United States of America

Congressional Record

PROCEEDINGS AND DEBATES OF THE 112th CONGRESS, SECOND SESSION

Vol. 158 WASHINGTON, THURSDAY, MAY 24, 2012 No. 76

House of Representatives

The House was not in session today. Its next meeting will be held on Friday, May 25, 2012, at 10 a.m.

Senate

THURSDAY, MAY 24, 2012

The Senate met at 9:30 a.m. and was called to order by the Honorable TOM UDALL, a Senator from the State of New Mexico.

PRAYER

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

Let us pray.

Eternal God, the giver of every good and perfect gift, thank You for all that makes life worthwhile. Thank You for tasks to do, for health of body, for accuracy of hand and eye, for skill of mind, and for friends and loved ones.

Today, equip the minds of our Senators with three assurances to sustain them. Remind them of Your sovereignty, Your power, and Your love. Give them the wisdom to believe that there is no problem or circumstance beyond Your control. May this knowledge guide their thinking, speaking, and decisions in a way that will glorify You.

We pray in Your holy Name. Amen.

PLEDGE OF ALLEGIANCE

The Honorable TOM UDALL 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. INOUYE).

The assistant clerk read the following letter:

U.S. SENATE,
PRESIDENT PRO TEMPORE,
Washington, DC, May 24, 2012.

To the Senate:

Under the provisions of rule I, paragraph 3, of the Standing Rules of the Senate, I hereby appoint the Honorable TOM UDALL, a Senator from the State of New Mexico, to perform the duties of the Chair.

DANIEL K. INOUYE,
President pro tempore.

Mr. UDALL of New Mexico 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, we are now considering S. 3187, the FDA user fees legislation. There is an agreement now reached to complete this legislation today. Under the agreement, debate time will expire at 2 p.m. today, but if we are able to yield back time, up to 12 rollcall votes could begin earlier in order to complete action on the bill and to have a couple of votes in relation to the student loan interest rate hike. We will notify everyone if time is yielded back, but people should be aware of the need to come here—we hope before noon—to have a couple of votes. There will be no votes between 1 and 2 o'clock because of meetings both sides have.

We also worked out a tentative agreement yesterday on flood insurance, which is important to 6 million people. We need to get that done today also. I hope we can get that done.

I was pleased yesterday to reach an agreement with the Republican leader on how to move forward with this FDA bill. This legislation addresses shortages of lifesaving medicines by establishing a protocol to accomplish just that. It will ensure that FDA resources are there to approve new drugs and medical devices quickly and efficiently. We are going to consider, as I indicated, a number of relevant amendments. I am optimistic we will pass this strong, bipartisan bill.

This week has been productive. We have not had to break or try to break a single Republican filibuster. That is a good day in Washington. It doesn't happen very often. I hope it happens more often. If this trend continues, we could return to the way we used to be; that is, do what is good for the country and not be trying to stop everything that comes along.

I am also hopeful that this week the Senate will be able to find a path ahead to temporarily renew the Flood Insurance Program, as I have already indicated. We need a long-term solution to this problem. We have about 40,000 loans every day that are approved, and they are approved because you can make that check that you do have flood insurance. If there is no way to buy flood insurance, you cannot make that check in that box and you cannot get a loan. This would be devastating to our fragile economy, so we have to

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

Printed on recycled paper.

get this done and get it done before the end of this month.

The collaborative work on that measure and the FDA bill renews my hope that Congress will reach an agreement to prevent student loan interest rates from doubling for 7 million young men and women. We will move to two proposals to freeze student interest rates at their current levels. The Republican proposal is paid for by stripping Americans of lifesaving preventive health care. I can't say it any more clearly than that. It would be a shame to use that pay-for. That program has already been stripped bare. To take any more from it would really hurt the health of America. Our proposal is paid for by closing a loophole that allowed wealthy Americans to dodge their taxes. I am certainly aware of how things work around here. Neither one of these is going to pass, I am sorry to say. These two proposals were not created equal. But I hope a few reasonable Republicans will join with us. We should not put Americans' health at risk. We need to come to an agreement on the student loan issue. We only have until the end of June to do this.

I also hope to resolve an issue dealing with paycheck fairness over the next work period. In addition to that, we are going to deal with the farm bill, flood insurance, as I have talked about, a small business tax relief program, cybersecurity, and some appropriations bills.

In the last Congress we passed the Lilly Ledbetter Fair Pay Act, named after a stalwart woman from the South who was in effect cheated out of pay she deserved. She did the same work as men for many years but didn't get the same money. She sought redress in the courts, and they said: No, you can't do that; you should have done that when you first started working there. She didn't know she was being cheated at that time. We changed the law. Now people in the same situation as Lilly Ledbetter are not going to be bound by some phony set of rules that prevent someone from filing a lawsuit when they have been aggrieved.

While the wage gap has narrowed in the five decades since Congress declared women entitled to equal pay for equal work, gender discrimination remains a serious problem in the workplace. The work we did with Lilly Ledbetter was the single most important piece of legislation to ensure women have a chance to protect themselves. It is something we should have done before. We didn't. It is done now. Women make up about half of today's workforce. More than half the students in our law schools are women. More than half the students in medical schools are women. They still, though, will only earn 77 cents on every dollar compared to their male colleagues for doing the same work, and with an increasing number of women leading American households, this is a problem that affects children and families across the country.

The legislation, led by Senator BARBARA MIKULSKI, the Paycheck Fairness Act, is a logical extension of protections under the Equal Pay Act. It will help close the gap by empowering women to negotiate for equal pay and creating strong incentives for employers to obey the laws already in place.

Republicans deny waging war on women. Yet they have launched a series of attacks on women's access to health care and contraception this year. Now they have an opportunity to back up their excuses with action, and we are going to give them that opportunity. We hope they will join us and send a clear message that America values the incredible contributions women make every day.

Would the Chair be so kind as to announce the work we are going to do here today.

RESERVATION OF LEADER TIME

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

FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT

The ACTING PRESIDENT pro tempore. Under the previous order, the Senate will resume consideration of S. 3187, which the clerk will report.

The assistant legislative clerk read as follows:

A bill (S. 3187) to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

Pending:

Durbin/Blumenthal amendment No. 2127, to require manufacturers of dietary supplements to register dietary supplement products with the Food and Drug Administration.

Sanders amendment No. 2109, to revoke the exclusivity of certain entities that are responsible for violations of the Federal Food, Drug, and Cosmetic Act, the False Claims Act, and other certain laws.

Coburn/Burr amendment No. 2131, to require an independent assessment of the Food and Drug Administration's review of drug applications.

