney in the Southern District of New York. She was a commissioner for the New York City Civilian Complaint Review Board for some years, 1994 to 2003, and has been on the Columbia Law School faculty since 1994 as an associate professor, a professor in the year 2000, and

vice dean from 2005 to 2006. She has been rated unanimously well qualified by the American Bar Association. I believe she is an extraordinary prospect to go to the Court of Appeals for the Second Circuit.

There has been conversation, discussion, about the confirmation process. I commend the distinguished chairman for what he has done to date. We work together very closely. In the 109th Congress, he was ranking member. I liked it better when he was ranking member and I was chairman, but we have had bipartisan teamwork.

The record for confirmations of circuit judges in the last 2 years of a Presidential term, when the control of the Senate is in the opposite party, has been in the 15 to 17 range. I am hopeful, perhaps even optimistic, that we can get there this year.

A good bit remains to be done by the administration in submitting nominations. We have some 8 vacancies on the court of appeals which do not have nominations from the White House. Toward that end, there has been a leadership meeting with the White House counsel. We have tried to structure a plan which would enable us to go forward to confirm more circuit judges and to fill the vacancies of district court judges.

Many of these courts are in the category of judicial emergencies. As a practicing lawyer for many years, I can attest firsthand to the importance of having judges on the bench so that litigants can have a speedy disposition of their trials.

There is an adage: Justice delayed is justice denied. I think that is very true.

I ask unanimous consent that the full text of a prepared statement be printed in the CONGRESSIONAL RECORD following my extemporaneous remarks and that the specific text of my introduction be printed in the RECORD. Sometimes comments are made extemporaneous and then the written statement appears in the RECORD. If anybody reads the CONGRESSIONAL RECORD, they must wonder why there is so much repetition, so I would like to have an explanation included.

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

STATEMENT ON THE NOMINATION OF DEBRA LIVINGSTON TO THE U.S. COURT OF APPEALS FOR THE SECOND CIRCUIT AND CALLING FOR A FAIR CONFIRMATION PROCESS

(Senator Arlen Specter)

Mr. President, I seek recognition today as the ranking member on the judiciary committee to discuss the state of judicial nominations in the 110th Congress and the nominee pending before the Chamber today.

Today, the Senate will confirm Professor Debra Livingston to the U.S. Court of Appeals for the Second Circuit. She was first nominated over 300 days ago to a vacancy judged to be a ''judicial emergency'' by the nonpartisan Administrative Office of the Courts. She is a very fine choice for this important court and I am glad she will soon bring her much needed skills to the Second Circuit.

Before discussing judicial nominations more generally, I would like to say a few words about Professor Livingston's impressive background as an accomplished attorney, prosecutor, and legal scholar.

She graduated magna cum laude from both college and law school: Princeton University in 1980 and Harvard Law School in 1984. At Princeton, she was elected to Phi Beta Kappa. At Harvard, she was the Editor for the Harvard Law Review. Following law school, Professor Livingston worked as a law clerk to the Honorable J. Edward Lumbard of the U.S. Court of Appeals for the Second Circuit. In 1985, after her clerkship with Judge Lumbard, she joined the firm of Paul, Weiss, Rifkind, Wharton and Garrison as an associate, where she worked on a variety of State and Federal litigation.

The following year, Professor Livingston joined the Office of the U.S. Attorney for the Southern District of New York as an Assistant U.S. Attorney. Her work in the U.S. Attorney's Office focused on criminal trials and appeals. In 1990, she was elevated to serve as Deputy Chief of Appeals, an assignment that had her handling appeals before the Court to which she is now nominated.

After a successful career in the public sector, she briefly returned to Paul Weiss in 1991 before leaving the following year to become a law professor. She worked as an assistant professor at the University of Michigan Law School until 1994, when she joined the faculty of Columbia Law School as an associate professor. She became a full professor in 2000 and in 2004 became the Paul J. Kellner Professor of Law. Her principal areas of teaching at Columbia have been criminal investigations and evidence and she has published numerous articles in the area of criminal law and co-authored the casebook Comprehensive Criminal Procedure.

Professor Livingston has received a unanimous ''well qualified'' rating from the American Bar Association, the highest rating that organization gives. I'm sure she will enjoy a strong positive vote today.

Chairman LEAHY must be commended for working with Senators on both sides in order to get us off on the right foot during this Congress. Professor Livingston will be the 18th judge, and the third circuit court judge, confirmed this year. This is, admittedly, a much more auspicious beginning than that made by the Republican controlled Congress during President Clinton's final 2 years in office. That said, much work remains to be done.

The average for similarly situated Congresses in recent times is 17 circuit court confirmations. Despite its slow beginning, even the 106th Congress ultimately confirmed 15 men and women to the circuit courts and a total of 73 article III judges. And this was a historical low point. At the very least, the 110th Congress should meet or exceed this standard.

On several occasions, members of the majority have indicated that we can expect a dramatic slow down in confirmations in the latter part of next year. While I do not agree that historical record supports any kind of ''rule'' in this regard, we do know that the press of a Presidential election has a tendency of slowing down work in the Senate. If nothing else, we can expect the Congress will be in recess for a substantial portion of the second half of next year.

Therefore, in order to meet the standards set by similar Congresses in recent times, it will be necessary for us to confirm approximately one circuit court judge for every month we are in session.

There are five circuit court nominees currently pending before the Judiciary Committee. Three of these nominees are to vacancies designated as ''judicial emergencies'' by the Administrative Office of the Courts. Some of these nominations are being delayed by home state Senators who have not returned blue slips. It has generally been the practice of the Senate to not proceed without the consent of home state Senators. I have urged these Senators to return these blue slips and allow the process to go forward.

Although there is an understandable focus on the circuit courts, it should also be noted that there are 18 district court nominees pending in the Committee, eight of whom have been pending over 120 days, and 14 of whom are awaiting a hearing. These nominations also deserve prompt action.

I said before that Chairman LEAHY deserves to be commended for the progress made so far. The President also deserves to be commended for acknowledging the reality of a Democratic controlled Congress and withdrawing nominations that the other side has adamantly opposed. This was a very productive step that was rightly commended by Senators of both parties and the editorial pages of major newspapers including the Washington Post and the Los Angeles Times.

I have urged the President to build on this precedent by consulting with Senators of both parties as he moves to fill additional vacancies on the federal courts. As of today, eight circuit court and fifteen district court vacancies still do not have nominees. Three additional circuit court vacancies are imminent. In addition, 15 district court vacancies await nominees. The Senate cannot fulfill its duty to provide advice and consent until the President first sends us nominees. I am hopeful he will do so soon.

It will take both Republican and Democratic Senators, and the White House, working together to ensure an orderly confirmation process. Both sides have ample reason to complain about past grievances over the last two decades. But we cannot continue settling old scores. The partisan tit-for-tat over judges got so bad that it virtually paralyzed this body during the last Congress. This environment is deleterious to the Senate, to the nominees, and ultimately to litigants who wait for justice as judgeships go unfilled.

I believe the 110th Congress provides an opportunity to turn the page. Today's confirmation is further evidence that we are off to a good start. I look forward to working with Chairman LEAHY, and all my colleagues, in this effort.

IMMIGRATION

Mr. SPECTER. Mr. President, I now intend to take some of the time allocated for the judicial issue to talk very briefly about the immigration question which is front and center in the Congress today. It is second only to the concerns about the Iraq war and the current funding impasse which we have in the constitutional confrontation between the Congress and the President, and the sustaining of a veto and our efforts to try to work that out.

I believe there is a universal agreement that the immigration situation in the United States today is an unmitigated disaster. Strong language, but not strong enough for what is going on with immigration. We have a porous border and undocumented immigrants are coming into the United States. They pose a security risk. Terrorists are free to wander across our borders and come into our country and pose potentially grave threats to our national security.

We find a significant number of incidents of crime among undocumented immigrants. Crime does not have a sole source, but it is a problem. We definitely need to get a handle on immigration.

We worked very hard in the 109th Congress in the Senate. I give my colleagues in the House of Representatives credit for working very hard too. We produced a bill out of the Judiciary Committee. It was reported to the floor, and it passed the Senate. It was comprehensive reform, which is what was called for by the President, a bill which would deal with the 11 million undocumented immigrants, would provide for a Guest Worker Program, and would, as a preliminary to secure our borders, provide for employer sanctions if employers hired illegal immigrants.

The House of Representatives chose a different course to provide only for border security, and it was embarrassing, in my judgment, that we were unable to have a conference and pass an immigration bill last year with both Houses—the Senate and House of Representatives—controlled by the Republicans and President Bush, a Republican in the White House. But we find ourselves this year with the unmitigated disaster of immigration, worse now than ever.

There have been major efforts to try to find consensus legislation to present to the Senate for consideration. The first meeting was held on February 13 of this year, and the meetings have been held continuously right up to the present time, almost 3 laborious months. These were not abbreviated meetings. These meetings were held every Tuesday, Wednesday, and Thursday from 4 to 6 o'clock. They were attended by an average of 8 to 10 to 12 Senators. They were attended also by the Secretary of Commerce and the Secretary of Homeland Security, signifying the President's deep concern and deep interest in the issue.

They started off with Republicans meeting separately, and then we moved into bipartisan meetings. Last week, illustratively, we had 12 Senators meeting off the Senate floor for 2½ hours. It is pretty hard to keep 12 Senators in one room for 2½ hours, but we did.

We have come to what has been categorized as a ''grand bargain.'' That is a term one of our most active participants, Senator LINDSEY GRAHAM, gave to it because we had the overall structure of an immigration bill. We did not have all the aspects of it worked out, but we were proceeding to provide for real border security—border security which would increase the number of border guards from 12,000 to 18,000 and border security which would encompass a fence. We cannot have one across the entire border, but we can have a fence to secure our major metropolitan areas, illustratively San Diego and southern Arizona.

We have worked laboriously to craft identification so an employer would know whether an applicant for a job was legal or illegal. When an employer has the opportunity to be certain of the legal status of those he hires, then the stage is set for tough sanctions on employers so that we can reduce the magnet to bring people to the United States for jobs when they are not legally in the United States.

We have provided the mechanism for dealing with the 11 million undocumented immigrants. We have structured a program so it would not be fairly or accurately characterized as amnesty. The requirements of that program are that immigrants learn English, that the immigrants have roots in the United States, that they have held a job for a protracted period of time, that they pay a fine, and that there be a so-called touchback provision. It is still not decided as to the issue of back taxes, but that is a consideration which is on the table. We have provided for a Guest Worker Program which is what it says; that is, people come to the United States for the purpose of filling jobs and then will return to their native homes.

We provided that if there are people living in the United States legally, citizens or legal immigrants, they would have the first opportunity at these jobs.

We have held some 23 meetings over the course of the past 3 months. So I was a little surprised to see the statement by the majority leader at a press conference yesterday. Perhaps it was said partially in jest, but Senator REID pointed out that there had been notice for some 2 months that the immigration bill would be taken up in the last 2 weeks before the Memorial Day recess. Then he said:

> And anyone who thinks that 2 months is not enough time to get ready should get another occupation.

Maybe he said it in humor, but certainly I would fit into that category of looking for another occupation. The distinguished chairman of the committee has elected to have the matter go through the negotiating process which I have just described, so he doesn't have to seek another occupation. But there are many people on both sides of the aisle, under the Reid dictum, who now must seek another occupation.

I think it is a fair representation to say we have worked tenaciously. The problem we face now is that the so-called stakeholders all want more than can be divided from what is available. There are stakeholders who want more green cards and who want the advantages of family admission on a widespread basis, and if it were left up to me alone I would be in favor of the broadest reach of family unification. But if we are to find the realism of enough green cards to accommodate the undocumented immigrants who are going to come through the process at the end of the line, there has to be some give somewhere.

The critics of the immigration bill are descending on us from all sides before we even have an immigration bill. The Hill publication reports today of opposition from Members of the House of Representatives for Senate legislation when we don't even have legislation in existence. One Member of the House is quoted as saying:

> It is important that the Senate knows there will be strong bipartisan opposition to amnesty.

Well, we don't even have a bill that could be accused of having included amnesty, and the outline which we are considering and contemplating is certainly not amnesty by any fair interpretation.

The majority leader has said he intends to file under rule XIV today and go to the legislation on Monday. As I said yesterday, there is strong opposition to such a practice, at least on this side of the aisle. It is my hope that we will not face a contested motion to proceed. It is my hope we will not face the threat of a filibuster against the motion to proceed, which would doom immigration reform.

We have encapsulated our views in a letter, following the majority leader's news conference of today, where a number of us are asking that we rethink the schedule we have. If we bring last year's Senate-passed bill to the floor, it is going to have substantial opposition. That has already been announced on both sides of the aisle. Both Democrats and Republicans who supported it last year are opposed to it. If we start there, the floor action is likely to be a free-for-all.

I understand the problems of Senate scheduling, but I also understand the vicissitudes, problems, and pitfalls of proceeding where you don't have the structure of a bill which can be reasonably and realistically debated, with amendments, and then decided upon. We don't even have 2 weeks. We have to act on the supplemental before the Memorial Day recess if we are to provide the troops with the funding they need.

So it is my hope the current process can be allowed to continue. There has been a massive good-faith effort by Republicans and Democrats meeting for very protracted periods of time to come to agreement on a bill and to reduce it to written form. I will concede that there has been a lot of wheel spinning in the process which we have undertaken. Perhaps it was an error to abandon the traditional committee process. But that is where we are, and we need more time to flesh out the grand compromise, the grand bargain which we have structured so far.

If we are not able to legislate, we are not going to be able to provide for people who are interested in bringing 11 million undocumented immigrants out of the shadows, which is the main benefit that comes from those who want to proceed in the traditional American way to welcome the immigrants under a systemized plan. If we don't have comprehensive reform, we are not going to provide the border controls and the employer sanctions to stop illegal immigration.

It may be this is our last best chance. I would urge all sides to take a deep breath and to rethink positions on all sides and try to find a rational, bipartisan way to proceed.

Mr. President, how much time remains on my side?

The ACTING PRESIDENT pro tempore. The Senator has 58 minutes remaining.

Mr. SPECTER. Fifty-eight minutes remaining.

Mr. LEAHY. Mr. President, how much time do I have?

The ACTING PRESIDENT pro tempore. The Senator from Vermont has 49½ minutes.

Mr. LEAHY. Mr. President, I know the Senator from Pennsylvania has the floor, but the Senator from New York wants to speak briefly, and I have also been advised there are a number of Republicans who want to go to a burial service. So just so people can plan, as soon as the Senator from New York has finished his speech, which will be very brief, I am prepared to yield back our time to accommodate those who wish to go to the burial service.

Mr. SPECTER. Mr. President, do I understand the Senator from Vermont, the distinguished chairman, is proposing a grand bargain?

Mr. LEAHY. No, sir.

Mr. SPECTER. A grand bargain which would allocate 1 minute to Senator SCHUMER, and then all time yielded back?

Mr. LEAHY. I am told the Senator wishes 2 minutes.

Mr. SPECTER. Sounds excessive to me, but I will go along. When he finishes his speech, if we are prepared to yield back time, I will consider the proposal for the grand bargain.

The ACTING PRESIDENT pro tempore. The Senator from Vermont yields time.

Mr. LEAHY. Mr. President, I yield to the grand marshal.

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

Mr. SCHUMER. Mr. President, I thank my colleagues, and Raskolnikof as well, since he made the grand bargain once before. It didn't work out so well, so I would say to my colleague from Pennsylvania, I hope his grand bargain works out better than Raskolnikof's grand bargain.

Anyway, I rise to speak on our nominee, the confirmation of Debra Livingston. She is a legal superstar from my home State of New York, and she is nominated to the Second Circuit Court of Appeals.

Let me just say we in New York have a system in place for nominating Federal judges that works. The President and I work together to name highly qualified consensus candidates to the Federal bench. There is often rancor when it comes to judges from other parts of the country, but there has been very little when it comes to New York. It shows that when both sides wish to compromise, we can probably get there. That is because in New York we have an effective and bipartisan way to select qualified and, almost without exception, moderate candidates for the bench.

Ms. Livingston is squarely in that mold. Her career so far has spanned private practice, criminal prosecution, and academia, so she has a deep understanding of the law gained from many perspectives, from the courtroom to the classroom. Ms. Livingston is a graduate of Princeton University, received her J.D. from Harvard Law School—also my alma mater—where she served as an editor of the Harvard Law Review.

From 1986 to 1991, Ms. Livingston was an assistant U.S. attorney in the Southern District, where she prosecuted public corruption cases and served as deputy chief of appeals. Before and after her time as a prosecutor, Ms. Livingston was an associate at one of the very prestigious law firms in New York, Paul, Weiss, Rifkin, Wharton, and Garrison. She is currently the vice dean and Paul J. Kellner professor of law at Columbia University, where she focuses on criminal procedure, evidence, and national security.

I think it is great that we will have an appellate judge who has both a scholarly mind and practical courtroom experience. It is a perfect combination, in my view, for an appeals court judge. I hope my colleagues will join me in voting for her confirmation.

In keeping with the prelude to the grand bargain, I yield the floor.

Mr. LEAHY. Mr. President, I am prepared to yield back time.

Mr. SPECTER. Sealing the grand bargain, I, too, yield back the remainder of my time.

The ACTING PRESIDENT pro tempore. All time having been yielded, the question is, Will the Senate advise and consent to the nomination of Debra Ann Livingston, of New York, to be U.S. circuit judge for the Second Circuit? On this question the yeas and nays were previously ordered.

The clerk will call the roll.

The bill clerk called the roll.

Mr. DURBIN. I announce that the Senator from South Dakota (Mr. JOHNSON), the Senator from Michigan (Mr. LEVIN), and the Senator from West Virginia (Mr. ROCKEFELLER) are necessarily absent.

I further announce that, if present and voting, the Senator from Michigan (Mr. LEVIN) would vote ''yea.''

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from Idaho (Mr. CRAPO), the Senator from North Carolina (Mrs. DOLE), the Senator from Arizona (Mr. MCCAIN), the Senator from Kansas (Mr. ROBERTS), and the Senator from Louisiana (Mr. VITTER).

Further, if present and voting, the Senator from North Carolina (Mrs. DOLE) would have voted ''yea.''

The PRESIDING OFFICER (Mr. SANDERS). Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 91, nays 0, as follows:

[Rollcall Vote No. 158 Ex.]

YEAS—91

Akaka	Dorgan	Menendez
Alexander	Durbin	Mikulski
Allard	Ensign	Murkowski
Baucus	Enzi	Murray
Bayh	Feingold	Nelson (FL)
Bennett	Feinstein	Nelson (NE)
Biden	Graham	Obama
Bingaman	Grassley	Pryor
Bond	Gregg	Reed
Boxer	Hagel	Reid
Brown	Harkin	Salazar
Bunning	Hatch	Sanders
Burr	Hutchison	Schumer
Byrd	Inhofe	Sessions
Cantwell	Inouye	Shelby
Cardin	Isakson	Smith
Carper	Kennedy	Snowe
Casey	Kerry	Specter
Chambliss	Klobuchar	Stabenow
Clinton	Kohl	Stevens
Coburn	Kyl	Sununu
Cochran	Landrieu	Tester
Coleman	Lautenberg	Thomas
Collins	Leahy	Thune
Conrad	Lieberman	Voinovich
Corker	Lincoln	Warner
Cornyn	Lott	Webb
Craig	Lugar	Whitehouse
DeMint	Martinez	Wyden
Dodd	McCaskill	
Domenici	McConnell	

NOT VOTING—9

Brownback	Johnson	Roberts
Crapo	Levin	Rockefeller
Dole	McCain	Vitter

The nomination was confirmed.

The PRESIDING OFFICER. Under the previous order, the motion to reconsider is considered made and laid on the table.

The President will be immediately notified of the Senate's action.

LEGISLATIVE SESSION

The PRESIDING OFFICER. The Senate will return to legislative session.

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

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

CONGRESSIONAL BUDGET FOR THE UNITED STATES GOVERNMENT FOR FISCAL YEAR 2008

Mr. CONRAD. Mr. President, I ask unanimous consent that the Senate proceed to the House message to accompany S. Con. Res. 21, the budget resolution; provided further that the motion to disagree to the House amendment be agreed to, the motion to agree to the request of the House for a conference be agreed to, and the motion to authorize the Chair to appoint conferees be agreed to; provided further that prior to the appointment of conferees, the following motions to instruct conferees be in order and that no amendments be in order to the motions: No. 1, Senator KYL, relating to the estate tax; No. 2, Senator GREGG,

relating to the extension of certain tax cuts; No. 3, Senator CONRAD, alternative to Senator GREGG's extension of certain tax cuts; No. 4, Senator CORNYN, relating to the point of order on increasing tax rates; No. 5, Senator DEMINT, relating to the increase of taxes; and No. 6, Senator STABENOW, relating to energy.

I further ask consent that each motion be limited to 60 minutes equally divided in the usual form, that there be an additional 1 hour of general debate equally divided between the chairman and ranking member; further, that following the use or yielding back of time on each motion, the motion be set aside and that the votes occur in a stacked sequence this evening, Wednesday evening, beginning at 7:30 p.m., with no intervening action or debate.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. CONRAD. Mr. President, I thank the ranking member for his courtesy in working out this matter so we can complete action on the naming of conferees today. I think we have done this in a way that will give all Senators a right to express themselves on issues that are before the conference.

The PRESIDING OFFICER. The Senator from New Hampshire.

Mr. GREGG. Mr. President, I thank the chairman of the committee for his cooperation. Obviously, he wants to get to conference. He wants to complete the conference on the budget. Although we disagree with the budget that was passed here—and I am sure we will disagree with the final product that is produced, regrettably—I think it is important the process go forward. It is not our intention to be dilatory, to try to slow this process down. That certainly is something we could do, but we certainly have no intention of doing that. Rather, we just want to be able to have a fair opportunity to make the points which we think are important relative to the budget.

So I appreciate the chance to work with the Senator and the chairman's willingness to work with us to reach an accommodation that seems to be constructive, which is constructive, and which will hopefully move the process along.

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. CONRAD. Mr. President, I ask unanimous consent that when the items are considered for a vote, there be 2 minutes equally divided before each vote, and that after the first vote, the votes be limited in duration to 10 minutes.

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

The Presiding Officer laid before the Senate the following message from the House of Representatives:

Resolved, That the House insist upon its amendment to the resolution (S. Con. Res. 21) entitled ''Concurrent resolution setting forth the congressional budget for the United States Government for fiscal year 2008 and including the appropriate budgetary levels for fiscal years 2007 and 2009 through 2012'', and ask a conference with the Senate on the disagreeing votes of the two Houses thereon.

The PRESIDING OFFICER. The Senate disagrees to the House amendment, agrees to the conference requested by the House, and authorizes the Chair to appoint conferees.

The Senator from North Dakota.

Mr. CONRAD. Mr. President, it would now be in order for the Senator from Arizona to proceed with his motion. Again, I want to thank all Senators. These things are difficult. They are always last-minute considerations. But I think we have worked out a reasonable accommodation.

I thank the Presiding Officer and again thank the ranking member, and I believe now Senator KYL's motion is in order. I also thank Senator KYL for his patience as we worked through some of these procedural hurdles that cropped up at the last minute.

I say to Senator KYL, we thank you for your patience.

The PRESIDING OFFICER. The patient Senator from Arizona.

Mr. KYL. Thank you, Mr. President. I compliment both the chairman of the Budget Committee and the ranking member, who both have to have the patience of Job to work with all of their colleagues—all of them who have a little different idea of how things should proceed. I appreciate the comments.

MOTION TO INSTRUCT CONFEREES

Mr. President, I send a motion to instruct conferees to the desk and ask for its consideration.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Arizona [Mr. KYL] moves that the conferees on the part of the Senate on the disagreeing votes of the two Houses on the concurrent resolution S. Con. Res. 21 (the concurrent resolution on the budget for fiscal year 2008) be instructed to insist that the final conference report include the Senate position to provide for a reduction in revenues, sufficient to accommodate legislation to provide for permanent death tax relief, with a top marginal rate of no higher than 35%, a lower rate for smaller estates, and with a meaningful exemption that shields smaller estates from having to file estate tax returns, and to permanently extend other family tax relief, so that American families, including farmers and small business owners, can continue to enjoy higher after-tax levels of income, increasing standards of living, and a growing economy, as contained in the recommended levels and amounts of Title I of S. Con. Res. 21, as passed by the Senate.

Mr. KYL. Mr. President, let me take a few moments to discuss what this motion to instruct conferees embodies.

The subject is the death tax, the tax which requires millions of American families and small businesses to spend millions of dollars preparing against the possibility that they will have to pay very large amounts of money to the Federal Government upon the death of the person in the family who is responsible for that small business or who owns the property.

For a long time, there has been a bipartisan understanding that this death tax is not a good thing. The Gallup poll and other polls consistently show that at least 60 percent of the American people think it is an unfair tax, that we should not be taking money from people at the time of death. They have already paid income taxes on it, frequently capital gains and dividends taxes, and yet again they are taxed at the time of death on an amount of asset that remains.

But just as pernicious as that tax is the planning, and the expensive planning, that has to go into trying to prepare for the possibility that the tax will be imposed—if you have a very large estate, frankly, trying to avoid having to pay a large amount of taxes into that estate because that frequently means you have to sell the small business, the farm, in order to liquidate assets to pay the tax.

This is not a theoretical proposition. A good friend of mine from Phoenix, AZ, who was one of the great contributors to eleemosynary concerns in Phoenix—especially the Girls and Boys Clubs; he has one named after him—moved from New York City to Phoenix and with another person started a printing company. Years later, they had over 200 employees. They were a great printing company in Phoenix. When Jerry died, his family could not afford the death tax liability because most of the money in the business was in the equipment. In that business, you have to constantly get new equipment to stay up with your competitors. They took out a small amount each year in salaries, but the rest of it was tied up in the business. So he did not have the liquidity to pay the substantial death tax that would be required. The business was sold.

Interestingly enough, as to the argument that we have a death tax to prevent the concentration of wealth, it was sold to a big corporation. By the way, corporations do not pay death taxes. Also, this corporation has not contributed, as far as I know, a nickel to any of the great charity causes in Phoenix that Jerry contributed to every single year. It was really a shame when he died. More than the head of that household passed away at that time.

What we are trying to do is to permanently reform the death tax. Now, in the past we have tried to repeal it. What this motion to instruct conferees does is embodies concepts that have been agreed to by both Democrats and Republicans to reform the death tax so that most people do not have to worry about it, they just do not have to go to the lawyers and the accountants, the estate planners, they do not have to pay money for insurance to get around it because they know the way we have constructed it, they are not going to have to pay it. It is still there for the very large estates, but most people would be exempted from it.

Specifically, the motion to instruct conferees would call on Senate conferees to insist that the final budget

resolution provide for a reduction in revenues relative to the baseline sufficient to allow Congress to approve meaningful death tax relief, defined as follows: A top marginal rate of no higher than 35 percent with a lower rate for smaller estates, and an exemption level that is sufficient to shield smaller estates from having to file a death tax return. While the motion does not specify that amount, an exemption of $5 million per estate indexed for inflation is what is contemplated.

As I said, I think repeal of the death tax is the best option. I have been trying to find some agreement on reform since we haven't been able to get the votes for repeal. It is a nightmare for families now, and that is why I want to see if we can find a bipartisan way to do that this year. America's small business owners, farmers, and ranchers deserve this kind of certainty now.

I might say, this might be a bonanza for insurance companies, but I think they have plenty of other ways to offer products to us. There is plenty to insure against. They can still make a very comfortable living without putting us through the burden to invest without insurance to avoid paying much of the death tax. This concept, by the way, would be sufficient to accommodate the death tax reform similar to the proposal introduced by the senior Senator from Louisiana last year and which was endorsed by the junior Senator from Arkansas on his Web site.

I might say I have worked with other Members of the majority party now, and I thought last year we were very close to having an agreement that might have been achieved in a bipartisan way. In particular, the Landrieu bill provides for a $5 million exemption indexed for inflation, which is great, a family business carve-out, a top rate of 35 percent, as I mentioned, and it recaptures the benefit of the $5 million exemption for estates valued at over $100 million.

The motion to instruct does not specify any revenue offsets. We don't believe extensions of existing law should require that. Indeed, this would be a retreat from existing tax law. It would be less generous to taxpayers, and none of our provisions last year contemplated an offset. We don't offset extensions of existing mandatory spending, and we don't think this extension of tax relief should be offset either.

Some have said we should freeze the 2009 law in place. That provides for a $3.5 million exemption and a gift tax exemption that would be separate, a 45-percent rate, but a 45-percent rate means the Government takes almost half your property above the exempted amount, and that is frankly not acceptable to most small businesses or farmers. Forty-five percent is a rate most Americans deem to be unfair. So what we would suggest is a proposal that would be able to accommodate no higher than the 35-percent rate.

Now, a couple of final points here. We all know budget resolutions don't dictate policy of the Finance Committee. It would be my intention to work with the Senators whom I have mentioned here, in addition to Senator LINCOLN, who worked very hard on this the last couple of years, and others, to craft an estate tax reform proposal that would provide for this $5 million exempted amount indexed for inflation, a lower rate for the smallest estates, and it provides for a top marginal death tax that is no higher than 35 percent. I would love to see it lower than that. The Joint Tax Committee tells us anecdotally that a rate any higher than 35 percent would drive families into aggressive tax planning to avoid the tax. That is what we are trying to avoid here, the extra expense of planning. I might add that the last study done that I know of determined that the amount spent on trying to avoid the payment of the death tax each year is almost exactly the same amount that is collected by the U.S. Government. So in effect, we have a double tax here. People are paying maybe $30 billion, roughly, in these taxes to the Government, and spending another $30 billion to try to avoid paying the tax. That is $30 billion that could be going to much more productive activities than paying lawyers, accountants, and insurance folks.

I conclude by saying it is important to provide the lowest rate for the smallest estates, because we don't want to have to have them go to the trouble of trying to protect their assets against the payment of the tax. We could accommodate that through a high exempted amount and a very low rate. That means they simply wouldn't have the incentive to go pay the money to the accountants and the lawyers.

There is much more I could say about this. Right now I know the distinguished chairman of the committee might have something to say.

I am happy to reserve the balance of the time on this side, subject to the ranking member's concurrence with that.

Mr. CONRAD. Mr. President, I again thank the Senator from Arizona for his motion to instruct which he has offered. I ask our colleagues to resist this motion to instruct. I ask our colleagues to resist it on two grounds. No. 1, we have already provided for estate tax reform in the budget resolution that passed the Senate. I will do everything I can, as chairman of the Senate delegation and chairman of the conference, to uphold the Senate position, which is to reform the estate tax.

The motion of the Senator from Arizona is not paid for. It will blow a hole in the budget. We are trying very hard to balance this budget by 2012. Our budget and what will come back from conference does balance by 2012. But if we adopt the Senator's amendment, we will not balance.

Let me say what the budget resolution that passed the Senate did. All of us know, first, there is no death tax. It is good language, but it is not accurate. There is no death tax. Nobody pays a specific tax on death in America. We do have an estate tax on larger estates. In fact, in 2009, only two-tenths of 1 percent of estates will pay any tax. That means 99.8 percent of estates will pay zero. So this talk about a death tax—I am reminded of a colleague of ours who was in Missouri and was stopped by a baggage handler and he told him: You have to stop this death tax. He said: My family is so worried about that death tax. That gentlemen wasn't going to pay any death tax. Mr. President, 99.8 percent of Americans are going to pay no death tax, because there is no death tax. There is an estate tax on larger estates. Right now, it applies to estates of over $4 million a couple. Under $4 million, you pay nothing. It is going up. In 2009, the it will be $7 million a couple who will be exempt. So in 2007, the year we are in now, there is a $4 million exemption per family. You pay nothing if you have an estate of less than $4 million. In 2008, it is $4 million. In 2009, it goes to $7 million. In 2010, there is no estate tax. Then in 2011, it goes back to $2 million a couple. That makes no sense. It goes backward. It goes from a $7 million exemption in 2009 to no estate tax in 2010. In 2011, it goes back to $2 million per couple. We don't permit that in this budget resolution. We stay at the $7 million exemption per couple, index it for inflation, so as values go up, the estate tax exemption will go up. We have covered this out of the resources of the budget so we are able to balance the budget by 2012.

Now, the Senator from Arizona is absolutely well-intended. He has been very persistent on this. I give him high marks for that. He is absolutely dedicated to this cause. I give him high marks for that. The problem is he doesn't pay for it. Unfortunately, what he would do is throw the budget out of balance in 2012. I think that is a mistake.

In the budget resolution we have passed, beyond providing for a $7 million exemption indexed for inflation, $7 million for couples, anybody who has an estate of $7 million or less will pay zero, will pay no estate tax, which means, again, 99.8 percent of estates in our country will pay zero, nothing, not a penny. We have paid for it. In addition, we have provided a reserve fund that says if you want to go further, you can if you pay for it. The difference, the big difference we have is the Senator from Arizona doesn't want to pay for it. He wants to put it on the charge card. He wants to stack it on the debt. He wants to shove it off on our kids, let them pay. No. That shouldn't be the way we go. We have stacked up enough debt during this administration. This administration has added $3 trillion to the national debt, and if they have their way over the next 5 years, they are going to stack another $3 trillion on the debt.

Where are they getting the money from? They are taking it from Social Security. That is what they are doing. They have already taken over $1 trillion of Social Security money and used it to pay other bills, and they are getting ready to take another $1 trillion of Social Security money and use it to pay other bills. If you were in any other organization and you tried to take the retirement funds of your employees and use it to pay operating expenses, you would be on your way to a Federal institution, but it would not be the Congress of the United States, it would not be the White House—you would be headed to the big house, because that is the violation of Federal law. What the Senator from Arizona is doing by refusing to pay is he is going to take the money from Social Security. He is going to take Social Security money and use it to pay other bills. I think that is a mistake.

We have provided for fundamental estate tax reform in the budget. We ought to continue to support that, but we paid for it. Let's not go back to the bad old days of doing things around here and not paying for them.

I thank the Chair and yield the floor.

The PRESIDING OFFICER. The Senator from Arizona is recognized.

Mr. KYL. Mr. President, let me make three quick comments and then I would like the ranking member to respond as well.

It is true the budget already provides for some form of death tax relief. The problem is that form is a 45-percent rate—45 percent. Almost half of your estate would be paid to the Federal Government. I want a show of hands for everybody who believes that is fair.

Let the RECORD show one person in the Chamber raised his hand.

Second, the idea of the chart which the chairman pointed out showing the irrational treatment of the death tax, I totally agree with that. It is irrational, and there is a reason why it is irrational: because Democrats would not agree to cause the death tax relief to be permanent. All they would do is agree to the budget window, which at the time was a 10-year budget window. After that, it is done. That is why you have this crazy system where we have a declining rate. In the year 2010 it goes away, and in the year 2011 it comes right back again. We are all for making it rational by making it permanent. All in favor of that, raise your hands. The problem is, we can't get 60 Senators to vote for that, which is why we are stuck with this irrational system.

Finally, the most irrational thing of all, the idea—and this is an odd concept if you stop to think about it. The Government takes citizens' money in taxes, and then if we decide to let people keep more of their hard-earned money, they have to pay for that. We decide you should be able to keep more of your money because you know how to spend it better than Washington, but this odd concept on the other side of the aisle is: We can't let people keep more of their own money unless they ''pay for it.'' Pay who for it? Pay Washington for it. In effect, we are going to raise your taxes in some other way to make up for the relief in taxes we are providing here. That is what the American people are stuck with under the Democratic budget's idea of a good time, of what is fair. That is not good policy, and it is not fair. When we decide it is good policy to let the American people keep more of their hard-earned money, they shouldn't have to ''pay Washington an equivalent amount in some other kind of taxes.''

We wish to instruct conferees to pass a budget that can accommodate real relief from the death tax. I think the way we have laid this out is the best way to provide that kind of relief, as evidenced by the fact that several of our colleagues on the other side of the aisle have joined with us in proposing precisely that.

The PRESIDING OFFICER. The Senator from North Dakota is recognized.

Mr. CONRAD. Mr. President, let me correct one matter of history here. The Senator from Arizona says this bizarre circumstance with the estate tax ending in 2010 and then coming back in 2011 with lower exemption amounts is the fault of the Democrats. Whoa, whoa, whoa, whoa. That is a whopper. That is a double whopper. As the Senator knows, we weren't in charge when that tax policy was put in place. Our friends on the other side were in charge. They controlled the Senate, they controlled the House, they controlled the White House. They wrote this tax policy. Why? They did it because they wanted to put more tax cuts into the bill than they could afford, so they played an old Washington game and an old Washington trick.

They sunsetted their tax provision at the end of the period to reduce its cost. They are the ones who constructed this monstrosity. It is their responsibility, and we are fixing it. We are fixing it in this budget resolution and we are paying for it. That is a fundamental American value.

I thank the Chair.

The PRESIDING OFFICER. The Senator from Arizona is recognized.

Mr. KYL. Mr. President, I have one last comment regarding the ''whopper,'' as the Senator put it. It is absolutely true that Republicans were in charge when we passed the lower tax rates for Americans to help Americans out. We had 55 votes at the top amount; to make tax policy permanent, we needed 60. We could not get enough of our Democratic friends—not even six or seven of them—to join us to make the tax policy permanent; we could not get 60 votes so we could eliminate that irrational system.

So it wasn't a ''whopper'' that I told; it was the truth. Republicans were in charge. If we had about seven more votes, we could have had a rational tax system rather than the one we have today.

Mr. CONRAD. Mr. President, look, let's be absolutely direct with those who are watching and with our colleagues. Democrats did not construct this estate tax charade that takes us up to a $7 million exemption in 2009 and then goes to no estate tax in 2010 and comes back in 2011 with a $2 million exemption. That was a construction totally and completely of our friends on the other side of the aisle.

The Senator says we did not support the tax cuts that were disproportionately extended to the wealthiest among us and that plunged us into debt. He is absolutely right, we did not. Unfortunately, it has proven to be extraordinarily expensive to this country. We will pay for this for a very long time because the debt of the country exploded as a result of that policy.

Look, we supported tax reductions; we supported a more modest package of tax reductions—about half as much as they passed—and reserved the rest of the money to strengthening Social Security, getting us back into a situation where we weren't raiding the Social Security piggy bank around here to pay other bills. I am proud of that. We did the right thing.

I am happy to yield 5 minutes to the Senator from Florida.

Mr. GREGG. Mr. President, is this a morning business speech?

Mr. CONRAD. Does the Senator wish to talk on the estate tax matter?

Mr. NELSON of Florida. Both.

Mr. GREGG. I am going to be here for a while, so we can let the Senator from Florida go ahead.

Mr. CONRAD. I thank the Senator from New Hampshire for his courtesy.

The PRESIDING OFFICER. The Senator from Florida is recognized.

Mr. NELSON of Florida. Mr. President, we have a saying in the South: being between the devil and the deep blue sea. That somewhat illustrates the position this Senator is in regarding the estate tax, for this Senator has been a sponsor of the elimination of the estate tax for the last 7 years. The problem—as I have conferred with colleagues here, including the Senator from North Dakota, as well as colleagues on the other side—is finding the 60 votes out of 100 Senators in order to be able to pass some form of estate tax relief.

The fact is we have Senators who are all over the lot. There are some Senators who don't want to have any estate tax relief, and there are others on the opposite side of the spectrum who think there should be a total abolition of the estate tax and nothing short of that is any good.

Well, the truth is, if we had been able to eliminate the estate tax back in 2001, when the Federal Government had a healthy surplus, we would not be facing what we are today, which is trying to eliminate the estate tax, or part of it, when we have a drastic shortage of revenue, the consequences of which keep running up the red ink of the Federal Government and continued deficit

financing. Of course, you know who is buying our debt: the banks in China and Japan.

So earlier this year, when we crafted a compromise, with Senator BAUCUS in the lead, having a $3.5 million exemption and lowering the estate tax on that above $3.5 million per person, or a $7 million exemption for a couple, lowering that tax rate from 55 to 45, that seemed to be the compromise by which we could get the 60 votes.

I ask the chairman of the committee to confirm that what this Senator is saying is correct—having been able to get that 60 votes, then if we go off onto something else, what is going to happen is that those of us who want some relief for the family farms and the family businesses are not going to be able to make that stick. You cannot have it all. This Senator's attitude is to get something if you cannot have it all. I ask the chairman, the Senator from North Dakota, if the reasoning this Senator has laid out in the compromise that was crafted, to give some estate tax relief, if that is correct?

Mr. CONRAD. The Senator is entirely correct. As a valuable and valued member of the Senate Budget Committee, he knows, with great precision, how difficult it was to put this package together. He also knows if we go the route of Senator KYL, we will jeopardize the middle-class tax relief that is in this resolution. We provided full relief for the marriage penalty. We provided full relief for the 10-percent bracket. We provided full relief for the child tax credit.

If Senator KYL's amendment is adopted, one of two things will happen: It will reduce the funds available for the middle-class tax relief to transfer the money to the wealthiest among us or it will stick it on the debt. There are only two possibilities. I think it would be unfortunate to do either. I think it would be a mistake to reduce the middle-class tax relief in our budget resolution. I think it would be a mistake to reduce the child tax credit. I think it would be a mistake to reduce the cut in income taxes that are provided for by the 10-percent bracket. I think it would be a mistake to reduce the marriage penalty relief that is here in order to stack more benefits on the estate tax or to put it on the charge card and add it to the debt.

Mr. NELSON of Florida. Mr. President, I will conclude with this thought: Naturally, the vote that this Senator will cast on Senator KYL's motion to instruct conferees is a very uncomfortable one because, for this Senator, if I had my druthers, would I want the estate tax lowered? The answer to that is yes. I have been a sponsor of eliminating the estate tax. But the question is: What is the doable deal? What is the deal that will avoid this ridiculous outcome that is going to occur in 2010, when the estate tax will go away completely in one year and the next year come roaring back—back to its original position in the law back in 2000? That is the compromise we have crafted that is in the budget resolution.

I want anybody who is within earshot to understand the position of this Senator in supporting the budget resolution.

Mr. CONRAD. Mr. President, I ask unanimous consent that the following remarks of Mr. NELSON of Florida be moved so as to not interrupt the flow of debate.

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

The Senator from Florida is recognized.

(The remarks of Mr. NELSON of Florida are printed in today's RECORD under ''Morning Business.'')

The PRESIDING OFFICER. The Republican leader is recognized.

IMMIGRATION

Mr. MCCONNELL. Mr. President, based on comments we have heard from some of our colleagues on the other side over the last 2 days, there is some genuine concern that the bipartisan immigration compromise that Members and staff have been working on so diligently over the last 2 months might be brushed aside in favor of last year's unsuccessful bill. I strongly urge all of our colleagues to reconsider this approach, if, indeed, it is the one they plan to take.

This exercise needs to be a bipartisan one or it will not—it will not—succeed. That is an indisputable fact. Any effort to move legislation on this issue that isn't the result of an ongoing bipartisan discussion would be a clear signal from the Democrats they are not yet serious about immigration reform.

So I urge my colleagues on both sides of the aisle to stay at the table. Let this bipartisan working group finish its work so we can achieve immigration reform this year. Scrapping their work now will only end in frustration and defeat for both sides.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from New Hampshire.

Mr. GREGG. Mr. President, I thank the Republican leader for reminding us how we should be approaching the immigration issue, which is in a rational way.

I wish to respond to a few comments that have been said, and then I want to offer the motion to instruct, which I have reserved in the order that has been entered into, and then yield to the Senator from South Dakota for his comments, and then, obviously, the Senator from North Dakota, I presume, will want to respond, if that is acceptable to the Senator from North Dakota as the procedure.

To begin with, there has been a lot of references to what is going on in the area of tax policy and what the implications are, both relative to the death tax—and I did find it ironic that the Senator from North Dakota said it wasn't a death tax. Well, the only way you can pay it is if you are dead, or the only way your relatives can pay it. That is the only way this kicks in is to be hit by a truck. I think ''death tax'' is a fairly reasonable explanation of what it is.

Regarding the issue of the tax cuts which are obviously at the essence of much of the debate relative to this budget, this chart reflects the underlying question of what these tax cuts have accomplished. The Senator from North Dakota correctly reflects the fact that revenues fell off as the tax cuts originally were put in place. That is correct. Why did they fall off? They fell off because we were coming out of the largest bubble in the history of organized cultures, an economic bubble, where the Internet bubble of the nineties exploded on us, caused a significant contraction in the economy, which obviously caused a contraction in revenues. That was coupled with the attacks of 9/11, which disrupted the economy to a degree that our economy has never been disrupted, except for the Great Depression and probably World War II. So those two events created a huge retardation of revenue.

It was actually quite fortunate in the middle of that disruption, and a little bit prior to that, we had put in tax cuts during President Bush's first term which would stimulate the economy. As a result of those tax cuts going into place—yes, initially there was a revenue reduction, but that revenue reduction was in large part due to the bubble burst and the 9/11 contraction in the economy.

Since that time, we have seen those tax cuts energize an economic recovery which has truly been historic and extraordinary, and it has done a great deal for our country from the standpoint of creating jobs, which is the bottom line most important thing we can do but also generating revenue to the Federal Government.

We have now had 3 years of the largest growth in revenue in the history of our country, the largest growth, year after year. We are seeing revenues explode literally at the Federal level. They went up 11 percent in 2005 and 18 percent in 2006. They are projected to grow 18 percent in 2007. These growth rates are truly extraordinary. And revenues not only have grown year to year in an extraordinary way, but they have grown in a relationship to the overall historic burden of revenues paid by the American people to the Federal Government.

Historically, the American people have paid 18.2 percent of the gross national product to the Federal Government. That is represented by the blue line on the chart. We are actually well above that now so that we are seeing a rate of income to the Federal Government of about 18.6 percent of GDP. That means we are actually generating more revenues to the Federal Government than we have on average generated to the Federal Government.

We have a tax law in place which is doing a number of things. It is generating huge revenues, and it is generating revenues that exceed what has

been the historical norm for this Nation, and it is a tax law which is creating jobs and causing the economy to expand.

We have now had 22 straight quarters of economic expansion as a result of tax cuts, and we have had 44 consecutive months of expansion in jobs, 7.8 million jobs created. Those are massive expansions, people getting work.

In addition, two of the essential elements of this tax cut, the capital gains and dividends rates, have actually generated a huge explosion of economic activity in this country because they have unlocked, in the instance of the capital gains area, funds which have been locked up for years in relatively unproductive assets have now been sold, the revenue has been turned over, and people have reinvested, entrepreneurs and risk takers, in items that have created more return, which has had two effects: It has created more jobs and more revenue to the Federal Government.

The tax cuts have been good for this country from the standpoint of creating jobs, from the standpoint of economic growth, and from the standpoint of revenues to the Federal Government. Yes, one can look at this period from 2001 to 2003 and say revenues dropped. Yes, they did, but I would argue that was a function of the bursting of the internet bubble and 9/11 more than the tax cuts. But if you look at the most recent period, one cannot argue with the fact that we are seeing an explosion in revenues to the Federal Treasury, which has dramatically, in addition to the other two things, caused economic growth, jobs creation, the revenues, and has dramatically reduced the deficit of the Federal Government. In fact, we projected the deficit of the Federal Government. It was projected 3 years ago that it would be somewhere in the $350 billion range. It looks as if it is going to be under $200 billion, and significantly under $200 billion. And on a $3 trillion budget, you are basically talking a deficit number, which is really getting well under what has been the historic deficit of the Federal Government and, more importantly, had we not had the Katrina catastrophe where we had to spend over $150 billion approximately on that, and were we not at war, a war which we did not ask for when we were attacked on 9/11, we would be in surplus, significantly in surplus.

These tax cuts have been good for this economy. They have been good for the country. They have been good for employment. They have been good for economic growth. They certainly have been good for the Federal Treasury.

On the specific issue of the death tax, which is the motion which is pending, the motion by Senator KYL, I think the point Senator KYL makes is the one on which people should focus, which is what his proposal says is, we are going to put in place a compromise proposal on the death tax which was, ironically, a compromise proposed from the other side of the aisle. I think it was the senior Senator from Louisiana, Ms. LANDRIEU, who basically came up with this idea, which is we would have a higher rate for bigger estates, 35 percent, and for little estates, small businesses, farmers, ranchers, we would have a lower rate, and you would have an exemption of I believe about $5 million.

This proposal makes a lot of sense. There is no reason why it should be a taxable event to die. A taxable event should involve economic activity. It should be you went out, made some money, and as a result you got taxed.

But the way the death tax works is, the taxable event is that you, unfortunately, die. You end up getting hit by a truck, fall off your motorcycle, you get some serious disease, and as a result, your family gets hit with a tax bill. In many instances, if you are a small businessperson or you are running a farm or some other thing that involves one person and is the essence of the whole operation, that death is a huge, traumatic economic event, to say nothing, obviously, of the personal trauma that is involved. But that is a huge, traumatic event, if somebody runs a restaurant and he is the cook, the bottle washer, and maitre d', or runs a gas station, runs a small business or a farm; that person is usually the key person. When they die, that business is in extreme distress usually. That distress should not be multiplied and dramatically increased by having the tax man come in and say: I'm sorry, we are going to take half the value of your business, which is the way the law works now.

So this proposal, which was a compromise worked out among a variety of people around here, and actually the essence of it was put forth by the Senator from Louisiana, makes a lot of sense. So what Senator KYL has said is let's do it. Let's put it in the budget.

The argument is, that is going to increase the deficit. That is a fairly specious argument because it is the essence of that argument: If you let people keep their own money, you are making a mistake. The Federal Government should take the money and then they should have to pay money to get their money back. They should have to pay more in taxes. It makes no sense at all.

In addition, let's remember this proposal of the Democratic budget, as it left the Senate, had over a $700 billion tax increase in it. As it left the House, it has over a $900 billion tax increase in it. That is on the American people. What Senator KYL is suggesting is you take a very small percentage of that huge tax increase that is in this budget and use it to basically put in place proper procedures and policies relative to the death tax.

MOTION TO INSTRUCT CONFEREES

And that brings me to my motion to instruct. I ask unanimous consent that the pending motion be set aside and that my motion be ordered.

Mr. CONRAD. Reserving the right to object, one thing we have to do is make sure we have the time figured out because we have an hour on the Kyl matter. I will want some time to respond to the Senator's comments, and Senator THUNE wants to apparently talk about the Senator's motion. So we would be reserving our time on the Kyl motion while we go next to the Senator's motion?

Mr. GREGG. That is fine to me, or yield it back and use the time altogether.

Mr. CONRAD. It will all wash out. Let's do that.

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

The clerk will report the motion.

The legislative clerk read as follows:

The Senator from New Hampshire (Mr. GREGG) moves that the conferees on the part of the Senate on the disagreeing votes of the two Houses on the concurrent resolution S. Con. Res. 21 (the concurrent resolution on the budget for fiscal year 2008) be instructed to reject the House amendment that assumes a $916 billion tax increase, the largest tax increase in U.S. history, and insist that the final conference report include in the recommend levels and amounts in Title I of S. Con. Res. 21, reductions in revenues commensurate with extending the existing tax policy:

$1,000 child tax credit;

marriage penalty relief;

10% income tax bracket—so those earning $15,000 or less continue to benefit from low tax rate;

lower marginal rates for American families and small businesses (15%, 25%, 28%, 33%, and 35%);

Earned Income Tax Credit relief for military families;

adoption tax credit;

dependent care tax credit;

college tuition deduction;

deduction for student loan interest;

$2,000 Coverdell Ed. IRA;

15% rate on capital gains and dividends; and death tax repeal.

Mr. GREGG. Mr. President, I will speak quickly to this because I know the Senator from South Dakota has been courteous and is waiting, and I know he wants to speak to it. So I will highlight a little and then come back to the substance of it.

The essence of this motion is that the $916 billion tax increase, the largest tax increase in history, which is in the House budget, be rejected; that the $700-plus billion tax increase in the Senate budget—again, that would be the largest tax increase in history were the House not outbidding us—be rejected; and that instead we extend a series of tax breaks which are already in place and which are very beneficial to the American people, including the $1,000 child credit, the marriage penalty relief, the 10-percent income tax bracket, the lower marginal rates for American families and small businesses, the earned-income tax credit for military families, the adoption tax credit, the dependent care tax credit, the college tuition deduction, the deduction for student loan interest, a $2,000 Coverdell education IRA, the 15-percent rate on capital gains and dividends, and essentially the Kyl death

tax proposal. That is what this instruction would do.

I would ask that, instead of increasing taxes by the largest amount in history on the American people, we continue tax policies which have produced this huge economic expansion.

I yield to the Senator from South Dakota for his comments.

Mr. THUNE. Mr. President, I wish to thank the Senator from New Hampshire for yielding and also to just elaborate on some of the things he talked about with regard to his motion. I congratulate him on offering this motion to instruct because I believe it gets at the heart of this issue, which is whether we are going to continue this economic expansion, the job growth that has come with it, the explosion in Government revenues associated with the tax relief that was enacted in 2001 and 2003 or whether we are going to go down the opposite path and increase taxes by, as he said, the largest amount in American history.

Now, up until this last year, this budget we are talking about today, the largest tax increase in American history happened in 1993. That was $293 billion in increased taxes that was put through the Congress in that year. What has been proposed this year, through the budget process in the other body, in the House of Representatives, was a $916 billion tax increase, and, as the Senator from New Hampshire has noted, here in the Senate it is a $700 billion tax increase.

The only question really before us is whether this conference committee which is going to meet is going to adopt the House version, which is triple the largest tax increase in American history, or adopt the Senate version, which is double the largest tax increase in American history. Either way, whether we adopt the Senate-passed budget or the House-passed budget, we will be adopting the largest tax increase in American history—if we adopt the House version, three times the largest tax increase in history and, if we adopt the Senate version, more than two times the largest tax increase in American history.

So the gentleman from New Hampshire, the Senator who has proposed a motion that would instruct the conferees who will be meeting, the Senate conferees who will be meeting with the House conferees to work out and reconcile the differences between these two budget resolutions—one, as I said, is the House, which is triple the largest tax increase, or the Senate version, which is double—his motion would essentially instruct the Senate conferees to go into that conference with a position that doesn't accept the House tax increase or the Senate tax increase; rather, it allows these existing tax cuts to stay in law—in other words, not to allow them to expire.

I have a chart here which illustrates a little bit about what I am speaking of today, and this chart essentially shows what is included in that $900 billion tax increase. As I said earlier, the Senate, in its budget resolution, adopted a position that restored about $180 billion of the tax relief that would expire under the House-adopted budget resolution. As we can see, this is the amount taxes will go up if this budget is adopted. This is the amount the Senate said we will put back with the Senate budget resolution here, which our colleagues on the other side were able to get through the Senate. It puts back $180 billion.

I will give the House credit because the House voted yesterday on a motion to instruct their conferees to adopt the Senate language. That makes sense because I think they heard what a lot of people said when they went home and met with their constituents; that is, we don't want to see the largest tax increase in American history. We don't want another $900 billion in taxes imposed on the American economy at a time when the economy is growing and expanding and creating jobs.

Just look at the last few years here: 7½ million new jobs, unemployment at 4.5, 4.6 percent, the lowest historical average in the last three decades, 21 consecutive quarters of economic growth.

This is the counterintuitive part about this because, as was pointed out back in 2001 and 2003 when these tax cuts were being debated, if we reduce taxes the revenues are going to go down. Well, in fact, the opposite has happened. What has happened is what has happened throughout the course of history—under the Harding administration in the 1920s, the Kennedy administration in the 1960s, the Reagan administration in the 1980s, and now currently; that is, when you reduce marginal income tax rates, capital gains income rates, what happens? People take their realizations, they pay their taxes, they reinvest, and you get not less Government revenue but more Government revenue—in this case, dramatically more Government revenue.

Between 2004 and this year, we have seen Government revenues increase by $300 billion; that is, revenue coming into the Federal Treasury between 2004 and 2005 was up almost 15 percent, 14.7 percent; between 2005 and 2006, around 13 percent; and in this current fiscal year, the first 7 months of this current fiscal year, Government revenues are up 11.3 percent over last year. In fact, in the month of April, we have $70 billion more Government revenue than April a year ago.

These tax cuts are working not only to stimulate the economy and to create jobs but, as I said before, miraculously, to generate more Government revenue. We have $300 billion more Government revenue coming in as a result of reducing taxes, which again proves the historical fact that when you reduce marginal income tax rates and capital gains tax rates on the American people, they take their realizations, they pay taxes, they invest, they create more jobs, the economy continues to expand, and you get not less Government revenue but more Government revenue.

So I think what is happening here in the Senate is an attempt to provide a fig leaf of cover when it comes to this issue of taxes. The problem with that is this particular cover is a cover not for the taxpayers in this country, it is perhaps a cover for the tax raisers in this country. It is a small cover, however, because if you take $180 billion of tax relief that is restored under the budget resolution adopted here in the Senate, you can cover some of this stuff.

What they propose is that we are going to put back some of the marriage penalty that would come back into play under the House-passed version, and we are going to restore some of the 10-percent tax rate—the lowest tax rate, which applies to people making $15,000 and less—and we are going to provide some death tax relief. We will lower the top death tax rate from 55 percent to 45 percent. Well, what does that do? What do you do, then, about the alternative minimum tax, which is going to hit 20 million additional taxpayers if this budget is adopted? What about the child tax credit, which under the Democratic plan is slashed from $1,000 back to $500? What about lower tax rates throughout the rest of the rate schedule? Even if you fix, as they attempt to do with this small amount of tax relief, the 10-percent tax bracket, the lowest tax bracket, you still have tax increases in every other tax rate on the schedule. In fact, those who are paying 25 percent taxes are now going to go up to 28 percent. Those who were paying at the 28-percent rate currently will see their tax rate going up to 31 percent. Those paying at the 33-percent rate are going to see their tax rates go up to 36 percent. Those fortunate few paying at the 35-percent rate, the highest marginal tax rate today, are going to see their tax rates go up to 39.6 percent.

My point is, you can provide a fig leaf to say that we are doing something to allow for some of these tax cuts, this tax relief which has benefited our economy and the American people into the foreseeable future, but what about the rest of all these tax breaks that are going to expire, which means the largest tax increase in American history?

If we look at what the motion of the Senator from New Hampshire does, it says we want to extend these tax breaks to include the deduction for student loan interest. There are a lot of working families trying to put their kids through college who are taking advantage of that tax break.

How about the earned-income tax credit, which is helping a lot of our military families, many of them serving in Iraq and Afghanistan?

As I said before, the child tax credit is being slashed from $1,000 down to $500, essentially cutting in half the amount of credit a working family can get for their children when they file their tax returns. That was something

which was put in place to help working families.

I can go right down the list. Let's take senior citizens' dividend income—currently taxed at the capital gains rate of 15 percent, but under this proposal it goes up to 39 percent. We have a lot of seniors in this country who have invested and now have dividend income, capital gains income. Their capital gains income rates are going to go up as well. If they have capital gains income they are going to show, that will go up from 15 percent to 20 percent.

My point very simply is that if you pay taxes in America today, the prescription in this budget resolution which was adopted here by the Senate, put forward by our colleagues on the other side and the one adopted by the House, has one prescription: higher taxes. Every working American who pays taxes today is going to see their tax bill go up. In fact, in my State of South Dakota, which I will use as an example, the average tax increase on a working family in South Dakota would be $2,596 under this budget, with 2,840 jobs being lost and $262 million lost in our economy. That is in my State of South Dakota, and probably, if you take any other State, you would find the numbers to be dramatically higher in terms of job loss, in terms of the loss to the local economy and the impact it is going to have on taxpayers.

Again, just in an attempt to summarize what I am saying here, the Democrats have attempted, in the form of a fig leaf, to provide some amount of tax relief cover in this budget. What they do not tell us is that the amount of tax relief does nothing to cover the increase in taxes that will occur under this budget. They take about $180 billion off the table and say to the American people: Keep that. But they are still going to be raising taxes by over $700 billion, even if the Senate version of this budget resolution is adopted in conference. If the House version ends up being adopted, it will be over a $900 billion tax increase—the largest tax increase in American history by three times in the House, over two times in the Senate.

Again, if you take this amount, this fig leaf, and you say: We are going to put the 10-percent rate back, we are going to do something to provide some marriage penalty relief because we think married couples ought not to be penalized for being married, which I happen to agree with, and that was part of the tax relief passed in 2001 and 2003, and I think they realize that is a popular piece of tax relief, so they are going to attempt to restore some of these things—that still doesn't do anything about capital gains and dividends, which will hit seniors, or anything about R&D tax credits or the per-child tax credit or anything on the rate structure, the rates which go from 25 percent up to 28, from 28 to 31, from 33 to 36, and from 35 to 39.6. Every rate on the rate schedule is going up under this particular proposal.

So I am here today to support the motion of the Senator from New Hampshire to instruct the conferees as they go into conference between the House and the Senate to leave these tax cuts alone. Don't allow them to expire. Don't permit the largest tax increase in American history at a time when the economy is growing and expanding and creating jobs and we are seeing not less Government revenue but dramatically more Government revenue, to the tune of a $300 billion increase in Government revenues just in the past 3 years alone.

These tax cuts are working. They are having their desired effect. They are accomplishing what was intended in the first place when this Congress, in its wisdom, enacted these tax cuts in 2001 and 2003. It would be a shame to take a fig leaf and try to say to the American people, to the taxpayers of this country, that we are going to provide a little bit of cover for the tax raisers here in the Congress, but we aren't going to do anything to provide cover for the American taxpayer, those people who are going to pay higher rates in all these areas if this budget is passed and if the conference report comes back either with the Senate version or the House version, both of which increase taxes, it is just a question of by how much.

So I hope we can adopt and get the votes necessary to pass the motion of the Senator from New Hampshire to instruct our conferees to allow these tax cuts to stay in place. Don't allow them to expire, don't raise taxes, don't do something that would harm our economy and the jobs being created by passing the largest tax increase in American history.

With that, Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. CONRAD. Mr. President, this is the most amusing chart that has been presented in the Senate this year. The biggest block of the Senator's chart is about alternative minimum tax relief. He is talking about the Gregg amendment. Read the Gregg amendment. There is no mention of alternative minimum tax relief. That chart—I am glad he is taking it down because it is a complete concoction. It has no relevance to anything that is being suggested here.

The Senator says the biggest tax increase in history—not true. There is no tax increase in the proposal before us. Here are the facts.

The President, when he produced his budget, said, through his agency of Office of Management and Budget, an agency he completely controls, that his budget would produce $14.826 trillion of revenue over the next 5 years. That is what the President said his budget would do. What does the budget I have presented do, according to the Congressional Budget Office? It produces $14.827 trillion of revenue. That is $1 billion of difference on an almost $15 trillion base. And they are talking about the biggest tax increase ever? Come on.

It is a great speech. It is the same speech the Republicans have delivered for 20 years. They are so used to it, they keep giving it. It doesn't matter what the facts are or what the budget is before us. There is no big tax increase that is in this budget. In fact, there is no tax increase that is contained in this budget.

I don't know what the Republicans are going to say next year when there has been no tax increase, after all these speeches about the biggest tax increase in history. What are they going to say? I can hardly wait until next year. I am looking forward to that.

There is a little more revenue in our plan. As I say, the President said his budget would produce $14.826 trillion of revenue. The CBO says ours will produce $14.827 trillion. That is virtually no difference.

On a straight CBO score, apples-to-apples comparison, there is a 2-percent difference between our budget and the President's budget. Our friends on the other side come here with no budget—none. They have no budget for the country this year. Amazingly enough, they had no budget last year. They never agreed on a budget. They never agreed on a budget the year before. So they come here complaining about a budget that actually will exercise some discipline. It is pretty easy to be here with no budget, but of course they produced no budget when they controlled everything. They controlled the House of Representatives, they controlled the Senate, they controlled the White House—no budget. It is no wonder the debt is up, up, and away.

According to a CBO analysis of the two budgets, the President's budget and our budget, there is a 2-percent difference in revenue.

How could you get 2 percent more revenue with no tax increase? That is a good question. That is a fair question. I submit it is pretty easy to do. First, we have a tax gap in this country that the Internal Revenue Service says in 2001 was $345 billion. Today that tax gap, I believe, is in the range of $400 billion a year. That is the difference between what is owed and what is paid.

To collect taxes that are already owed is not a tax increase. That is simply insisting everybody pay what they legitimately owe. That is the first place we ought to look. Now $400 billion a year times 5 years of this budget is $2 trillion. We would only need 15 percent of that to get the revenue that is called for in this budget with no tax increase.

But it does not stop there, because the Permanent Subcommittee on Investigations says we are losing another $100 billion a year to offshore tax havens. I have showed this building before. This building is in the Cayman Islands. It is a five-story building. This building is the home to 12,748 companies that say they are doing business

out of this building. That is the most efficient building in the world. Are they really doing business out of this little building? Twelve thousand companies? No. They are engaged in an enormous tax dodge out of this building. We ought to shut that down. That is $100 billion a year, according to the Permanent Subcommittee on Investigations.

It does not stop there. Here is what the Permanent Subcommittee said:

> Experts have estimated that the total loss to the Treasury from offshore tax evasion alone approaches $100 billion per year, including $40 to $70 billion from individuals and another $30 billion from corporations engaged in offshore tax evasion.

If our friends on the other side of the aisle want to protect these abusive tax havens, let them do it. Let's see what the American people say about that. Let's see what the American people think about having wealthy individuals and wealthy corporations avoiding what they legitimately owe in this country by going off to these tax havens and claiming they are doing business out of this five-story building down in the Cayman Islands—12,700 companies—come on.

It doesn't end there. I say go onto the Internet. If you wonder whether this thing is real on tax havens, enter in ''offshore tax planning,'' Google it, and what do you get? You get 1,260,000 hits. What do you find out there? Here is my favorite:

> Live worldwide on a luxury yacht, tax free.

That is what our friends over here are defending.

> Live worldwide on a luxury yacht, tax free . . . Live tax free and worldwide on a luxury yacht . . . Moving offshore living tax free just got easier . . . Live tax free and worldwide on a luxury yacht—exciting stuff.

Indeed it is. It is costing us $100 billion a year, and it doesn't end there. We have these other scams that are going on.

I guess this is my favorite. This is a sewer system. It is a sewer system in Europe. What does that have to do with the budget? It turns out it has a lot to do with the budget. Why? Because we have now learned through an investigation that wealthy investors, corporations in the United States, have bought European sewer systems and are depreciating them on the books in the United States to reduce their tax obligation here and then leasing them back to the countries that paid for them in the first place.

This assertion that there is a big tax increase here is mumbo jumbo. There is no tax increase here.

Yes, we do have modestly more revenue, 2 percent more—although in the President's estimates we have virtually no change in revenue. But let's take the CBO numbers we use here in Congress. We have 2 percent more revenue. We say let's go after the tax gap, let's go after these tax havens, let's go after these abusive tax shelters.

My colleague from New Hampshire talked about the explosion of tax revenue, but he didn't tell the whole story. He didn't go back to when this story started, in 2000, because here is the whole story. The revenue of the United States back in 2000 was just over $2 trillion for the year. Then we had big tax cuts put in place in 2001 and revenue went down. Revenue went down the next year. Revenue went down the next year. Revenue stayed down in 2004—which is the fifth this year. Revenue stayed down in 2005.

Only in 2006, 6 years later, did we get back to the real revenue base we had all the way back in 2000. Is it any wonder the debt of the country exploded? Is it any wonder?

When they talk about the extraordinary economic performance of this administration, that is not the record I see. Let's compare it to the previous administration. The previous administration, in the first 75 months, produced 18.7 million new jobs. This administration in the same period of time: 5.2 million, less than one-third the job creation of the previous administration in the same period.

But it doesn't end there. If you compare this economic recovery to the nine recoveries since World War II, here is what you see. On job creation, the dotted red line is the average of all of the recoveries, the major recoveries since World War II. That is the dotted red line, job creation.

The black line is this recovery. It is lagging 7 million private sector jobs compared to the average recovery since World War II. That is job creation.

On business investment, again the dotted red line is the average of the nine largest recoveries since World War II. The black line is this recovery. In every one of these you see the same pattern: This recovery is tepid compared to every one of the other major recoveries since World War II.

Here on business investment we are 69 percent below the average recovery.

It doesn't end there. If you look at revenues, revenues lag by $127 billion, the average of the nine major recoveries since World War II.

If you look at real median household income—why is it our friends on the other side talk about how good things are, yet the significant majority of the American people say things aren't so good? The big reason is people at the top, all of us, we have done very well. The people at the top in this society—and, of course, there are many who are far above us who have done really well. But you know the majority of people in this country have not done really well. Their position has stagnated. For many of our countrymen, their position has dropped. And this shows it.

Here is real median household income from 2000—it was $47,599—to today, it is $46,326. That is why people, when they are asked, say they don't see this economy performing in the splendid fashion described by our friends on the other side.

It has been splendid for the top 1 percent in this country. The top 1 percent has seen an explosion of their income. They have also enjoyed a disproportionate share of the tax cuts granted by our friends on the other side. That is what has happened.

Ms. STABENOW. Will the Senator yield for a question?

Mr. CONRAD. I am happy to yield.

Ms. STABENOW. Mr. President, I first thank our esteemed budget chairman for raising what is so important in the context of this debate. I thank him for raising the chart that actually shows the majority of Americans are not seeing their incomes go up. They are seeing them go down.

As the chairman knows, we have lost 3 million manufacturing jobs in the last few years under this administration—3 million good-paying jobs with health care and with pensions. The reality is that, in listening to the debate with my colleagues on the other side, I don't know what they are describing. They certainly are not describing what is happening to the majority of Americans.

I did also want to thank the chairman for bringing up a building in the Cayman Islands he has shown us a number of times, a picture of a five-story building where there are over 12,000, I believe, different businesses that have filed that they are part of that building. In the Finance Committee, I used the chairman's chart and asked—I don't know if the chairman will remember this, but in the Finance Committee I actually asked the IRS and the Treasury if they had sent anybody down to look at that building. Has anybody walked through that building?

We have seen our distinguished leader on Budget point out a specific address, a specific address where we know there are not 12,748 different companies in that building. Yet, Mr. Chairman, to your knowledge, has anybody taken any legal action on this even now? You have raised this time and again.

This is the way we ought to be focusing on what happens on taxes. But the majority of people see their incomes going down, and what do we see? Ships, yachts where people can go offshore to live to avoid paying their taxes and avoid contributing to the war and the economy and schools and roads and everything that is important to us.

Then you have a building. I don't know if the chairman would want to speak to this. Has there, to the Senator's knowledge, been any action taken on this building and what is happening with over 12,748 companies?

Mr. CONRAD. Well, the Senator asked the witnesses before the committee. They seemed totally flummoxed by the question. It was pretty amazing. Here we have this building in the Cayman Islands, this five-story building. We have got 12,748 companies that claim it as their home.

Now, why did they do that? They do it because the Cayman Islands has no taxes. So guess what they do. They have subsidiaries in the United States

that report no earnings in the United States. Then they sell to a subsidiary in the Cayman islands at a reduced price, and they show their profits in the Cayman Islands.

When I was tax commissioner, I found this kind of tax abuse going on repeatedly. It was quite amazing. This was 20 years ago that companies were engaged in this kind of activity. It has absolutely exploded. That is what the Permanent Subcommittee on Investigations is telling us, that we are losing $100 billion a year to this kind of scam. Of course, the abusive tax shelters are on top of that. The tax gap, the difference between what is owed and what is paid, is on top of that.

But when you ask the relevant officials: Have you audited these companies to see if they really are doing business out of this building? Well, you got sort of—they were sort of in a trance. They had no answer.

I would say let's go after these people who are not paying what they owe legitimately and fairly in this country.

Ms. STABENOW. Well, I just want to thank the chairman again. I am very proud of this budget because it focuses on hard-working, middle-class families, people I represent in Michigan who will get the tax cuts in this budget. It addresses the kind of things we are talking about here. I am not interested in a tax policy that rewards this kind of tax evasion or folks moving offshore in their yacht to avoid being part of America and contributing to our way of life. I just want to thank the chairman.

Mr. CONRAD. Let me make one other point, if I can, that is with reference to the Gregg amendment. I will provide an alternative that insists on the tax relief that is provided in the budget resolution and asks our Senate conferees to fight for the tax relief that is provided. The tax relief that is in the budget resolution that passed the Senate provides for every dime required to extend the middle-class tax cuts, the 10-percent tax bracket, the child credit, the marriage penalty relief. Every dime of those middle-class tax cuts is provided for in the resolution that passed the Senate.

In addition, we provided for reform of the estate tax, to have $7 million a couple exempt from any estate tax. We index it for inflation. That will exempt 99.8 percent of the estates in America from paying any estate tax.

In addition, we provided for extension of the adoption tax credit, the dependent care tax credit, the treatment of combat pay for purposes of the earned-income tax credit. In addition, we insist that the Senate conferees support section 303 of the Senate resolution that provides for additional tax relief, including extensions of expiring provisions and refundable tax relief provided that such relief would not increase the deficit over the period of the total fiscal years 2007 to 2012.

In other words, we provide for all of the middle-class tax relief. We provide for estate tax reform. We provide for the appropriate treatment of combat pay. We provide for the dependent care tax credit, the adoption tax credit. And we say: You can have other tax relief if you pay for it. There is an interesting idea. Start paying for things around here.

The difference between my amendment and the amendment of the Senator from New Hampshire is he puts another $250 billion on the charge card, adds to the debt, sticks it on our kids. We say: No, let's start paying for things. That is the difference. We insist on the Senate position that any additional revenues meet these tax policies that are achieved by closing the tax gap, shutting down abusive tax shelters, addressing offshore tax havens, and without raising taxes. That is the resolution that passed this body. That is the resolution that is before the conference committee. It does not raise taxes by one thin dime.

MOTION TO INSTRUCT CONFEREES

Mr. President, I call up my motion.

The PRESIDING OFFICER. The clerk will report the motion.

The legislative clerk read as follows:

The Senator from North Dakota [Mr. CONRAD] moves that the managers on the part of the Senate at the conference on the disagreeing votes of the two houses on the House amendment to the concurrent resolution S. Con. Res. 21 (setting forth the congressional budget for the United States Government for fiscal year 2008 and including the appropriate budgetary levels for fiscal years 2007 and 2009 through 2012) be instructed to—

(A) insist on the Senate amendment with regard to to relief, which cuts taxes in the resolution by $180 billion to provide for extension of the child tax credit, marriage penalty relief, and ten-percent bracket; reform of the estate tax to protect small businesses and family farms; extension of the adoption tax credit, dependent care tax credit, treatment of combat pay for purposes of EITC; and other tax relief;

(B) insist on Section 303 of the Senate resolution that provides for tax relief, including extensions of expiring tax relief and refundable tax relief, provided that such legislation would not increase the deficit over the total of the period of fiscal years 2007–2012; and

(C) insist on the Senate position that any additional revenues to meet these tax policies are achieved by closing the tax gap, shutting down abusive tax shelters, addressing offshore tax havens, and without raising taxes.

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

The PRESIDING OFFICER. The Senator from New Hampshire is recognized.