Coburn/Burr amendment No. 2132, to provide that a portion of the performance awards of each employee of the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research be connected to an evaluation of the employee's contribution to goals under the user fee agreements.

Burr/Coburn amendment No. 2130, to ensure transparency in Food and Drug Administration user fee agreement negotiations.

Murkowski amendment No. 2108, to prohibit approval by the Food and Drug Administration of genetically engineered fish unless the National Oceanic and Atmospheric Administration concurs with such approval.

Paul amendment No. 2143, to amend the Federal Food, Drug, and Cosmetic Act concerning claims about the effects of foods and dietary supplements on health-related conditions and disease, to prohibit employees of the Food and Drug Administration from carrying firearms and making arrests without warrants, and to adjust the mens rea of certain prohibited acts under the Federal Food, Drug, and Cosmetic Act to knowing and willful.

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

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

The assistant legislative clerk proceeded to call the roll.

Mr. MCCAIN. 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.

AMENDMENT NO. 2107

Mr. MCCAIN. I ask unanimous consent to call up amendment No. 2107 and make it pending.

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

The assistant legislative clerk read as follows:

The Senator from Arizona [Mr. MCCAIN] proposes an amendment numbered 2107.

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

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

The amendment is as follows:

(Purpose: To allow the importation by individuals of safe and affordable drugs from Canada)

At the end of title XI, add the following:

SEC. 11___. SAFE AND AFFORDABLE DRUGS FROM CANADA.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by this Act, is further amended by adding at the end the following:

"SEC. 810. IMPORTATION BY INDIVIDUALS OF PRESCRIPTION DRUGS FROM CANADA.

"(a) IN GENERAL.—Notwithstanding any other provision of this Act, not later than 180 days after the date of enactment of this section, the Secretary shall promulgate regulations permitting individuals to safely import into the United States a prescription drug (other than a controlled substance, as defined in section 102 of the Controlled Substances Act) that—

"(1) is purchased from an approved Canadian pharmacy;

"(2) is dispensed by a pharmacist licensed to practice pharmacy and dispense prescription drugs in Canada;

"(3) is purchased for personal use by the individual, not for resale, in quantities that do not exceed a 90-day supply;

"(4) is filled using a valid prescription issued by a physician licensed to practice in the United States; and

"(5) has the same active ingredient or ingredients, route of administration, dosage form, and strength as a prescription drug approved by the Secretary under chapter V.

"(b) APPROVED CANADIAN PHARMACY.—

"(1) IN GENERAL.—In this section, an approved Canadian pharmacy is a pharmacy that—

"(A) is located in Canada; and

"(B) that the Secretary certifies—

"(i) is licensed to operate and dispense prescription drugs to individuals in Canada; and

"(ii) meets the criteria under subsection (c).

"(2) PUBLICATION OF APPROVED CANADIAN PHARMACIES.—The Secretary shall publish on

the Internet Web site of the Food and Drug Administration a list of approved Canadian pharmacies, including the Internet Web site address of each such approved Canadian pharmacy, from which individuals may purchase prescription drugs in accordance with subsection (a).

''(c) ADDITIONAL CRITERIA.—To be an approved Canadian pharmacy, the Secretary shall certify that the pharmacy—

''(1) has been in existence for a period of at least 5 years preceding the date of enactment of this section and has a purpose other than to participate in the program established under this section;

''(2) operates in accordance with pharmacy standards set forth by the provincial pharmacy rules and regulations enacted in Canada;

''(3) has processes established by the pharmacy, or participates in another established process, to certify that the physical premises and data reporting procedures and licenses are in compliance with all applicable laws and regulations, and has implemented policies designed to monitor ongoing compliance with such laws and regulations;

''(4) conducts or commits to participate in ongoing and comprehensive quality assurance programs and implements such quality assurance measures, including blind testing, to ensure the veracity and reliability of the findings of the quality assurance program;

''(5) agrees that laboratories approved by the Secretary shall be used to conduct product testing to determine the safety and efficacy of sample pharmaceutical products;

''(6) has established, or will establish or participate in, a process for resolving grievances and will be held accountable for violations of established guidelines and rules;

''(7) does not resell products from online pharmacies located outside Canada to customers in the United States; and

''(8) meets any other criteria established by the Secretary.''.

Mr. MCCAIN. Mr. President, this is not a new issue. This has been before this body on several occasions. I want to assure my colleagues that if the lobbyists for the pharmaceutical companies in this town are able to block this, we will be revisiting this issue. This is an issue of fundamental fairness and decency and giving Americans the opportunity to have access to very important medication that in many cases is lifesaving. It has been blocked by one of the most powerful lobbies in Washington, that of the pharmaceutical companies.

For years, along with many other Senators and the current occupant of the White House—the President of the United States, when he was a U.S. Senator, supported this amendment. I would love to see the administration weigh in and take the same position that then-Senator Obama took on this issue of basic and fundamental decency and fairness to people who are badly in need of medicine to, in many cases, literally save their lives.

Industry opponents of the comprehensive importation proposals have found various ways to confuse the issue, raise red herrings about safety, or cut secret deals to block passage of reasonable and widely supported prescription drug importation programs.

Let me give an example—this recently came up—of the activities of the pharmaceutical companies in the formulation of ObamaCare. ''GOP probe uncovers deal between Obama and drug companies,'' by Philip Klein, the senior editorial writer of the Washington Examiner.

Three years ago, President Obama cut a secret deal with pharmaceutical company lobbyists to secure the industry's support for his national health care law. Despite Obama's promises during his campaign to run a transparent administration, the deal has been shrouded in mystery ever since. But internal emails obtained by House Republicans now provide evidence that a deal was struck and GOP investigators are promising to release more details in the coming weeks.

What the hell?'' White House Deputy Chief of Staff Jim Messina, who is now Obama's campaign manager, complained to a lobbyist for the Pharmaceutical Research and Manufacturers of America (PhRMA) in January 15, 2010 email. ''This wasn't part of our deal.''

This reference to ''our deal'' came two months before the final passage of Obamacare in an email with the subject line, ''FW: TAUZIN EMAIL.''

At the time Billy Tauzin was president and CEO of PhRMA—

And I might add, one of the highest paid lobbyists in history, millions of dollars—

the e-mail was uncovered as a part of Obama's closed-door health care negotiations that was launched by the House Energy and Commerce Committee oversight panel:

''In the coming weeks the Committee intends to show what the White House agreed to do as part of its deal with the pharmaceutical industry and how the full details of this agreement were kept from both the public and the House of Representatives,'' the committee's Republican members wrote in a memo today.

On June 20, 2009, Obama released a terse 296-word statement announcing a deal between pharmaceutical companies and the Senate that didn't mention any involvement by the White House.