Mr. GREGG. Mr. President, I have referred to this as the Wizard of Oz budget because there is someone behind the curtain somewhere on the other side of the aisle who is going to pay for all of those proposals they have put into the budget. No matter how you do the numbers, it works out that this budget has in it, as proposed by the Democratic Party, the largest tax increase in the history of the country.

It is interesting that the Senator from North Dakota continues to bring forward the chart that says his tax revenues are about the same as the administration's, failing to mention—well, he did mention it, he just did not highlight it—that he is using one accounting scheme to get to one number, and another one to get to the other.

But when you do compare apples to apples and oranges to oranges, you realize that under CBO scoring the difference is very significant between the two. Under OMB scoring the difference is significant between the two.

The fact is, there is a dramatic increase in taxes in both packages. In the Democratic package, if you score it consistently the difference is about $300 billion if you do not take into effect the AMT. So you have got a $300 billion tax increase in this bill.

Now, if it were not there, why would they have cut taxes to begin with as their first amendment? Their first amendment was a $180 billion revenue reduction. They were at the House number of $900 billion in new taxes. They cut that by $180 billion, which the Senator from South Dakota has ably laid out in his chart with his fig leaf, that $180 billion was their first amendment out of the box.

They obviously needed that amendment to reduce the tax burden which they had in their budget. Yet they claim they don't have a higher tax burden in their budget. Totally inconsistent on its face. Not defensible. If they were at the House number, which they were when they originally proposed the budget, they had a $900 billion tax increase. They are now at the new number, which is a $700 billion tax increase. If you take out the AMT number, they are at a $300 billion tax increase.

If it looks like a duck and walks like a duck, talks like a duck, it is a duck. This is a tax increase. This budget has a major tax increase. It is incredible to me that they can argue they do not have a tax increase and then oppose my motion, which basically says do not increase taxes. If they are not increasing taxes, they did not have to oppose my motion. They should be supporting it on its face. So the inconsistency is palpable. Palpable.

Then the idea that they are going to cover this $300 billion of new taxes, plus the AMT, of an extra $500 billion out of one building in the Grand Caymans—oh, yeah, that is where it is. That is where all of the money is. They are going to get $1 trillion dollars of new taxes out of this building.

Granted, we all accept the fact that there is obviously something wrong, when you have 12,000 companies filed there, and they are in a tax haven. But to represent that they can generate this type of revenue by closing tax loopholes on overseas tax activity is absurd on its face; or that they can collect this from unpaid taxes is absurd on its face.

The Commissioner of the IRS came to us, the Commissioner. He said the most they can collect over what they

are already collecting over the next 5 years is about $20 to $30 billion of unpaid obligated taxes. They have obviously put in place, they believe, a very robust effort to try to collect unpaid obligated taxes.

They think the incremental increase they can get, no matter how much more money it gave them, would be $20 to $30 billion, not $300 billion, not $700 billion. That was the testimony before the committee.

The Senator, the former chairman and present ranking member of the Finance Committee, came down and spoke at length about the effort to close overseas loopholes and what they have been able to recover. Yes, there may be more dollars there, but there is nothing in the realm of $300 billion, $700 billion, which is what this tax bill—what this tax bill, which is what you should call this budget; it is a tax bill—proposes.

No, this is a budget which has in it a huge tax increase. That is simply the way it is. If it did not, people would not be opposing my motion. They would be accepting it, taking it, because it is a reasonable motion. My motion continues tax cuts for the child credit, for the marriage penalty, 10 percent bracket, the lower marginal rates for Americans and small business, earned-income tax credit, relief for military families, adoption tax credit, dependent care tax credit, college tuition deduction, deductions for student loans, $2,000 Coverdell IRAs, 15 percent capital gains and dividend rate, and the Kyl-Landrieu death tax reform.

It is a very reasoned approach. It is what we should be doing. We should not be raising taxes on the American people. Now, the argument is that raising taxes won't have an effect on the economy; that passing this budget, if it were put in full operation, will not have an effect on the economy. Of course, it will. It will have a dramatic effect on the economy.

You cannot put $700 billion of new taxes on this economy and not expect this economy to adjust rather dramatically to a slowdown as a result. You cannot ask people who are entrepreneurs, who are taking risks, who are creating jobs, you cannot say to them: We are going to raise your capital gains rate up to 30 percent. We are going to raise your dividends rate, potentially, up to 39 percent. You cannot say that to them and not expect there to be a reaction in the marketplace.

People are going to stop taking risks. One thing we have learned in this economy is, if you give people a fair tax system, one where they are taxed at a rate that is reasonable, they will go out and take risks. That is the great genius of the American economy.

But, if you give them a tax rate which is unreasonable, they are going to take action to avoid that tax rate, which will mean ineffective use of dollars, inefficient use of capital. It will also mean a lot more people thinking of ways like going to the Cayman Islands to try to avoid taxes.

The practical effect of that is you slow the economy, you contract the economy. This proposal will do that. This proposal increases spending over the period of 5 years by, I think it is $147 billion.

They have to pay for that, so they raise taxes. It is the old approach. I don't know why it is denied by the other side of the aisle. Why don't they simply admit they like to spend money; they like to take tax dollars and spend money? That is what they are going to do, take people's taxes and spend on it their priorities. Our philosophy is, let people keep their money and they get to spend it on their priorities. They usually do a better job. It is more efficient. They create more jobs, and they create more economic activity. I thought the chart of the Senator from South Dakota was one of the better ones we have seen. It was a pretty good example of what the problem is. I call it the Wizard of Oz budget, where there is somebody behind a curtain who will pay for this. He calls it a fig leaf.

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

Mr. GREGG. I am many happy to yield.

Mr. THUNE. I understand my colleague from North Dakota. We both come from an area of the country where we have a lot of hard-working, plain-spoken people. They get this. If you have a bunch of tax cuts that are in law today and you allow them to expire, which is what this budget does, that constitutes a tax increase. People in my part of the country get that. If you are not trying to hide something, why would you put a fig leaf on it? The amendment offered to the budget by our colleagues on the other side said: We will take the more popular things, and we will allow those tax cuts to be extended, which to me and those I represent very simply implies that the ones you aren't extending are going to expire, which constitutes a tax increase. We can talk about whether that is $300 billion or whether, if you include the AMT, it is $700 billion. But the fact is, the House budget resolution allows the tax cuts to expire to the tune of $916 billion. The Senate said: We are going to put a fig leaf on that, and we are going to allow $180 billion in tax relief, which to me implies they understand exactly what they are doing. They are trying to hide this tax increase by putting a fig leaf on it.

To the people in my State and the people of New Hampshire and the people of North Dakota, this is a very simple thing. They get this. They understand what they tried to accomplish when this was debated in the Senate during the debate on the budget resolution was simply to put a fig leaf on this to offer up some tax cuts, some tax relief, and they wouldn't have had to do that, if they weren't raising taxes by $916 billion. It is pretty straightforward.

The motion of the Senator from New Hampshire is very straightforward. All it says is: Let's allow these tax cuts to be extended because they have created jobs, 7.5 million new jobs, 21 consecutive quarters of economic growth, 4.5-percent unemployment rate, and $300 billion in additional Government revenue over the past 3 years. Government revenues have not gone down. They have gone up. We have not less Government revenue; we have more as a result. Why would you fix something that is not broken? That is something people in the part of the country I represented understand clearly. If you are allowing tax cuts to expire, if you are not extending them, you are raising taxes.

Mr. GREGG. That was an excellent question. I appreciated that.

Mr. THUNE. I am not sure it was a question.

Mr. GREGG. Why would you fix it, if it is not broken?

Mr. CONRAD. Under the rules, it has to be a question. We will permit a very generous reading of the rules.

Mr. GREGG. I wished to comment on a couple other points. We went through this when we debated the budget and the Senator from North Dakota used his charts and I responded with an occasional chart, not quite as many. But I think it is important to make these points in a couple of areas.

He says there is a 2-percent difference now between his tax revenues and the President's tax revenues over the 5 years. When he brought the budget out, it was 3 percent; 3 percent came out to $½ trillion. He is at the 2 percent number now because he has factored in the fact that they reduced taxes or they at least allowed some of the tax extenders to go forward with the Baucus amendment which, basically, by accepting that amendment as a first amendment, the Senator from North Dakota made our argument for us, which was that they were raising taxes. That 2 percent would translate into about $300 billion today, a lot of money. If you decide you are going to create a chart and you use small enough incrementals, you can end up with those two lines being together, but $300 billion is big-time dollars. That is the American taxpayer having to pay a lot of money in order to cover new spending under the Democratic proposal.

In addition, this whole issue of economic expansion, the Senator from North Dakota pooh-poohs the last few years of economic expansion. He says it is not that good compared to the Clinton years. Nearly eight million jobs is a lot of jobs; 22 continuous quarters of economic growth is a lot of economic growth. Equally important, is the fact that we now have a revenue stream which exceeds the national average. Let's put that chart up there again because that is one of the most important charts we have. We have a revenue stream which exceeds the historic average of what we generate for revenues to the Federal Government. That is a critical issue and a critical point. We

have a tax law which has actually gotten lower rates in a lot of areas for working families, for families with children, for people who have dividend income and take capital gains and, thus, take risk. By the way, senior citizens who are on fixed incomes are by far the biggest receivers as a group of dividend income. When you start raising the rate on dividend taxes, you are hitting seniors who are on a fixed income.

The fact is, with these lower rates, which we put in place, we are generating revenues to the Federal Government today—we have been for the last 3 years—which dramatically exceed the amount of revenues which have historically been generated to the Federal Government. As a result, the deficit is coming down precipitously. We will be in balance. I said Humpty Dumpty could balance the budget by 2011. In fact, under CBO's scoring, the budget goes into a dramatic surplus by 2011. They don't take into account a couple of major issues, but it doesn't matter. The fact is, you can get to balance because revenues are coming in dramatically. Why are they coming in dramatically? Because we have a tax law that works today. What does the other side want to do with that? They want to throw it out. They want to go back to the old ways, when you just significantly increase the taxes on productive America, on working Americans, on Americans who unfortunately die and run small businesses and their families get wiped out. Why does the other side of the aisle want to do that? Why does the other side of the aisle want to say to a family who has a death, who runs a small restaurant or a small farm or small business: We are going to put you out of business; we are going to hit you with a 45-percent tax rate? That makes no sense at all. Why not agree to the Kyl motion which was a balanced approach, worked out by both sides of the aisle, a fair, bipartisan approach? Why not be willing to extend the capital gains and dividends rate which has generated so much revenue, so much economic activity?

In fact, capital gains has actually been a net winner for us. By reducing rates, we have now generated significantly more income from capital gains taxes than we did when the rates were higher. Why is that? It is called human nature. If you own an asset, a stock, a bond, a piece of real estate, and you know you are going to be taxed at 25 percent or maybe 30 percent, the odds of your selling that asset and realizing the gains are pretty slim. Maybe you are figuring, I will hold onto it. But when that tax rate went down to 15 percent, there was an immediate incentive for Americans to go out and sell those locked-up assets. What was the effect of that? The first effect was they got cash, which they then reinvested in something that was much more efficient. They put their capital into a better working situation so they created more economic activity. It is human nature that they would go out and invest to try to earn more money, which means they are basically investing in taking maybe more risk or creating more opportunity for jobs.

In addition, they generated a huge windfall to the Federal Government which we are continuing to receive because those assets which were not going to get sold under the higher tax rates were getting sold. We were getting the revenues. The proceeds were being reinvested, and that generated more jobs, more economic activity, which generated additional revenues. That is why we have seen this dramatic increase in Federal revenues. In fact, the vast majority of the Federal revenue that we have seen jump has been a function of capital gains revenue. That is where most of this new revenue comes from. Yet the other side doesn't want to extend the rates on capital gains, doesn't want to extend the rates on dividends. They want to kill that goose that has been laying significant revenues for the Federal Government and giving people an incentive to be productive and helping senior citizens who are on a fixed income meet the challenges of living on a fixed income.

It makes no sense to me that they would oppose this amendment, if their argument is they have no tax increases in their budget. The only way you can oppose my motion is if you do have tax increases in your budget because the only way my motion has any impact is to address tax increases. So if you didn't have any tax increases in your budget, you would have to support my motion. If that is their position, that there are no tax increases in their budget, then my motion should be a nonevent and should be supported. But it appears they do have tax increases in their budget because they are opposing my motion. In fact, if we go back to the chart that shows the actual calculation of tax increases, the 3 percent chart or the apples to apples, it is true. There is a $300 billion tax increase over and above the AMT, even after the Baucus language, and there is, in addition, an issue of where that $300 billion is going to come from. The concept that it is going to come out of a building in the Grand Caymens or from uncollected taxes is not valid in the face of the testimony before our committee and the history of our attempts to try to close those, to address those two issues.

No more than 10 percent of that tax increase could possibly be gained out of those two accounts. The rest will have to come out of working Americans who today are benefitting from the tax cuts which are in place and using those tax cuts to significantly expand this economy and, as a result, generate significantly more revenues to the Federal Treasury.

That is obviously why I put this motion forward. The Senator has put forward his alternative, which is responded to by the summary I have given of mine and speaks to the fact that his third paragraph, which is you are going to get the money from the tax gap and abusive tax shelters is not credible in the face of the facts and the situation. Although we certainly want to get as much as we can from those two accounts, we are not going to get anywhere near what is proposed, nowhere near the $300 billion. Of course, he held up my motion. He said: It doesn't address the AMT to the Senator from South Dakota. I would note that his also does not address the AMT. At least we are consistent on that point.

It is my understanding that Senator CORNYN is going to be back in 10 minutes to offer his motion.

I yield the floor.

The PRESIDING OFFICER (Mr. OBAMA). The Senator from North Dakota.

Mr. CONRAD. Mr. President, I have enjoyed this presentation so much. It is perhaps the most creative presentation I have heard on the Senate floor. The Senator wonders why we aren't going along with the policies of this administration. Here is why. Here is what our friends on the other side never want to talk about. You will never hear this word leave their lips—debt. They don't want to talk about debt because that is what they have been running up. They have run up the debt of the country by $3 trillion in 5 years. If their policy is followed, they will run it up another $3 trillion, doubling the debt and doing it all before the baby boomers retire, putting us in a deep hole.

Here is the record. The debt at the end of the first year of this administration stood at $5.8 trillion, the gross debt of the United States, $5.8 trillion.

At the end of this year, the gross debt of the United States is going to be up to $9 trillion because of the policies that our friends on the other side put in place. But you will never hear them talk about that part of the record. You will never hear them talk about where it is headed if we continue with their policies. They are going to add another $3 trillion. You will never hear my colleague say the motion he has presented will cost another $250 billion that is not paid for—not a dime of it. He will not tell you that our budget balances in 2012, but if we adopt his motion, it will not because he does not want to have to be under the constraints of making things add up.

I admit, it is tough. It is very hard to actually balance the budget. But our friends have not even had a budget for the last 2 years for the United States of America. Hard to believe, isn't it? They had been in charge of everything, and they didn't have a budget.

Mr. GREGG. Will the Senator yield for a clarification?

I will acknowledge there was no budget last year. But 2 years ago, there was a budget, if you recall, and it actually had a reconciliation instruction in it—a very significant instruction.

Mr. CONRAD. Yes, 3 of the last 5 years there has been no budget.

Mr. GREGG. I want the Senator to be correct. Was the third year the year you were in charge when we did not have a budget?

Mr. CONRAD. No. That was when we had split responsibility and could never reach agreement because we would not go along with running up the debt. I am proud that we would not go along with it. No, we insisted on having budgets that actually balance, which is a novel idea around here.

Let me show what the results have been of the fiscal policy that our friends on the other side have engaged in.

I have pictured on this chart all the other Presidents of the United States—all 42 of them—because it took all these Presidents pictured 224 years to run up $1 trillion of debt held by foreign countries, and this President has exceeded them. This President, alone, in 6 years, has exceeded all the foreign debt run up by the previous 42 Presidents over 224 years.

Now, this is a fiscal record they are proud of? I would not be proud of that. What is the result of this? The result of this is, we owe the Japanese over $600 billion. We now owe the Chinese over $400 billion. We owe the United Kingdom over $100 billion. We owe the oil-exporting countries over $100 billion. We owe the Caribbean banking centers over $60 billion. That is their record. Their record is plunging this country into deeper and deeper debt.

Now, let's go back to this question of taxes. I have heard over and over from the other side that somehow I have compared apples to oranges in the OMB scoring and the CBO scoring of the revenue of our proposals. Let me say this to you. I think it is relevant because the President said about his budget—nobody else's claim; it is his statement about his budget—that it would raise $14.826 trillion over the next 5 years. Do you know what my budget will raise over the 5 years? Virtually the identical amount: $14.827 trillion.

Now, my friends on the other side say there is going to be an economic calamity because I am raising virtually the identical amount the President called for. I do not think so. Was the President calling for an amount of revenue that would derail the economy? Was he? I do not think the other side would make that assertion. But the President's own statement about what his budget would raise said it was going to raise $14.826 trillion over the next 5 years. My budget raises $14.827 trillion.

The one thing I probably should do is reduce our revenue by $1 billion. Then we would have absolutely the same amount of revenue the President said his budget would raise. Now, the point the Senator makes that has validity is that if you use Congressional Budget Office scoring on both, there is a 2-percent difference. I have 2 percent more revenue. Why? Because I actually want to balance the budget. The President's budget does not balance. Mine does. We have 2 percent more revenue, although according to the President's estimates, we have almost identical revenue streams over the 5 years.

But under CBO scoring, we have 2 percent more revenue. I say, without hesitation, we can raise that amount of revenue with no tax increase. Why? Let's do the math. The tax gap—that is the difference between what is owed and what is paid—the tax gap is roughly $2 trillion over 5 years.

Then we have the tax havens. The Permanent Subcommittee on Investigations said we are losing $100 billion a year there. So $100 billion times the 5 years of this budget is another $500 billion. That is $2.5 trillion of revenue that is out there that could be recovered with no tax increase—none—$2.5 trillion. We would only need about 10 percent of that in my budget—about 10 percent—and you would have all the revenue you need to balance and to provide the middle-class tax relief and to provide the estate tax reform and to provide the increase to veterans health care that so desperately is needed and to provide the kind of investment in education that is critical to secure our future and to provide for law enforcement.

The President's budget cuts the COPS on the street program by over 90 percent. Why would we do that? Why would we cut the COPS Program 94 percent? We do not agree with that.

We also think that veterans, who have served so gallantly and at such great personal cost, deserve to have the promise kept to them about their health care. Our budget does that. You can do this without any tax increase—none.

The Senator from New Hampshire says: Well, the Revenue Commissioner says he can only recapture $20 billion of the $2 trillion that is out there. What is that percentage?

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

Mr. CONRAD. It is 1 percent. We have a Revenue Commissioner who acknowledges you have $2 trillion out there that is not being collected. He says he can collect 1 percent of it. I would say, we better get a new Revenue Commissioner. In fact, the Revenue Commissioner is leaving. Maybe we can get a Revenue Commissioner who can do better than 1 percent. We ought to get a Revenue Commissioner who can do better than 1 percent. But that is one factor.

The tax havens: $100 billion a year that is leaking out the backdoor because of these tax havens. That is not acceptable. We ought to close that door. If we closed that door, if we shut it halfway, we would provide for the revenue here.

There are no tax increases in the budget—none. In fact, there is dramatic tax relief. Of course, the reason we left AMT out of my motion is because AMT relief is in our budget. We do not have to put it in my motion. It is in our budget. We provide for 2 years of AMT relief. The President provided for only 1.

If you were going to apply the same argument to the President's budget that they are applying to my budget, here is what you would find. You would find the President has a big tax increase in his budget. If you apply their same logic to the President's budget, what you find is the President has a $500 billion tax increase in his budget. He has 1 year of AMT tax relief, which means he does not have any for the 4 following years. That would constitute a tax increase of $328 billion. By our friend's logic, that means the President has a $328 billion tax increase in the alternative minimum tax.

For the tax extenders, it is the same way. It provides for just 1 year. So you have $104 billion in the succeeding 4 years he does not provide for. Under their logic, that is a tax increase.

His health tax proposal is another $52 billion.

If you add it all up, the President has, according to their logic, a $500 billion tax increase. Do you know what the Secretary of the Treasury said when we confronted him with this? He said: That is the law. That is the law. I guess I could give that same flip answer here. I do not do that. Instead, I provide in the budget that we would provide for the middle-class tax relief, we would provide for estate tax reform, and we would pay for it so we can balance this budget and stop the explosion of debt in this country. That is exactly what we should do.

I thank the Chair and yield the floor.

The PRESIDING OFFICER. The Senator from New Hampshire.

Mr. GREGG. Mr. President, to respond quickly, we have been over this ground many times in our discussions, but I do think it is important to reinforce the differences.

First off, I ask unanimous consent to have printed in the RECORD the letter from Director Portman which reflects the fact that CBO scores the administration revenues significantly different than what is used as a chart by the Senator from North Dakota and reflects the fact there is a $300 billion increase in the proposal of the Senator from North Dakota.

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

EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF MANAGEMENT AND BUDGET,

Washington, DC, March 16, 2007.

Hon. JUDD GREGG,
U.S. Senate,
Washington, DC.

DEAR JUDD: You asked for a comparison of the revenue levels in the Senate-reported budget resolution and the President's Budget under the Administration's economic and technical assumptions.

The Senate-reported budget resolution uses the Congressional Budget Office's (CBO) economic and technical assumptions and makes a policy assumption that tax relief enacted in 2001 and 2003—the child credit, marriage penalty relief, the 10 percent bracket, and other tax relief—ends in 2010,

unless offset by other tax increases. In addition, the resolution does not reflect the impact of other revenue proposals contained in the President's Budget. With these assumptions, the Administration has developed an estimate of the revenue levels in the Senate-reported budget resolution.

The table below compares the revenue levels in the President's Budget to the Senate-reported budget resolution based on the Administration's and CBO's economic and technical assumptions. While the resolution also includes 22 ''reserve funds,'' a procedure that allows revenues to be increased above the levels set forth in the resolution for higher spending, the estimates below do not include higher revenue levels that could result from these reserve funds.

COMPARISON OF PRESIDENT'S BUDGET & SENATE-REPORTED RESOLUTION

[FY 2008–2012; revenue in billions]

	Administration	CBO
President's Budget	14,826	14,568
End 2001/2003 tax relief	+374	+392
Drop other Administration revenue proposals	+225	+43
Other changes	.....	+4
Subtotal	+599	+439
Senate-reported budget resolution	15,425	15,007

Please let me know if you have any additional questions.

Sincerely,

ROB PORTMAN.

Mr. GREGG. He holds up the wall of debt chart. Let me hold up the wall of taxes chart which the Senator from North Dakota is showing in his budget. He is basically proposing dramatic increases in the tax burden on the American people. He claims it is going to come from this Grand Cayman building and that the Commissioner of Revenue is not doing his job in collecting the funds that are owed and obligated.

But the fact is, the Commissioner has aggressively pursued this. We have given him more money. He will continue to aggressively pursue this. Yes, there is more that can be collected, but the numbers are nowhere near what the Senator from North Dakota has represented they might be.

Mr. CONRAD. Mr. President, will the Senator yield on this chart?

Mr. GREGG. Not right now.

Mr. CONRAD. The Senator does not want to be able to answer questions on this chart?

Mr. GREGG. I will answer questions in a second.

Mr. CONRAD. I would look forward to the opportunity to ask a question about that chart.

Mr. GREGG. Well, let me finish my statement on the points which I am making; which is that the Grand Cayman building is not going to pay for the tax increases in the Senator's budget.

Now, the Senator says he has a 2-percent increase in the tax burden. Two percent translates into about $300 billion. That has to come from somewhere. Do you know why that tax increase is in this budget? Because he spends the money. He spends that money.

In all the numbers that are being thrown out here on the floor, all the different ideas, all the different arguments about OMB and CBO and this and that and this and that and Grand Cayman buildings, the bottom line is that the budget of the Senator and the Democratic Party increases spending. In the discretionary accounts, the Democrats' budget is about $145 billion above the President's request over the 5 years. It increases mandatory spending by nearly $460 billion. It increases taxes, above the AMT issue, by about $300 billion over 5 years. It does not extend those tax cuts and rates which have generated the huge explosion in revenue for this Government; specifically, things such as the dividend and capital gains tax rates and the rates that assist working Americans. So it is not necessarily—if it did extend those rates, you would think there wouldn't be so much resistance to my motion. You can't make the argument that you are not raising taxes on Americans and then oppose my motion, which essentially says: Don't raise taxes on Americans. That is the bottom-line inconsistency of the Senator from North Dakota's arguments when you get beyond all the numbers.

I will yield to the Senator from Iowa, but the Senator from North Dakota had a question, and I look forward to his question. Remember, it has to be a question.

Mr. CONRAD. Mr. President, I am ready with a question. I say to the Senator, I look at this ''Building a Wall of Taxes'' and the numbers don't match the visual. The Senator's chart shows under our budget that taxes would be 18.6 percent of GDP in 2007 and 18.8 percent of GDP in 2012, and it shows visually this huge increase in taxes. By his own chart, there is almost no difference. I would ask the Senator, how can it be that the Senator shows a chart that makes it look as though there is some big increase in taxes, when by the Senator's own designations, it is 18.6 percent of GDP in 2007 and 18.8 percent in 2012?

Mr. GREGG. Well, because—

Mr. CONRAD. How does this chart accurately depict the change?

Mr. GREGG. Because the tax burden is going up in the billions on the side there, the x-axis. Does my colleague see that on the side? It is the amount of tax in billions—the actual taxes you are taking from people, the tax burden, that is the problem.

Look at it this way: If you are taking $2.5 billion from people today and then at the end of your budget you are taking $3.15 billion from people, that is all coming out of those tax numbers.

Mr. CONRAD. But as the Senator's chart demonstrates, if you adjust that for inflation, what your GDP figure does, there is virtually no difference in tax burden—virtually none. There is 18.6 percent in GDP tax burden in 2007 and 18.8 percent in 2012.

Mr. GREGG. Mr. President, if I may reclaim my time, the Senator has made my argument for me. My motion should not be opposed because my motion would accomplish what the Senator wishes, which is to maintain a reasoned tax law in this country and a tax burden on the American people which would be consistent. If you oppose my motion, you are saying you have to raise taxes. By definition you do.

Mr. CONRAD. Mr. President.

Mr. GREGG. I reclaim my time, Mr. President. As much as I would like to hear from the Senator from North Dakota, I have told the Senator from Iowa I would grant him some time.

Mr. CONRAD. But the Senator can't hand off the floor. This Senator enjoys the first right of recognition, Mr. President.

Mr. GREGG. But I have the floor.

Mr. CONRAD. If the Senator is yielding, at that point I will ask for recognition to respond. The Senator cannot hand off recognition, as the Senator knows, under the rules of the Senate.

Mr. GREGG. Well, I believe I control the time.

Mr. CONRAD. The Senator cannot hand off recognition from himself to another Senator. That violates the rules of the Senate.

The PRESIDING OFFICER. The Senator can only yield time. He cannot hand off the floor.

Mr. GREGG. Well, I believe the Senator from Iowa had a question.

The PRESIDING OFFICER. The Senator from New Hampshire controls the time.

Mr. GREGG. I believe the Senator from Iowa had a question. I heard him say he wanted me to yield for a question.

The PRESIDING OFFICER. The Senator may yield for a question.

Mr. GREGG. I am sure the Senator from North Dakota has some succinct comment he wants to make before we turn to the Senator from Iowa.

Mr. CONRAD. I thank the Senator.

The good thing is we debate strenuously, but we do it in good humor and we like and respect each other. I might say I even extend that to the Senator from Iowa, the esteemed ranking member of the Finance Committee, whom I have grown fond of.

Let me say this: We don't have any tax increase in our proposal. The reason we resist the motion of the Senator from New Hampshire is because we would have a budget that would not be in balance. Our budget is in balance by 2012; with his motion it would not be. He has $250 billion of tax expenditures not paid for. In our budget, we provide for the middle-class tax cuts, we provide for estate tax reform, and we say if you want to have additional tax cuts, you can have them, but you have to pay for them.

I thank the Senator for his courtesy.

Mr. GREGG. I yield to the Senator from Iowa such time as he may consume.

The PRESIDING OFFICER. The Senator from New Hampshire controls 1 minute on this motion.

Mr. GRASSLEY. I can only speak for 1 minute? Is that what you are saying? There is no point in my speaking if I only have 1 minute.

The PRESIDING OFFICER. The Senator also has 30 minutes of general time.

Mr. GREGG. I yield to the Senator from Iowa as much time as he may consume.

Mr. CONRAD. Mr. President, let me say to my colleague, I know Senator GREGG has another matter he has to attend to, and I have time remaining. We will try to be fair and work things out so people don't get shut out.

The PRESIDING OFFICER. The Senator from Iowa is recognized.

Mr. GRASSLEY. Mr. President, I speak in favor of the motion by the Senator from New Hampshire, the ranking member of the Budget Committee, to make sure we continue existing tax policy throughout the period of time of this budget resolution.

Considering the issue of taxes and this budget, press reports have indicated we may be in the ninth inning of this budget season. The President sent his budget to Capitol Hill 3 months ago. The Senate Budget Committee marked up a budget resolution. It passed the Senate. That resolution lays out the Democratic leadership's fiscal priorities for the next 5 years. As everyone knows, the American people spoke last November and as a result of that election, we have a new Democratic majority in both Houses of Congress. So for the first time in 12 years, Democrats have the privilege, but also the responsibility, for our budget.

The Senate spoke very clearly in support of some tax relief. The voice came in the form of Senator BAUCUS and his amendment. My friend, the chairman of the Finance Committee, secured $180 billion to prevent part of the big tax increase that will go into effect January 1, 2011. Although the Baucus amendment only provides 44 percent of the tax relief room that is actually needed to keep existing tax policy in place so there is no tax increase, it is, in fact, far superior, though, to the position on the same issue by the other body, because the House position is zero tax relief. That is right: zero tax relief. What does zero tax relief mean? It means a total tax increase of $936 billion over 5 years. That, in fact, is the largest tax increase in history, and it is a tax increase that will occur automatically without a vote of Congress. Of course, it is inconceivable that people say: Well, we aren't responsible for a tax increase. If you like the tax policy we have today and you don't do anything to stop it, and you automatically have a tax increase, then the people who let it automatically happen are responsible for increasing taxes—the biggest tax increase in the history of the country.

That tax increase means real dollars out of the wallets of real middle-income families. I have a chart here. The chart shows a wall of tax increases. The chart shows a family of four at $40,000 a year average income—the national average—will face a tax increase of $2,052. Now, for a lot of my rich liberal friends, that may not seem like a lot of money, but for a hard-working family of four in my State of Iowa, a $2,052 increase in taxes without even a vote of the Congress happening on January 1, 2011 is a lot of money, and it matters. That is why that wall of tax increases ought to be clear to everybody, and we ought to do everything we can to bring down that wall.

As a senior Republican member of the Budget Committee, I have not been consulted on the budget by our chairman, but I have made my views clear to our distinguished chairman. What I know about the budget I have learned from press reports. If those reports are true, I would encourage the chairman and the Senate leadership to stand strong for the Senate position, which is taking care of some of the tax increase that would have taken place—44 percent of it—not as good as it ought to be, but it is surely better than the other body.

Press reports indicate that the Democratic Budget Committee chairmen are working on a compromise that would condition the tax relief on a surplus. That is, the Baucus amendment would be subject to a trigger.

Now, what is a trigger? Well, I have another chart. This chart deals with perhaps the most famous trigger. The chart shows, as my colleagues can see, Trigger, the cowboy actor Roy Rogers' horse. You can see from the chart that Trigger is a pretty impressive looking horse. We would definitely like to have such a Trigger on my farm to help with the chores, and I am sure my grandkids would enjoy a ride with Trigger were he stabled on my farm. He is a beautiful horse.

As western movie buffs know, Trigger is no longer with us. Trigger is stuffed and on display at the Roy Rogers-Dale Evans Museum in Branson, MO. Although Trigger was an impressive looking horse, this trigger device the Democrat leadership is looking at is far from impressive. The trigger notion is something that has a long history with Democratic leadership. Back in 1996, as an example, the Clinton administration and the Democratic leadership argued for a trigger for the $500 per-child tax credit and other family tax relief issues. They took this position after President Clinton had vetoed the bill containing the family tax relief proposals. If the Clinton administration and the Democratic leadership had prevailed, millions of American families would have received the $500 per-child tax credit perhaps in 1999 through 2001—only in those years. If President Clinton and the Democratic leadership had won and the trigger were in place, then millions of families would have lost the child tax credit in the years 2002 until now. So why would anybody in Congress want to be so antifamily and put in a trigger policy, as the practice was at that time, that would deny families with children the child tax credit? It doesn't make sense, but that is the way triggers work.

The same dynamic occurred in 2001. With surpluses, the Democratic leadership opposed broad-based, bipartisan tax relief, including a doubling of the $500 per-child tax credit. One of the ideas the Democratic leadership flirted with at that time was the trigger. There were a few Republicans attracted to the idea as well, I have to confess.

The trigger was debated somewhat, but it was never found to be workable. It wasn't workable. So if it wasn't workable 6 years ago, why are they bringing it out of the attic now for consideration? Because a trigger is a complicated matter. It could be suggested that the mechanics of a broad-based tax trigger are a little bit like trigonometry. Trigonometry is a division of mathematics that deals with triangles. It is simple on its face, but you can see from this textbook, it can become pretty complicated pretty easily. Look at this. That is complicated.

Interweaving the complexities and uncertainties of triggered tax relief with the vast American economy could lead to a new term. That new term would be ''trigonomics.'' As much as folks complain about the uncertainty and complexity of the tax policy, I don't think the Democratic negotiators should want us to take us to the land of trigonomics.

To some degree, the current law sunset of 2001 and 2003 is a de facto trigger. If you look at those in opposition to permanence of the bipartisan tax relief, you will find that it is, with very few exceptions, the same folks who like triggers.

The tax system is a very complex, very pervasive force in our society.

It affects real Americans, all Americans, and it affects all economic activity. So creating conditional tax relief through a trigger mechanism would destabilize an already unwieldy tax system. How are families, how are businesses, how are investors supposed to plan their affairs with a trigger hanging over their current tax law rules that keeps taxes low? Think about that. What would we be doing to the hard-working American taxpayers?

Now, as an aside, those taxpayers, by the way, are sending record amounts of revenue to the Treasury Department. This very day, it is reported in the Wall Street Journal that more taxes came in in April than we have ever had in the history of our country—because the bipartisan tax relief plans of 2001 and 2003 are growing the economy. They are the goose that laid the golden egg, for 3 years in a row, bringing in massive amounts of revenue into our Federal Treasury, to a point where, by the end of this fiscal year, the annual deficit will be less than 1 percent of gross national product. When you are dealing with a $13 trillion economy, 1 percent up or down is about as good as you can do 12 months ahead in planning a budget and tax policies for this

great country of ours. So the American taxpayer is doing his or her part to reduce the deficit.

I ask unanimous consent to have printed in the RECORD a couple of articles from the BNA Daily Report for Executives, one dated May 3, 2007, another dated May 7, 2007.

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

[From the Daily Report for Executives, May 3, 2007]

ROBUST REVENUES LEAD TREASURY TO DROP THREE-YEAR, CONSIDER BUYING DEBT AGAIN

The U.S. Treasury Department said May 2 it was scrapping sales of the three-year note and that it has discussed with Wall Street representatives the issue of debt buybacks, a finance management tool last seen when the government was in surplus, as tax collections continue to come in at a healthy pace.

''As you all know, receipts have been strong and largely consistent with our forecasts. Based on this and other factors, we're announcing this morning our decision to discontinue the issuance of the three-year note,'' Anthony Ryan, Treasury assistant secretary for financial markets, said at the department's quarterly press briefing. The change will allow Treasury to ensure auctions of remaining issues are large enough to attract active bidding, help balance its portfolio of debt and ''manage the improving fiscal outlook,'' Ryan said.

The three-year note was revived in May 2003 after being discontinued previously when the government began posting surpluses from 1998 through 2001.

TALKS WITH ADVISORY PANEL

The discussion of debt buybacks was held with the Treasury's Borrowing Advisory Committee, a panel of private sector representatives from the securities industry. Treasury officials meet quarterly with the group to receive input on issues facing Treasury's debt managers, who aim to sell U.S. Treasuries to finance government borrowing at the lowest possible cost over time.

Treasury had asked the TBAC to address ''what practices Treasury and market participants should consider in a significantly improving fiscal or surplus environment, given volatility in budget forecasts and the Administration's long-term plan to balance the budget,'' according to minutes of the meeting released by Treasury.

Ryan called the talks ''an initial discussion'' that did not signal any decisions and intended merely to broach the issue.

''We asked this question in an attempt to continue to be proactive and forward-looking,'' he said. ''Given some of the volatility associated with our projections, it can't hurt to be prepared.''

RECENT SWINGS VOLATILE

Budget swings over the past decade have been particularly volatile. In 1997, a Democratic White House and a Republican Congress reached agreement on a 5-year plan to bring the budget into balance. Thanks in large part to surging capital gains revenues, balance was reached in 1998.

On the other hand, few analysts expected the sharp drop-off in revenues that followed the relatively light 2001 recession and the enactment of President Bush's tax cut plan. Revenues have surprised on the upside in recent years, and that trend is expected to continue this year, according to analysts watching the early data on April tax returns, which bring in a sizeable chunk of the government's overall annual revenue.

A Treasury chart prepared for the TBAC showed the possible range of borrowing outcomes if historic ranges of forecast error, either positive or negative, occurred. If the surprises kept to the positive side, the chart showed a potential need for a large paydown of debt as soon as 2010.

Asked if that implied a budget surplus in 2010, 2 years ahead of what Congress and the White House have targeted for a surplus, Matthew Abbott, deputy assistant secretary for federal finance, said, ''What the chart illustrates is that it's possible. Not that it's expected, but that's possible.''

'PREMATURE' TO DISCUSS EARLIER SURPLUSES

A Wall Street economist also warned that reaching surplus ahead of 2012 was unlikely, given uncertainty about what the government will do about the Alternative Minimum Tax as well as the temporary tax cuts that expire in 2010.

''I think it would be premature to think about buybacks because of expected budget surpluses,'' said Michael Moran, chief economist with Daiwa Securities. However, he said buybacks could be used instead as a tool to affect the maturity of outstanding debt, a factor that influences interest costs.

Moran also said the ''excellent inflows in April'' on the tax side were likely to lead him to revise downward his deficit forecast from $175 billion in 2007.

HOYER HOPEFUL ON BUDGET

Democrats in Congress are continuing to work on hammering out the framework for a budget resolution that can pass both chambers of Congress and reach balance in 2012. With an informal deadline of May 15 for completing action on the budget, the House has yet to name members of a conference committee for its side.

Majority Leader Steny Hoyer (D-Md.) remained optimistic, telling reporters May 2, ''We want to move ahead on the budget. The answer to your question is I'm hopeful we'll move the budget in the next couple of weeks, that we think that's important to do.''

A House Democratic aide said conferees may not be named in the April 30 week, as had been expected, but could instead be named early in the May 7 week. ''We can see our way to get there'' to a resolution, the aide told BNA.

[From the Daily Report for Executives, May 7, 2007]

CBO LOWERS PROJECTION OF 2007 DEFICIT TO $150–$200 BILLION RANGE ON TAX RECEIPTS

The Congressional Budget Office said May 4 that the projected 2007 federal budget deficit could come in much lower than had been expected at the beginning of the year, possibly as low as $150 billion, based on continued strength in tax revenues.

''Revenues have risen by about 11 percent compared with receipts in the same period of 2006, only slightly more than CBO anticipated when it prepared its most recent budget estimates in March; outlays have grown by only 3 percent,'' the CBO said in its projection issued ahead of the monthly financial statement to be released by the Treasury Department on May 10.

''CBO now expects that the government will end 2007 with a deficit of between $150 billion and $200 billion, assuming enactment of pending supplemental appropriations,'' the agency said.

In March, the agency had projected about a $214 billion deficit, assuming an Iraq war supplemental is passed by Congress. In 2006, the deficit totaled $248.2 billion.

FURTHER RECEIPT GROWTH SEEN

Healthy tax revenues were cited May 2 by Treasury Department officials in their decision to eliminate sales of the three-year note from their regular auctions of government debt (85 DER EE–2, 05/3/07). Treasury officials also disclosed they had discussed the issue of debt buybacks with an advisory committee made up of private sector experts. While debt buybacks were seen when the government last ran a surplus, Treasury officials said the discussions with the panel were only made in an effort to be forward-looking and proactive.

Prior to the CBO release, Rob Portman, director of the White House's Office of Management and Budget, said the budget was benefiting from a healthy economy.

''Solid economic growth is pushing Federal tax receipts up, and will drive the deficit down even faster as we move toward balance,'' he said in a statement.

''We've just seen a record-breaking April tax collection, and the outlook is for further growth in tax receipts. That's good news for our federal budget, and underscores the need for making the pro-growth tax relief permanent and having spending restraint in place.''

LAWMAKERS AIM FOR BALANCE IN 2012

On Capitol Hill, lawmakers are struggling to close the differences between House- and Senate-passed versions of the 2008 budget blueprint. Democrats have said they are aiming for a budget that can pass both chambers of Congress by May 15 and reach balance by 2012. However, negotiators have been stuck on several issues, including whether to allow room for extending some temporary tax cuts.

In its report, the CBO said it expected the government to post a $176 billion surplus in April, well above the $119 billion surplus seen in April 2006. Because of the mid-month deadline for individual tax payments, April is a crucial month for government revenues. If the April projection is correct, the year-to-date deficit will be about $83 billion, or about $101 billion less than in the first seven months of fiscal 2006, the said.

CBO said receipts from individual income taxes were up by about $105 billion, or 17.5 percent, through April compared with the same period in the previous year, while payroll taxes were up by $27 billion, or 5.5 percent in the same time frame.

''About 85 percent of the growth in total receipts through April occurred in receipts from individual income and payroll taxes, the two largest sources of revenues,'' the agency said. It noted, however, that some nonwithheld receipts appeared to be booked earlier by Treasury in 2007 than in 2006, shifting some receipts from May to April. If that factor is adjusted for, the agency said, overall receipts would have been up by closer to 9 percent, ''only slightly more'' than CBO had projected in March.

Mr. GRASSLEY. So then why trigger tax increases when the current law tax levels are bringing plenty of revenue into the Federal Treasury? Why would you want to mess with a policy that is bringing in what would now have to add up to $750 billion more than what we anticipated would be coming into the Federal Treasury from that tax policy when we adopted it? And in the process, we would be punishing the American taxpayers, who are already working hard and paying additional revenue at a lower level of taxation, as we passed it in 2001 and 2003.

The biggest problem I have with a trigger is that it creates yet another budget process bias for higher Federal spending. If Congress decides to spend more than planned, the trigger gives the American taxpayer the shaft. Spending taxpayers' money then trumps future promised tax relief if a

trigger is in place. The American taxpayer need look no further than the budget resolution conference report that we are debating now to see triggered future tax relief's futility.

After winning the November elections by claiming to enforce fiscal discipline, Democrats have done three things with the budget in conference: One, they have guaranteed new spending of at least $205 billion over the budget baseline. Secondly, with multiple reserve funds, they have set up many arenas of new spending and new taxes. Thirdly, for the first time in 6 years—I emphasize this—with a new majority in Congress, a tax hike on virtually every American taxpayer is built into the budget in future years. Now, did the American people know this was how the term ''fiscal discipline'' would be defined after the votes were counted last November? Higher taxes and higher spending. Did the American people vote for this definition of ''fiscal discipline'' after the last election? My guess is the answer is the American taxpayers didn't think ''fiscal discipline'' meant higher taxes and higher spending.

If fiscal discipline were the real goal of the new Democratic leadership, they would employ a trigger, then, on the new spending they baked into this budget cake. How about that. The new spending in this budget would only be triggered if the Federal budget were in surplus. Do I have any takers among the Democratic budget negotiators on that issue?

Before the Democratic leadership rolls out its budget, I challenge them to show a proposal with a single dollar of spending restraint dedicated to deficit reduction. It is a challenge I have issued for several years since bipartisan tax relief has been attacked on fiscal discipline grounds. My challenge has not been met. If you go back a decade, you will not find a proposal for spending restraint from the Democratic leadership. Check the record. You won't find anything on the spending side of the ledger.

The use of a trigger is more evidence of this obsession with higher taxes and more spending. Instead of accepting the Baucus amendment, which is supported by a strong bipartisan vote in both bodies because it passed here with only one dissenting vote and it had more than two-thirds on a motion to instruct in the House of Representatives—so instead of accepting the Baucus amendment, which is supported strongly by bipartisan votes in both Houses, the Democratic negotiators are taking a different path, ignoring the overwhelming votes of both the Senate and the House. They want to use a trigger as cover. The trigger will mean that future Democratic spending proposals will gut future tax relief, thereby guaranteeing a tax increase on virtually every American taxpayer, without even a vote of the people, because it is automatically going to happen.

I don't think it is too late. I suggest that if the Democratic budgeteers want to talk the talk of fiscal discipline, then walk the walk of fiscal discipline, apply the trigger to spending, but apply it to the $205 billion in brandnew spending. Don't build a wall of tax relief on the American people; build a wall of fiscal discipline against runaway Federal spending. In other words, we will tear down that wall of tax increases that are automatically going to happen.

I yield the floor.

The PRESIDING OFFICER (Ms. CANTWELL). The Senator from North Dakota is recognized.

Mr. CONRAD. Madam President, it is hard to debate the Senator from Iowa, the ranking member of the Finance Committee, because he has been a really good colleague and he has strong feelings about these issues. In many of these matters, I find myself in agreement with him.

I want to say to those who are listening that we don't believe there is any tax increase in our proposal. We believe there is significant fiscal discipline because we are balancing the budget by 2012. There has been no balancing of budgets around here during the 6 years of this administration. They have run up record deficits. They have run up record debt. It is not a matter of speculation, what they have done.

If you look at the record of this administration on debt, it is just as clear as it can be. This is what happened on their watch. They have been in control of everything—the House, the Senate, and the White House.

This is what has happened. They took the debt of the United States from $5.8 trillion at the end of the President's first year—we don't hold him responsible for the first year because he was operating under the previous administration's budget. But look at what he is responsible for. He has taken this gross debt of the United States from $5.8 trillion to $9 trillion, and if his fiscal policies are pursued the next 5 years, he will have taken the debt to $12 trillion. He will have more than doubled the debt of the United States.

One of the major consequences of that is, increasingly, this funding is from abroad. We are dependent upon the kindness of strangers. It took 42 Presidents 224 years to run up a trillion dollars of debt held by foreigners. This President, in just 6 years, has more than doubled that amount. Now, that is a fiscal train wreck, and this administration is responsible, along with his party in the House and the Senate. It is undeniable. They controlled things here, not the Democrats. It wasn't the Democrats who ran up this debt, it was the Republicans.

I don't like to be partisan, but the fact is, when I hear the other side claim that we are going to do something, they have already done it. It is not a matter of projection or of conjecture; it is a matter of fact. That is the debt they have run up. We are left to try to clean up the mess.

How do you clean up the mess? You spend less money. That is what we have tried to do here. We have controlled spending. We have a chart that shows this. Here is the spending under the budget resolution. We go from 20.5 percent of GDP in 2008 down to 18.8 percent of GDP in 2012. It is by having spending discipline that we get this budget moving in the right direction and we are able to balance the budget by 2012 and we are able to stop this dramatic expansion of the debt.

Here is what happens. Under our resolution, the debt, as a percentage of the GDP—which economists say is the best way to measure it—goes down each and every year after 2009. Finally, we get the debt going down instead of jumping up. That is what we should do. That is what is so defective about the Gregg motion. If it is adopted, the budget will not balance in 2012 because he has $250 billion of tax expenditures not paid for. So he is, once again, going to return to the bad old days of borrow and spend, borrow and spend, borrow and spend.

Look, the spending on their watch has gone up dramatically. The revenue, as I have shown before, stagnated. All their revenue charts on which they talk about revenue increasing have one big problem: They only show the revenue from 2004 to now. They don't show the revenue in the previous years. Here is a chart here. Spending has gone up, and revenue has been stagnant. Look at all their charts. They only show the revenue from 2004. They want you to forget about these years. Yes, if you look at 2004, revenue has gone up since then. But go back to 2000. Quite a different picture emerges when you give people the whole story, when you give them all the years, not just a few of the years. No, no, no, give them all the years, tell them all the story, give them all the facts. Then you see something quite different.

We are just getting back now to the real revenue level we had 6 years ago. Yet spending under our friends has gone up more than 40 percent. The result has been to explode the debt of the United States.

We are going in a different direction. We are going to balance this budget, but not if the motion of the Senator from New Hampshire is adopted. Then there will be no balance. Then we will be right back in the same old deficit-and-debt ditch that we have been in for 6 years.

Let's climb out of that ditch. Let's stop it. If we are going to have spending on this war, let's pay for it. If we are going to spend money, as we should, to take care of our Nation's veterans, let's pay for it. If we are going to have educational initiatives to assure that America remains the dominant force in the world, let's pay for it. If we are going to insure children in this country so that every child has health insurance, and we should, let's pay for it. That is what our budget is about. It is about the values of the American people.

I can tell my colleagues, in my State, they believe if you are going to spend money, you ought to cover the spending and not just put it on the charge card.

I thank the Chair and yield the floor. My colleague is here, and I understand there is some time left on the Republican side. I recommend we use that, and then if Senator CORNYN comes, if we are out of time, I will extend time to him so he has time to present his motion.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Madam President, I thank the Senator from North Dakota. I always appreciate his ability to find charts and give excellent explanations. We both have degrees from the George Washington University. My speech will not be nearly as adequate as his because I just have an undergraduate degree, whereas he has a graduate degree. I am sure that is where they covered the chartmaking. I usually don't use very many charts.

Mr. CONRAD. Madam President, I would be glad to lend some to the Senator.

Mr. ENZI. I don't think the ones the Senator has have quite the spin on them that I prefer. That is what we do during this process of the budget. I am always fascinated with the budget process anyway because the President sends us a bunch of suggestions on how we ought to spend money. I know the people back in Wyoming think that is the way it is all going to come out.

In Wyoming, we have just one process, and it is called the budget process. It is really the appropriations process. When the budget is done, balanced, and the money is spent, they think that is the point we are at right now instead of just suggestions from the President. We all know that Senators are going to change, and we are the ones in charge of making those changes. They really don't understand that the federal budget process puts in place some constraints on spending, some areas of spending, and some suggestions on spending that the Appropriations Committee may or may not pay any attention to anyway. But discipline can come from this part of the process.

I commend everybody on the Budget Committee for all the diligence they put in to covering a variety of issues. There is some good debate we have over issues, where we are, where things were, and where things are going.

I do note when the President came into office, he had no idea that September 11 was going to happen or that Katrina was going to happen. Both of those events put major dents in the budget.

There was also a little recession that was happening about the time he took office, which is one of the reasons there is a dip in revenue. We tried to figure out how to reverse that dip in revenue. If we have more revenue, unfortunately, we do more spending. It really is spending that is the problem.

It would be fascinating to see how the Democratic side of the aisle deals with that situation. I have noticed quite a change in rhetoric. People at one time were talking about No Child Left Behind, how it had a tin-cup budget. I hear those same people now saying: Yes, No Child Left Behind has to have a few targeted resources to make a difference. That is quite a bit different wording, and when you are in charge of spending it, it hits a little bit different than when you are on the criticism side of the spending. I am sure those in charge will appreciate that as time goes by.

I wish to address the way the Democrats balance the budget, though. This budget, as it is showing coming down to a more balanced position and even a little faster than what the President showed, does that because of the way the taxes are handled.

Without dealing with taxes at all, taxes for Americans will go up. There needs to be an extension of certain tax provisions or taxes will go up. When taxes go up, will that increase revenue? I don't think so. That is one of the problems with which we have to deal with.

We found that with the tax cuts, revenue has gone up, and it has gone up in excess of what was projected. That means the American people are excited over the ability to spend their own money for what they want to spend it on, and the spending of their money also results in additional taxes.

I have a chart that shows the projections—they are in blue—and the actual revenue. The growth in revenue is in red. In 2004, they projected a 2-percent increase and came in at 5.5 percent; 2005, 9.4 percent, came in at 14.6 percent; 2006, 7.3 percent, came in at 11.7 percent; 2007, the projection is 5.2 percent; to date it is 11.3 percent.

I am sure somebody else has mentioned this article earlier today, but the Wall Street Journal has an editorial titled ''April Revenue Shower.'' It says:

> Here's the ''surge'' you aren't reading about: the continuing flood of tax revenue into the Federal Treasury. Tax receipts for April were $70 billion above the same month in 2006, and April 24 marked the single biggest day of tax collections in U.S. history, at $48.7 billion, according to the latest Treasury report.

It goes on and explains that the IRS did process more returns than usual this year. Does that mean more people are paying taxes? Let me put up another chart. The tax cuts also resulted in additional jobs. The employment expanded for 44 consecutive months, generating 7.8 million jobs. People who have jobs pay taxes. More returns, more people working. I think that is one of our goals. We would like to have more people working, and we would like to have people who are working make more money. Then, of course, we would like them to keep a bigger percentage of the money they earn to spend the way they think it ought to be spent.

I mentioned there is more money coming in than what we had expected, than what was projected. That does affect the deficit. The more money we get beyond what was expected is a reduction in deficit, unless we spend it.

There are more ways of figuring out how to spend money around here than there are ways to save money. The President has had a number of proposals for different programs that have been evaluated. There is a process by which we do expect different programs and agencies to set their own goals, and then to report how they did on their own goals. The White House followed up on that process to see how they did on the report and how they did on their own goals and found 160 programs that were not doing what they said they would do. That is according to their own goals. He asked us to eliminate those programs.

We kind of did four. Now ''kind of did'' means they are still in existence, and they are flat lined. It doesn't mean we eliminated what was being spent on them because every program in the Federal Government has a constituency. Every time, even in the President's suggested budget, that he shows cutting an agency, all of us in this body have dozens of people come to our office to show how important that program is to them personally. A lot of them are the ones who work in that program. They have a job in that program, and if the program disappeared, they would have to get a job somewhere else. So they are definitely involved in the program and concerned with the program and feel the need to sell the program.

I have had experience with some of those programs in Wyoming. When the President says in his budget he is going to cut a program, they gang up on us at home, too. One of the programs dealt with children's preschool education. The moms and the kids showed up, and they visited with me a little bit. I asked them what they would be losing if the program went away. The answer was their daytime babysitting service.

The program in question was designed for an hour or two a week in conjunction with the parent, not with the parent absent from the program. It is a little bit of instruction on parenting education, as well as child education, preschool education. This is how the goals get a little skewed. They serve a purpose; it just doesn't happen to be the purpose we are funding. Probably the other purpose could be funded with a lot less money than with the requirements we have for education.

It is the spending that gets us into problems. The way we are going to balance the budget under the Democratic budget proposal, of course, is to allow decreases we have had in effect because they have a limited amount of time in place. It allows them to go up. For instance, there will be an increase in taxes of 33 percent for families earning less than $15,000. It cuts the child tax

credit in half to $500. It cuts the standard deduction by $1,700 for married couples. It puts that marriage penalty back into effect.

For a family of four with $50,000 in earnings, the tax bill for a family of four with $50,000 in earnings would see their taxes go up 132 percent to $3,675 in 2011 if the President's tax relief is not made permanent. Those taxes will reduce take-home pay by more than 6 percent.

Let's talk about a single parent with two children and about $30,000 in earnings. The tax bill for a single parent with two children and $30,000 in earnings will see their taxes go up by 67 percent in 2011 if the President's tax relief is not made permanent. Those taxes will reduce take-home pay by more than 4 percent.

So a family of four with $50,000 in earnings, their take-home pay is reduced by 6 percent. A single parent with two children with $30,000 in earnings, their take-home pay will be reduced by more than 4 percent.

What about the average family? What are they going to forego if the current tax policy is not extended? Some of the tax cuts have not been extended to 2011.

I am also distressed with the way the scoring happens on taxes versus spending because there is a lot of assumption built into the process. If they were corporate assumptions, the directors of the corporation would be in a lot of trouble.

For the average family under the current tax policy, if it is not extended, they might have to forego $3,347. That could be spent on groceries, or a year's worth of home heating oil and electricity. It would be $2,927 or almost 2 years of gasoline for two cars, $3,196, and that was before last week's increases, and, yes, we need to be concerned about that issue. There are some policies that we can do that will make a difference in that situation.

It will also mean more than a year's worth of health spending, which is $2,574 for the average family. Again, there needs to be some things done in the health area. Most of those cost money and those will add to the deficit too.

So it will be interesting to see how everyone gets around to balancing the budget in whatever number of years we talk about because all the spending happens in the next year. We are working on the 2008 spending right now, but we are spending the 2007 budget that went into effect last October and extends until this October. So there are some timelines that get into this that make it a little confusing.

It is wrong to balance the budget by increasing taxes on middle America, who is feeling the squeeze. The burden is placed onto low-income people. So I hope we will not balance the budget by eliminating the tax relief that has been put in place by the Republicans, which increased the number of jobs and brought the revenues back up.

I yield the floor, and 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. CONRAD. 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. CONRAD. Madam President, I am told Senator CORNYN is on his way, but I would ask my colleague, Senator STABENOW, if she would like to take a few minutes at this time to address her motion and then if we could have an agreement that when Senator CORNYN comes, we could interrupt your presentation at a reasonable point in time and then go to the Cornyn motion.

That is the order, but I think it would be unwise for us to waste any time here, given the fact we are very close to out of time. Would that be acceptable?

Ms. STABENOW. Yes.

Mr. CONRAD. Why don't we do that, and I thank Senator STABENOW very much for allowing us to proceed in that manner.

MOTION TO INSTRUCT CONFEREES

Ms. STABENOW. Madam President, I rise to offer a motion to instruct conferees to include section 307 of the Senate-passed budget resolution in the conference report.

The PRESIDING OFFICER. The clerk will report the motion.

The legislative clerk read as follows:

The Senator from Michigan [Ms. STABENOW] moves to instruct conferees on S. Con Res. 21, the concurrent resolution on the budget for fiscal year 2008, to insist on including in the conference report the Deficit-Neutral Reserve Fund for Energy Legislation in Section 307 of S. Con. Res. 21 as it passed the Senate which would provide for legislation to reduce our Nation's dependence on foreign sources of energy and lower gas prices.

Ms. STABENOW. Madam President, this provision will clear the way for the Senate to pass legislation that will ultimately lower gas prices. This is an issue right now of great concern, I know, to people throughout Michigan and throughout the country, as we see prices going up and up and up. This provision does that by putting into place a reserve fund that will reduce our Nation's dependence on foreign sources of energy and expand production and use of alternative fuels and alternative fuel vehicles.

This is a very important part of the budget resolution, and I wish to commend the chairman for putting aside a reserve fund so we can create revenues to do a number of things that will create energy independence and that will create competition, frankly, for the oil companies in this country so we can lower gas prices.

Today, in Michigan, the average price of a gallon of gas is $3.15, and it goes up as high as $3.24. I know it is going to go up and up. We are constantly hearing, of course, it is not arbitrary, that it is all based on competition. Yet I will bet you that right before Memorial Day, in Michigan—a great tourism State, and people want to have an opportunity to travel and see our Great Lakes—the prices are going to continue to go up even further. This summer, again because we are a great tourism State, prices are going to go up, and they will go down when it is not a peak season for driving. We all know that this is a serious issue, and, frankly, it affects every single family in their wallet or in their pocketbook.

A couple years ago, I offered, successfully, a provision in the Energy bill that required the Federal Trade Commission to do a study, an investigation into whether there was price gouging. They came back basically and said there wasn't and that they didn't have the authority because we didn't define what price gouging was. I am pleased to say that as a result of our presiding officer and her legislation, we can address what is happening as it relates to the definition of price gouging, which anyone in Michigan can tell you what it is, and also to be able to give the authority to the FTC to do something about it.

I see my colleague on the floor whom I basically jumped ahead of, so I think if he is ready, I will turn it over to him and will later proceed to talking about gas prices and how we are going to bring them down and how the budget resolution lends itself to that.

I yield to my colleague from Texas.

The PRESIDING OFFICER. The Senator from Texas is recognized.

MOTION TO INSTRUCT CONFEREES

Mr. CORNYN. Madam President, I send a motion to the desk and ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report the motion.

The legislative clerk read as follows:

The Senator from Texas [Mr. CORNYN] moves that the conferees on the part of the Senate on the disagreeing votes of the two Houses on the concurrent resolution S. Con. Res. 21 (the concurrent resolution on the budget for fiscal year 2008) be instructed to insist that the final conference report include the supermajority point of order against consideration of any bill, resolution, amendment, amendment between Houses, motion, or conference report that includes a Federal income tax rate increase, in order to protect the pocketbooks of working and middle-class families, college students, seniors, farmers, small business owners and entrepreneurs, and to promote the elimination of government waste, fraud, and abuse to reduce the deficit and offset new spending, as contained in section 210 of S. Con. Res. 21, as passed by the Senate.

Mr. CORNYN. Madam President, this motion to instruct conferees should sound familiar to my colleagues. This actually was an amendment to the budget resolution that received 63 affirmative votes in a bipartisan show of support for what I believe is a commonsense provision. This provision says that before we raise income taxes, we need to have a 60-vote point of order to do that.

This made so much sense that my colleague, the distinguished chairman of the Budget Committee, said he would be willing to accept the amendment by voice vote, although we went ahead and had a vote. I thought the vote was necessary to demonstrate, and did demonstrate, the broad bipartisan support for this amendment. This amendment, which was section 210 of the Senate-passed budget, creates a 60-vote budget point of order against any legislation that raises income taxes on taxpayers, including, of course, hard-working, middle-class families, college students, entrepreneurs, and you name it.

As I pointed out, this was a bipartisan vote, which is an insurance policy of sorts so that Congress can look and make sure any increase in income taxes is justified and that it would require a vote of 60 Senators to overcome the budget point of order before proceeding. The reason I thought this was a good idea in the first place is that before we look at raising taxes on hard-working American taxpayers, we ought to look at ways to eliminate Government waste, fraud, and abuse.

We all know the power to tax is the power to destroy, and, indeed, it is a powerful tool at Congress's disposal but one we ought to use advisedly. This point of order puts in place a safeguard that will protect the pocketbooks of all of us.

Some, though, are now advocating that we pull the rug out from under our economy and roll back the kind of tax relief and low taxes—progrowth policies—that have resulted in an incredible blossoming and blooming of the American economy. The last thing we should do would be to throw a wet blanket over this kind of economic growth that has created so much prosperity, so much opportunity, and so many new jobs over the last few years.

The progrowth tax relief has helped this economy grow and particularly in the small business sector, which has created a lot of jobs. We should view this as a matter of great pride because it is one of the good things that this Congress has done in the last 4 years. These progrowth tax policies are working. As a matter of fact, we have some charts that demonstrate 22 straight quarters of growth and almost 7.9 million new jobs. That is nothing to be sneezed at. There have been almost 7.9 million new jobs over the past 44 consecutive months, with 22 quarters of growth.

As we move forward, the last thing we should consider doing is reversing the policies that have helped bring about America's booming economy, which has reduced the deficit by producing more money for the Federal Treasury and also put more money in the pockets of hard-working American taxpayers.

As a matter of fact, I think we ought to take a further step and make these tax relief provisions, which are set to expire unless we fail to act, I think we ought to make them permanent. If we don't, we will not only jeopardize future economic growth but also the financial well-being of millions of Americans, all of whom will face higher tax bills unless we act.

Not making this tax relief permanent will result in a tax increase for every American taxpayer. For example, a family of four, with two children, making $50,000 in annual income would see an increase of $2,092 in their tax bill or a 132-percent increase.

This point of order will not hinder our efforts to close down illegal tax shelters or close perceived loopholes in the IRS Code, a concern that I know the chairman expressed. In the colloquy we had when the amendment was passed, I think I was able to satisfy him that we would still be able to do what we both agree needs to be done but not see a tax increase on American taxpayers virtually assured.

The point of order covers the tax tables contained in the 1040 form the IRS sends to taxpayers every year. It will not hinder efforts to overhaul the IRS Code. I support efforts to overhaul the IRS Code by making it fairer, flatter, and simpler. Any tax simplification and reform efforts will need bipartisan support in the Senate, so I ask my colleagues to support my motion to instruct the conferees to include the point of order against raising income taxes on hard-working taxpayers through the budget conference committee.

I might add, in closing, I have had conversations with the distinguished chairman of the Budget Committee. I know he has concerns as a result of conversations he has had with the Parliamentarian. There has been some suggestion that to include this provision in the conference report would render the conference report unprivileged. I believe there was demonstration of broad bipartisan support for this provision, which enjoyed a 63-to-35 vote on the Senate floor. While I certainly understand the budget chairman's desire to maintain a special privileged status for the budget resolution, I think in this case it would be warranted.

Including this provision will act as an insurance policy against undesirable and unnecessary tax increases, especially until such time as we do our dead level best to reduce the waste, fraud, and abuse that, unfortunately, is present in Government today and to try to save money there before we begin raising taxes. It is particularly important because we have this silent tax increase that is, unfortunately, included in this framework that will now occur if we do nothing. This will be the only tax increase I am aware of that will actually happen if we fail to act, but that is what, unfortunately, we are on course to do with this budget resolution.

So I would respectfully ask my colleagues to support the motion to instruct conferees on this matter.

The PRESIDING OFFICER. The Senator from North Dakota is recognized.

Mr. CONRAD. Madam President, let me first thank my colleague for his service on the Budget Committee. He has been a valuable member there. We do not always agree, but he has been a very constructive member of the Budget Committee. He comes with a point of view and he does his homework. All of us appreciate that, I and the other members of the committee. I thank the Senator from Texas.

Let me say it would be fine with me that we adopt this motion because there is no contemplation in this budget resolution of a tax rate increase. There just is not. I want to make that clear.

We do have a problem. I want to be very direct with colleagues. This motion will not survive the conference committee. It will not. It has nothing to do with its merits. It has to do with the procedural ramifications of bringing this back from the conference. We have been informed by the Parliamentarian, if the conference agreement reflects this motion, the budget resolution would be in danger of losing its privileged status on the floor. That would be a very serious matter for all of us. That would be a serious matter for this institution.

We have a hard enough time getting a budget. If it were to lose its privileged status on the floor, I suggest to my colleague, we would never reach conclusion on a budget. That is in none of our interests. It is not in the interests of the country, it is not in the interests of the Senate, it is not in the interests of the House.

I regret that is the reality we confront, but it is. I don't want anybody to be under any misapprehension about that. It is fine with me if we adopt that as an instruction to the conferees because it reflects the will of the Senate. We voted very clearly: 63 votes, as the Senator has indicated.

I say to my colleagues, there is absolutely no intention in this budget of increasing tax rates, which is what the Senator is trying to guard against. But I do have to emphasize if we were to bring it back from conference, we have been informed that would put at risk the privileged nature of the budget resolution, and we simply cannot do that. If we did that, we truly will never agree on a budget here.

Does the Senator seek more time?

The PRESIDING OFFICER. The Senator from Texas is recognized.

Mr. CORNYN. Madam President, if I can respond briefly to the distinguished chairman of the Budget Committee, I appreciate his willingness to take this motion to instruct because he said it will not survive; it will not see the light of day; it is going to be killed in the dark recesses of the conference committee room.

Mr. CONRAD. Even in the lighted room.

Mr. CORNYN. So it is a very strange process we are engaged in here. I respect the distinguished chairman, but I

remind him, at the time we voted on this, to quote him, the distinguished chairman of the Budget Committee said, ''It certainly will not do any damage to this resolution if it were to pass.''

I understand there was a subsequent conversation with the Parliamentarian that raised this issue. But I suggest in most proceedings that I am familiar with, there is some notion of waiver, that you have a responsibility to speak early, rather than to create a false impression that we are going to do something here to keep taxes low, to create a 60-vote budget point of order, rather than lay low and then raise an issue late in the game that could have been raised and addressed earlier.

None of that is to impute any bad faith to the distinguished chairman of the Budget Committee. It is just to say this is a very strange process, one I think the American people, anybody who happens to be listening or watching, would say: This must be a Washington, DC phenomenon where we suspend reality, we accept amendments by a bipartisan vote and now a motion to instruct, only to ignore them even though they represent the will of the Senate. I think that does not enhance the image of the Senate or the Congress in the eyes of the American people. The fact is, if we do raise taxes, it will be like a wet blanket on the American economy.

I want to allude briefly to an article that was in the Wall Street Journal today that I think demonstrates my point. It is entitled ''April Revenue Shower.'' It says:

> Tax receipts for April were $70 billion above the same month in 2006, and April 24 marked the single biggest day of tax collections in U.S. history, at $48.7 billion.

It is the low taxes and the progrowth policies that this Federal Government has embraced since roughly August of 2003 which has generated the economic activity which has resulted in a windfall to the Treasury. As a matter of fact, this article goes on to say:

> The deficit this year could tumble to $150 billion, or an economically trivial 1 percent of GDP.

That is the kind of benefit—one of the kinds of benefits—I think low taxes have produced. I think it would be a crying shame to raise taxes and jeopardize job growth and economic development in this country.

I understand what the Senator says, that he doesn't intend that there is going to be a tax increase, but we have seen proposals for dramatic increases in spending. The money has to come from somewhere. We have adopted a pay-as-you-go provision which has a built-in bias against tax cuts because it says before you can have a tax cut, you are going to have to have some way to balance it out, a revenue raiser, which means in the end we are going to see a dramatic increase in taxes, whether—and I take him at his word that is not his intention. But we are on a dangerous course to seeing a huge tax increase, perhaps one of the biggest in our Nation's history. That, I believe, is against the best interests of the American people in this big economy.

I accept what the Senator has to say. He is willing to accept my motion to instruct, but it will not be to any effect. It will be ignored. I guess that is the way it is. But I think the American people, and particularly the hard-working taxpayers, are the losers. I think that is a shame.

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. CONRAD. Madam President, let me say to the Senator, I know he doesn't intend to impugn my motives. I hope that impression hasn't been left, because I operated in absolute good faith in the committee. I told him his motion would do no harm because there was no intention of increasing rates in this budget resolution. There truly is not.

I only learned subsequent to that that there was a procedural problem. As soon as I learned, I think the Senator will acknowledge, I came to him on the floor, some weeks ago, and told him of what we had learned and urged him to send his staff to the Parliamentarian to verify that what I was saying was in fact the case. I have been in communication with him subsequent to that, to confirm that he had heard the same thing. In fact, he told me that on the floor late this afternoon.

I regret that I told him it would do no harm. I absolutely believed that was the case when I told the Senator that. It was only subsequently that I learned from my staff that the Parliamentarian advised us of that. I should have known it. In the back of my mind I was worried about the Budget Committee overstepping its bounds.

It is very important for people to understand, we tell the Finance Committee how much money to raise. We do not have the authority to tell them how. Unfortunately, the motion of the Senator crosses that line.

We tell the Appropriations Committee how much money they have to spend. We do not have the authority to tell them how to spend it. If we exceed our authority, there are consequences.

I must say I was concerned at the time of the Senator's amendment in the committee that maybe we were crossing that line, and in fact it turns out we were. That is the fact of the matter. That is what we confront here. I say to the Senator, I hope he would acknowledge I have tried to communicate with him, as soon as I knew it, that these are the facts we confront.

The PRESIDING OFFICER. The Senator from Texas.

Mr. CORNYN. I said it once and I will say it again. The distinguished chairman of the Budget Committee, I am confident, is shooting as straight as he could possibly do with me. I do not question his motive or his actions. I express my profound regret that an amendment that reflects the will of 63 Senators, that is bipartisan, and one that is so important to maintaining the prosperity of this Nation and relieving the burden on hard-working American taxpayers will not see the light of day in this budget resolution. I am expressing my regret to him. But he has been nothing but straight to me.

Mr. CONRAD. Madam President, I thank the Senator very much for that. I say I have so many regrets, as we go through this budget process, that we do not have authority that one might assume the Budget Committee does. But we simply do not. We are in this role of telling the Finance Committee how much money to raise, but we cannot tell them how to do it. We tell the appropriators how much money they spend, but we do not have the authority, as much as we might like it, to tell them how to spend it. If we cross that line, there are real consequences.

In any event, I very much appreciate the Senator from Texas.

The PRESIDING OFFICER. The Senator from New Hampshire.

Mr. GREGG. Madam President, I express my support for the efforts of the Senator from Texas. I understand the parliamentary situation. It has been ruled that if his amendment were accepted and finds it way through the entire process—it is going be accepted, but if it were to come back, it would put in jeopardy the privileged status of the budget and that is obviously not appropriate.

But the fact is this amendment highlights an essential point. Even though it may not come back, it is important that we be on record as having supported it, as the 63 people did, and as we will be when we adopt this amendment in this motion to instruct, because it makes the statement, which the Senator from North Dakota has agreed with, that rates should not be increased.

Unfortunately, the structure of this budget, in my humble opinion, militates toward increasing rates. I do not see how it does anything else in the final analysis. That, of course, is why I have offered my own motion to instruct here, so the rates will not be increased, or at least we will have that statement.

But I think the Senator from Texas has hit the nub of the issue, which is we should not be increasing tax rates on the American people. No matter what the structure of this budget is when it comes back, even if it doesn't have this language, there will be a pretty clear statement by this Senate that rates should not be increased, and should at some point down the road there be a bill brought to the floor, which will be, I am afraid, reflective of the priorities of this budget, which does increase rates—or fails to maintain the rates which are presently in place and thus in the alternative is increasing rates—we can turn to the excellent amendment of the Senator from Texas and say that was not the position of this Senate. The position of the Senate was that would not happen.

I think his amendment, even if it may not return from conference because of the effect it would have on the privileged status of the budget resolution, is still a very effective statement and one that needs to be made.

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. CONRAD. Madam President, would it be appropriate at this moment to take the motion of the Senator?

Madam President, could we then consider the Cornyn motion on a voice vote?

The PRESIDING OFFICER. If all time is yielded back, the question will be put on the motion.

Mr. CONRAD. We yield back our time on this side.

Mr. CORNYN. We likewise yield back our time on this motion.

The PRESIDING OFFICER. If all time is yielded back, the question is on agreeing to the motion.

Ms. STABENOW. Madam President, I have a question. The yielding back is time on this motion only?

Mr. CONRAD. Yes. We would not be yielding the good Senator's time.

Ms. STABENOW. I thank the Senator.

The PRESIDING OFFICER. If all time is yielded back, the question is on agreeing to the motion.

The motion was agreed to.

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. CONRAD. I would ask if we could have a report on the time remaining on the motion of the Senator from Michigan.

The PRESIDING OFFICER. The sponsor of the motion has 27 minutes remaining, and the opposition has 30 minutes remaining.

Mr. CONRAD. We have a problem. We have less time left than time allocated because the vote has been set at 7:30. So we will try to be reasonable so that both sides have a fair shot at the remaining time.

Madam President, I ask unanimous consent that on the motion of the Senator from Michigan, we divide the remaining time 15 minutes apiece before the vote.