''The investigation has determined that the White House, primarily through Office of Health Reform Director Nancy Ann DeParle and Messina, with involvement from Chief of Staff Rahm Emmanuel, was actively engaged in these negotiations while the role of Congress was limited,'' the committee members wrote. For example, three days before the June 20th statement, the head of PhRMA—

That is Mr. Tauzin—

promised Messina, ''we will deliver a final yes to you by morning.''

Meanwhile, Ms. DeParle all but confirmed that half of the Legislative Branch was shut out in an e-mail to a PhRMA representative: ''I think we should have included the House in the discussions, but maybe we never would have gotten anywhere if we had.''

What went on in the formulation of ObamaCare is still one of the worst, sleaziest exercises I have seen in my many years here, and this involvement by the pharmaceutical companies was probably the most egregious. All this amendment does is allow U.S. consumers who need more affordable prescription drug options to either go without their medications or pay higher prices than they could get from legitimate Canadian pharmacies. But that is not a reason. It is not a reason for us to stop fighting for those in the United States who need more affordable prescription medications.

There are Americans in this country today who cannot afford their medications. They have a choice between eating or taking their prescription drugs. Meanwhile, there is a way for them to get much cheaper drugs, and this amendment does that.

We will hear from the pharmaceutical company supporters in the Senate who will talk about safety and how Canadians don't have the same standards we do. Really? Do we really believe the Canadian regulations and oversight are any better or worse than the United States? To ensure that U.S. patients have at least one option, this amendment takes a very narrow approach to safe importation by focusing on legitimate Canadian pharmacies.

Under this amendment the Secretary of Health and Human Services will certify ''approved Canadian pharmacies'' based on certain safety and quality criteria. To ensure that patients are not exposed to unsafe medications ''approved Canadian pharmacies'' can only sell drugs to U.S. customers that are the same as U.S. approved drugs. To protect U.S. patients against rouge distributors, a list of approved Canadian pharmacies must be published by the Secretary of Health and Human Services so Americans know which Canadian pharmacies are legitimate.

The cost of health care, including prescription drugs, continues to increase. However, there is nothing in the underlying FDA bill that will bring down the cost of prescription drugs. I wonder if the bill should be enacted when it doesn't do anything to address costs. The quality of pharmaceuticals in this country is outstanding, and I recognize that. But don't we all know how expensive it is?

For example, don't we know that in the United States of America, Nexium, 20-milligram, 30 tabs, is $195.99. The Canadian brand is $108.55, and Canadian generic is $69. For Plavix, the U.S. brand is $195; the Canadian brand, $132.

I am sure many Americans whose health coverage does not include these very expensive pharmaceuticals would be eager to take advantage of the same quality brand of prescription drugs that are available at these pharmacies in Canada.

As we all know, unemployment remains over 8 percent, and millions of families have mothers and fathers who remain unemployed or underemployed and have no health insurance coverage. But the unemployed and uninsured still have health conditions, and they need medications. Millions continue to search for more affordable ways to get their needed prescription drugs.

Unfortunately, in my State many of my fellow citizens who cannot afford it go to Mexico to get drugs, and I cannot guarantee what they purchase there will always be what it is purported to be. That is not a criticism of my friends south of the border. But the fact is in Canada they have the same kind of process we do. Despite there being no official program to import medications from Canada, approximately 1 million U.S. consumers use

their own money to safely get their medications from legitimate Canadian pharmacies.

In Arizona, over 20,000 patients purchase their medications safely from Canadian pharmacies. In Florida over 85,000 patients purchase their medications safely from Canadian pharmacies. A recent study from Roger Bate, an AEI scholar, confirms that in drugs dispensed from legitimate Canadian pharmacies there was no failure of authenticity between drug samples obtained online from U.S. pharmacies compared to the same drug from Canadian pharmacies. Within the verified pharmacies U.S. prices on average were 52.5 percent higher than Canadian pharmacy prices. In other words, the drugs from Canadian pharmacy sites are the same dosage, form, and potency as drugs in the United States, only much less expensive.

The drugs are the same as I mentioned. This amendment doesn't authorize insurance companies, huge pharmacy chains, or drug wholesalers to import massive quantities into the U.S. system. This is about safely allowing uninsured, unemployed, and the underemployed to individually import these drugs they need.

So, please, somebody explain to me how we tell the struggling family who needs their medications that they cannot use their own money to get the same drug from legitimate Canadian pharmacies where the costs can be more than 50 percent lower than U.S. prices. It is not about the alarms of safety because this amendment requires the Secretary of Health and Human Services to promulgate regulations permitting individuals to safely import medications from Canada, and the following safety criteria must be met for a patient to import drugs from FDA-approved Canadian pharmacies: The prescribed drug must be dispensed by a licensed Canadian pharmacist; the prescribed drug must be for personal use in quantities that don't exceed a 90-day supply; the prescribed drug must be dispensed in accordance with a valid prescription issued by a physician licensed to practice in the United States; the imported drug must have ''the same active ingredient or ingredients, route of administration, dosage form, and strength as a prescription drug approved by the Secretary.''

The amendment recognizes that approved Canadian pharmacies meeting safety criteria can and should provide needed alternatives to U.S. patients using their own money to affordably obtain their medications. The Secretary is required to publish on the FDA Web site a list of ''approved Canadian pharmacies'' that meet the following stringent criteria: The pharmacy has been in existence for 5 years prior to enactment of the program and has a purpose other than to participate in the U.S.-Canadian safe drug importation program; the pharmacy operates in accordance with provincial pharmacy rules and regulations; the pharmacy complies with all inspection and data reporting procedures; the pharmacy agrees that labs approved by the Secretary shall be used to conduct product testing to determine the safety and efficacy of sample pharmaceutical products; the pharmacy does not resell products from online pharmacies located outside Canada to consumers in the United States.

Safe drug importation is a bipartisan issue. People in all of our States are still struggling with family budgets, and the Senate cannot do anything to give patients more choices about where they can get their needed drugs because the drug industry opposes allowing individual Americans to use their own money to safely get the same drugs from Canada, and it doesn't make sense.

Just a word about the types of medications that are eligible. I have been asked by colleagues whether biologic medicines can be part of the program. The answer is not unless they can be safely imported under the provisions of the amendment and regulations issued by the Secretary.

The amendment doesn't discriminate against the type of conditions or medicines that patients should be able to safely import under this program. Not all biologics are the same. Some biologic medicines are available in capsules; others are injectable medications that require refrigeration. Some injectables don't require refrigeration and are shipped to patients throughout the United States every day.

I don't believe U.S. patients should be necessarily prevented from saving money on biologics. If a biologic medicine cannot meet the various safety provisions in the amendment, it should not be eligible. If it can meet the requirements of the amendment, then a biologic can be available to U.S. patients.