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

The Senator from Michigan.

Ms. STABENOW. Madam President, first, following the debate we have just been engaged in, let me say that I am very proud of this budget resolution because we are not only not raising taxes, but we are focused on lowering taxes, tax cuts for the middle class. That is what I am most proud of in this budget. Our budget is focused on middle-class families, what families need who are feeling the crunch at every turn right now in their lives. So we specifically focus on tax cuts for middle-class families.

We also focus on what I want to talk about now as it relates to the motion to instruct; that is, an energy reserve fund that puts in place a set of policies and allows us to move forward to lower gas prices. I mean, ultimately, that is what it is about. Let's get off of foreign oil. Let's become energy independent. Let's focus on alternatives.

We have a whole range of things we can and should do together, but the bottom line is what people are asking me about right now in Michigan is why in the world gas prices today are $3.15 per gallon on average. They ask it in the context of another very important question; that is, since this President, President Bush, has taken office, gas prices in my State have increased by $1.75 per gallon—$1.75 per gallon, an increase of 123 percent. This is according to the Federal Highway Administration. Right now in Michigan, families, businesses, farmers will spend $789 million more this month than they did in January of 2001. That is according to the Department of Energy motor gasoline consumption, price, and expenditures.

Now, what is happening, though? What is wrong with this picture? While I have been seeing my constituents, and I know the Chair shares this concern, that while we see these prices going up, what has happened on the other side with the oil companies? Well, last year, ExxonMobil had $39.5 billion in profits, the largest annual corporate profit in U.S. history, the largest corporate profit in U.S. history, while the people in my State—the farmer planting in the fields, the businesspeople who are doing their jobs, the families, the folks going back and forth to work, taking the kids to childcare, the students trying to go back and forth to school—saw their gas prices go up.

In fact, they will go up higher right before Memorial Day. I will bet you they are going to go up higher in a beautiful State like Michigan, where we want everyone to come in and swim in our Great Lakes and boat and fish and enjoy what is beautiful about Michigan. When the tourism season comes—you can count it on your watch—gas prices are going to go up.

We hear all about how there is competition when, in fact, we know there is not competition. When you are driving down the road, this gas station says one thing and the one on the other side says the same thing.

Now, this has to stop. We are seeing, not only last year—I am speaking about ExxonMobil, but let me just say there are others. Chevron had an 18-percent increase in the first quarter this year—an 18-percent increase. But we are seeing with Exxon that they kicked off a 10-percent rise in profits, the best ever first quarter, ever, in net profit. To put it another way, with Exxon, their take-home pay equals $1,080 every time the second hand ticks on your clock—every second, $1,080—while the folks in Michigan today are paying $3.15. If you happen to be up north, it is $3.24. This is not right. I know you agree with this. This is not right.

There are a number of things we need to do about it. In the short run, we need to make sure the Federal Trade Commission has the authority—and understands that we expect them to use it—to define price gouging.

Now, in the Energy bill that passed in 2005, a requirement that I offered was put into the Energy bill that the FTC had to investigate price gouging. They came back and said they did not have the authority, we had not defined what it was. They made some general statements that really did not reflect what was going on. So now I am very pleased that Senator CANTWELL from Washington State and others have introduced legislation that will clearly define what price gouging is, although I have to say, after years and years of witnessing it, if it walks like a duck and quacks like a duck, I think most people in Michigan, anyway, would call it a duck. So we find ourselves in a situation where the FTC says they do not have the authority or the definitions to use. So we want to give them that. We want to give them that in the short run to make sure they can address what is clearly an unfair situation.

Families are seeing increases on all sides, not just gas prices; it is the cost of college; it is the costs that relate to health care in my State. In fact, I should just remind folks that when we hear about all of the rosy pictures in the last 6 years, we have lost 3 million manufacturing jobs since this President has taken office—3 million. Those were good-paying jobs with health care and pensions, and those families now, those workers, are out working other kinds of jobs. Maybe it is two jobs now to try to make up that salary or maybe it is three jobs. They are paying more for health care, if they have it, and worrying about whether they will have their pension.

So that is the backdrop to what I see now happening as it relates to gas prices. One more time, people see those prices going up as they are trying to get to work, as they are trying to take care of their families. This motion to instruct focuses on the fact that we have put aside a reserve fund that gives us the opportunity to address it throughout the budget.

In addition to the fact that we have legislation to stop price gouging right away, and that is very important, I am very pleased our majority is focused on going after those who are price gouging and bringing down gas prices, but we also know we have to look more long term.

There is some wonderful work being done in the Senate by our Energy Committee, Environment Committee, and Finance and Agriculture Committees as it relates to the farm bill and what can be done with alternative fuels, and so on. We are committed to that as well. The structure of this budget allows us to be able to do those things without procedural motions and hoops getting in the way to stop us from going forward. We all know we need to invest more in ethanol and cellulosic ethanol and biodiesel. We want to be

able to say: Buy your fuel from Middle America, not the Middle East. That is what I am hoping. I know we are committed to doing that.

We also know there is much we can do to together, and, in fact, there are many exiting things that are already happening. I am very proud of our American domestic auto companies that are moving very aggressively. In less than 5 years, we expect that our alternative-fuel vehicles will constitute more than 50 percent of the vehicles that are being produced. That is very positive. I commend them for that.

GM has installed displacement-on-demand technology where the cylinders shut off when not needed, consuming less fuel. DaimlerChrysler has taken the lead on clean diesel and biodiesel. There is excellent work being done in Michigan. Next Energy and other critical research organizations are doing excellent work that would deliver 20 percent to 40 percent more fuel efficiency than conventional automobiles. The Ford Escape hybrid and the work that is being done through hybrids is very significant. Our plug-in hybrids, technology we see being worked on that relates to plug-in electric vehicles, and so on, that is so important. I am excited about the Volt by GM, which will be configured in a way that it will be able to run on electricity, gasoline, E85, or biodiesel. The work goes on on hydrogen and other kinds of things.

But we know that in the end, in addition to focusing on these long-term strategies which are very significant, very important to the environment, to address climate change, to address energy independence, we have an issue right now we have to address; that is, the fact that we continue to see, quarter by quarter, record profits by the oil companies because of the lack of competition. We are seeing, quarter by quarter, increases that end up with those increases and profits, that do not cause them to lower prices for people. They are making more dollars. They do not lower the price. The price goes up as the profits go up.

More and more of our families, our workers, our businesses are feeling squeezed on all sides. We have to make sure the FTC has the ability to call price gouging for what it is, that it is defined and they are given the authority to do something about it.

The American people, unfortunately, are forced to be in a situation right now of choosing between stations and pumps where the prices look awfully much the same. We need to create more competition. We are going to do that in the long run. We are going to create competition in the short run. We need to start putting consumers first, our consumers first. That is what we do in this budget.

I yield the floor.

The PRESIDING OFFICER (Mr. CASEY.) The Senator from New Hampshire.

Mr. GREGG. Mr. President, how much time remains?

The PRESIDING OFFICER. The sponsor has 3 minutes 4 seconds; the Senator from New Hampshire has 14 minutes 30 seconds.

The Senator from New Hampshire is recognized.

Mr. GREGG. Mr. President, let me say that we expect to accept this amendment. The issue of energy and its cost in this country is a pretty complex issue. It is not simple. There is no magic wand to resolve it. Obviously, the things which the Senator mentioned—alternative-fuel cars, lowering consumption, renewables—these are all a big part of the energy resolution. But it is a complex matrix.

One of the essences of it, which was not mentioned, is supply. The fact is that the world demand for energy has increased dramatically, especially as China and Southeast Asian countries have begun to have very robust economies. The demand for the supply is such that the price of oil has increased dramatically.

We in this country are going to have to accept the fact that we are going to have to look for other sources of energy. I regret that in the past domestic supply has been curtailed. For example, the opportunity to get supply from the northwest slope of Alaska or the opportunity to search for potential supply States which are willing to accept having oil exploration off their coasts—all of these opportunities to get more supply are being resisted, especially from the other side of the aisle. Yet this has to be part of the equation of how we resolve the energy issue. There is more than one element to the formula of resolution.

The bottom line is that we should do everything we can to get off of our dependance, as much as possible, on foreign sources of oil. We find ourselves purchasing oil from countries which have antipathy toward us and which create problems for us.

It would be good if we could supply the oil domestically or at least within the Western Hemisphere and not have to go beyond the Western Hemisphere in the manner we do. Another proposal is to get ethanol brought to the east coast out of Brazil. There is a 24-percent tariff on that ethanol. The last time we tried to repeal that tariff, it was opposed, opposed on both sides of the aisle but especially from the other side of the aisle. So there are a lot of different elements to the matrix of how we resolve the energy problem. I certainly am able to support the Senator's motion, but I don't think the answer is simply one or two items. It is a long list of items.

On the underlying bill, there is still this fundamental issue, which is going to be raised by three of the motions that were offered, of the effect on revenues and tax policy on the American wage earner of this budget. There has been a lot of representation, a lot of numbers thrown out. The bottom line is pretty simple. Beginning in the year 2010, a number of tax rates which benefit Americans who create jobs and take risks and especially benefit senior citizens who live on fixed incomes, benefit people who have gone out and been entrepreneurs and created jobs, benefit people who have fixed incomes because they are living off of dividends to a large degree and they are retired, a number of these rate structures are going to expire, and the cost to those people who benefit from that rate structure is going to go up dramatically. Of course, it is always characterized by the other side that this is just a benefit to the wealthy. It is not.

More than 75 percent of those who claim dividend and capital gains income earn less than $100,000. Yet under this budget, their taxes will double on those dividends and capital gains income. Thirty percent of tax-paying seniors claim capital gains income, and more than 50 percent of tax-paying seniors claim dividends income. Almost all those seniors are living on a fixed income. They are not extremely wealthy. They just happen to be at a point in their life where they are cashing in their assets in order to live. They have capital gains as a result. They sell their home. They sell their stock. Yet under this budget, their taxes are going to double on those items. In fact, dividend income accounts for 11 percent of the total income of seniors who earn less than $30,000 and 14 percent of the earnings of those who earn $30 to $50,000. For moderate-income seniors, they are dependent on a dividend in many instances.

That is not unusual. Our society encourages people to invest in the stock market. Even though we have heard about the gloomy economic situation in this country, while we have added 7.4 million jobs and have had 22 quarters of recovery and we have had tax revenues exceeding historic levels, the stock market is now at a historic high and continues to go up. Obviously, some people don't think it is all that gloomy. The fact is, a lot of seniors throughout their earning career invest, either through an IRA account or a pension account. They invest in assets which are now subject to the benefit of a capital gains and dividends rate, which is very helpful to them in making ends meet because it is a fair rate. Yet those people's taxes are going to go up under this budget.

Fifteen million seniors would see their taxes increased if the current tax policy is not extended. This budget makes no room for the extension of the capital gains or dividend tax rate. That is an important point to remember. Equally important is the underlying philosophical difference. There is a belief on the other side that the Government should be able to take more money out of people's pockets and decide how to spend it. That is why the discretionary spending in this budget is significantly over the President's level, $18 billion in the first year of the budget. It is why there is no effort in this

budget at all to discipline entitlement spending, which is clearly the most serious issue we face as an economy and as a society after the threat of Islamic terrorism, the problem of confronting the baby boom generation and the demands it will put on our society economically, to say nothing of the social change of having the largest retired population in the history of the country.

There is no attempt at all to get into that issue of how we are going to handle this fiscal meltdown we are facing if we don't address the impending retirement of the baby boom generation.

Those philosophical differences are very large. What we have tried to do through the motion to instruct is to highlight those differences, the fact that we believe these tax rates which benefit so many Americans should be extended, that we do not believe the spending should be increased well above the proposal of the President—and the President was rather generous, to say the least, in his increase in discretionary spending.

We also believe there should be an effort made to address expansion of entitlement spending, which is going to be a function of the retirement of the baby boom generation, and the fact that will simply overwhelm our capacity to support those programs in their present form, and our children and our children's children will be put in a position of having to pay so much in increased costs for the burden of the Government that they will be unable to benefit from the good life we have benefited from. They will have trouble sending their children to college, buying their first home, doing the discretionary things people want to be able to do with discretionary money because most of that discretionary money will have to be used to support the entitlement programs to support the retired baby boom generation which will double the number of people retired in this country. None of that is addressed in this budget. We think that is a failure that is unfortunate.

These are some of the concerns that remain at this time. However, I would be happy to ask unanimous consent that the motion of the Senator from Michigan be accepted and that the time remaining be divided between myself and the Senator from North Dakota so he can get some more time to respond to my comments which I am sure he will want to do.

The PRESIDING OFFICER. Is all time yielded back on this particular motion to instruct?

If so, the question is agreeing to the Stabenow motion.

The motion was agreed to.

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. GREGG. Did we also agree that the time between now and 7:30 would be equally divided.

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

The Senator from North Dakota.

Mr. CONRAD. Mr. President, let me indicate, on the motion just adopted, the strategy in the reserve fund is not just one item, as the Senator referenced, but involves all of these things—expanding production and use of alternative fuels and alternative-fuel vehicles to promote renewable energy development, to improve electricity transmission, to encourage responsible development of domestic oil and natural gas resources, and to reward conservation and efficiency. There is a production component of what is in the reserve fund. I want to emphasize that and thank the Senator from Michigan for her constructive proposal.

I also want to take a moment to respond to a number of points made by my colleague from New Hampshire. Once again, there is no tax increase in this proposal. The fact is, what the President said his budget would produce in revenue is virtually identical to what is in this budget. In fact, there is virtually no difference between what the President said his budget would produce in revenue over the 5 years. He said his budget would produce $14.826 trillion of revenue. My budget produces $14.827 trillion of revenue, virtually no change. If you look at a CBO basis, there is a 2-percent difference. We believe that can be easily accommodated with no tax increase by going after the tax gap, by going after abusive tax havens and fraudulent tax shelters.

When the Senator asserts there is no long-term savings, that is not accurate. We have $15 billion of Medicare savings, and we have a reserve fund on health information technology and other health savings. Just on health information technology, the Rand Corporation estimates that if that were employed, we would save $81 billion a year. We also have another health care reserve fund that relates to looking at best practices around the country so that we can ensure savings in the health care accounts in that way and many other proposals to address the long-term fundamental imbalances we have.

We all understand the only way those long-term entitlement challenges are going to be fully addressed is in a bipartisan approach outside a 5-year budget resolution because those are much longer term challenges.

How much time do we have on this side?

The PRESIDING OFFICER. The Senator has 30 seconds.

Mr. CONRAD. Mr. President, I thank all my colleagues for participating in this debate. These instructions to the conferees will have attention paid to them, and we will do our level best to bring back a budget that will reflect the will of this body.

The PRESIDING OFFICER. The Senator from New Hampshire.

Mr. GREGG. How much time do I have?

The PRESIDING OFFICER. The Senator has 3 minutes 25 seconds.

Mr. GREGG. Mr. President, of course, there is a lot of back and forth. So many numbers are thrown out, nobody can keep up. The $15 billion in Medicare savings is a nice number. The only problem is, it is coupled with about $30 billion of new spending in the SCHIP program and, as a result, it is a net loss. So the long-term savings are not there. In fact, they are a long-term cost. Of course, the health care proposals, if they score, that would be great, but they don't score. So when you throw out a number of $81 billion, you are throwing out a number that CBO won't support. If it did support it, we would immediately capture those funds and use them constructively to reduce the deficit or to give people a tax benefit. As a practical matter, they don't score so the number is not relevant.

I want to speak quickly to the Senator's response to my motion. My motion says: These tax reductions which are very important, which address issues which are important to the American people and which are not covered by the proposal which we have before us, unfortunately, need to be continued. These tax reductions cover the $1,000 child credit, the marriage penalty, the 10-percent income tax bracket, all of which the Senator has said are going to be picked up by the Baucus amendment—maybe, maybe not—the lower marginal rates, definitely not. The earned-income tax credit relief for military families does not appear to be in here. The adoption tax credit is not in here. The dependent care tax credit is not in here. The college tuition deduction for student loan interest for $2,000, Coverdale IRA, and the 15-percent rate on capital gains and dividends, which as I just went through, is very critical to seniors and to the economy generally and has been a huge revenue windfall for us as a government, and adjusting the death tax so that it properly reflects fairness to small businessmen and farmers, those are not in here.

All of those are not in the proposal of the Senator from North Dakota.

In addition, there is the operative language of the Senator's proposal which essentially is the fig leaf or the Wizard of Oz approach which says we are going to get this money from somewhere—we really don't know where, the tax gap or some building in the Cayman Islands—when, in fact, the practical effect is, you are going to have to raise taxes on the American people to accomplish what the Senator from North Dakota is proposing with his motion.

That is why I will be opposing this. I suspect some of my colleagues will support it because obviously the Baucus language makes sense, although it doesn't go far enough.

In light of that, I guess the time is probably used up, isn't it?

The PRESIDING OFFICER. It is.

The Senator from North Dakota has 10 seconds.

Mr. CONRAD. Mr. President, I would like to correct the record and indicate the motion I have offered, and which supports the underlying resolution, does contain the adoption tax credit, does include the dependent care tax credit, does include the $1,000 child tax credit, the marriage penalty relief, the 10-percent income tax bracket and estate tax reform. So it is all in there.

Mr. GREGG. Mr. President, how much time do I have remaining? I don't have 10 seconds? I could fit everything into it.

Mr. President, I ask unanimous consent that the motions be voted in the following order and that the provisions relating to debate—I guess this is something you ask, I say to the Senator. It was just handed to me. You ask that.

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. CONRAD. Mr. President, I thank my colleague. I thank him for his good humor and for working through this as we have proceeded to be ready to vote.

Mr. President, I ask unanimous consent that the motions be voted in the following order and that the provisions relating to debate time and vote time limitation remain in effect: the Kyl motion to instruct regarding estate tax, the Conrad motion to instruct regarding certain tax cuts, the Gregg motion to instruct regarding certain tax cuts.

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

Mr. CONRAD. Mr. President, when I indicated that the vote time limitation remain in effect, I think we should probably send that signal to our colleagues. There will be 2 minutes equally divided on each of the motions, and after the first vote, the next two votes will be 10-minute votes.

Mr. GREGG. Mr. President, I ask unanimous consent that it be in order to ask for the yeas and nays on the Kyl motion and all the other motions.

Mr. CONRAD. All three motions?

Mr. GREGG. All three motions.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. GREGG. Mr. President, I ask for the yeas and nays on all the motions.

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The yeas and nays were ordered.

The PRESIDING OFFICER. Under the previous order, there will now be 2 minutes of debate equally divided on the motion to instruct conferees offered by the Senator from Arizona, Mr. KYL.

The Senator from North Dakota.

Mr. CONRAD. Mr. President, we have in the resolution estate tax reform. Mr. President, $3.5 million a person, $7 million a couple is completely exempt from any estate taxation. That will exempt 99.8 percent of the estates, and it is paid for. The Kyl motion is not paid for, would blow a hole in the deficit, would take us back to a failure to balance the budget.

I hope our colleagues will support what is in the resolution, what passed the Senate and which does reform the estate tax but does so in a fiscally responsible way.

The PRESIDING OFFICER. The Senator from New Hampshire.

Mr. GREGG. Mr. President, the Kyl motion is a bipartisan proposal, or at least it was. Actually, the original language came from the Senator from Louisiana. It basically sets a rate of 35 percent—the proposal of the Senator from North Dakota sets a top rate of 45 percent—it sets that rate on estates, and on small estates and small businesses it sets a lower rate. It exempts estates of $5 million or less. It is an extremely reasonable approach to the death tax.

People should not be taxed because they die, to begin with. But if we are going to tax them, let's not put them out of business. Let's allow families with small businesses to survive. That is what the Kyl motion does.

The PRESIDING OFFICER. Is all time yielded back on the motion?

If so, the question is on agreeing to the Kyl motion to instruct conferees. The yeas and nays have been ordered. The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from South Dakota (Mr. JOHNSON) and the Senator from West Virginia (Mr. ROCKEFELLER) are necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Idaho (Mr. CRAPO), the Senator from Arizona (Mr. MCCAIN), the Senator from Louisiana (Mr. VITTER).

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 54, nays 41, as follows:

[Rollcall Vote No. 159 Leg.]

YEAS—54

Alexander	Dole	Martinez
Allard	Domenici	McConnell
Baucus	Ensign	Murkowski
Bayh	Enzi	Nelson (NE)
Bennett	Graham	Pryor
Bond	Grassley	Roberts
Brownback	Gregg	Sessions
Bunning	Hagel	Shelby
Burr	Hatch	Smith
Chambliss	Hutchison	Snowe
Coburn	Inhofe	Specter
Cochran	Isakson	Stevens
Coleman	Kyl	Sununu
Collins	Landrieu	Tester
Corker	Leahy	Thomas
Cornyn	Lincoln	Thune
Craig	Lott	Voinovich
DeMint	Lugar	Warner

NAYS—41

Akaka	Clinton	Kerry
Biden	Conrad	Klobuchar
Bingaman	Dodd	Kohl
Boxer	Dorgan	Lautenberg
Brown	Durbin	Levin
Byrd	Feingold	Lieberman
Cantwell	Feinstein	McCaskill
Cardin	Harkin	Menendez
Carper	Inouye	Mikulski
Casey	Kennedy	Murray
Nelson (FL)	Salazar	Webb
Obama	Sanders	Whitehouse
Reed	Schumer	Wyden
Reid	Stabenow	

NOT VOTING—5

Crapo	McCain	Vitter
Johnson	Rockefeller	

The motion was agreed to.

The PRESIDING OFFICER. Under the previous order, there will now be 2 minutes equally divided on the motion to instruct offered by the Senator from North Dakota, Mr. CONRAD.

Mr. CONRAD. Mr. President, if I could prevail on colleagues to be quiet for 1 more minute. They can speak on my colleague's time.

I ask colleagues to support this motion. It says to the conferees: Let's insist on those provisions that are in the budget resolution to provide for extension of the $1,000 child tax credit, the marriage penalty relief, the 10-percent bracket, the reform of the estate tax to protect small business and family farms, the extension of the adoption tax credit, the dependent care tax credit, and the treatment of combat pay for EITC purposes.

It also insists on section 303 which provides for tax relief, including extensions of other expiring tax provisions if they are offset.

This is a tax relief amendment. I hope my colleagues will support commonsense tax relief for middle-income taxpayers and for basic estate tax reform.

The PRESIDING OFFICER. The Senator's time has expired.

The Senator from New Hampshire is recognized.

Mr. GREGG. Mr. President, this amendment is essentially a cover amendment, and it is to cover up the fact that it is the Wizard of Oz at work on the Democratic budget, and it doesn't work. If you spread pixie dust over this by Tinker Bell, it still wouldn't fly. The fact is, you cannot produce these funds in the manner in which the Senator from North Dakota has suggested by some building in the Cayman Islands and other proposals.

If you want to extend the tax cuts and you want to be concerned about the middle-income American who is benefiting from those tax cuts, you should vote for the next motion to instruct.

The PRESIDING OFFICER. The question is on agreeing to the Conrad motion to instruct.

The yeas and nays are ordered.

The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. DURBIN. I announce that the Senator from South Dakota (Mr. JOHNSON) and the Senator from West Virginia (Mr. ROCKEFELLER) are necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Idaho (Mr. CRAPO), the Senator from Arizona (Mr. MCCAIN), and the Senator from Louisiana (Mr. VITTER).

The PRESIDING OFFICER (Mr. SALAZAR). Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 51, nays 44, as follows:

[Rollcall Vote No. 160 Leg.]

YEAS—51

Akaka	Dorgan	Mikulski
Baucus	Durbin	Murray
Bayh	Feinstein	Nelson (FL)
Biden	Harkin	Nelson (NE)
Bingaman	Inouye	Obama
Boxer	Kennedy	Pryor
Brown	Kerry	Reed
Byrd	Klobuchar	Reid
Cantwell	Kohl	Salazar
Cardin	Landrieu	Sanders
Carper	Lautenberg	Schumer
Casey	Leahy	Snowe
Clinton	Levin	Stabenow
Coleman	Lieberman	Tester
Collins	Lincoln	Webb
Conrad	McCaskill	Whitehouse
Dodd	Menendez	Wyden

NAYS—44

Alexander	Domenici	Martinez
Allard	Ensign	McConnell
Bennett	Enzi	Murkowski
Bond	Feingold	Roberts
Brownback	Graham	Sessions
Bunning	Grassley	Shelby
Burr	Gregg	Smith
Chambliss	Hagel	Specter
Coburn	Hatch	Stevens
Cochran	Hutchison	Sununu
Corker	Inhofe	Thomas
Cornyn	Isakson	Thune
Craig	Kyl	Voinovich
DeMint	Lott	Warner
Dole	Lugar	

NOT VOTING—5

Crapo	McCain	Vitter
Johnson	Rockefeller	

The motion was agreed to.

The PRESIDING OFFICER. Under the previous order, there will now be 2 minutes of debate equally divided on the motion to instruct offered by the Senator from New Hampshire, Mr. GREGG.

The Senator from New Hampshire is recognized.

Mr. GREGG. Mr. President, this motion is the opportunity to speak out on behalf of seniors, working Americans, families, and children in this country. If you believe the tax rates should stay in place, which include the $1,000 child tax credit, marriage penalty relief, the 10-percent income tax bracket, the lower marginal rates for working American families and small businesses, the earned income tax credit for military families, the adoption tax credit, independent care tax credit, the college tuition deduction, the deduction for student loan and interest, the $2,000 Coverdell——

The PRESIDING OFFICER. The Senate will be in order.

Mr. GREGG. Mr. President, the next two are important—the 15-percent capital gains dividend rate, which helps seniors and people on fixed income and gives our economy a boost, and revenues to the Federal Government a boost, and the death tax, structured along the lines of what Senator KYL's motion put forward—if you believe in those proposals, you will want to vote for this motion to instruct the conferees.

The PRESIDING OFFICER. The Senator from North Dakota is recognized.

Mr. CONRAD. Mr. President, if you like debt, this is your amendment. This will add $250 billion to the debt. If you don't want to balance the budget in 2012, vote for this amendment, because we have a balanced budget in 2012 now. If you pass this amendment now, we will not.

The Senator says it is like the Kyl amendment on the estate tax. No, it is not. He preserved part of the estate tax for those at the very highest income level. This eliminates the estate tax.

Please, we have made so many strides to balance the budget by 2012. Let's not have another unbalanced budget, one that adds to the debt.

The PRESIDING OFFICER. The question is on agreeing to the Gregg motion to instruct. The yeas and nays have been ordered. The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from South Dakota (Mr. JOHNSON) and the Senator from West Virginia (Mr. ROCKEFELLER) are necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Idaho (Mr. CRAPO), the Senator from Arizona (Mr. MCCAIN), and the Senator from Louisiana (Mr. VITTER).

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 44, nays 51, as follows:

[Rollcall Vote No. 161 Leg.]

YEAS—44

Alexander	DeMint	Lugar
Allard	Dole	Martinez
Bennett	Domenici	McConnell
Bond	Ensign	Murkowski
Brownback	Enzi	Roberts
Bunning	Graham	Sessions
Burr	Grassley	Shelby
Chambliss	Gregg	Smith
Coburn	Hagel	Specter
Cochran	Hatch	Stevens
Coleman	Hutchison	Sununu
Collins	Inhofe	Thomas
Corker	Isakson	Thune
Cornyn	Kyl	Warner
Craig	Lott	

NAYS—51

Akaka	Feingold	Murray
Baucus	Feinstein	Nelson (FL)
Bayh	Harkin	Nelson (NE)
Biden	Inouye	Obama
Bingaman	Kennedy	Pryor
Boxer	Kerry	Reed
Brown	Klobuchar	Reid
Byrd	Kohl	Salazar
Cantwell	Landrieu	Sanders
Cardin	Lautenberg	Schumer
Carper	Leahy	Snowe
Casey	Levin	Stabenow
Clinton	Lieberman	Tester
Conrad	Lincoln	Voinovich
Dodd	McCaskill	Webb
Dorgan	Menendez	Whitehouse
Durbin	Mikulski	Wyden

NOT VOTING—5

Crapo	McCain	Vitter
Johnson	Rockefeller	

The motion was rejected.

The PRESIDING OFFICER. Under the previous order, the Chair appoints Mr. CONRAD, Mrs. MURRAY, Mr. WYDEN, Mr. GREGG, and Mr. DOMENICI conferees on the part of the Senate.

MORNING BUSINESS

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

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

The PRESIDING OFFICER. The Senator from Florida is recognized.

NATIONAL GUARD EQUIPMENT

Mr. NELSON of Florida. Mr. President, it is timely for me to make these remarks because there has been a conversation that has occurred in Kansas today between the Governor of Kansas and the President of the United States over the question of the adequacy of the National Guard and its equipment.

The reason I am making these remarks is that this Senator from Florida has sounded this alarm bell several weeks ago on the basis of a GAO report of the inadequacy of the equipment of the National Guard in each of the States. In my State of Florida, the GAO report says they only have 53 percent of their equipment. In the State of New Mexico, they only have 33 percent of their equipment. You now heard the commentary from both the Governor of Kansas, as well as the head of the National Guard, the adjutant general of Kansas, who state they are short of equipment.

I can tell you that, in Florida, we are 500 humvees short. We are 600 trucks short—that is both 5 ton and deuce and a half. We are 4,400 night vision goggles short. Why I am saying this today as a follow-on to sounding this alarm several weeks ago is we are not far from June 1, which is the beginning of hurricane season. The Florida National Guard is the best trained as a National Guard but especially so for taking care of the aftermath of a hurricane. If we only have category 1, 2, and 3 hurricanes, the Guard tells me they have the equipment. But if the big one hits—the big one being a category 4 or 5 hitting from the water—a highly densely urbanized area of the coast, they will be short. Then the Guard would rely on their compact with other Guard units to supply equipment.

For example, Pennsylvania is one of those States in the compact. But Pennsylvania is short of equipment as well. We are trying to put additional appropriations in this war funding bill for equipment for our National Guard units, but as Lieutenant General Blum, the head of the National Guard for the country, said, they are $40 billion short of equipment. I will read you a statement from the Florida National Guard in case there is any doubt in anybody's mind:

> It is true that we are short of equipment. We need these pieces of equipment to speed up our response to local emergencies and to help save lives.

And he continues:

> They can draw on these additional units and equipment through that compact.

But in the case of a major hurricane—

And I continue to quote the Florida National Guard—

we plan to have these other assets prepositioned prior to landfall or moving to Florida as soon as possible. However, we cannot afford any additional significant losses of equipment. Losing more equipment from Florida to support our active duty mobilization sites will put us at risk to respond effectively to our State during a time of great need.

We have to be serious all over this country about the equipment needs for our National Guard when it is called on to respond to that aspect of their job, which is to be activated by the Governor of the respective States under statewide emergencies.

HONORING OUR ARMED FORCES

CAPTAIN JONATHAN DAVID GRASSBAUGH

Mr. GREGG. Mr. President, I rise today to pay special tribute to U.S. Army Ranger CPT Jonathan David Grassbaugh of Hampstead, NH. Sadly on April 7, 2007, while supporting Operation Iraqi Freedom, this brave 25-year old leader and three of his fellow soldiers gave their lives for our Nation when an improvised explosive device detonated near their patrol in Zaganiyah, Iraq. Captain Grassbaugh was assigned to Headquarters and Headquarters Troop, 5th Squadron, 73rd Cavalry Regiment, 82nd Airborne Division, out of Fort Bragg, NC, and was protecting our country in his second deployment to Iraq.

Jonathan, or Jon to family and friends, was born in Ohio, but his family moved to Hampstead, NH, when he was in the third grade. He attended Hampstead Central School, graduated from Hampstead Middle School, where his mother Patricia is principal, went on to Phillips Exeter Academy, where he was a 4 year honor student, and then to Johns Hopkins University, where he studied computer science, graduating in 2003. While at Johns Hopkins University he was a distinguished member of the Army ROTC program and Pershing Rifles, served as captain of the Ranger Challenge Team, commanded the ROTC Battalion during his senior year and won the National two-man duet drill team competition.

Following completion of the arduous U.S. Army Ranger School in April 2004, Captain Grassbaugh was assigned to the 7th Cavalry in the Republic of South Korea. He was later assigned to the 3rd Battalion, 505th Parachute Infantry Regiment where he assumed another leadership position serving as an antitank platoon leader. Jon also served as an aide de camp for the 82nd Airborne deputy commanding general, scout platoon leader, and logistics officer for the 5th Squadron, 73rd Cavalry. In July of 2006, he was deployed for a second tour of duty in Iraq in support of Operation Iraqi Freedom. Friends say Jon was laser focused, never questioned his service or his need to be in Iraq, cared deeply for the soldiers in his command, and always put a 110 percent effort into everything.

Captain Grassbaugh's awards and decorations serve as testimony to his stellar character and performance. They include the Bronze Star Medal, Purple Heart, Meritorious Service Medal, Army Commendation Medal, 4 Oak Leaf Clusters, Joint Service Achievement Medal, Army Achievement Medal, National Defense Service Medal, Iraq Campaign Medal, Global War on Terrorism Service Medal, Korean Defense Service Medal, Army Service Ribbon, Overseas Service Ribbon, Parachutist's Badge, Combat Action Badge, and the Ranger Tab.

Patriots from the State of New Hampshire have served our Nation with honor and distinction from Bunker Hill to Zaganiyah, Iraq—and U.S. Army Ranger CPT Jonathan Grassbaugh served, led, and fought in that same fine tradition.

My sympathy, condolences, and prayers go out to Jon's wife Jenna, his parents Mark and Patricia, brother Jason, and to his other family members and many friends who have suffered this most grievous loss. All will sorely miss Jon Grassbaugh, the caring husband, dedicated son, loyal brother, good friend, outstanding Ranger. Laid to rest at Arlington National Cemetery, Captain Grassbaugh joins his fellow heroes in eternal peace at our military's most sacred place. In the words of another son of New Hampshire, Daniel Webster may his remembrance be as long lasting as the land he honored. God bless Jonathan David Grassbaugh.

ADDRESSING THE DROPOUT EPIDEMIC

Mr. KENNEDY. Mr. President, education has long been the key to opportunity, progress, and prosperity in America. Our schools and teachers prepare young Americans to compete and succeed in an ever-changing economy. Good schools shape the character of our citizens. They train Americans to participate in our democracy, and to serve our country and our communities. And a strong education system helps protect our national security. Above all, it's a force to move America forward. It is the engine of the American dream.

When we enacted the No Child Left Behind Act 5 years ago, we sought to modernize and reform our public schools, and reaffirm the original commitment made in the Elementary and Secondary Education Act in 1965. The No Child Left Behind Act sets lofty goals for all schools to meet, and requires States to establish strong standards, a rigorous curriculum, and reliable assessments.

Congress should not abandon those fundamental goals as it works to reauthorize the law this year.

Nevertheless, we must acknowledge that too many of America's students still don't receive all that is needed to engage and succeed in school, learn to high standards, and graduate on time. Each year, approximately 1 million students do not finish high school in time to graduate with their peers.

The Nation's dropout rate is more than a problem—it is a national crisis—and one that a Nation so deeply committed to the fundamental value of equal justice and opportunities for all cannot afford to ignore.

In 1963, President Kennedy decried the fact that four out of 10 fifth graders did not finish high school. At that time, he called it ''a waste we cannot afford.''

Forty-four years later, the statistics on high school graduation rates are still staggering. About 1,000 high schools across the country only graduate half their students. Among African Americans and Latinos, only 55 percent graduate on time. Every day, 7,000 young Americans drop out of school.

Reaching these dropouts—and giving them a chance to get back on track—is a national imperative. We have a moral commitment and an obligation to children, to parents, and to our communities to provide each and every one of our students with the chance to attend an excellent public school and graduate with a diploma. Delivering on that basic commitment is a measure of our strength as a democracy, and it's an expression of our values and our belief as a nation that our children are our future.

Reducing the dropout rate in our schools is not just the right thing to do. This epidemic has very real consequences for our country, and addressing it is an economic necessity.

High school dropouts earn, on average, $260,000 less than high school graduates over the course of their lifetime, and nearly $1 million less than individuals with a college degree. If each student who dropped out of the class of 2006 had graduated, America's economy would have been $309 billion stronger in future years.

If the approximately 1.2 million young people who are estimated to drop out of school in the United States this year could earn high school diplomas instead, States could save more than $17 billion in costs under Medicaid and expenditures for uninsured care over the course of these young people's lifetimes.

Curbing the dropout rate requires a comprehensive solution. Our high schools clearly need greater assistance in supporting and retaining their students.

We must recognize, however, that this problem does not begin in high school. Intervention should start in the elementary and middle school years, when standards and expectations are set. Children who do not learn to read or do basic math in these grades will fall farther and farther behind, and find it increasingly difficult to catch up in the faster-paced high school grades.

Research shows that we can identify students who are most at-risk for not

completing high school as early as sixth grade. With early intervention, quality teachers, small classes, and data-driven instruction, we can ensure that these students make progress, stay in school and succeed.

Once students reach high school, we must do more to engage them in the learning process. States and cities across the country are already taking steps to address this challenge, such as offering extra help during the school day, extending learning time, and adopting other school-based interventions.

In Massachusetts, Boston public schools are working with private partners to create smaller learning communities, improve instruction, and strengthen professional development for teachers. Our high schools are undergoing a transformation to focus on business, technology, health professions, arts, public service, engineering, sciences, international studies, and social justice. In many of them, students can prepare for future opportunities after they graduate, by enrolling in courses for college credit or pursuing hands-on experience in a career that interests them.

We must all work in Congress to help more districts like Boston mount significant efforts to address these issues and make progress in reducing the dropout rate.