If the past is a prologue, then obviously this amendment will go down. Then after this amendment is rejected, I hope none of my colleagues have any curiosity about the way the American people feel about us; about the incredible, inordinate, illegitimate, outrageous influence of the pharmaceutical companies in America over the average American citizen. American citizens should be able to purchase pharmaceuticals from an approved pharmacy in Canada that many times is saving them half the money.

I am sure the distinguished chairman, my friend from Iowa, knows how many families do not have prescription drug coverage who are making a choice today between eating and medicine. What are we going to do? We are going to turn down this commonsense amendment.

Congratulations ahead of time to the corrupt pharmaceutical companies and their influence in the United States Senate and Capitol.

Mr. President, I ask for the yeas and nays on the amendment.

The ACTING PRESIDENT pro tempore. Is there a sufficient second?

There appears to be a sufficient second.

The yeas and nays were ordered.

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

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

The assistant legislative clerk proceeded to call the roll.

Mr. HARKIN. 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.

Mr. HARKIN. Mr. President, I understand the Republican leader is about to come to the floor to give his leader remarks.

I just wish to let Senators know we are moving ahead on the bill. Senator MCCAIN just brought up his amendment and spoke about it. I know there are some who want to speak in opposition to the McCain amendment. We still have amendment No. 2111 by Senator BINGAMAN to be called up. We have two amendments, No. 2146 and No. 2145, by Senator PORTMAN that need to be called up. I ask Senators to please come over and call up their amendments so we can debate them and move ahead to expeditiously voting on those amendments and final passage of the bill.

I see the Republican leader is on the floor, and I yield the floor.

RECOGNITION OF THE MINORITY LEADER

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

Mr. MCCONNELL. Mr. President, I think we are under a time agreement on the bill; is that correct?

The ACTING PRESIDENT pro tempore. The leader is correct.

Mr. MCCONNELL. I wish to proceed under my leader time.

The ACTING PRESIDENT pro tempore. The Senator has that right.

STUDENT LOAN INTEREST RATES

Mr. MCCONNELL. Mr. President, today we will once again attempt to prevent student loan interest rates from going up. This problem could have been solved literally weeks ago, but our friends on the other side were not interested in solving the problem; they wanted a scapegoat more than a solution.

So this afternoon we will vote on two different ways of addressing the issue. The Democratic plan is designed to fail. In order to cover the cost of a temporary rate freeze that both parties actually want, they propose to divert $6 billion from Medicare and to raise taxes on small businesses, hurting the very companies we are counting on to hire today's college graduates. They have known for months that we would not support this tax hike and that it couldn't pass this Chamber or the House of Representatives. It has already failed, but they are proposing it anyway, for a second time.

If our Democratic friends would allow it, the chairman and ranking

member could write a bill that could actually pass. But since passage isn't their goal, our friends on the other side huddled behind closed doors, out of sight of the public and the press, and produced the tax hike instead of letting the committee actually do its work.

We already know how this story is going to end. We know exactly, already, how the story will end. So why are the Democrats forcing us to vote on their failed proposal yet again? Because, as I have said, they are more interested in drawing our opposition—of trying to create a bad guy—than in actually solving the problem.

When it comes to college graduates today, the bigger issue is the President's economic agenda which has created an environment in which most of them can't find a decent job. So I can understand why our Democratic friends want to change the subject, but if we are actually going to do something to solve the problem, we are going to need to get past the political theatrics.

If Senate Democrats reject the bipartisan fix the House already passed—one that doesn't raise taxes or divert a single dollar away from Medicare and is an offset they have used themselves before—then I hope they will turn around and work with us on a bipartisan fix that doesn't tax small businesses—a proposal that is actually designed to pass and become law.

But let's be clear about something. The real issue isn't the fact that certain students are going to see an interest rate hike because we will address that concern; it is that so many young people today can't find a job that will enable them to pay off their loans in the first place. That is the much larger problem. The solution is a progrowth agenda that would make it easier for U.S. businesses to hire, not a tax hike that will actually make it harder for them to hire.

In the short term, Republicans are ready to work to offer this temporary relief, but we are still waiting on the Democratic leadership to propose a solution of their own that can actually pass either one or two Chambers of Congress.

I would, once again, urge the President to get involved. If the President has time to run around to late-night comedy shows and college campuses talking about this issue, then he can pick up the phone and work out a solution with Democrats in the Senate.

Last week at the White House, I pressed the President to get involved in order to prevent the student interest rates from going up—a goal we all share. Think about it. If the President wants to pass this bill so badly, then why on Earth hasn't he picked up the phone and called the chairman or ranking Republican of the relevant committee? As with so many pressing issues, the President has not led on this issue. He has campaigned on it, but he has not worked to actually fix it.

The American people are tired of the posturing and the games. It is time for the President to lead. It is time for Senate Democrats to stop the political theater and to find a real solution.

THANKING SENATOR ENZI

Mr. President, on another matter, I wish to take a moment to thank my good friend, the senior Senator from Wyoming, MIKE ENZI, for the work he has done shepherding the FDA bill through the markup and across the Senate floor. This is an incredibly complex piece of legislation that strikes a difficult balance of protecting consumers while avoiding the stifling regulation that slows the process of bringing lifesaving drugs and devices to market.

Throughout a lengthy process, MIKE has shown the command of complex topics, steady leadership, and interest in his colleagues' priorities that have characterized his tenure at the HELP Committee. For that, those of us on this side of the aisle would like to thank him very much.

HONORING OUR ARMED FORCES

SPECIALIST DAVID W. TAYLOR

Mr. MCCONNELL. Mr. President, I wish to address one other matter. I have a sad task today of informing my colleagues that a valued and honorable Kentuckian who enlisted in the U.S. Army has fallen in the performance of his duty. On March 29, 2012, SPC David W. Taylor of Dixon, KY, died from injuries sustained in an accident at an ammunitions supply point in Kandahar Province, Afghanistan. He was 20 years old.

For his service in uniform, Specialist Taylor received several awards, medals, and decorations, including the Army Commendation Medal, the Army Good Conduct Medal, the National Defense Service Medal, the Afghanistan Campaign Medal with Bronze Service Star, the Global War on Terrorism Service Medal, the Army Service Ribbon, the Overseas Service Ribbon, the NATO Medal, the Parachutist Badge, and the Overseas Service Bar.

After his tragic death at entirely too young an age, one of Specialist Taylor's commanders, Sergeant Addington, delivered a tribute to his fallen brother in arms. This is what he said:

> When his country called for young lives to offer themselves up for the preservation of freedom, young David Taylor answered the call and said, ''Here am I, take me.'' Specialist Taylor was my soldier, my battle buddy, and my friend. He was a fast learner and my greatest student. He sacrificed himself so we might be free.

Before he was a soldier, his mother Sarah Taylor recalled that David was a compassionate, dedicated young man. From a young age, he was always looking for ways to help others. Sarah says of her son: ''One Christmas he had received a large amount of gifts.''

David asked his parents ''if he could give some of his gifts to a classmate of his who he knew would not receive many items.''

David was a great athlete who played football and soccer and ran track. He loved to hunt and hunted turkey and deer, but his real passion was for duck hunting. He had many friends, was the life of the party, and he was popular with the girls. David ''would change outfits multiple times before going to school, as his hair and clothes had to be perfect,'' Sarah says.

David was also very dedicated to physical fitness. He worked out multiple times a week to stay in shape. Perhaps that is because young David knew his body was his instrument, and he had made up his mind to join the military by age 14.

David's high school did not have an ROTC program, so David worked hard to graduate 6 months early and eagerly enlisted. He skipped both the prom and graduation to take up his more important pursuit, enlisting in January 2010. He even waived his signing bonus saying, ''It is every young man's duty to serve.''

David planned to make the military his career and hoped to go into the medical field. He dedicated himself to the military handbook and doing everything ''by the book.'' He went on to serve as a paratrooper in a parachute infantry regiment, one of the most demanding specialties in the Army.

LT Eric Fitzgerald was Specialist Taylor's platoon leader. He says:

> David was one of the most outstanding paratroopers in the whole platoon, just striving to be the best. When you wanted something done, when you wanted it done right, you went to Taylor for it.

CPT Brian Bifulco, David's company commander, concurs:

> It was evident since the day I met him that David had all the qualities desirable in a paratrooper: Smart, aggressive, committed, and reliable. He displayed them readily in everything he did.

David maintained his rigorous workout schedule in the Army by following the Crossfit physical fitness programs 5 to 6 days a week so he could excel at the Army's physical fitness test. He could run his 2-mile fitness test in a full minute faster than anyone else in his platoon. Specialist Taylor was assigned to D Company, 2nd Battalion, 508th Parachute Infantry Regiment, 82nd Airborne Division, based out of Fort Bragg, NC. He deployed to Afghanistan for Operation Enduring Freedom in February of this year for what would be his first and only deployment.

David's fellow soldiers from his platoon named the small gym in their Afghanistan outpost in his honor as a remembrance of David's commitment to excellence. Nearly every soldier in the platoon wears a metal bracelet honoring Specialist Taylor. SFC Russ Kelley had this to say:

> For many of the guys, this is the first friend they've ever lost to combat. They wear the bracelets to remember.

At this time we are thinking of SPC David W. Taylor's family and his friends as I recount his story for the Senate, including his mother Sarah Taylor, his grandmother Laura Klutey,

and many other beloved family members and friends. David was preceded in death by his father Kevin Taylor.

David's mother Sarah says David loved the Army and was excited to be in Afghanistan.

Sergeant Addington remembers:

> David seemed to live for the job, and while others would whine and complain in the field, David would just sling up his hammock and settle in. He was at home in the woods, a natural outdoorsman.
>
> David, who grew up in the woods, fit in perfectly. He seemed born to do this job, and I felt sorry for any Taliban that he was bound to run into in Afghanistan. The Taliban got lucky this time.

Even if that is the case, the tragedy of Specialist Taylor's death is certainly not lucky for anyone else, most of all not for the family he has left behind or his friends and fellow soldiers.

I know it is small solace in place of what they have lost, but I want them to know this Senate holds SPC David W. Taylor in the highest regard for his service on behalf of our country. We are honored, just a few days before Memorial Day, to recognize his enormous sacrifice on behalf of this Nation.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from New Jersey is recognized.

Mr. MENENDEZ. Mr President, I rise in strong support of the underlying bill we are debating, the Food and Drug Administration Safety and Innovation Act.

This legislation, which has been the model of bipartisanship and effective legislating on the part of Chairman HARKIN and Ranking Member ENZI, is critically important to the people of New Jersey and the Nation.

This bill is about more than drug safety. It is about more than protecting patients. It is about improving the approval process to speed access to new lifesaving, life-enhancing drugs and devices, and making sure the FDA is a partner in the production of safe and effective products.

This bill does this and accomplishes several key goals that are critically important to our Nation's health care system. Not only does it reauthorize the key user fee agreements for prescription drugs and medical devices, but it establishes agreements for generic drugs and generic biologic drugs called biosimilars.

Together, these user fee agreements will provide the FDA with the resources necessary to improve the drug and device approval process to more quickly and efficiently bring new products to market. It will enhance communication between manufacturers and the agency to foster a more cooperative environment, and it will allow for better and more thorough postmarket reviews to ensure continued patient safety and product efficacy.

There is more to this bill than the FDA user fees.

It permanently reauthorizes two vital programs that are a lifeline to our Nation's children—the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, which are incredibly important to our children. It helps reduce and mitigate the ongoing problem of drug shortages we have heard about throughout the country. It provides for enhancements to the prescription drug supply chain and increases the accountability and transparency of the Food and Drug Administration.

It is good for children. It is good for business. It is good for patients. It makes the FDA a more effective partner in the process, and it demonstrates that we can reach across the aisle and work together to tackle tough issues and find solutions that benefit the people we collectively represent.

This just touches the surface of what this bill will accomplish. However, this incredibly hard work could very easily be unraveled by some of the amendments being considered.

AMENDMENT NO. 2107

It seems that, once again, despite the countless times—the countless times—the Senate has rejected the policy my friend from Arizona pursues, he has brought us an amendment that I believe puts Americans at risk, undermines FDA's authority, and would have a devastating ripple effect throughout our country's drug supply by allowing untraceable foreign pharmaceuticals into our country.

This amendment would ostensibly only allow drugs from Canada into the United States. However, nothing in the amendment comes close to ensuring that is the case. In fact, this amendment would easily allow Web-based pharmacies within Canada to provide untraceable, unaccountable drugs from all over the globe into the U.S. market without any FDA oversight whatsoever.

This amendment does not provide the FDA with any additional resources to monitor the drugs coming in from Canada, and even the Canadian authorities have said they cannot be expected to monitor all the drugs coming through their country and into ours. Once one of those drugs hits and causes consequences to some family, then we will all be running and saying: How did we allow that to happen?

The Senate has soundly and repeatedly voted against this type of drug importation because we understand the implications it has on bringing counterfeit and dangerous products into our Nation. As we work to strengthen the FDA, I ask my colleagues to join me in opposing this amendment, which would significantly weaken the agency and put Americans at risk.