I have joined my colleagues on the HELP Committee—Senator BINGAMAN and Senator BURR—in introducing the Graduation Promise Act, which would fund state efforts that target resources and reforms to turn around high schools with low graduation rates. 15 percent of America's high schools produce half of our dropouts. In these schools—some of which have as many as 400 students in a freshman class—8 out of 10 of the students start high school already having repeated a grade, or are special education students, or are two years or more below grade level.

It's very clear that these schools need more assistance in supporting and retaining these students, and that's what we hope to provide.

We must also do more to better connect schools with the communities around them, and provide the safety-net of services that at-risk students need to help them stay in school. The Keeping PACE Act would provide federal funds for these efforts.

Supporting the social, emotional, intellectual, and physical development of our youth is a key strategy for breaking down the barriers to learning.

Finally, in order to target reforms, we must accurately measure and track graduation rates throughout the country. Today, in some districts, students who leave school are counted as dropouts only if they have registered as dropouts. In other districts, a promise to earn a GED is all it takes to be counted as a ''graduate.'' That's unacceptable. Obtaining reliable data is the only way to identify and target the level of reform and resources necessary to assist schools struggling with high dropout rates.

We have an obligation to encourage these and other creative reforms in our schools, and provide the support structure and safe harbor needed to present students at-risk from dropping out. But we must also back up these essential reforms with real investments.

Today, the federal investment in education at all levels—especially in the middle and high school grades—is not sufficient. Only 8 percent of students who benefit from the federal investment in Title I are in high school. Ninety-percent of high schools with very low graduation rates have high concentrations of low-income students—but only a quarter of them receive federal assistance. We need to dedicate more resources and support for secondary schools to improve academic achievement and ensure that every student has a fair opportunity to graduate. We need to target our efforts, resources, and ideas for effective reform to the schools that need them most.

As we consider ways to strengthen and advance our national commitment to leave no child behind, we have an opportunity to give teachers, schools, districts and states the support they need to ensure a high-quality education for every student.

We can no longer turn a blind eye to the millions of young people who fall through the cracks. Let us demand more of ourselves. Let us recommit ourselves to the spirit and the principles of excellence and equal opportunity that have shaped our historic commitment to improving public education. Above all, let us commit ourselves to the great goal of making this silent but severe epidemic—America's dropout crisis—a thing of the past.

TRIBUTE TO KATE MARTIN

Mr. THUNE. Mr. President, today I rise to recognize Kate Martin, an intern in my Washington, DC, office, for all of the hard work she has done for me, my staff, and the State of South Dakota over the past several months.

Kate is a graduate of Ellendale High School in Ellendale, ND. Currently she is attending the University of North Dakota, where she is majoring in marketing and is pursuing a minor in international business. She is also active in her sorority Kappa Alpha Theta. She is a hard worker who has been dedicated to getting the most out of her internship experience.

I would like to extend my sincere thanks and appreciation to Kate for all of the fine work she has done and wish her continued success in the years to come.

ADDITIONAL STATEMENTS

HONORING THE BRIGHT STAR RESTAURANT

• Mr. SHELBY. Mr. President, I wish to honor the Bright Star Restaurant, one of my favorites in Bessemer, AL. The Bright Star celebrated its 100th anniversary last week on May 2, 2007.

I know from personal experience that the Bright Star has endured for a century due to its excellent menu. Though the restaurant has grown from a cafe that served only 25 people to its current size, seating 330 people, the quality of the food has not changed a bit. I attribute this fact to Bill and Pete Koikos, the family-owned restaurant's patriarchs. Bill and Pete immigrated to the United States from Greece in 1923. Two years later they purchased ownership interest in the restaurant. Since 1966, Bill's sons Jim and Nick have owned and operated the business very successfully.

Jim and Nick Koikos are hard workers who are nearly always in the restaurant greeting customers as they walk through the door. Jim and Nick's dedication to keeping customers happy, along with their wonderful menu, account for the Bright Star's longevity.

Although the menu has a wide assortment of delicious dishes, I am partial to the seafood, which is always fresh from the gulf. My personal favorite is the excellent Greek snapper, thought their special gumbo, not to mention the lemon pie, are also stand-outs.

For the last 100 years, the Bright Star has been one of the best restaurants in the South. The emphasis on quality food and service has not changed since the restaurant was founded in 1907, and I sincerely congratulate the Koikos brothers on their anniversary and wish them continued success.•

COMMENDING PAT SEAMANS WALKER

• Mr. PRYOR. Mr. President, it is with great pleasure that I commend an outstanding Arkansan on her birthday for her truly amazing gifts to the State of Arkansas. Mrs. Pat Seamans Walker, a Springdale resident, has always been a leader in Arkansas philanthropy by providing donations for many worthwhile causes, especially healthcare, education and human service organizations.

Mrs. Walker and her late husband Willard founded the Willard and Pat Walker Charitable Foundation in 1986. Since that time, their generosity has touched the lives of thousands of Arkansans. Mrs. Walker is a member of the Foundation Board for the Arkansas Cancer Research Center, and an active member of First Christian Church of Springdale. She also participates in the oversight of the Walker Charitable Foundation.

Pat Walker has received many awards in recognition of her philanthropy, including the 2002 American Heart Association Tiffany Award, the Distinguished Services Award from the Razorback Foundation, the prestigious Arkansas Children's Award, and the University of Arkansas Medical School Distinguished Services Award. She has been recognized as one of the Most Distinguished Women in Arkansas and was named to the Top 100 Women in Arkansas list by Arkansas Business in 1999.

The Willard and Pat Walker Charitable Foundation has made countless donations over the years, including millions to educational institutions in Arkansas, millions to healthcare research and community health centers in Arkansas, and the hundreds of thousands of dollars to build libraries in Arkansas.

I would like to personally thank Mrs. Walker and the members of the Walker family for their unwavering support of the State of Arkansas. It is an honor to stand here before you today and wish such a remarkable person a happy birthday.●

F–117'S ARRIVAL AT HOLLOMAN AIR FORCE BASE

● Mr. DOMENICI. Mr. President, I wish to commemorate the arrival of the first F–117 Nighthawk fighters at Holloman Air Force Base, NM, 15 years ago today.

On May 9, 1992, with the arrival of its first four F–117s at Holloman Air Force Base, the 49th fighter wing became the sole operator of the F–117. The F–117 was the world's first stealth aircraft and is still one of the world's most advanced fighters. Since that date the men and women of the 49th have flown the F–117 with distinction throughout the world. In 1999 the F–117s of the 49th deployed in support of Operation Allied Force, and flew more than 1,000 missions against heavily defended targets in Serbia. The 49th also played a key role in the opening hours of Operation Iraqi Freedom, attacking critical leadership targets.

I would like to take this opportunity to thank all those at Holloman for keeping the F–117 flying, and for their service to our Nation. I am proud New Mexico has been the home to this amazing aircraft and the outstanding individuals who fly them.●

CONGRATULATING DALE B. ENGQUIST

● Mr. LUGAR. Mr. President, today I wish to congratulate fellow Hoosier Dale B. Engquist who will be recognized today with the Department of the Interior's Distinguished Service Award honoring his leadership with the National Park Service as superintendent of the Indiana Dunes National Lakeshore.

Under Dale's leadership the Lakeshore has undergone remarkable changes, including a 15 percent increase in the size of the area being preserved. Dale has also developed an environmental education program that currently serves over 35,000 students per year. Recently Dale worked closely with local and State leaders to design and build the new Dorothy Buell Memorial Visitor Center, a shared resource which welcomes the two million visitors from Indiana and across the nation who come each year to learn about and enjoy the precious natural ecosystem along the southern tip of Lake Michigan which spans northwest Indiana.

I look forward to each opportunity to be with Dale and to learn about the many initiatives he and his staff have undertaken to preserve and share the spectacular beauty of the Indiana Dunes National Lakeshore. I am certain that in the coming years the staff of the Indiana Dunes National Lakeshore will continue Dale's important work to preserve this resource for generations to come.

I congratulate Dale on his recent retirement following a career dedicated to public service, and wish him and his wife JoAnn good health and happiness as they embark upon this new chapter in their lives, together.●

CONGRATULATING ALBERT YARNELL

● Mr. PRYOR. Mr. President, in 1932 Ray Yarnell bought a bankrupt dairy in Searcy, AR, and created the Yarnell Ice Cream Company. At the time, there were 43 ice cream companies in business in Arkansas.

Ray's son Albert began working for the company at the age of 12, riding his bicycle to deliver bills. During World War II, Albert Yarnell left to serve his country as a member of the Army Signal Corps. After his service, he studied dairy production at the University of Missouri and returned to work at the Yarnell Ice Cream Company in 1948. With the passing of his father in 1974, Albert Yarnell became the president of the company. In 1978, he personally created the Nation's first all-natural ice milk, and after becoming chairman of the company in 1985, he led the team that invented the Nation's first nonfat, no-sugar-added ice cream in 1990. He is affectionately known in his hometown of Searcy and at the company as ''Mr. Albert.''

A very successful family business, the Yarnell Ice Cream Company now stands as the only remaining ice cream producer in Arkansas. Albert's son Rogers is the current president of the company and Albert's granddaughter Christina is the treasurer. Albert and his wife Doris both contribute to and are deeply respected in the community they have called home for so many years. Mr. Yarnell also serves on several boards, including Main Street Searcy, the Baptist Health Corporation, the Searcy Chamber of Commerce, as well as the Arkansas State Chamber of Commerce.

Earlier this year, Albert Yarnell was inducted into the Arkansas Business Hall of Fame. He joins other distinguished members such as Sam Walton, Jackson Stephens, Don Tyson, and J.B. Hunt.

Mr. President, I ask that my colleagues join me in congratulating both Albert Yarnell, the patriarch of the Ice Cream Industry, and the Yarnell Ice Cream Company on the company's 75th anniversary.●

HONORING THE INN AT LONG SANDS

● Ms. SNOWE. Mr. President, today I wish to honor and recognize a small business from my home State that has triumphed over adversity in the wake of several major coastal storms. The Inn at Long Sands in York Beach, ME, suffered extensive damage as the result of a devastating storm on Mother's Day weekend of May 2006. With Memorial Day weekend approaching, signaling the unofficial beginning of summer—a busy time for York County's tourism industry—Arline Shea, the Inn's co-owner watched countless hotel and meal reservations get washed away. As a result of the storm, the Inn sustained over $100,000 in damage. This was not a welcome beginning for Arline, who had just purchased the Inn in February 2006.

Although the storm dealt Arline a heavy blow, she exemplified Maine's entrepreneurial spirit by reopening in a matter of weeks. To recover from the damage the Inn had sustained, Arline wisely made good use of the tools available to small businesses in the wake of disasters. She contacted the Federal Emergency Management Agency and the Small Business Administration to find out what kinds of assistance she would be able to receive. Arline's exemplary decision to find out what help was available to her, along with her hard work and dedication, allowed her to reopen the Inn and Long Sands in time for last year's Fourth of July holiday.

Despite all of the tragedy that befell Arline Shea and her employees, her optimistic spirit shined through just a month following the storm, when the Portsmouth Herald interviewed her for a story on the recovery from the storm. ''Nobody died,'' Arline said. ''We all have our health. That and the ice cream cone I have every day from the Village Scoop helps,'' she added with good humor. Arline displayed an entrepreneurial spirit, combined with a sense of humor, that allowed her to prevail following the devastation.

Unfortunately, the nightmare did not stop there for Arline. Just last month, Maine suffered, as did most of the east coast, a crippling storm, known to Mainers as the ''Patriots Day Storm.'' This time, however, Arline was prepared for the storm, with sandbags and new sump pumps. Because of the lessons learned—and her preparation—Arline sustained minimal damage from

a storm that caused major flooding in most parts of the country, and certainly across Maine.

While countless Maine businesses have overcome obstacles and succeeded, Arline's story sticks out as an outstanding example to all Maine business owners. Shortly after purchasing the Inn, Arline's father passed away. She rebounded from this personal tragedy, and from the disaster that beset her business, by utilizing the resources available to her, maintaining an optimistic spirit, and learning how to deal with disaster in the process. Arline's inspiring example shows all Maine business owners that they can persevere from any challenge that they face.

And so, I want to congratulate Arline Shea and the Inn at Long Sands for providing small businesses with a beacon to look forward to. She is truly a small business owner of whom we are all so proud. We wish her future success and offer her, and all of Maine's small businesses, our complete assistance. Maine, and indeed the nation, can benefit from Arline Shea's optimism, determination, and entrepreneurship.●

MESSAGES FROM THE PRESIDENT

Messages from the President of the United States were communicated to the Senate by Ms. Evans, one of his secretaries.

EXECUTIVE MESSAGES REFERRED

As in executive session the Presiding Officer laid before the Senate messages from the President of the United States submitting sundry nominations which were referred to the Committee on Armed Services.

(The nominations received today are printed at the end of the Senate proceedings.)

MESSAGE FROM THE PRESIDENT

The following message from the President of the United States was transmitted to the Senate by one of his secretaries:

REPORT ON THE CONTINUATION OF THE NATIONAL EMERGENCY WITH RESPECT TO THE BLOCKING OF PROPERTY OF CERTAIN PERSONS AND PROHIBITING THE EXPORTATION AND REEXPORTATION OF CERTAIN GOODS TO SYRIA AS DECLARED IN EXECUTIVE ORDER 13338 OF MAY 11, 2004—PM 12

The PRESIDING OFFICER laid before the Senate the following message from the President of the United States, together with an accompanying report; which was referred to the Committee on Banking, Housing, and Urban Affairs:

To the Congress of the United States:

Section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)) provides for the automatic termination of a national emergency unless, prior to the anniversary date of its declaration, the President publishes in the *Federal Register* and transmits to the Congress a notice stating that the emergency is to continue in effect beyond the anniversary date. In accordance with this provision, I have sent to the *Federal Register* for publication the enclosed notice, stating that the national emergency declared in Executive Order 13338 of May 11, 2004, and expanded in scope in Executive Order 13399 of April 25, 2006, authorizing the blocking of property of certain persons and prohibiting the exportation and reexportation of certain goods to Syria, is to continue in effect beyond May 11, 2007.

The actions of the Government of Syria in supporting terrorism, interfering in Lebanon, pursuing weapons of mass destruction and missile programs, and undermining United States and international efforts with respect to the stabilization and reconstruction of Iraq pose a continuing unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. For these reasons, I have determined that it is necessary to continue in effect the national emergency declared with respect to this threat and to maintain in force the sanctions I have ordered to address this national emergency.

GEORGE W. BUSH.

THE WHITE HOUSE, *May 8, 2007*.

MESSAGE FROM THE HOUSE

At 2:50 p.m., a message from the House of Representatives, delivered by Ms. Niland, one of its reading clerks, announced that the House has passed the following bills, in which it requests the concurrent of the Senate:

H.R. 1294. An act to extend Federal recognition to the Chickahominy Indian Tribe, the Chickahominy Indian Tribe-Eastern Division, the Upper Mattaponi Tribe, the Rappahannock Tribe, Inc., the Monacan Indian Nation, and the Nansemond Indian Tribe.

H.R. 1595. An act to implement the recommendations of the Guam War Claims Review Commission.

H.R. 2080. An act to amend the District of Columbia Home Rule Act to conform the District charter to revisions made by the Council of the District of Columbia relating to public education.

The message also announced that the House has agreed to the followmg concurrent resolutions, in which it requests the concurrence of the Senate:

H. Con. Res. 105. Concurrent resolution supporting the goals and ideals of a National Suffragists Day to promote awareness of the importance of the women suffragists who worked for the right of women to vote in the United States.

H. Con. Res. 117. Concurrent resolution commemorating the 400th Anniversary of the settlement of Jamestown.

MEASURES REFERRED

The following bills were read the first and the second times by unanimous consent, and referred as indicated:

H.R. 1025. An act to authorize the Secretary of the Interior to conduct a study to determine the feasibility of implementing a water supply and conservation project to improve water supply reliability, increase the capacity of water storage, and improve water management efficiency in the Republican River Basin between Harlan County Lake in Nebraska and Milford Lake in Kansas; to the Committee on Energy and Natural Resources.

H.R. 1294. An act to extend Federal recognition to the Chickahominy Indian Tribe, the Chickahominy Indian Tribe—Eastern Division, the Upper Mattaponi Tribe, the Rappahannock Tribe, Inc., the Monacan Indian Nation, and the Nansemond Indian Tribe; to the Committee on Indian Affairs.

H.R. 1595. An act to implement the recommendations of the Guam War Claims Review Commission; to the Committee on the Judiciary.

The following concurrent resolutions were read, and referred as indicated:

H. Con. Res. 105. Concurrent resolution supporting the goals and ideals of a National Suffragists Day to promote awareness of the importance of the women suffragists who worked for the right of women to vote in the United States; to the Committee on the Judiciary.

H. Con. Res. 117. Concurrent resolution commemorating the 400th Anniversary of the settlement of Jamestown; to the Committee on the Judiciary.

MEASURES READ THE FIRST TIME

The following bills were read the first time:

H.R. 2080. An act to amend the District of Columbia Home Rule Act to conform the District charter to revisions made by the Council of the District of Columbia relating to public education.

S. 1348. A bill to provide for comprehensive immigration reform and for other purposes.

EXECUTIVE AND OTHER COMMUNICATIONS

The following communication was laid before the Senate, together with accompanying papers, reports, and documents, and was referred as indicated:

EC–1875. A communication from the Secretary of Commerce, transmitting, the report of a draft bill that would reauthorize the Hydrographic Services Improvement Act of 1998; to the Committee on Commerce, Science, and Transportation.

PETITIONS AND MEMORIALS

The following petitions and memorials were laid before the Senate and were referred or ordered to lie on the table as indicated:

POM–79. A resolution adopted by the Senate of the State of Pennsylvania urging Congress to provide equitable funding to the Department of Housing and Urban Development for the operation of quality affordable housing; to the Committee on Banking, Housing, and Urban Affairs.

SENATE RESOLUTION NO. 45

Whereas, Pennsylvania's public housing authorities are essential in the Commonwealth of Pennsylvania; and

Whereas, Pennsylvania is home to 90 public housing authorities serving an estimated 245,819 residents of the Commonwealth of Pennsylvania; and

Whereas, Pennsylvania's public housing authorities provide high-quality affordable housing to residents in the Commonwealth of Pennsylvania through the use of Fedeal programs; and

Whereas, Pennsylvania's public housing authorities have successfully assisted residents of the Commonwealth of Pennsylvania with Moving to Work programs and preapprenticeship training, resulting in greater self-sufficiency and a reduced burden on Commonwealth resources; and

Whereas, developments built by Pennsylvania's public housing authorities have in some instances increased the values of neighboring properties and communities in the Commonwealth of Pennsylvania by as much as 142%; and

Whereas, new funding guidelines developed by the United States Department of Housing and Urban Development may result in reduced funding for the Commonwealth of Pennsylvania, its public housing authorities and the Pennsylvanians who rely on these services; and

Whereas, Pennsylvania's public housing authorities are a major employer in the Commonwealth of Pennsylvania, and funding cuts from the United States Department of Housing and Urban Development may result in drastic layoffs and diminished services to the residents of public housing; therefore be it

Resolved, That the Senate of the Commonwealth of Pennsylvania recognize the importance of the quality services, support and housing provided by Pennsylvania's public housing authorities and respectfully urge the Congress to provide equitable funding to the United States Department of Housing and Urban Development for the operation of quality affordable housing; and be it further

Resolved, That copies of this resolution be transmitted to the presiding officers of each house of Congress and to each member of Congress from Pennsylvania.

POM-80. A resolution adopted by the Senate of the State of Michigan urging Congress to enact legislation to increase protections for the Great Lakes from Asian carp; to the Committee on Environment and Public Works.

SENATE RESOLUTION NO. 15

Whereas, two species of Asian carp, not native to the United States, are on the verge of invading the Great Lakes. Silver carp and bighead carp escaped from confinement at southern fish farms in past decades and have migrated up the Mississippi and the Illinois River to within less than 100 miles of the Great Lakes; and

Whereas, Asian carp could become a dominant species in the Great Lakes, threatening the $4.5 billion Great Lakes commercial and recreational fishery and recreational boaters. Asian carp are voracious feeders that compete with native fish and wildlife for food. In addition, silver carp can weigh up to 70 pounds and jump up to 10 feet out of the water when disturbed by boats. Boaters have suffered cuts, blackened eyes, broken bones, back injuries, and concussions from leaping silver carp; and

Whereas, the only thing preventing the movement of Asian carp into the Great Lakes is a temporary electrical barrier in the Chicago Sanitary and Ship Canal operated by the United States Army Corps of Engineers. A permanent electrical barrier is also under construction to replace the temporary barrier; and

Whereas, to date, over $12 million has been spent on construction and operation of the electrical barriers. To help match federal funding, the state of Michigan has contributed nearly $70,000 toward the completion of the permanent electrical barrier; and

Whereas, current funding is insufficient to complete construction of the permanent barrier and only finances operation of the temporary barrier through the first half of fiscal year 2007. In addition, there is no funding to renovate the temporary barrier as a permanent backup to the new barrier; and

Whereas, there are provisions in several measures before the Congress that would provide funds to upgrade the current barrier and complete construction of the permanent barrier. Bills with this language include the Great Lakes Asian Carp Barrier Act (H.R. 553 and S. 336), the Water Resources Development Act of 2007 (H.R. 1495), the National Aquatic Invasive Species Act of 2007 (S. 725), and the Great Lakes Collaboration Implementation Act (H.R. 1350). It is of the utmost importance that Congress protect the Great Lakes by providing the funding and authority for the ongoing operation and maintenance of the barriers, compensate states for their contributions to the project, and provide for research into controlling Asian carp and other exotic species; now, therefore, be it

Resolved by the Senate, That we memorialize the United States Congress to enact legislation to increase protections for the Great Lakes from Asian carp; and be it further

Resolved, That copies of this resolution be transmitted to the President of the United States Senate, the Speaker of the United States House of Representatives, and the members of the Michigan congressional delegation.

POM–81. A resolution adopted by the Senate of the State of Hawaii urging Congress to propose amendments to the No Child Left Behind Act of 2001; to the Committee on Health, Education, Labor, and Pensions.

SENATE RESOLUTION NO. 33

Whereas, the United States Congress must decide in 2007 whether to reauthorize the No Child Left Behind Act of 2001 or let it die and replace it with a new law; and

Whereas, the No Child Left Behind Act, unprecedented in the history of federal and state roles in public education by the mandated imposition of a federally prescribed, single accountability model for all public schools, undermines the established constitutional role of state and local public education governance; and

Whereas, the No Child Left Behind Act, while purporting to create an accountability system for public schools, has in reality, been an enormous financial and programmatic burden on schools and taxpayers; and

Whereas, even if states and schools are satisfied with their educational programs and outcomes, they are forced to participate in this top-down system in order to continue to receive federal funds for education, such as Title I funds; and

Whereas, the No Child Left Behind Act mandates consequences to schools if just one of thirty seven possible adequate yearly progress calculation outcomes are not met, and makes no distinction in the consequences imposed on schools that did not meet one or did not meet all thirty seven, resulting in dilution of energy, time, and money by mandating the treatment of all such schools to include identical sanctions; and

Whereas, the No Child Left Behind Act employs a view of motivation that is misguided and objectionable, using threats, punishments, and pernicious comparisons to ''motivate'' teachers, students, and schools; and

Whereas, private K–12 schools have chosen not to spend their time or money adopting key elements of the No Child Left Behind Act's intensive testing and accountability regimen; and

Whereas, the No Child Left Behind Act's narrow focus on the ''basics'' has discouraged the implementation of best practices and cutting edge educational research in order to achieve higher test scores; and

Whereas, the No Child Left Behind Act has driven many schools and school systems into a narrowing of curriculum, often focused on only tested subjects, to the detriment of subjects and rich educational experiences, such as the arts; and

Whereas, the goal of achieving one hundred percent proficiency, including special education students, is unrealistic, and the pursuit of which channels millions of dollars into tactically targeted programs that divert limited resources from other critical school programs, professional training, as well as the educational and physical environment of schools; and

Whereas, the requirements of the No Child Left Behind Act penalize schools who enroll students who have inherent educational deficiencies and who, as a group, will continue to remain below ever increasing No Child Left Behind ''annual measurable objectives''; and

Whereas, while there has recently been some interest in the development of so-called ''growth models'' to recognize the contributions of a school to individual students over time, the lack of adequate funding and the prohibition against states developing their own growth models has rendered this initiative almost meaningless; and

Whereas, the No Child Left Behind Act does not provide additional funds for teacher education or training if a school is in ''status'' or under restructuring, which creates a punitive environment with little commitment on the part of the federal government for improving teaching and learning, or for supporting increased school success; and

Whereas, Adequate Yearly Progress does not take into account a school's adoption of meaningful educational innovation or judicious use of research; and

Whereas, the No Child Left Behind Act has channeled countless dollars into high-stake testing, which has largely benefited national private testing companies, but at the expense of ignoring genuine student accomplishments; and

Whereas, the No Child Left Behind Act appears biased towards a one size fits all multiple choice testing system, and tends to ignore other means of engaging and assessing students such as project-based, hands-on, or problem-solving demonstrations of competency; and

Whereas, the United States Department of Education has shown little or no interest in creating incentives among colleges and universities to incorporate innovative portfolios or project-based competencies into their admissions decisions, thus reinforcing the use of high-stake, multiple-choice private contractors; now, therefore, be it

Resolved by the Senate of the Twenty-fourth Legislature of the State of Hawaii, Regular Session of 2007, That the United States Congress is strongly urged to propose specific amendments to, or recommend the repeal of, the federal No Child Left Behind Act of 2001; and be it further

Resolved, that among the issues and amendments the United States Congress should address are the following:

(1) Improving teacher quality, preparation, and training by:

(A) Building support for a comprehensive incentive program to recruit, place, and retain experienced, well-qualified teachers in high-need schools (e.g., high poverty, or geographically isolated communities);

(B) Providing significant support for teacher education, professional development, in-service training, and career opportunities;

(C) Improving the occupational status and compensation of teaching as a career;

(D) Improving qualifications of teacher candidates at colleges of education;

(E) Providing financial incentives for institutions of higher learning to incorporate portfolios and demonstrations of competency into their admissions decisions;

(F) Strengthening teacher education preparation programs in areas such as science, mathematics, technology, measurement, data analysis, and evaluation;

(G) Recognizing teachers having achieved certification by the National Board for Professional Teaching Standards as ''highly qualified'' in their respective fields; and

(H) Providing flexibility in recognizing certified secondary level special education teachers as qualified teachers in their own right, and removing the unrealistic expectation that such teachers be additionally certified in every single core subject area;

(2) Improving assessment measures and systems by:

(A) Refining student assessment instruments designed specifically for use in improving instruction as well as school accountability;

(B) Encouraging states and school districts to utilize a wider range of useful assessments, including project-based competency and portfolios;

(C) Developing more appropriate means of assessing the academic progress of English Language Learners, special education students, and those with behavioral health issues; and

(D) Supporting the development and implementation of comprehensive statewide data collection and exchange systems that allow for more efficient support for student record keeping and informed educational policy decision making (e.g., electronic student transcript systems, and longitudinal analyses of growth in academic achievement);

(3) Improving accountability models, indicators of performance, and consequences by:

(A) Supporting states and the educational research community in research and development efforts to further the pioneering work required in refining the technology underlying growth (toward standards) analysis models;

(B) Permitting each state to adopt and pilot its own growth model to calculate adequate yearly progress under the No Child Left Behind Act to take advantage of inherent benefits that motivate students at all levels of proficiency;

(C) Supporting wholesale changes to the ''adequate yearly progress'' model for educational accountability that would prov1de for a fairer and more balanced appraisal of school performance and quality;

(D) Replacing punitive, conjunctive ''miss one, miss all'' criteria;

(E) Expanding accountability indicators to reflect performance on standards in other important disciplines and countering unintended consequences such as a narrowing of curriculum;

(F) Allowing for current limitations in reliable and valid assessments of students within a wide range of disability classifications; and

(G) Allowing for deferrals to test new immigrant students with limited English proficiency for up to three years of entering the country;

(4) Augmenting resources to assist states in efforts to accomplish challenging educational initiatives by:

(A) Requiring schools to maintain a broad and comprehensive curriculum to support adopted content and performance standards, including the arts and physical education;

(B) Fully funding special education programs, as once promised;

(C) Providing adequate funding to research and develop multiple and more valid means of assessing student competence, skills and knowledge for use in both improvement and educational accountability; and

(D) Providing funding and training support for data and technology infrastructure requirements;

(5) Supporting innovation, capacity building, and flexibility to address state and local education needs by:

(A) Recognizing schools that demonstrate successful strategies using innovative curriculum and methodologies;

(B) Developing new initiatives for school facilities that do not push educational funding toward ever larger schools and economy-of-scale construction mentality;

(C) Avoiding simplistic ''one size fits all'' solutions for assessment, accountability, and intervention;

(D) Addressing unique needs of ''high-need'' schools (e.g., high poverty, high immigration, extreme geographic isolation); and

(E) Allowing states to determine which and how many grade levels are best to test; and

(6) Returning to the original intent and purpose of the Elementary and Secondary Education Act (ESEA) by:

(A) Restoring the foundational precepts of ESEA and its focus on equity in educational attainment despite disadvantages stemming from socio-economic background;

(B) Allowing states to ''opt out'' of requirements that impact schools that do not receive ESEA entitlements, without loss of federal funds;

(C) Promoting strategies that directly reduce achievement gaps through better instruction, such as incentives for experienced, well-qualified teachers to accept positions in high-need schools and for reducing class size;

(D) Resolving to build the best public education system and teacher work force in the world, rather than promoting lofty rhetoric and ploys that undermine and divert public funds to private schools; and

(E) Returning policy setting and curriculum and teaching decision making control back to states, school districts and local communities; and be it further

Resolved, That certified copies of this Resolution be transmitted to the President of the United States, the Vice President of the United States, the President pro tempore of the United States Senate, the Speaker of the United States House of Representatives, and the members of Hawaii's Congressional delegation.

POM–82. A joint resolution adopted by the Legislature of the State of Washington urging Congress to raise the authorized funding levels of the No Child Left Behind Act to cover the costs that states and districts will incur to carry out its recommendations; to the Committee on Health, Education, Labor, and Pensions.

SUBSTITUTE SENATE JOINT MEMORIAL 8011

Whereas, Washington State supports, believes in, and has been diligently working on the attainment of the goals of the No Child Left Behind legislation, all students achieving at high levels; and

Whereas, the state welcomes the additional support No Child Left Behind has brought to focus on quality education, the improvements needed to reach all children, and the urgency nationwide to close achievement gaps; and

Whereas, the state supports a fair, feasible, and creditable accountability system; and;

Whereas, Washington State has attached approval and is in compliance with the requirements provided in the regulations; and

Whereas, the reauthorization of the No Child Left Behind legislation will provide the opportunity for essential changes to be made to reach the goals and purposes of the law; and

Whereras, students with limited English proficiency are in a program because they cannot speak, read, or write English and they must be provided appropriate and valid measures for accountability that are not included in the overall accountability until such students develop English academic language proficiency, for a period of not more than three years; and

Whereas, students with disabilities need appropriate assessments that meet the requirements of the Individuals with Disabilities Education Act (IDEA), are aligned with their individual educational plans, and tested according to students' ability and not limited to their grade level; and

Whereas, all students, all schools, and all districts do not improve on a uniform basis across any state as required by the state uniform bar, so the state uniform bar should be replaced with realistic requirements for continuous growth and improvement based on required yearly percentage increases in performance at the school, district, and state levels, which would provide fairness to accountability and an increased motivation for very low and very high performing schools; and

Whereas, the Act imposes a significant testing burden on states, schools, and districts and unless appropriate federal funding is provided for administering and scoring quality large scale assessments in the new grade levels required, states should be allowed to continue to assess students annually in selected grades in elementary schools, middle schools, and high schools and even if funding is provided for these assessments in the new grade levels, states should be able to use that funding to assess students in a variety of ways that would inform improvements in instruction but would not have to meet the extensive technical standards now required; and

Whereas, the adequate yearly progress provisions are overly prescriptive and rigid, and they identify too many schools ''in need of improvement'' by creating too many ways to fail, which reduces the opportunities and funding to assist schools that truly are in need of improvement; and

Whereas, the Act requires all teachers to be highly qualified regardless of state systems of certification and licensure in place, states must continue to have authority to use flexibility in meeting these requirements so that the educational needs of the students and the diverse conditions in the state are met; and

Whereas, career and technical education teachers are often hired from industries in which a bachelor's degree is not the preferred level of certification; and

Whereas, the Washington State Legislature passed legislation in 2006 that recognizes credit for core academic subjects learned through career and technical education, but if the teacher does not have a bachelor's degree the school district must report them to parents as ''not highly qualified,'' which places these teachers at a disadvantage in school districts; and

Whereas, positive changes in the definition of highly qualified teachers will assist in the awarding of equivalency credits and remove the stigma surrounding industry-certified teachers; and

Whereas, providers of supplemental services instruct students and are funded with federal funds, therefore these providers must meet the same safety and qualification standards required of public school educators; and

Whereas, supplemental services are most appropriately provided by public schools,

public school educators should be allowed to offer supplemental services to qualifying students; and

Whereas, the Act imposes significant costs on the state and local school districts, teachers, and paraprofessionals; and

Whereas, these costs include the administration of newly required assessments, and the costs of staff development, certification upgrades, and coursework; now, therefore, your Memorialists respectfully request that the President and Congress of the United States work together with state legislatures and the United States Department of Education to raise authorized funding levels of the No Child Left Behind Act to cover the costs that states and districts will incur to carry out these recommendations, and fully fund the law at those levels without reducing expenditures for other education programs and to improve language in the Act and regulations concerning its implementation, to make improvements to address the issues raised in this Memorial, and to grant the time, flexibility, and changes that will ensure successful nationwide implementation of the No Child Left Behind Act; be it

Resolved, That copies of this Memorial be immediately transmitted to the Honorable George W. Bush, President of the United States, the President of the United States Senate, the Speaker of the House of Representatives, each member of Congress from the State of Washington, and the Governor of the State of Washington.

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 Mrs. LINCOLN (for herself, Ms. COLLINS, Mr. KOHL, Mr. KERRY, Ms. MIKULSKI, Mrs. CLINTON, Mrs. BOXER, and Mr. CASEY):

S. 1340. A bill to amend title XVIII of the Social Security Act to provide Medicare beneficiaries with access to geriatric assessments and chronic care coordination services, and for other purposes; to the Committee on Finance.

By Mr. KYL (for himself and Mr. MCCAIN):

S. 1341. A bill to provide for the exchange of certain Bureau of Land Management land in Pima County, Arizona, and for other purposes; to the Committee on Energy and Natural Resources.

By Mr. HARKIN:

S. 1342. A bill to improve the health of Americans and reduce health care costs by reorienting the Nation's health care system toward prevention, wellness, and self care; to the Committee on Finance.

By Mrs. CLINTON (for herself and Ms. COLLINS):

S. 1343. A bill to amend the Public Health Service Act with respect to prevention and treatment of diabetes, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

By Mrs. MURRAY:

S. 1344. A bill to designate the Department of Veterans Affairs outpatient clinic in Wenatchee, Washington, as the Elwood ''Bud'' Link Department of Veterans Affairs Outpatient Clinic; to the Committee on Veterans' Affairs.

By Mr. AKAKA (for himself, Mr. LIEBERMAN, Ms. COLLINS, Mr. LEVIN, Mr. LEAHY, Mr. FEINGOLD, and Mrs. CLINTON):

S. 1345. A bill to affirm that Federal employees are protected from discrimination on the basis of sexual orientation and to repudiate any assertion to the contrary; to the Committee on Homeland Security and Governmental Affairs.

By Ms. MIKULSKI (for herself, Mr. CARDIN, Mr. WARNER, Mr. BIDEN, Mr. ROCKEFELLER, Mr. CARPER, and Mr. WEBB):

S. 1346. A bill to amend conservation and biofuels programs of the Department of Agriculture to promote the compatible goals of economically viable agricultural production and reducing nutrient loads in the Chesapeake Bay and its tributaries by assisting agricultural producers to make beneficial, cost-effective changes to cropping systems, grazing management, and nutrient management associated with livestock and poultry production, crop production, bioenergy production, and other agricultural practices on agricultural land within the Chesapeake Bay watershed, and for other purposes; to the Committee on Agriculture, Nutrition, and Forestry.

By Mrs. FEINSTEIN:

S. 1347. A bill to amend the Omnibus Indian Advancement Act to modify the date as of which certain tribal land of the Lytton Rancheria of California is deemed to be held in trust and to provide for the conduct of certain activities on the land; to the Committee on Indian Affairs.

By Mr. REID (for himself, Mr. LEAHY, Mr. KENNEDY, Mr. MENENDEZ, and Mr. SALAZAR):

S. 1348. A bill to provide for comprehensive immigration reform and for other purposes; read the first time.

By Mr. DURBIN (for himself, Mr. WARNER, Mrs. MURRAY, Mr. OBAMA, Mr. GRAHAM, Mr. WEBB, and Ms. CANTWELL):

S. 1349. A bill to ensure that the Department of Defense and the Department of Veterans Affairs provide to members of the Armed Forces and veterans with traumatic brain injury the services that best meet their individual needs, and for other purposes; to the Committee on Armed Services.

ADDITIONAL COSPONSORS

S. 22

At the request of Mr. WEBB, the name of the Senator from Ohio (Mr. BROWN) was added as a cosponsor of S. 22, a bill to amend title 38, United States Code, to establish a program of educational assistance for members of the Armed Forces who serve in the Armed Forces after September 11, 2001, and for other purposes.