AMENDMENT NO. 2109

Additionally, I wish to address another critically important issue brought up by my friend from Vermont. The Sanders amendment would lead to a radical change in how our Nation's biotech and pharmaceutical industry achieves the process of bringing lifesaving, life-enhancing drugs into the marketplace.

I certainly respect the passion for the issues he pursues. But there are over 200,000 people in New Jersey who work in the biopharmaceutical industry every day who take pride in the work they do creating breakthrough, lifesaving, life-enhancing drugs, and I take issue with this characterization of an industry which is responsible for some of the world's most important medical breakthroughs that have saved millions of lives. If you are one of those people waiting for one of those drugs to come to the marketplace, hoping that for your mother's Alzheimer's—the Alzheimer's that took my mother's life—we will finally have a breakthrough; that for your husband with Parkinson's, we will finally have a breakthrough; that for your loved one with cancer, we will finally have a breakthrough, you want to see that come to the marketplace.

This industry is responsible for finding the cures and treatments for diseases that kill people and destroy family incomes. This is the industry that has more than 1,600 active clinical trials in New Jersey on drugs to treat cancer, cardiovascular disease, diabetes, HIV/AIDS, mental and behavior disorders, and, especially important to me personally, trials for drugs treating Alzheimer's and other forms of dementia. Families look forward to those breakthroughs coming to the market to help cure their loved ones.

This work is what keeps our Nation competitive and on the cutting edge of medical science, providing billions of dollars in economic impact annually—roughly $900 billion nationally and more than $35 billion in New Jersey—and it provides countless people across the globe with lifesaving medications.

The amendment being offered could have a chilling effect on all this—all the hope for new treatments and perhaps new cures for diseases, having an opportunity for that to be turned around, to stop having those families lose a loved one who succumbs to a disease, ruining countless lives. It has the potential to dry up investment in the next cure and severely curtail the number of high-skill, high-paying jobs and billions of dollars in economic investment in the biopharmaceutical industry.

I know my friend from Vermont wants to prevent fraudulent behavior, and I wholeheartedly agree that bad actors who willfully commit fraud need to be punished, which is why we have the most incredible, stiff civil and criminal penalties in current law to prosecute those who commit fraud. But ultimately taking away the incentives we have in place to attract investment in this important research, especially when the penalties could be triggered by a minor, unrelated offense—the way the amendment is written—is just plain and simple bad policy. It is akin to having the death penalty for a simple assault.

The current intellectual property laws that protect pharmaceutical products provide researchers and their investors with a stable and predictable timeline that allows them to recoup the risky investments in research and development of new drugs.

We only think about the drugs that have success. But remember, out of every 5,000 to 10,000 potential drug compounds identified, only 1—only 1—of those 5,000 to 10,000 potential drug compounds will result in a new medicine on the market.

Do we want the companies not to take the risk of going through all those thousands and thousands of compounds to come up with the one that can be the cure for so many lives and save so much money in the government under Medicare and Medicaid and in our entire health care system? That is risky investing by anybody's standard, so removing incentives is bad policy for the public health of the United States.

This amendment will lead to uncertainty among investors. It will dry up capital. It will further delay access to new medical products. It will pull us back from the cutting-edge research and development that has always made this Nation great.

As I have said—and as my friends who are managing this bill have said—this FDA reauthorization is too important not to pass. So I urge my colleagues to reject these harmful amendments so we can move forward and have an FDA that has the ability to do its job on behalf of the American people to create a process that will be safe but will give us the lifesaving, life-enhancing cures that ultimately will lead to a better life for all of us.

With that, 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.

Mr. HARKIN. 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.

Mr. HARKIN. Mr. President, I ask unanimous consent that the time in quorum calls be evenly divided on the McCain amendment.

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

Mr. HARKIN. Mr. President, I again say we are rapidly coming to a close. Again, the sooner we can get to voting, the sooner we will close out the business for the day and probably for the week.

I again would point out that we have Senator BINGAMAN's amendment No. 2111 yet to be called up. Senator PORTMAN has two amendments—Nos. 2146 and 2145. Those basically are the only ones left to be brought up. So I would urge them to come and others who have indicated they want to come and speak on the amendments that are pending. The McCain amendment, the Sanders amendment, the Murkowski amendment, the Durbin amendment, and the Paul amendment are still pending. People have indicated they want to come over and speak on these various amendments. I would hope they would do so, so we can perhaps get to voting on the amendments and final passage of the bill sooner rather than later.

With that, I suggest the absence of a quorum.

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

The legislative clerk proceeded to call the roll.

Mr. GRASSLEY. 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.

AMENDMENT NO. 2107

Mr. GRASSLEY. Mr. President, I support Senator MCCAIN's amendment. That amendment would allow drug importation from approved pharmacies in Canada. I have been a long-time proponent of safe drug importation. I am currently a cosponsor of the Pharmaceutical Market Access and Drug Safety Act, a bill I have worked on for many years with Senator SNOWE and Senator MCCAIN.

In 2002 and 2003, I supported amendments similar to the one before us today that would permit the importation of prescription drugs from Canada. In the year 2004, the late Senator Kennedy and I worked together on a bill that would authorize drug importation, but it did not survive the partisan politics of this Chamber.

I then introduced my own comprehensive drug importation bill in 2004. I entitled that bill the Reliable Entry of Medicine and Everyday Discounts Through the Importation of Effective Safeguard Act, and that naturally works out to an acronym. we called it the REMEDIES Act.

In 2005, I combined that bill with the proposal sponsored by then-Senator Dorgan and Senator SNOWE. And in 2007 and 2009, we reintroduced the version of that legislation with hopes that our combined efforts would finally lower the cost of prescription drugs for all Americans.

During the health care reform debate in 2009, drug importation had a much better chance to pass than ever before. We had a Democratic supermajority in Congress and we had a Democratic President who supported drug importation in the past. But in backroom deals between the Obama White House and the pharmaceutical industry, those deals prevented us from finally lowering the drug costs for all Americans.

So after all of this decade-and-a-half effort, we are back here again trying to accomplish the same goal with Senator MCCAIN's amendment. I have always considered drug importation a free-trade issue. Imports create competition and keep domestic industry more responsive to consumers. Consumers in the United States pay far more for prescription drugs than those in other countries.

For instance, U.S. prices are, on average, 52½ percent higher than Canadian pharmacy prices. If Americans could legally and safely access drugs outside the United States, then drug companies would be forced to reevaluate their pricing strategies. They would no longer be able to gouge American consumers by making them pay more than their fair share for the high cost of research and development. Because that is a fact. We pay for most of the research and development of new drugs because other countries are getting by dirt cheap and there is not enough money coming in from those countries to pay for all of the research it takes, because, as you know, most of the cost of a drug is the research and development, it is not the manufacture of that little pill or a big pill, for that matter.

In the United States, it is a fact. We import everything consumers want. So why not pharmaceuticals? In fact, I look back at all my years working on trying to free up trade around the world through efforts to pass free-trade agreements, through efforts to get the President trade promotion authority, everything that would make global policies available to American consumers, and I can only think of two things our law prevents consumers in America from importing from other countries when everything else the consumers buy they can buy anywhere in the world if they want to—but not for pharmaceuticals or not for Cuban cigars.

Some opponents of this amendment have concerns about what drug importation would mean to the safety of drugs. Obviously, we have to be concerned about drug safety because that is what the FDA is all about—two things, making sure drugs are safe, and, No. 2, to make sure they are effective.

Everyone who knows me knows I care deeply about the safety of drugs. I would not be standing here today urging support for Senator MCCAIN's amendment if I did not think it would properly protect the safety of the Nation's prescription drug supply chain. The fact is that the unsafe situation is what we have today. Today patients who need a cheaper alternative are ordering drugs over the Internet from who knows where, and the FDA does not have the resources to do much of anything about it. The fact is the McCain amendment would not only help to lower the cost of prescription drugs for all Americans but will also establish a system where American patients can be certain that the drugs they are importing are safe.

The amendment has requirements that a pharmacy must meet before the Secretary may approve them for participation. This includes product testing in labs designated by the Secretary. A list of approved pharmacies

will be published on the FDA Web site. Patients who are already forced to purchase their medications outside the United States would be able to access the list to choose a safe option. Additionally, the amendment lays out criteria that must be met before any patient may import drugs from an FDA-approved pharmacy. Patients must have a valid prescription from a physician licensed to practice in our country. The purchase must be for personal use, and the drug must have the same active ingredient, route of administration, dosage form, and strength as a prescription drug approved by the Secretary of HHS.

The McCain amendment would improve drug safety, it would not threaten drug safety. It would open trade to lower-cost drugs, and it would make other consumers around the world start paying for some of the research and development the American consumer is paying such a high price to provide. We should do all we can to get miracle drugs originated and developed, but the American consumer should not be paying the entire bill. We need to make sure Americans have even greater, more affordable access to lifesaving drugs by opening the doors to competition in the global pharmaceutical industry.

Obviously, after a decade and a half, I am continuing to urge my colleagues to join in this effort on the importation of drugs, and in this particular area to give support to Senator MCCAIN and support his amendment. I applaud him for the leadership he has shown in this area over a long period of time.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Wyoming.

Mr. ENZI. Mr. President, I rise in opposition to the McCain amendment No. 2107, which would facilitate the importation of prescription drugs from Canada. We are not talking about bus trips of seniors to reputable brick-and-mortar pharmacies right across the border. We are talking Canadian Internet pharmacies, which may not even be in Canada, which pose a significant threat to American patient safety.

This amendment would require the Food and Drug Administration to allow individuals to import prescription drugs into the United States from Canada, notwithstanding any other provision of the Federal Food Drug and Cosmetic Act.

Drugs that supposedly come from Canada can originate in any country in the world, and merely be shipped to the United States from Canada. Canadian law does not prohibit the shipment of drugs from any country into Canada and then into the United States. They do not care.

In 2005, FDA conducted an investigation of drugs that American patients thought they were ordering from Canada. Eighty-five percent of the drugs represented as coming from Canada actually came from 27 other countries. A number of drugs were found to be counterfeit.

A letter from Assistant Deputy Minister of Health, Canada, to the U.S. Surgeon General again said that Canada does not assure that products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to do so in the future.

The pending amendment would allow importation from Canadian Internet pharmacies. Canadian Internet pharmacies openly acknowledge they obtain most of their drugs from other countries. The specific language of the pending amendment gives rise to the additional safety concerns. For example, it will not prevent the importation of drugs that need special handling, such as refrigerated or photosensitive drugs. It would not prevent the importation of special drugs, such as those inhaled during surgery or administered intravenously.

The pending amendment would not require Canadian wholesalers that would be involved in the importation to be licensed or registered in any way. There would be a list but not a licensing or registration. Do we want anyone, even someone under investigation or with a suspended or revoked license, to be in the business of importing drugs, given the well-known risks?

FDA advises consumers that some imported drugs, including those that bear the name of U.S.-approved products, may, in fact, be counterfeit versions that are unsafe or completely ineffective. You know, they can have all of the ingredients to it, but if it is not put together the right way, it will not even dissolve as it goes through the body, and therefore there would be no benefit from that drug, even though it looked like the real thing, it tasted like the real thing, it went down like the real thing. But if it is not the real thing, it can cause some real trouble with people's health.

This is not a hypothetical concern. Last year Homeland Security Secretary Napolitano testified that counterfeit drugs are a growing problem. Two months ago, FDA testified about the dangers of purchasing counterfeit, unapproved, or diverted prescription drugs on line. My colleague Senator MIKULSKI has highlighted the growing involvement of organized crime in this area. Prescription drug counterfeiting can be dramatically more profitable than narcotic smuggling. Imported drugs pose additional dangers because their labels may lack important information or warnings.

FDA advises consumers that an imported medication may lack information allowing patients to be promptly and correctly treated for dangerous side effects.

We know imported drugs pose severe risks to American patients. The FDA and the Department of Health and Human Services have repeatedly said they cannot assure the safety of imported drugs. A side-by-side amendment that we used to put on this all the time was that you could import drugs as long as the Secretary of Health and Human Services said it was safe. Well, there hasn't been a Secretary of Health and Human Services who has been willing to sign that drugs imported from anywhere—even Canada—are safe.

FDA's Web site advises consumers that imported drugs—including drugs imported from Canada—may not have been manufactured under quality assurance procedures designed to produce a safe and effective product. That is the FDA Web site.

The Federal Food, Drug, and Cosmetic Act represents over 100 years of lawmaking to protect the public health. It gives the FDA authority to make sure drugs are properly approved, manufactured, labeled, shipped, handled, and stored, that factories are inspected, and that numerous other protections are in place for American patients. Adopting this amendment would endanger American patients, and I therefore urge my colleagues to oppose it.

There is a lot more that could be said. I have been saying this for years and trying to find a way it could be done. At the present time, the safety of it makes me oppose this particular amendment. They keep revising the amendment. It is still online and everybody knows how things online can be redone. They talked about putting an official seal on each Web site, but I know fourth graders who can duplicate any seal you can put on the Internet. Any list can be changed—and who checks lists, anyway? The problem is not knowing where the drugs come from that go through Canada to the United States. If they are counterfeit, they can sell them for less. The Canadian secretary of health also doesn't want to be the pharmaceutical supplier to the United States. They have a little different system up there. It is a way of driving prices down, which is something we would not stand for in the United States, a mechanism where they have to bid on the drugs. The people who make hard medicine bid against each other, and your doctor might prefer the one that doesn't win the bid. That is how they drive the price down. It is probably something we would not allow in the United States.