S. 185

At the request of Mr. SPECTER, the name of the Senator from Rhode Island (Mr. WHITEHOUSE) was added as a cosponsor of S. 185, a bill to restore habeas corpus for those detained by the United States.

S. 261

At the request of Ms. CANTWELL, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of S. 261, a bill to amend title 18, United States Code, to strengthen prohibitions against animal fighting, and for other purposes.

S. 309

At the request of Mr. SANDERS, the name of the Senator from Illinois (Mr. DURBIN) was added as a cosponsor of S. 309, a bill to amend the Clean Air Act to reduce emissions of carbon dioxide, and for other purposes.

S. 326

At the request of Mrs. LINCOLN, the names of the Senator from South Dakota (Mr. JOHNSON) and the Senator from Missouri (Mrs. MCCASKILL) were added as cosponsors of S. 326, a bill to amend the Internal Revenue Code of 1986 to provide a special period of limitation when uniformed services retirement pay is reduced as result of award of disability compensation.

S. 430

At the request of Mr. LEAHY, the name of the Senator from Missouri (Mrs. MCCASKILL) was added as a cosponsor of S. 430, a bill to amend title 10, United States Code, to enhance the national defense through empowerment of the Chief of the National Guard Bureau and the enhancement of the functions of the National Guard Bureau, and for other purposes.

S. 439

At the request of Mr. REID, the name of the Senator from Missouri (Mrs. MCCASKILL) was added as a cosponsor of S. 439, a bill to amend title 10, United States Code, to permit certain retired members of the uniformed services who have a service-connected disability to receive both disability compensation from the Department of Veterans Affairs for their disability and either retired pay by reason of their years of military service or Combat-Related Special Compensation.

S. 600

At the request of Mr. SMITH, the name of the Senator from California (Mrs. BOXER) was added as a cosponsor of S. 600, a bill to amend the Public Health Service Act to establish the School-Based Health Clinic program, and for other purposes.

S. 602

At the request of Mr. PRYOR, the name of the Senator from North Dakota (Mr. DORGAN) was added as a cosponsor of S. 602, a bill to develop the next generation of parental control technology.

S. 604

At the request of Mr. LAUTENBERG, the name of the Senator from Missouri (Mrs. MCCASKILL) was added as a cosponsor 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. 625

At the request of Mr. TESTER, his name was added as a cosponsor of S. 625, a bill to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products.

At the request of Mr. CORNYN, the name of the Senator from Pennsylvania (Mr. SPECTER) was added as a cosponsor of S. 625, supra.

S. 644

At the request of Mrs. LINCOLN, the name of the Senator from Missouri

(Mrs. MCCASKILL) was added as a cosponsor of S. 644, a bill to amend title 38, United States Code, to recodify as part of that title certain educational assistance programs for members of the reserve components of the Armed Forces, to improve such programs, and for other purposes.

S. 648

At the request of Mr. CHAMBLISS, the name of the Senator from Missouri (Mrs. MCCASKILL) was added as a cosponsor of S. 648, a bill to amend title 10, United States Code, to reduce the eligibility age for receipt of non-regular military service retired pay for members of the Ready Reserve in active federal status or on active duty for significant periods.

S. 691

At the request of Mr. CONRAD, the names of the Senator from South Dakota (Mr. JOHNSON) and the Senator from Maryland (Mr. CARDIN) were added as cosponsors 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. 755

At the request of Mr. SCHUMER, the name of the Senator from Rhode Island (Mr. WHITEHOUSE) 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. 790

At the request of Mr. LUGAR, the name of the Senator from Vermont (Mr. SANDERS) was added as a cosponsor of S. 790, a bill to amend the Richard B. Russell National School Lunch Act to permit the simplified summer food programs to be carried out in all States and by all service institutions.

S. 805

At the request of Mr. DURBIN, the name of the Senator from Illinois (Mr. OBAMA) 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. 829

At the request of Ms. MIKULSKI, the name of the Senator from Ohio (Mr. BROWN) was added as a cosponsor of S. 829, a bill to reauthorize the HOPE VI program for revitalization of severely distressed public housing, and for other purposes.

S. 831

At the request of Mr. DURBIN, the name of the Senator from New York (Mrs. CLINTON) 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. 878

At the request of Mr. KOHL, the name of the Senator from Connecticut (Mr. LIEBERMAN) was added as a cosponsor of S. 878, a bill to prevent anti-competitive mergers and acquisitions in the oil and gas industry.

S. 879

At the request of Mr. KOHL, the name of the Senator from Connecticut (Mr. LIEBERMAN) was added as a cosponsor of S. 879, a bill to amend the Sherman Act to make oil-producing and exporting cartels illegal.

S. 961

At the request of Mr. NELSON of Nebraska, the names of the Senator from Mississippi (Mr. LOTT) and the Senator from Missouri (Mrs. MCCASKILL) were added as cosponsors of S. 961, a bill to amend title 46, United States Code, to provide benefits to certain individuals who served in the United States merchant marine (including the Army Transport Service and the Naval Transport Service) during World War II, and for other purposes.

S. 969

At the request of Mr. DODD, the name of the Senator from Washington (Mrs. MURRAY) was added as a cosponsor of S. 969, a bill to amend the National Labor Relations Act to modify the definition of supervisor.

S. 1060

At the request of Mr. BIDEN, the name of the Senator from New York (Mr. SCHUMER) was added as a cosponsor of S. 1060, a bill to reauthorize the grant program for reentry of offenders into the community in the Omnibus Crime Control and Safe Streets Act of 1968, to improve reentry planning and implementation, and for other purposes.

S. 1087

At the request of Mr. HARKIN, the name of the Senator from Pennsylvania (Mr. CASEY) was added as a cosponsor of S. 1087, a bill to amend the Fair Labor Standards Act of 1938 to prohibit discrimination in the payment of wages on account of sex, race, or national origin, and for other purposes.

S. 1146

At the request of Mr. SALAZAR, the name of the Senator from West Virginia (Mr. BYRD) was added as a cosponsor of S. 1146, a bill to amend title 38, United States Code, to improve health care for veterans who live in rural areas, and for other purposes.

S. 1164

At the request of Mr. CARDIN, the name of the Senator from Vermont (Mr. SANDERS) 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. 1229

At the request of Mrs. BOXER, the name of the Senator from California (Mrs. FEINSTEIN) was added as a cosponsor of S. 1229, a bill to amend the Agricultural Marketing Act of 1946 to provide for the application of mandatory minimum maturity standards applicable to all domestic and imported Hass avocados.

S. 1237

At the request of Mr. LAUTENBERG, the name of the Senator from Hawaii (Mr. AKAKA) 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. 1263

At the request of Ms. CANTWELL, the names of the Senator from Massachusetts (Mr. KENNEDY) and the Senator from New Jersey (Mr. LAUTENBERG) were added as cosponsors of S. 1263, a bill to protect the welfare of consumers by prohibiting price gouging with respect to gasoline and petroleum distillates during natural disasters and abnormal market disruptions, and for other purposes.

S. 1276

At the request of Mr. DURBIN, the name of the Senator from Missouri (Mrs. MCCASKILL) was added as a cosponsor of S. 1276, a bill to establish a grant program to facilitate the creation of methamphetamine precursor electronic logbook systems, and for other purposes.

S. 1308

At the request of Mr. DORGAN, the names of the Senator from Missouri (Mrs. MCCASKILL) and the Senator from Montana (Mr. TESTER) were added as cosponsors of S. 1308, a bill to prohibit the Secretary of Agriculture from allowing the importation of certain cattle and beef from Canada until the implementation of country of origin labeling requirements.

S. 1332

At the request of Mr. KENNEDY, the names of the Senator from Hawaii (Mr. AKAKA), the Senator from Ohio (Mr. BROWN), the Senator from New Mexico (Mr. BINGAMAN) and the Senator from Illinois (Mr. OBAMA) were added as cosponsors of S. 1332, a bill to amend the Public Health Service Act to revise and extend projects relating to children and violence to provide access to school-based comprehensive mental health programs.

S.J. RES. 4

At the request of Mr. BROWNBACK, the name of the Senator from Hawaii (Mr. AKAKA) was added as a cosponsor of S.J. Res. 4, a joint resolution to acknowledge a long history of official depredations and ill-conceived policies

by the United States Government regarding Indian tribes and offer an apology to all Native Peoples on behalf of the United States.

S. CON. RES. 26

At the request of Mrs. CLINTON, the name of the Senator from North Carolina (Mrs. DOLE) was added as a cosponsor of S. Con. Res. 26, a concurrent resolution recognizing the 75th anniversary of the Military Order of the Purple Heart and commending recipients of the Purple Heart for their courageous demonstrations of gallantry and heroism on behalf of the United States.

S. CON. RES. 27

At the request of Mrs. CLINTON, the name of the Senator from North Carolina (Mrs. DOLE) was added as a cosponsor of S. Con. Res. 27, a concurrent resolution supporting the goals and ideals of ''National Purple Heart Recognition Day''.

S. CON. RES. 29

At the request of Mr. NELSON of Florida, the names of the Senator from Michigan (Mr. LEVIN), the Senator from New Mexico (Mr. BINGAMAN), the Senator from New Jersey (Mr. MENENDEZ), the Senator from Massachusetts (Mr. KENNEDY), the Senator from Minnesota (Mr. COLEMAN), the Senator from Wisconsin (Mr. KOHL), the Senator from Illinois (Mr. DURBIN), the Senator from Washington (Ms. CANTWELL), the Senator from Connecticut (Mr. LIEBERMAN) and the Senator from Mississippi (Mr. COCHRAN) were added as cosponsors of S. Con. Res. 29, a concurrent resolution encouraging the recognition of the Negro Baseball Leagues and their players on May 20th of each year.

At the request of Mr. SALAZAR, his name was added as a cosponsor of S. Con. Res. 29, supra.

S. RES. 171

At the request of Ms. COLLINS, the names of the Senator from Missouri (Mrs. MCCASKILL) and the Senator from West Virginia (Mr. ROCKEFELLER) 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.

AMENDMENT NO. 998

At the request of Mr. GRASSLEY, the names of the Senator from Connecticut (Mr. DODD), the Senator from Maine (Ms. SNOWE) and the Senator from New Mexico (Mr. BINGAMAN) were added as cosponsors of amendment No. 998 proposed to S. 1082, an act 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.

AMENDMENT NO. 1039

At the request of Mr. GRASSLEY, the names of the Senator from Maryland (Ms. MIKULSKI), the Senator from Ohio (Mr. BROWN), the Senator from Maine (Ms. SNOWE) and the Senator from New Mexico (Mr. BINGAMAN) were added as cosponsors of amendment No. 1039 proposed to S. 1082, an act 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.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. KYL (for himself and Mr. MCCAIN):

S. 1341. A bill to provide for the exchange of certain Bureau of Land Management land in Pima County, Arizona, and for other purposes; to the Committee on Energy and Natural Resources.

Mr. KYL. Mr. President, today I am pleased to be joined by Senator MCCAIN to introduce the Las Cienegas Enhancement and Saguaro National Park Boundary Adjustment Act of 2007. This legislation directs a land exchange between the Bureau of Land Management, BLM, and the Las Cienegas Conservation, LLC in southeastern Arizona. A similar bill was introduced last year, and it passed the House of Representatives. Unfortunately, the Senate was unable to pass it before the session ended.

We can turn this disappointment into a success. The bill we introduce today adds to the exchange a highly sought after private parcel, the ''Bloom Property.'' The Bloom Property would be added to Saguaro National Park. State and local officials, conservationists, and other stakeholders have worked together to include the Bloom Property in this bill and to structure an exchange that is fair and in the public interest.

Let me explain the details of the exchange. The land to be transferred out of Federal ownership, approximately 1,280 acres, is referred to as the ''Sahuarita property.'' This property is BLM-managed land south of Tucson near Corona de Tucson. The land is low-lying Sonoran desert and has been identified for disposal by the BLM through its land-use planning process.

The private land to be brought into Federal ownership consists of two parcels. The first parcel is approximately 2,392 acres of land referred to as the ''Empirita-Simonson property.'' This property lies north of the Las Cienegas National Conservation Area managed by the BLM. The Empirita-Simonson property lies within the ''Sonoita Valley Acquisition Planning District'' established by Public Law 106–538, which designated the Las Cienegas National Conservation Area. The act directed the Department of the Interior to acquire lands from willing sellers within the planning district for inclusion within the conservation area. The idea was to further protect lands with important resource values for which the national conservation area was designated.

The second parcel, the Bloom Property, is approximately 160 acres of land that was identified for inclusion in the Saguaro National Park during a boundary study conducted by the National Park Service in 1993. In 1994, using the data from the study, Congress enacted legislation expanding the park and changed Saguaro's designation from monument to park. At that time, the Bloom Property did not have a willing seller. I am pleased to say circumstances have changed, and we are able to include it in this exchange. The Bloom Property, which lies just south of the Sweetwater Trail in Saguaro Park West, is a prime example of Sonoran desert important to maintain corridors for wildlife like the mountain lion.

Although this bill is centered on the land exchange I just described, it also accomplishes two other important objectives: addressing water withdrawals at Cienegas Creek and providing road access to a popular recreation destination, the Whetstone Mountains controlled by the Forest Service.

Let's talk about water. Arizonans understand that protecting our water supply is crucial to the State's future. For this reason, we continually seek ways to promote responsible use of our limited water supply. This bill promotes responsible use. There is a prior claim to a well site on the private land that will be exchanged. That prior claim would allow a developer to withdraw 1,600 acre-feet of water a year. Pima County and the community at large are concerned about the future of Cienegas Creek and the entire riparian area if these water withdrawals occur.

To address this concern, the land exchange is conditioned on Las Cienegas Conservation, LLC conveying the well site to Pima County and relinquishing those water rights it controls. The net result is a water savings of 1,050 acre-feet per year. This is a significant benefit to this riparian area.

Overall, this bill allows us to accomplish important environmental and conservation objectives while managing our development. It is a bill with broad support that includes Pima County, the city of Tucson, and many others. I urge my colleagues to work with me to approve this legislation at the earliest possible date.

By Mrs. CLINTON (for herself and Ms. COLLINS)

S. 1343. A bill to amend the Public Health Service Act with respect to prevention and treatment of diabetes, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

Mrs. CLINTON. Mr. President, today, Senator COLLINS and I will be introducing the Diabetes Treatment and Prevention Act, legislation to help our Federal, State and local governments address the growing epidemic of diabetes across our Nation.

According to the Centers for Disease Control and Prevention, CDC, the number of Americans with diagnosed diabetes has doubled over the past 15 years.

Over 20 million Americans are currently living with this disease, but 6 million of them have not yet been diagnosed. Another 54 million are classified as ''pre-diabetic,'' with a high risk of developing this condition. Diabetes accounts for over $92 billion in direct medical costs every year, and these numbers are only likely to increase.

Last year, the New York Times published an insightful series on diabetes that highlighted the obstacles faced by health care providers and institutions seeking to prevent complications from diabetes. The system will pay tens of thousands of dollars for amputations, but not a low-cost visit to the podiatrist that could have saved the foot. Hospitals struggle to provide preventive treatment and rehabilitation in the Byzantine system of reimbursements. The incentives inside our health care system are backwards, and the payment system is upside-down: too often paying for costly and debilitating treatment but not for low-cost prevention.

We know what works. The landmark Diabetes Prevention Program, a government funded clinical trial, found that moderate diet and exercise interventions helped to delay and prevent the onset of type 2 diabetes in persons at high risk for developing the condition. Indeed, the study was so successful that it was ended a year earlier than planned. Yet despite the success of this study, we still haven't found a way to implement these interventions in our communities.

The Diabetes Treatment and Prevention Act would provide additional support for the Federal, State and local programs that are working to fight this epidemic. Our legislation would codify the Division of Diabetes Translation at the Centers for Disease Control and Prevention, CDC, giving them definitive authority to carry out activities in diabetes surveillance, translational research, and education efforts. It would direct the CDC to continue its work in coordinating the National Diabetes Education Program, in conjunction with the National Institutes of Health, NIH, and would increase support for its diabetes control and prevention efforts at the State level.

This bill would also establish several demonstration projects. One would help to translate the interventions identified as effective by the Diabetes Prevention Program into clinical interventions that can be replicated at the State, local and provider level. Another would allow academic centers, in conjunction with state and local health departments, to examine ways to improve overall health outcomes in people living with diabetes and other co-occurring chronic conditions, such as heart disease, mental illness, or HIV. Finally, the bill would support efforts to increase surveillance and education at the State and local level.

The epidemic of diabetes has the potential to place great burdens on our health care system, but it doesn't have to. We can prevent diabetes, we can manage diabetes, and we can reduce the health care costs associated with care and treatment for this condition. The Diabetes Treatment and Prevention Act will help us take necessary steps to supporting our public health infrastructure in dealing with this crisis, and I would urge all of my colleagues to cosponsor this legislation.

By Mrs. MURRAY:

S. 1344. A bill to designate the Department of Veterans Affairs outpatient clinic in Wenatchee, Washington, as the Elwood ''Bud'' Link Department of Veterans Affairs Outpatient Clinic; to the Committee on Veterans' Affairs.

Mrs. MURRAY. Mr. President, I rise today to speak about legislation that my colleague from Washington, Congressman DOC HASTINGS, and I are introducing to name the soon-to-be-opened Community-Based Outpatient Clinic in Wenatchee, WA, after Elwood ''Bud'' Link. Bud provided both the inspiration and the energy necessary to make this project a reality, thereby fulfilling a longstanding and serious need for his community.

Bud, a World War II veteran and an active member of Veterans of Foreign Wars Post 10445, recognized the need for better, more accessible veteran medical services for those veterans living in north central Washington. Like countless others, Bud suffered from health problems attributed to his service in the Navy, where he bravely served aboard the USS *Tracy* escorting convoys throughout the South Pacific and protecting medical personnel after the deployment of the atomic bomb.

When Bud returned to the States, he, like so many other veterans, relied on the VA for health care. In order to receive the necessary treatment from the VA, however, Bud was forced to make a 3-hour drive in each direction to the VA medical center nearest to his home.

Realizing that this was the case for veterans all over his community, Bud, his wife of over 50 years, Helen, and his fellow VFW Post 10445 members, helped by the American Legion and other veteran service organizations, mobilized the community to work toward the creation of a new, more accessible outpatient veteran center.

I was proud to contribute to this effort. After several years of hard work, I stood with Congressman Doc Hastings at the Cashmere VFW hall on March 20, 2006 to announce the VA's final decision to create the Community-Based Outpatient Clinic in Wenatchee, WA.

Although Bud sadly passed away before this exciting announcement was made, the creation of this facility in Wenatchee represents the culmination of Bud and his fellow veterans' efforts to make veterans' medical care more accessible and, in turn, to hold the Federal Government accountable for fulfilling its promises to the veteran community.

Bud dedicated his time and energy to addressing this and other veteran needs as an advocate, a leader, and a concerned citizen. Due in large part to Bud's work, the new CBOC, set to serve six counties in north central Washington, is likely to make over 25,000 visits by veterans more accessible next year.

Bud's life of service and activism, coupled with this final victory, reaffirms a valuable lesson for all Americans: even a single citizen can see a problem and fix it.

Bud Link dedicated his time and energy to helping other veterans, and now that the clinic he fought for is going to open, we have a chance to honor his lifetime of service. My bill will ensure that Bud's efforts and good example will not be forgotten, but rather, that the new CBOC will carry on Bud's legacy.

I ask my colleagues to join me in honoring the work that Bud Link and his fellow veterans have done to make this new CBOC a reality.

By Mr. AKAKA (for himself, Mr. LIEBERMAN, Ms. COLLINS, Mr. LEVIN, Mr. LEAHY, Mr. FEINGOLD, and Mrs. CLINTON):

S. 1345. A bill to affirm that Federal employees are protected from discrimination on the basis of sexual orientation and to repudiate any assertion to the contrary; to the Committee on Homeland Security and Governmental Affairs.

Mr. AKAKA. Mr. President, as we celebrate Public Service Recognition Week and the dedication and professionalism of Federal employees, I rise today to introduce legislation to reassert protections for Federal employees and applicants for Federal employment against discrimination based on one's sexual orientation. The Clarification of Federal Employment Protection Act will spell out the protections that Federal employees currently have but have been denied by the Office of Special Counsel, OSC. I am pleased that Senators LIEBERMAN, COLLINS, LEVIN, LEAHY, FEINGOLD, and CLINTON are cosponsoring this important legislation and that Representative HENRY WAXMAN, CHAIRMAN OF THE HOUSE OVERSIGHT AND GOVERNMENT REFORM COMMITTEE, IS INTRODUCING A COMPANION BILL IN THE HOUSE.

When Congress passed the Civil Service Reform Act of 1978, it established a list of prohibited personnel practices, personnel actions that were clearly not in line with the Merit System Principles and were subject to prosecution by OSC. Examples include personnel actions, such as hiring, firing, and changes in pay, against employees based on a whistleblower disclosure, nepotism, or off-duty conduct.

The prohibition on personnel action based on off-duty conduct, found in section 2302(b)(10) of title 5, United States Code, has been interpreted for years to prohibit the taking of personnel actions against employees and applicants

for employment based on their sexual orientation. In 1980, Mr. Alan Campbell, Director of the Office of Personnel Management, OPM, at the time, wrote a memorandum to the heads of all executive branch agencies advising that, under 5 U.S.C. 2302(b)(10), employees and applicants were to be protected against inquiries into or actions based upon non job-related conduct, including religious or community affiliations, or sexual orientation. The position by OPM has been reaffirmed time and again, most recently by the current OPM Director, Linda Springer, in her responses to questions posed by the Homeland Security and Governmental Affairs Committee in relation to her nomination for the position. In fact, to this day, OPM's website contains a guide to Federal employee rights which states that section 2302(b)(10) has been interpreted by OPM to prohibit discrimination based upon sexual orientation.

OPM is not alone in this interpretation. The previous Special Counsel also interpreted 2302(b)(10) to protect against discrimination based on an individual's sexual orientation. For example, in 2003, OSC secured corrective and disciplinary action against a Federal supervisor who discriminated against Federal job applicant because he was gay in violation of section 2302(b)(10). In 2004, following the debate spurred by OSC over the interpretation of this provision, White House spokesman Trent Duffy said the president ''believes that no Federal employee should be subject to unlawful discrimination, and Federal agencies will fully enforce the law against discrimination, including discrimination based on sexual orientation.''

Upon the nomination of Scott Bloch to be the new Special Counsel, I asked the nominee about his interpretation of the laws protecting Federal employees and applicants against sexual orientation discrimination. When asked if he would support the interpretation of 2302(b)(10) by OPM and OSC, he said that he would not fail to enforce a claim of sexual orientation discrimination before OSC that shows through the evidence that the statute has been violated.

Nonetheless, after being in office for only a few months, Special Counsel Bloch conducted a review of the discrimination statute and claimed that section 2302(b)(10) only provides protection against discrimination based on conduct, including sexual conduct, but not one's sexual orientation. Instead, Mr. Bloch claims that for discrimination based on status, referring to sexual orientation, it would have to be listed under section 2302(b)(1), which protects employees from discrimination based on race, gender, religion, or marital status. This departure from the long-standing interpretation of (b)(10) by OSC and OPM is illogical. When a supervisor who dislikes gays or lesbians refuses to hire an applicant who the supervisor believes is gay or lesbian, it follows that the supervisor is basing the personnel action on disapproval of the applicant's presumed sexual conduct. In other words, in the context of sexual orientation discrimination, status implies conduct.

I believe that Congress must act to guarantee the protections it has provided to Federal employees and applicants for Federal employment. We cannot allow one administration official's opinion to undermine the merit system or the rights and protections Federal workers. The legislation I am introducing today would affirm that sexual orientation is protected by section 2302(b)(10) but also make it a clear protected status under section (b)(1). 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. 1345

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 ''Clarification of Federal Employment Protections Act''.

SEC. 2. DISCRIMINATION ON THE BASIS OF SEXUAL ORIENTATION PROHIBITED.

(a) REPUDIATION.—In order to dispel any public confusion, Congress repudiates any assertion that Federal employees are not protected from discrimination on the basis of sexual orientation.

(b) AFFIRMATION.—It is the sense of Congress that, in the absence of the amendment made by subsection (c), discrimination against Federal employees and applicants for Federal employment on the basis of sexual orientation is prohibited by section 2302(b)(10) of title 5, United States Code.

(c) AMENDMENT.—Section 2302(b)(1) of title 5, United States Code, is amended—

(1) by striking ''or'' at the end of subparagraph (D);

(2) by inserting ''or'' at the end of subparagraph (E); and

(3) by adding at the end the following:

''(F) on the basis of sexual orientation.''.

By Mrs. FEINSTEIN:

S. 1347. A bill to amend the Omnibus Indian Advancement Act to modify the date as of which certain tribal land of the Lytton Rancheria of California is deemed to be held in trust and to provide for the conduct of certain activities on the land; to the Committee on Indian Affairs.

Mrs. FEINSTEIN. Mr. President, I rise today to introduce the Lytton Gaming Oversight Act of 2007, a bill seeking to ensure that Native American tribes follow the regular process under Federal law prior to establishing and operating gaming facilities.

I believe this approach provides a good step forward as it has the support of both the local community and the Lytton tribe.

I am pleased to have worked closely with representatives of the local community, such as California Assemblymember Loni Hancock, D-Berkeley, as well as my colleague Senator SPECTER in crafting this piece of legislation.

I introduced similar legislation in the 108th and 109th Congresses, but these bills would have effectively required closure of the casino operations, until a point when and if the Lytton successfully completed the two-part determination process.

This legislation, however, stalled. The legislation introduced today breaks that stalemate and seeks to prevent a massive expansion of gaming in the Bay Area.

The bill requires that the Lytton Band of Pomo Indians follow critical oversight guidelines laid out in Section 20 of the Indian Gaming Regulatory Act, IGRA, before engaging in Class III gaming.

This legislation would amend language inserted into the Omnibus Indian Advancement Act of 2000.

That language mandated that the Secretary of Interior take a card club and adjacent parking lot in the San Francisco Bay Area into trust for the Lytton tribe as their reservation and backdate the acquisition to October 17, 1988, or pre-IGRA.

This backdating was done expressly with the goal of allowing the Lytton tribe to circumvent IGRA's ''two-part determination'' process, an important step that requires both Secretarial and Gubernatorial approval, in addition to consultation with nearby tribes and the local community and its representatives.

The legislation that I have introduced would simply return the Lytton tribe to the same status as all other tribes seeking to pursue Class III, or Nevada-style gaming, on lands acquired after the passage of IGRA in 1988.

It would allow the tribe to continue operating its Class II gaming facility provided it follows all IGRA regulations regarding gaming on newly acquired lands going forward.

Finally, it would also preclude any expansion of the facility used by the Lytton for Class II gaming.

I would like to emphasize what the bill would not do. It would not: Remove the tribe's recognition status; Alter the trust status of the new reservation; or take away the tribe's ability to conduct gaming through the normal IGRA process.

This legislation was solely crafted to restore IGRA's rightful oversight of the gaming process, just as Congress intended.

Section 20 of the Indian Gaming Regulatory Act provides clear guidelines for addressing the issue of gaming on so-called ''newly-acquired'' lands, or lands that have been taken into trust since the enactment of IGRA in 1988.

Most importantly, in my opinion, IGRA's ''two-part determination'' process provides for both Federal and State approval, while protecting the rights of nearby tribes and local communities.

Circumventing this process creates a variety of serious and critical multi-jurisdictional issues, issues which can negatively affect the lives of ordinary citizens and deprive local and tribal governments of their ability to effectively represent their communities.

Without passage of this bill, the Lytton could take the former card club and the adjacent parking lot that is now their reservation and turn it into a large gambling complex outside the regulations set up by the Indian Gaming Regulatory Act. In fact, this is exactly what was proposed in the summer of 2004.

While the tribe announced that it was dropping its pursuit of a sizable casino, it could reverse these plans at any time and proceed with Class III gaming without first going through the regular process.

Allowing this to happen would set a dangerous precedent not only for California, but every State where tribal gaming is permitted.

I do not think it is asking too much to require that the Lytton be subject to the regulatory and approval processes applicable to all other tribes by the Indian Gaming Regulatory Act.

This bill would do just that.

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. 1347

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. LYTTON RANCHERIA OF CALIFORNIA.

Section 819 of the Omnibus Indian Advancement Act (Public Law 106–568; 114 Stat. 2919) is amended—

(1) in the first sentence, by striking ''Notwithstanding'' and inserting the following:

''(a) ACCEPTANCE OF LAND.—Notwithstanding'';

(2) in the second sentence, by striking ''The Secretary'' and inserting the following:

''(b) DECLARATION.—The Secretary''; and

(3) by striking the third sentence and inserting the following:

''(c) TREATMENT OF LAND FOR PURPOSES OF CLASS II GAMING.—

''(1) IN GENERAL.—Subject to paragraph (2), notwithstanding any other provision of law, the Lytton Rancheria of California may conduct activities for class II gaming (as defined in section 4 of the Indian Gaming Regulatory Act (25 U.S.C. 2703)) on the land taken into trust under this section.

''(2) REQUIREMENT.—The Lytton Rancheria of California shall not expand the exterior physical measurements of any facility on the Lytton Rancheria in use for class II gaming activities on the date of enactment of this paragraph.

''(d) TREATMENT OF LAND FOR PURPOSES OF CLASS III GAMING.—Notwithstanding subsection (a), for purposes of class III gaming (as defined in section 4 of the Indian Gaming Regulatory Act (25 U.S.C. 2703)), the land taken into trust under this section shall be treated, for purposes of section 20 of the Indian Gaming Regulatory Act (25 U.S.C. 2719), as if the land was acquired on October 9, 2003, the date on which the Secretary took the land into trust.''.

By Mr. DURBIN (for himself, Mr. WARNER, Mrs. MURRAY, Mr. OBAMA, Mr. GRAHAM, Mr. WEBB, and Ms. CANTWELL):

S. 1349. A bill to ensure that the Department of Defense and the Department of Veterans Affairs provide to members of the Armed Forces and veterans with traumatic brain injury the services that best meet their individual needs, and for other purposes; to the Committee on Armed Services.

Mr. DURBIN. Mr. President, traumatic brain injury is the signature injury of the Iraq war. The widespread use of Improvised Explosive Devices, IEDs, has taken a terrible toll. Even those who have walked off the battlefield without visible scars often find they have suffered the internal trauma of a traumatic brain injury.

Today, I am introducing legislation, along with Senators WARNER, MURRAY, GRAHAM, OBAMA, WEBB, and CANTWELL, to create a Traumatic Brain Injury Program, operated jointly by the Department of Defense and the Department of Veterans Affairs, to ensure that those servicemembers who suffer a brain injury receive all the services they need. The legislation establishes a standard of care for each individual found to have suffered a brain injury, improves the coordination of care, strengthen the rights of brain injury patients, and expands brain injury research in the Departments of Defense and Veterans Affairs.

This legislation will reduce the number of our wounded soldiers who fall through the cracks and are left to fend for themselves as they struggle to recover from a traumatic brain injury. I am pleased to have the support of Veterans for America for this legislative effort.

We have made tremendous progress in battlefield medical care. During Vietnam, one in three servicemembers who were injured died. In Iraq and Afghanistan, 1 in 16 who are injured die. But with the changes in warfare and in medical technology, more of our servicemembers are coming home with serious brain injuries from Iraq and Afghanistan than from any other recent conflicts we've known.

For some of these wounded warriors, the greatest battle comes at home when they seek care. Many of these returning troops need long-term treatment and rehabilitation long after their discharge from active duty, as they fight to overcome the severe disabilities that a traumatic brain injury can cause.

For others, there is a different story. Some servicemembers don't even realize they suffered a traumatic brain injury until long after their discharge, because we don't do a very good job of identifying and treating those who may have suffered a brain injury.

Fortunately, many of those who suffer a brain injury are able to recover fairly quickly. But for some, the experience is life-altering, even life-shattering. We must not fail them in their time of need.

Consider the case of Sgt. Eric Edmundson. Eric left my home state of Illinois to serve in Iraq. In October 2005, he suffered a severe head concussion when a roadside bomb exploded near him. He was cared for at Walter Reed Hospital, then was transferred to a VA facility where he and his family felt he was not receiving the kind of treatment that would allow him to continue to make progress in rehabilitation.

He would have been stuck there if the family had not found a creative way to obtain the care he needed. The family found a way to ensure that Eric could receive treatment and rehabilitation at one of the premiere rehabilitation hospitals in the nation: the Rehabilitation Institute of Chicago. He is making great progress there and hopes to walk out of the hospital some day soon.

We need to use private hospitals more. In fact, we should use them whenever they are the best option for our returning soldiers who are wounded. In the case of traumatic brain injury, they often have the special expertise needed, because the leading facilities in this field deal with brain injuries day in and day out as a result of construction accidents and car crashes.

Now consider the case of Sgt. Garrett Anderson of Champaign, Illinois. Garrett went to Iraq with the Illinois National Guard. After 4 months there, an IED exploded next to his armored Humvee in Baghdad. The blast tore off his right arm below the elbow, shattered his jaw, severed part of his tongue, damaged his hearing, and punctured his body with shrapnel.

He spent 7 months at Walter Reed, where he received excellent care in Ward 57, the famous amputee ward. However, the outpatient care that followed has been filled with paperwork and red tape. It was months before the VA recognized that Garrett had suffered a traumatic brain injury. He has not received the kind of treatment for brain injury that could make a significant difference in the trajectory of his rehabilitation.

We need to change the way we handle patients with traumatic brain injury, so that they receive the care they need at the time they need it.

The legislation I am introducing takes a comprehensive approach to dealing with the traumatic brain injuries that plague our troops and veterans.

First, this legislation would establish a Traumatic Brain Injury Program, run by DOD and the VA, to provide treatment and rehabilitation to servicemembers and veterans who have suffered a service-connected traumatic brain injury.

Second, this bill would establish a standard of care for the participants in the TBI Program. Specifically, each individual in the program shall be provided ''the highest quality of care possible based on the medical judgment of qualified medical professionals in facilities that most appropriately meet the specific needs of the individual. ''And they shall be rehabilitated to the fullest extent possible using the most up-to-date medical technology, medical rehabilitation practices, and medical expertise available.''

That's the standard of care we should provide to these injured troops who gave so much of themselves for us. They should receive the best we have to give.

Third, the measure would direct the Defense Department to develop and administer a standardized cognitive pretest, which would be administered to all military personnel prior to deployment and again upon return from deployment to determine if they have suffered a brain injury.

It also would require DOD and the VA to refer any servicemember or veteran for TBI screening if it is found, in the course of later treatment or contacts, that the servicemember or veteran may have suffered a service-connected brain injury.

Anyone found to have suffered a traumatic brain injury would be enrolled in the TBI program and receive the care they need.

One of the things the families of TBI patients complain most about is the confusion that surrounds their efforts to ensure that their loved one received all needed care. The fourth thing this measure would do is to direct DOD and the VA to assign each patient a lead case manager to ease the stress on the patient and family, facilitate navigation through the DOD and VA systems, ensure proper care, present options for care outside of DOD and the VA, and ensure consistent guidance. Additionally, DOD and the VA would assign to each patient a lead primary care physician to coordinate and oversee the care provided to the patient, including all treatment, rehabilitation, and medications.

Another complaint of families and TBI patients is that they are sometimes blocked from receiving the care they need due to their status as either a veteran or an active duty member. DOD and the VA have different health benefit options. In some cases, servicemembers have found that, because they accepted a discharge, they lost access to benefits that would help them.

Our bill addresses this problem by establishing, for these TBI patients, a temporary overlap of benefits. The participants in the TBI Program will be allowed, for 2 years, to receive any of the benefits available to veterans and to active duty members, regardless of their active duty status. This will help ensure they receive the best care and rehabilitation available, wherever it may be.

Our bill would spell out some other rights that are important for the rehabilitation of TBI patients. First, DOD and the VA would be required to provide a referral to a medical professional outside of DOD and the VA when requested by a TBI patient. This will allow patients to determine whether there is better care in the private sector that is not being provided to that patient. They would also have a right to an appeals process to challenge any failure to provide the standard of care required in the TBI Program.

In some cases, undiagnosed traumatic brain injuries may contribute to behavior resulting in other than honorable discharges. Upon the request of a servicemember who served since 2001 and was discharged under other than honorable conditions, the DOD would be directed to review the discharge to determine whether a brain injury might be the root cause of the actions that precipitated the adverse discharge, with fair reconsideration of the discharge if such evidence is found.

Similarly, the VA would be required to make available, upon request, an appeals process to update the disability rating of a veteran who is found to have suffered a traumatic brain injury.

Finally, this measure authorizes additional funding for research related to traumatic brain injury both in DOD and in the VA, to improve screening, diagnosis, treatment, and rehabilitation for traumatic brain injury.

This is a comprehensive effort to improve the treatment of our Nation's wounded servicemembers who have suffered a traumatic brain injury. I can't imagine the anguish that must be associated with such an injury, but I can imagine the kind of medical system I would like to have in place if it were my son or daughter struggling to recover from such an injury. This legislation reflects that vision.

I thank my cosponsors, Senators WARNER, MURRAY, GRAHAM, OBAMA, WEBB, and CANTWELL, and I urge all of my colleagues to support this measure.

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. 1349

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 ''Military and Veterans Traumatic Brain Injury Treatment Act''.

SEC. 2. PROGRAM OF SERVICES FOR TRAUMATIC BRAIN INJURY FOR MEMBERS OF THE ARMED FORCES AND VETERANS.

(a) TRAUMATIC BRAIN INJURY PROGRAM REQUIRED.—The Secretary of Defense and the Secretary of Veterans Affairs shall jointly establish a program meeting the requirements of subsections (c) through (f) under which each member of the Armed Forces or veteran who incurs a traumatic brain injury during service in the Armed Forces—

(1) is enrolled in the program; and

(2) receives, under the program, treatment and rehabilitation meeting the standard of care specified in subsection (b).

(b) STANDARD OF CARE.—The standard of care for treatment and rehabilitation specified in this subsection is that each individual who is a member of the Armed Forces or veteran who qualifies for care under the program established under subsection (a) shall—

(1) be provided the highest quality of care possible based on the medical judgment of qualified medical professionals in facilities that most appropriately meet the specific needs of the individual; and

(2) be rehabilitated to the fullest extent possible using the most up-to-date medical technology, medical rehabilitation practices, and medical expertise available.

(c) REFERRALS.—

(1) IN GENERAL.—If a member of the Armed Forces or a veteran participating in the program established under subsection (a) determines that care provided to such participant by the Department of Defense or the Department of Veterans Affairs, as the case may be, does not meet the standard of care specified in subsection (b), the Secretary of Defense or the Secretary of Veterans Affairs, as the case may be, shall, upon request of the participant, provide to such participant a referral to a public or private provider of medical or rehabilitative care for consultation regarding the care that would meet the standard of care specified in subsection (b).

(2) LIMITATION ON REFERRALS.—The Department of Defense shall bear the cost of referrals under paragraph (1), except that the Secretary of Defense shall not be required to pay for more than one referral for each participant in any consecutive three month period.

(d) SCREENING FOR TRAUMATIC BRAIN INJURY.—

(1) PROTOCOLS FOR DETECTION AND DIAGNOSIS OF TRAUMATIC BRAIN INJURY.—

(A) IN GENERAL.—The Secretary of Defense shall, in cooperation with the Secretary of Veterans Affairs, establish protocols for the detection and diagnosis of traumatic brain injury, including the use of various types of screening tools as appropriate.

(B) FREQUENCY.—The protocol required by subparagraph (A) shall provide that examinations shall be administered at least once to each member of the Armed Forces—

(i) before deployment to a combat theater; and

(ii) during the period beginning on the 30th day after the member returns from such deployment and ending on the 90th day after the date on which such member returns to the member's permanent duty station after such deployment.

(C) PROTOCOL FOR DETERMINATION OF BASELINE COGNITIVE FUNCTIONING.—The protocols required by subparagraph (A) shall include a protocol—

(i) for the assessment and documentation of the cognitive functioning of each member of the Armed Forces before each such member is deployed in a combat theater, in order to facilitate the detection and diagnosis of traumatic brain injury of such member upon return from such deployment; and

(ii) for the comparison of the cognitive functioning determined under clause (i) with the cognitive functioning of the member upon return from deployment.

(D) ADMINISTRATION OF COMPUTER-BASED EXAMINATIONS.—The protocol required by subparagraph (C) shall include the administration of computer-based examinations to members of the Armed Forces.

(2) INCIDENTAL DETECTION.—If, while delivering health care services to a member of the Armed Forces or a veteran who is not a participant in the program established under subsection (a), the Secretary of Defense or the Secretary of Veterans Affairs, as the case may be, discovers that such member or veteran may have incurred a service-connected traumatic brain injury, the Secretary concerned shall test such member or veteran for traumatic brain injury.

(3) REFERRALS.—If the Secretary of Defense or the Secretary of Veterans Affairs receives a referral for the testing of a member of the Armed Forces or a veteran for traumatic brain injury, the Secretary concerned shall test such member or veteran for traumatic brain injury expeditiously.

(4) ENROLLMENT.—If a member of the Armed Forces or a veteran is diagnosed under this subsection with a traumatic brain

injury that was incurred during service in the Armed Forces, such member or veteran shall be enrolled in the program required by subsection (a).

(e) OUTREACH.—

(1) OUTREACH TO MEMBERS OF THE ARMED FORCES AND VETERANS.—The Secretary of Defense and the Secretary of Veterans Affairs shall conduct a program of outreach to members of the Armed Forces and veterans to inform such members and veterans of—

(A) the program required by subsection (a);

(B) the availability of screening for the diagnosis of traumatic brain injury under subsection (d);

(C) the consequences, with regard to the treatment and care of traumatic brain injury, of separation, discharge, and retirement from the Armed Forces; and

(D) the rights of such members or veterans described in subsection (f).

(2) JOINT MANUAL OF BENEFITS.—As part of the program of outreach under paragraph (1), the Secretary of Defense and the Secretary of Veterans Affairs shall annually and jointly publish and distribute a manual explaining the benefits available to participants in the program required by subsection (a) and their families.

(f) RIGHTS OF MEMBERS OF THE ARMED FORCES AND VETERANS WITH TRAUMATIC BRAIN INJURY.—The Secretary of Defense and the Secretary of Veterans Affairs shall inform members of the Armed Forces and veterans with traumatic brain injury and their families of their rights with respect to the following:

(1) The receipt of medical care from the Department of Defense and the Department of Veterans Affairs.

(2) The options available to such members and veterans for treatment of traumatic brain injury.

(3) The options available to such members and veterans for rehabilitation.

(4) Referrals under subsection (c)(1).

(5) The right to any administrative or judicial appeal of any agency decision with respect to the program established under subsection (a).

(6) Reviews of decisions under section 4.

(g) COORDINATION OF CASE MANAGEMENT AND HEALTH CARE SERVICES FOR PROGRAM PARTICIPANTS.—

(1) LEAD CASE MANAGERS.—The Secretary of Defense and the Secretary of Veterans Affairs shall assign a qualified lead case manager to each member of the Armed Forces or veteran, as the case may be, that participates in the program required by subsection (a). Each lead case manager shall, with respect to a participant in the program under subsection (a) to whom the lead case manager has been assigned—

(A) coordinate the work of any other case managers associated with such participant;

(B) help the participant and the family of such participant manage the stress associated with receiving treatment and rehabilitative services for traumatic brain injury;

(C) present the participant with options for the receipt of medical and rehabilitative care, including options for such care outside the Department of Defense and the Department of Veterans Affairs, that meet the standard of care specified in subsection (b);

(D) help the participant find and receive the care, including care from outside the Department of Defense and the Department of Veterans Affairs, to which the participant is entitled under subsection (a); and

(E) ensure that providers of care to participants in the program required by subsection (a) provide consistent guidance to such participants.

(2) PRIMARY CARE PHYSICIANS.—The Secretary of Defense and the Secretary of Veterans Affairs shall assign a lead primary care physician to each member of the Armed Forces or veteran, as the case may be, who participates in the program required by subsection (a). Such lead primary care physician shall coordinate and oversee the care provided to the participant, including all treatment, rehabilitation, and medications.

(3) REPORT.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Defense and the Secretary of Veterans Affairs shall report to Congress on the steps taken to coordinate care, as required by this subsection, along with recommendations, if any, for legislation to improve such coordination.

(h) RESOURCES.—

(1) FACILITIES.—The Secretary of Defense and the Secretary of Veterans Affairs may provide treatment and rehabilitation in accordance with subsection (a) in any of the facilities as follows:

(A) Facilities of the Department of Defense.

(B) Facilities of the Department of Veterans Affairs.

(C) Public or private medical facilities accredited or otherwise qualified to provide treatment and rehabilitation.

(2) ACCESS TO EQUIPMENT.—The Secretary of Defense and the Secretary of Veterans Affairs shall ensure, by procurement, contract, or agreement, that the program established under subsection (a) has access to all specialized programs, services, equipment, and medical expertise required to ensure that each participant receives the standard of care specified in subsection (b).

(3) COOPERATIVE AGREEMENTS, CONTRACTS, OR PARTNERSHIPS WITH PRIVATE AND PUBLIC MEDICAL CENTERS.—The Secretary of Defense and the Secretary of Veterans Affairs shall, separately or jointly, enter into cooperative agreements, contracts, or partnerships with private or public medical centers with expertise in the treatment or rehabilitation of individuals with traumatic brain injury to provide consultation, treatment, or rehabilitation to members of the Armed Forces or veterans as required by subsection (a).

(4) TRAINING PROGRAM.—The Secretary of Defense and the Secretary of Veterans Affairs shall, separately or jointly, provide grants to, or enter into contracts or agreements with, private or public medical centers with expertise in the treatment or rehabilitation of individuals with traumatic brain injury to provide training, education, or other assistance to personnel of the Department of Defense and the Department of Veterans Affairs to ensure that such personnel are consistently using the most up-to-date and best practices and procedures for the screening, treatment, and rehabilitation of members of the Armed Forces and veterans with traumatic brain injury.

(5) OVERLAP OF BENEFITS.—

(A) IN GENERAL.—During the 24-month period beginning on the date that a member of the Armed Forces or a veteran is enrolled in the program required by subsection (a), the member or veteran shall be entitled to all of the benefits otherwise available to a veteran (in the case of a member) or member (in the case of a veteran), including participation in the TRICARE program under chapter 55 of title 10, United States Code, and care provided in a facility of the Department of Defense, the Department of Veterans Affairs, or other public or private facility, regardless of the active duty status of such member or veteran.

(B) ALLOCATION OF COSTS.—Costs associated with the provision of care under subparagraph (A) shall be borne by the Department of Defense.

SEC. 3. FACILITATION OF CONTINUITY OF CARE FROM DEPARTMENT OF DEFENSE TO DEPARTMENT OF VETERANS AFFAIRS.

The Secretary of Defense and the Secretary of Veterans Affairs shall establish protocols to ensure that members of the Armed Forces receive, with regard to health care benefits and services from the Department of Veterans Affairs and otherwise, a continuity of care and assistance during and after the transition from military service to civilian life, including protocols for the following:

(1) The expeditious transfer of medical records from the Department of Defense to the Department of Veterans Affairs.

(2) Continuity of health care services, treatment, and coverage for members of the Armed Forces who are transitioning to civilian life, with particular emphasis on providing continued health care to participants in the program required by section 2.

(3) The development of a specific, individualized transition plan for each member, prior to discharge or release from the Armed Forces, outlining the member's seamless continuity of care.

SEC. 4. REVIEW OF CERTAIN DECISIONS OF THE DEPARTMENT OF DEFENSE AND THE DEPARTMENT OF VETERANS AFFAIRS.

(a) REVIEW OF OTHER THAN HONORABLE DISCHARGE STATUS FOR FORMER MEMBERS OF THE ARMED FORCES WITH TRAUMATIC BRAIN INJURY.—

(1) REVIEW REQUIRED.—The Secretary of Defense shall, upon the request of any former member of the Armed Forces who served in the Armed Forces after October 6, 2001, and has been discharged from the Armed Forces under other than honorable conditions, conduct a review (including a medical evaluation) to determine whether a traumatic brain injury was a cause of the actions of the member that precipitated the discharge under other than honorable conditions. Such request may also be made by an authorized representative of the member.

(2) RECONSIDERATION.—If the Secretary of Defense determines under this subsection that the traumatic brain injury of a member was a cause of the actions of the member that precipitated the discharge under other than honorable conditions, the Secretary shall reconsider the discharge and redesignate the status of such discharge if such action is warranted.

(b) REVIEW OF DECISIONS OF SECRETARY OF VETERANS AFFAIRS AFFECTING VETERANS WITH TRAUMATIC BRAIN INJURY.—Upon the request of any veteran diagnosed with a traumatic brain injury, the Secretary of Veterans Affairs shall review and adjust as the Secretary considers appropriate, the disability rating of such veteran.

SEC. 5. TRAUMATIC BRAIN INJURY RESEARCH.

(a) RESEARCH REQUIRED OF DEPARTMENT OF DEFENSE.—The Secretary of Defense shall conduct research—

(1) to improve the screening, diagnosis, and treatment of traumatic brain injury;

(2) to improve rehabilitation of members of the Armed Forces with traumatic brain injury;

(3) to improve best practices for the activities described in paragraphs (1) and (2); and

(4) to identify the mechanisms of brain injury and ways to prevent or ameliorate secondary effects of brain injuries.

(b) RESEARCH REQUIRED OF DEPARTMENT OF VETERANS AFFAIRS.—Section 7303 of title 38, United States Code, is amended—

(1) in subsection (a)(2), by inserting ''traumatic brain injury research,'' after ''mental illness research,''; and

(2) by adding at the end the following new subsection:

''(e) Traumatic brain injury research shall include research—

''(1) to improve the screening, diagnosis, and treatment of traumatic brain injury;

''(2) to improve rehabilitation of veterans with traumatic brain injury;

''(3) to improve best practices for the activities described in paragraphs (1) and (2); and

''(4) to identify the mechanisms of brain injury and ways to prevent or ameliorate secondary effects of brain injuries.''.

(c) GRANTS OR COOPERATIVE AGREEMENTS.—In conducting the research required by subsection (a) or in accordance with section 7303(e) of title 38, United States Code, the Secretary of Defense and the Secretary of Veterans Affairs may provide grants to, or enter into cooperative agreements with, private or public medical centers with expertise in research on traumatic brain injury, including the treatment or rehabilitation of individuals with traumatic brain injury.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

(1) to the Secretary of Defense, $20,000,000 to carry out the provisions of subsection (a); and

(2) to the Secretary of Veterans Affairs, $20,000,00 to carry out the amendments made by subsection (b).

SEC. 6. REPORT.

Not later than December 15 of each year, the Secretary of Defense shall, in conjunction with the Secretary of Veterans Affairs, submit to Congress a report that contains, with respect to the fiscal year ending in the year such report is submitted, the following:

(1) Descriptions of the activities, accomplishments, and limitations of the program on traumatic brain injury established under section 2.

(2) Recommendations of the Secretary of Defense and the Secretary of Veterans Affairs, if any, for improving the program established under section 2.

(3) Information on the following:

(A) The number of members of the Armed Forces and veterans tested for traumatic brain injury by the Department of Defense and the Department of Veterans Affairs under section 2(d).

(B) The number of members of the Armed Forces and veterans diagnosed with a traumatic brain injury.

(C) The number of members of the Armed Forces and veterans enrolled in the program on traumatic brain injury established under section 2.

(D) The types of treatment and rehabilitation provided as part of the program established under section 2.

(E) The types of facilities in which services were provided under section 2 and how such facilities were chosen to meet the individual needs of individual patients.

(F) The mechanisms used by the Department of Defense and the Department of Veterans Affairs to ensure continuity of care for members of the Armed Forces as they transition from receipt of health care services from the Department of Defense to the receipt of such services from the Department of Veterans Affairs.

(G) The number and nature of any cooperative agreements engaged in under section 2(h).

(H) The outreach activities carried out under subsections (e) and (f) of section 2.

(4) A description of the expenditures associated with the outreach, screening, diagnosis, treatment, rehabilitation, and other services provided to members of the Armed Forces and veterans under sections 2 and 3.

SEC. 7. DEFINITION OF TRAUMATIC BRAIN INJURY.

In this Act, the term ''traumatic brain injury'' means an acquired injury to the brain. Such term does not include brain dysfunction caused by congenital or degenerative disorders, nor birth trauma, but may include brain injuries caused by anoxia due to trauma. The Secretary of Defense and the Secretary of Veterans Affairs may jointly revise the definition of such term as the Secretaries determine necessary, after consultation with the following:

(1) The Secretary of Health and Human Services.

(2) Representatives of any organization recognized by the Secretary of Veterans Affairs for the representation of veterans under section 5902 of title 38, United States Code.

(3) Such public or nonprofit private entities that the Secretary of Defense or the Secretary of Veterans Affairs considers appropriate.

NOTICE OF HEARING

COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP

Mr. KERRY. I would like to inform the Members that the Committee on Small Business and Entrepreneurship will hold a public markup of S. 1256 ''Small Business Lending Reauthorization and Improvements Act of 2007'' on Wednesday, May 16, 2007, at 2:30 p.m. in room 428A of the Russell Senate Office Building.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

Mr. DURBIN. 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 Wednesday, May 9, 2007, at 9:30 a.m. in 328A, Russell Senate Office Building. The purpose of this committee hearing will be to consider Energy and Rural Development issues for the Farm bill.

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

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

Mr. DURBIN. 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 Wednesday, May 9, 2007, at 2:30 p.m., in room 253 of the Russell Senate Office Building. The purpose of the hearing is to review all-terrain vehicle, ATV, issues and possible legislative approaches to obtaining ATV safety.

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

COMMITTEE ON FOREIGN RELATIONS

Mr. DURBIN. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Wednesday, May 9, 2007, at 9:30 a.m. to hold a hearing on climate change.

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

COMMITTEE ON FOREIGN RELATIONS

Mr. DURBIN. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on Wednesday, May 9, 2007, at 2:30 p.m. to hold a nomination hearing.

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

COMMITTEE ON THE JUDICIARY

Mr. DURBIN. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet to conduct a markup on Wednesday, May 9, 2007, at 10 a.m. in Dirksen Room 226.

Agenda

I. Bills: S. 221, Fair Contracts for Growers Act of 2007, (Grassley, Feingold, Kohl, Leahy, Durbin); and S. 376, Law Enforcement Officers Safety Act of 2007, (Leahy, Specter, Grassley, Kyl, Sessions, Cornyn).

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

COMMITTEE ON VETERANS' AFFAIRS

Mr. DURBIN. I ask unanimous consent for the Committee on Veterans' Affairs be authorized to meet during the session of the Senate on Wednesday, May 9, 2007, to hold a hearing on pending benefits legislation. The hearing will take place in room 562 of the Dirksen Senate Office Building beginning at 9:30 a.m.

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

SPECIAL COMMITTEE ON AGING

Mr. DURBIN. Mr. President, I ask unanimous consent that the Special Committee on Aging be authorized to meet today, Wednesday, May 9, 2007, from 3 p.m.–5 p.m. in Dirksen 106 for the purpose of conducting a hearing.

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

SUBCOMMITTEE ON PRIVATE SECTOR AND CONSUMER SOLUTIONS TO GLOBAL WARMING AND WILDLIFE PROTECTION.

Mr. DURBIN. Mr. President, I ask unanimous consent that the Committee on Environment and Public Works Subcommittee on Private Sector and Consumer Solutions to Global Warming and Wildlife Protection be authorized to meet during the session of the Senate on Wednesday, May 9, 2007.

Agenda

Technologies and practices to reduce greenhouse gas emissions.

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

MEASURES READ THE FIRST TIME—S. 1348 AND H.R. 2080

Mr. CONRAD. Mr. President, I understand there are two bills at the desk, and I ask for their first reading, en bloc.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report.

The legislative clerk read as follows:

A bill (S. 1348) to provide for comprehensive immigration reform and for other purposes.

A bill (H.R. 2080) to amend the District of Columbia Home Rule Act to conform the District charter to revisions made by the Council of the District of Columbia relating to public education.

Mr. CONRAD. Mr. President, I ask for a second reading en bloc, and I object to my own request.

The PRESIDING OFFICER. Objection is heard. The bills will be read for the second time on the next legislative day.

THANKS TO STAFF

Mr. CONRAD. Mr. President, I thank all my colleagues for their cooperation today. I especially thank the ranking member of the Senate Budget Committee for his help and assistance and for his continuing graciousness as we consider the budget resolution, as well as all the Members who participated in the debate. I thought it was a very helpful debate—animated at times but genuine, sincere, and in the best traditions of the Senate.

I also wish to take this moment to thank the staffs, especially staff on my side, for unbelievable hours and devotion to getting a final product passed, and one we can be proud of. This staff has worked night and day, weekends, over and over, and I want to thank them publicly and commend them for it.

We should also acknowledge the staff on the other side, who have also worked long hours and have conducted themselves in the best tradition of the Senate.

ORDERS FOR THURSDAY, MAY 10, 2007

Mr. CONRAD. Mr. President, there is some additional business we have been asked to handle.

I ask unanimous consent that when the Senate completes its business today, it stand adjourned until 9:30 a.m., Thursday, May 10; that on Thursday, following the prayer and pledge, the morning hour be deemed expired and the time of the two leaders reserved for their use later in the day; that the Senate then resume consideration of the motion to proceed to Calendar No. 128, H.R. 1495, the Water Resources Development Act, and that the time until 9:45 a.m. be equally divided and controlled between the chair and ranking member of the Environment and Public Works Committee; that at 9:45 a.m., without further intervening action or debate, the Senate proceed to vote on the motion to invoke cloture on the motion to proceed.

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

ADJOURNMENT UNTIL 9:30 A.M. TOMORROW

Mr. CONRAD. Mr. President, if there is no further business to come before the Senate today, I ask unanimous consent that the Senate stand adjourned under the previous order.

There being no objection, the Senate, at 8:38 p.m., adjourned until Thursday, May 10, 2007, at 9:30 a.m.

NOMINATIONS

Executive nominations received by the Senate May 9, 2007:

IN THE AIR FORCE

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES AIR FORCE TO THE GRADE INDICATED WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, U.S.C., SECTION 601:

To be lieutenant general

MAJ. GEN. KEVIN J. SULLIVAN, 0000

THE FOLLOWING AIR NATIONAL GUARD OF THE UNITED STATES OFFICER FOR APPOINTMENT IN THE RESERVE OF THE AIR FORCE TO THE GRADE INDICATED UNDER TITLE 10, U.S.C., SECTION 12203:

To be brigadier general

COL. RANDALL M. FALK, 0000

IN THE ARMY

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE RESERVE OF THE ARMY TO THE GRADE INDICATED UNDER TITLE 10, U.S.C., SECTION 12203:

To be brigadier general

COL. JUAN A. RUIZ, 0000

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES ARMY TO THE GRADE INDICATED WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, U.S.C., SECTION 601:

To be lieutenant general

LT. GEN. RONALD L. BURGESS, JR., 0000

IN THE MARINE CORPS

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES MARINE CORPS TO THE GRADE INDICATED UNDER TITLE 10, U.S.C., SECTION 624:

To be brigadier general

COL. KENNETH F. MCKENZIE, JR., 0000

IN THE AIR FORCE

THE FOLLOWING NAMED INDIVIDUAL FOR APPOINTMENT IN THE GRADE INDICATED IN THE REGULAR AIR FORCE UNDER TITLE 10, U.S.C., SECTION 531(A):

To be major

ANIL P. RAJADHYAX, 0000

THE FOLLOWING NAMED INDIVIDUALS FOR APPOINTMENT IN THE GRADE INDICATED IN THE REGULAR AIR FORCE UNDER TITLE 10, U.S.C., SECTION 531(A):

To be major

DAREN S. DANIELSON, 0000
COLLEEN M. FITZPATRICK, 0000

THE FOLLOWING NAMED INDIVIDUALS FOR APPOINTMENT IN THE GRADES INDICATED IN THE REGULAR AIR FORCE UNDER TITLE 10, U.S.C., SECTION 531(A):

To be lieutenant colonel

BRET R. BOYLE, 0000

To be major

MICHAEL C. PAHANG, 0000
DIANA STANSBURY, 0000
CHAD A. WEDDELL, 0000

THE FOLLOWING NAMED INDIVIDUALS FOR APPOINTMENT IN THE GRADES INDICATED IN THE REGULAR AIR FORCE UNDER TITLE 10, U.S.C., SECTION 531(A):

To be lieutenant colonel

LILLIAN C. CONNNER, 0000

To be major

MARVIN CONRAD, 0000
JONATHAN L. RONES, 0000

THE FOLLOWING NAMED INDIVIDUALS FOR APPOINTMENT IN THE GRADES INDICATED IN THE REGULAR AIR FORCE UNDER TITLE 10, U.S.C., SECTION 531(A):

To be lieutenant colonel

NANCY J. S. ALTHOUSE, 0000
JAMES B. COWAN, 0000
MARY B. DURBIN, 0000
FRANKLIN H. HAUGER, 0000
SUSAN G. MARKEL, 0000
HENRY D. VAUGHAN, 0000

To be major

MICHAEL M. DUNN, 0000
BEVERLY J. EARLEY, 0000
SABRI Z. IBRAHIM, 0000
PHICK H. NG, 0000

IN THE ARMY

THE FOLLOWING NAMED INDIVIDUAL FOR REGULAR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES ARMY NURSE CORPS UNDER TITLE 10, U.S.C., SECTIONS 531 AND 3064:

To be major

GLEN L. DORNER, 0000

THE FOLLOWING NAMED INDIVIDUALS FOR REGULAR APPOINTMENT TO THE GRADES INDICATED IN THE UNITED STATES ARMY MEDICAL CORPS UNDER TITLE 10, U.S.C., SECTIONS 531 AND 3064:

To be lieutenant colonel

SHIRLEY S. MIRESEPASSI, 0000

To be major

SCOTT L. DIERING, 0000

IN THE NAVY

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES NAVY UNDER TITLE 10, U.S.C., SECTION 6221:

To be captain

GEORGE N. THOMPSON, 0000

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES NAVY UNDER TITLE 10, U.S.C., SECTION 624:

To be captain

STEVEN D. BROWN, 0000
MICHAEL E. DORY, 0000
KALAS K. MCALEXANDER, 0000
MICHAEL J. PARISI, 0000
MARK G. STEINER, 0000

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES NAVY UNDER TITLE 10, U.S.C., SECTION 624:

To be captain

RICHARD K. GIROUX, 0000
REX A. GUINN, 0000
DEAN W. LEECH, 0000
JEFFREY P. LUSTER, 0000
JAMES M. RYAN, 0000
ROBERT A. SANDERS, 0000
SUSAN C. STEWART, 0000
DENISE E. STICH, 0000

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES NAVY UNDER TITLE 10, U.S.C., SECTION 624:

To be captain

MARK A. ADMIRAL, 0000
JULIENNE E. C. ALMONTE, 0000
PAUL D. ASHCRAFT, 0000
JOSEPH M. CHENELER, 0000
JAMES E. FANELL, 0000
DAVID C. FOLEY, 0000
WILLIAM P. HAMBLET, JR., 0000
DARYL R. HANCOCK, 0000
CRAIG O. HAYNES, 0000
MICHAEL T. ORTWEIN, 0000
STEPHEN E. ROBERTS, 0000
ROBERT D. SHARP, 0000
CHRISTOPHER M. STRUB, 0000
ERIC A. TAYLOR, 0000
DANIEL F. VERHEUL, 0000

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES NAVY UNDER TITLE 10, U.S.C., SECTION 624:

To be captain

MICHAEL D. ANDERSON, 0000
GREGG W. BAUMANN, 0000
RICHARD P. BLANK, 0000
JEFFREY A. BURCHAM, 0000
TIMOTHY J. CORRIGAN, 0000
PATRICK COSTELLO, 0000
KURTIS W. CRAKE, 0000
JEFFREY R. DUNLAP, 0000
KENNETH L. FRACK, JR., 0000
GLENN D. HOFERT, 0000
PERNELL A. JORDAN, 0000
MICHAEL L. MALONE, 0000
BRIAN R. MCGINNIS, 0000
KEVIN R. PETERSON, 0000
MIGUEL G. SANPEDRO, 0000
RICKY A. SERAIVA, 0000
MICHAEL H. SMITH, 0000
STEVEN L. STANCY, 0000
JAMES E. STEIN, 0000
ERIC A. TAPP, 0000
BRUCE C. URBON, 0000

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES NAVY UNDER TITLE 10, U.S.C., SECTION 624:

To be captain

SCOT K. ABEL, 0000
TITO M. ARANDELA, JR., 0000
JAMES R. BREON, 0000
SILVESTER R. DELROSARIO, 0000
ROBERT W. DESANTIS, 0000
DANIEL P. HENDERSON, 0000
JOHN R. JONES, 0000
PETER R. LINTNER, 0000
JESUS A. MATUDIO, 0000
KEVIN K. NELSON, 0000
PATRICK B. SHEPLER, 0000
LELAND D. TAYLOR, 0000

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES NAVY UNDER TITLE 10, U.S.C., SECTION 624:

To be captain

MICHAEL J. CERNECK, 0000
DAVID D. DAVISON, 0000
TIMOTHY J. DUNIGAN, 0000
ANTHONY J. FERRARI, 0000
JAMES A. GLASS, 0000
HENRY M. JACKSON, 0000
DAVID P. JOHNSON, 0000
JOHN K. MARTINS, 0000
TIMOTHY J. MOREY, 0000
JOHN C. NICHOLSON, 0000
MICHAEL L. PEOPLES, 0000

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES NAVY UNDER TITLE 10, U.S.C., SECTION 624:

To be captain

JOHN W. CHANDLER, 0000
ROBERT D. GOODWIN, JR., 0000
JACQUELINE R. KOCHER, 0000
PATRICK K. LEARY, 0000
KATHERINE A. MAYER, 0000
STEPHANIE L. ONEAL, 0000
WILLIAM T. RICH, 0000
MARK A. SANFORD, 0000
DAVID M. SERBER, 0000
JAMES A. SULLIVAN, 0000

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES NAVY UNDER TITLE 10, U.S.C., SECTION 624:

To be captain

ARNE J. ANDERSON, 0000
THOMAS A. BALCOM, 0000
STEVEN L. BANKS, 0000
ELIZABETH G. BEAZLEY, 0000
KRIS M. BELLAND, 0000
PATRICK H. BOWERS, 0000
DAVID M. BURCH, 0000
DOUGLAS N. CARBINE, 0000
WILLIAM D. CRAIG, 0000
THOMAS P. DAVIS, 0000
GERALD D. DENTON, 0000
JAMES R. DUNNE, 0000
KENNETH L. EISENBERG, 0000
LARRY A. EVANS, 0000
JAMES P. FLINT, 0000
DANIEL A. FREILICH, 0000
THOMAS G. GAYLORD, 0000
BRENDON L. GELFORD, 0000
MARTHA K. GIRZ, 0000
LISA A. GLEASON, 0000
GARY S. GLUCK, 0000
ELISE T. GORDON, 0000
PAUL HAMMER, 0000
AMIR E. HARARI, 0000
SCOTT W. HELMERS, 0000
MICHAEL E. HOFFER, 0000
MICHAEL A. ILLOVSKY, 0000
LISA INOUYE, 0000
ROBERT A. IZENBERG, 0000
BETH R. JAKLIC, 0000
JOHN L. KANE III, 0000
PAUL D. KANE, 0000
ERIC J. KUNCIR, 0000
DAVID M. LARSON, 0000
JEFFREY T. LENERT, 0000
IVAN K. LESNIK, 0000
EDGAR M. LEVINE, 0000
MARK A. MALAKOOTI, 0000
GAIL H. J. MANOS, 0000
ROBERT W. MARTIN, 0000
MICHAEL A. MAZZILLI, 0000
JOSEPH A. MCBREEN, 0000
ELIZABETH A. G. MCGUIGAN, 0000
NALAN NARINE, 0000
JOHN T. NEFF, 0000
DANIEL F. NOLTKAMPER, 0000
LACHLAN D. NOYES, 0000
OTTO W. OHM II, 0000
LOUIS D. OROSZ, 0000
CARY A. OSTERGAARD, 0000
ERIC L. PAGENKOPF, 0000
JOHN F. PERRI, 0000
JACK S. PIERCE, 0000
ROBERT T. RULAND, 0000
MARGARET A. RYAN, 0000
DONALD R. SALLEE, 0000
THEODORE W. SCHAFER, 0000
MICHAEL S. SCHLEGEL, 0000
DANIEL P. SHMORHUN, 0000
TIMOTHY R. SHOPE, 0000
EDWARD D. SIMMER, 0000
DAVID J. TANZER, 0000
JOHN S. THURBER, 0000
DANIEL J. VALAIK, 0000
DARIN K. VIA, 0000
DAVID K. WEISS, 0000
LOYD A. WEST, 0000
WADE W. WILDE, 0000
ROBIN M. WILKENING, 0000
KEVIN E. ZAWACKI, 0000

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES NAVY UNDER TITLE 10, U.S.C., SECTION 624:

To be captain

LEIGH P. ACKART, 0000
ROBERT J. BESTERCY, 0000
MICHAEL B. BOHN, 0000
ROBERT L. BRUNSON, JR., 0000
JOHN F. COUTURE, 0000
GEORGE DEVRIES, 0000
BRIAN T. DRAPP, 0000
ROBERT A. GANTT, 0000
ERIC L. GLASER, 0000
JEFFREY K. GRIMES, 0000
SCOTT L. HAWKINS, 0000
DAVID K. HENDERSON, 0000
RODERICK R. HUBBARD, 0000
DAVID R. KLESS, 0000
TRACY A. LARCHER, 0000
TAE H. LEE, 0000
DOUGLAS C. NEWELL, 0000
TIMOTHY J. OBRIEN, 0000
MICHAEL P. PATTEN, 0000
JOHN P. POLOWCZYK, 0000
WILLIAM C. POWER, 0000
CHRISTOPHER J. RAY, JR., 0000
KEVIN D. REDMAN, 0000
JOYCELIN ROBINSON, 0000
MARK E. SEMMLER, 0000
JOHN D. TITUS, JR., 0000
TIMOTHY S. VARVEL, 0000
ROLAND G. WADGE, 0000
KURT E. WAYMIRE, 0000

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES NAVY UNDER TITLE 10, U.S.C., SECTION 624:

To be captain

PIUS A. AIYELAWO, 0000
JEFFREY M. ANDREWS, 0000
THEODORE P. BRISKI, JR., 0000
DERRIK R. CLAY, 0000
GILDA M. COLLAZO, 0000
ROBERT E. FULLER, 0000
BRENDAN K. GLENNON, 0000
RACHEL D. HALTNER, 0000
DEXTER A. HARDY, 0000
MICHAEL N. HENDEE, 0000
CHRISTINE L. HOWE, 0000
SCOTT R. JONSON, 0000
KEVIN R. KENNEDY, 0000
DAIZO KOBAYASHI, 0000
JOHN D. LARNERD, JR., 0000
DAVID R. LESSER, 0000
PATRICK S. MALONE, 0000
RONALD N. MCLEAN, 0000
DAVID L. MCNAMARA, 0000
JULIE L. MIAVEZ, 0000
TAMMY M. NATHAN, 0000
JONATHAN P. NELSON, 0000
MATTHEW E. NEWTON, 0000
BUHARI A. OYOFO, 0000
EDGARDO PEREZLUGO, 0000
JEAN T. SCHERRER, 0000
ALAN V. SIEWERTSEN, 0000
DAVID R. STREET, JR., 0000
PENNY E. WALTER, 0000

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES NAVY UNDER TITLE 10, U.S.C., SECTION 624:

To be captain

WENDY M. BORUSZEWSKI, 0000
ROBERTO J. CABASSA, 0000
BRENT J. CALLEGARI, 0000
RICHARD P. CAMPBELL, 0000
CHARLES L. ELLIS, 0000
ARTHUR T. GEORGE, 0000
KEITH C. KEALEY, 0000
JEFFREY N. KORSNES, 0000
JOANNE R. LEAL, 0000
WILLIAM J. LEONARD, JR., 0000
MARK B. LYLES, 0000
ROBERT H. MITTON, 0000
MONA M. MOOREMEAUX, 0000
KEVIN J. OTTE, 0000
MICHAEL L. POTTER, 0000
MARK S. QUAGLIOTTI, 0000
ANDREA L. SHORTEREVANS, 0000
MICHAEL A. STEINLE, 0000
PATRICIA A. TORDIK, 0000

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES NAVY UNDER TITLE 10, U.S.C., SECTION 624:

To be captain

CHERIE L. BARE, 0000
JOSEPH COSENTINO, JR., 0000
LAWRENCE J. DUANE, 0000
CONSTANCE J. EVANS, 0000
LORI S. FRANK, 0000
COLLEEN K. GALLAGHER, 0000
LINDA J. GRANT, 0000
DEBORAH L. HILL, 0000
GAYLE S. KENNERLY, 0000
LORI A. LARAWAY, 0000
ANNE M. LEAR, 0000
REGINA K. MERCADO, 0000
JOEL L. PARKER, 0000
NANCY L. PEARSON, 0000
LAURA E. PISTEY, 0000
CHRISTOPHER J. PRATT, 0000
JACQUELINE D. RYCHNOVSKY, 0000
CARLA J. STANG, 0000
KATHRYN A. SUMMERS, 0000

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT TO THE GRADE INDICATED IN THE UNITED STATES NAVY UNDER TITLE 10, U.S.C., SECTION 624:

To be captain

DARIUS BANAJI, 0000
BENJAMIN J. BARROW, 0000
DAVID A. BERCHTOLD, 0000
SCOTT A. BERNOTAS, 0000
FREDERICK F. BURGESS III, 0000
JOSEPH A. CAMPBELL, 0000
JOHN CORONADO, 0000
CRAIG A. FULTON, 0000
CLAYTON O. MITCHELL, JR., 0000
BRANT D. PICKRELL, 0000
ERICA L. SAHLER, 0000
DAVID J. SASEK, 0000
DAVID M. SMITH, 0000
JOHN T. SOMMER, 0000
MICHAEL D. WILLIAMSON, 0000

THE FOLLOWING NAMED INDIVIDUAL FOR APPOINTMENT TO THE GRADE INDICATED IN THE REGULAR NAVY UNDER TITLE 10, U.S.C., SECTION 531:

To be lieutenant commander

DEA BRUEGGEMEYER, 0000

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT TO THE GRADES INDICATED IN THE REGULAR NAVY UNDER TITLE 10, U.S.C., SECTION 531:

To be commander

NEAL P. RIDGE, 0000

To be lieutenant commander

RALPH L. RAYA, 0000

CONFIRMATION

Executive nomination confirmed by the Senate Wednesday, May 9, 2007:

THE JUDICIARY

DEBRA ANN LIVINGSTON, OF NEW YORK, TO BE UNITED STATES CIRCUIT JUDGE FOR THE SECOND CIRCUIT.