I ask my colleagues to oppose the amendment.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Arizona.

Mr. KYL. Mr. President, I will speak about two amendments that we will vote on later.

AMENDMENT NO. 2111

First is the Bingaman amendment. I urge my colleagues to oppose it. It ignores fundamental economic realities of pharmaceutical patent litigation, and it would ultimately result in fewer generic drugs being brought to market and delays in the launch of many of the generic drugs that do go to market.

Under current law, a generic drug company that is the first to file an abbreviated new drug application for an

existing patented drug is entitled to 180 days of market exclusivity once the generic drug is approved. In other words, they have the exclusive market on it for half a year. This creates a powerful incentive for drug companies to bring generic drugs to market.

The present amendment would dilute this right of 180 days of exclusivity and potentially require the exclusivity period to be shared with another drug company's product. Under the amendment, the only way a generic drug company that files the first ANDA could be assured of getting 180 days of market exclusivity is by litigating a challenge to the validity of the branded drug's patent all the way to a final judgment.

This is not a sound approach. First of all, patent litigation is very expensive. Full litigation of a drug patent suit typically costs between $3 million and $5 million. Second, most drug patents are ultimately found by the courts to be not invalid; that is, most validity challenges to these patents fail.

Generic drug companies, as everyone else, have limited litigation budgets. As a practical matter, if we force them to litigate every patent case to a final judgment in order to preserve their exclusivity rights, they will pursue fewer abbreviated new drug applications, and fewer ANDAs means fewer generic drugs and higher costs for consumers.

Finally, it is often the case that part way into a drug patent lawsuit, the generic drug company comes to the conclusion that the brand's patent is strong and that the challenge to the patent is likely to lose. In such a situation, everyone is better off if the suit is settled. Typically, such settlements allow the generic drug to go to market somewhat earlier but still preserve the bulk of the patent term. Obviously if the generic drug company is forced to litigate this all the way to judgment in order to potentially receive exclusivity and they lose, the full patent term will run and there will be no early generic market entry. This hurts both the generic drug companies and, more importantly, the consumers.

For these reasons, I urge my colleagues to oppose the Bingaman amendment.

AMENDMENT NO. 2109

Second, I urge my colleagues to oppose the Sanders amendment. This amendment would undermine the government's ability to fight fraud and will harm patients and U.S. competitiveness by eviscerating existing incentives to invest in medical innovation.

The Sanders amendment would result in the automatic revocation of any remaining regulatory exclusivity on a product when a company is convicted or even enters into a settlement agreement for certain violations of the Food, Drug, and Cosmetic Act, or any violations of the False Claims Act or several other listed statutes.

There are several reasons why this is the wrong approach. First and foremost, the amendment will result in less lifesaving drugs ever getting to patients. Obviously, we should be fighting for lifesaving drugs getting to patients even faster. We provide these periods for exclusivity, as I mentioned earlier, for a reason: to enable companies to recoup the significant investments they make—as high as $1.2 billion per drug—to develop new medicines. Some of the exclusivities the amendment would revoke are those we enacted to encourage companies to ensure the safe use of pharmaceuticals in children or to find a cure for rare diseases that affect a very small number of people.

Indeed, orphan drug exclusivity is a great example of how these exclusivity periods benefit patients. Since 1983, the year the Orphan Drug Act was signed into law, more than 350 medicines have been approved to treat rare diseases, compared to fewer than 10 in the 1970s. Why would we want to jeopardize such a great success story?

Second, reduced investment in U.S. drug development is not only bad for patients but for the economy. Because the Sanders amendment would create a disincentive to invest in drug development, the National Venture Capital Association has already expressed concerns, stating that the amendment has ''the potential to inadvertently undermine innovation and undermine decades of policies enacted by Congress with the goal of fostering medical innovation.'' Defined periods of exclusivity provide some small measure of predictability in what is otherwise a risky process, and companies and venture capitalists rely on these periods of exclusivity to make development and investment decisions.

By threatening the elimination of exclusivities for conduct that is likely many years removed from the development process, the Sanders amendment would introduce even greater uncertainty into the R&D process.

Let me restate that we need to reconsider the overall favorability of the environment for innovation in the United States. Yet here we are considering an amendment that, if enacted, would make the U.S. investment climate far less attractive for these companies, even as other countries are actively courting the biopharmaceutical industry.

Third, while the amendment purports to fight fraud, in reality it would actually undermine the ability of the government to fight fraud by undermining its ability to settle cases. The Sanders amendment would revoke exclusivity not only upon conviction—even if that conviction is later overturned on appeal—but also upon settlement. This is a huge problem because it creates a disincentive for companies to ever settle, as it would make more sense to drag out the district court litigation while any relevant exclusivity period is still running for the company.

Fourth, and finally, the amendment is not even necessary because the outcome called for by the Sanders amendment can already be achieved under current law in appropriate cases, because the government can, and does, have the power to negotiate the relinquishment of exclusivity as a condition of settlement. It can already do this. For example, this past January, the Department of Justice negotiated the relinquishment of a company's 180-day exclusivity as part of a settlement for violations of the Food, Drug, and Cosmetic Act. Mandating this serious outcome in every case undermines the government's ability to use it as leverage to negotiate settlements.

Large penalties already apply for violations of the statutes listed in the Sanders amendment. The world of drug manufacturing and marketing is very heavily regulated, and noncompliance is subject to considerable penalties under current law. This amendment is not necessary. Rather than being outraged by settlements that occur, perhaps we ought to take them as an indicator that the government is doing a good job of using existing authority to go after those who seek to defraud the health care system.

I urge my colleagues to oppose the Sanders amendment.

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

Ms. SNOWE. Mr. President, I rise to speak in support of the amendment offered by the Senator from Arizona.

NUCLEAR SUBMARINE FIRE

Before I do that, I want to recognize and acknowledge the tremendous and outstanding and remarkable work done by the crew at the Portsmouth Naval Shipyard and the local firefighters from numerous departments from the State of Maine, as well as from New Hampshire, because of the fire that occurred on the nuclear-powered submarine at the shipyard last evening, which was burning for more than 9 hours.

It was the extraordinary teamwork and coordination among all of the crews, as well as the firefighters and departments from both States, that managed to put out the fire. It is now smoldering. I offer my commendations and congratulations to those who did the exceptional and outstanding work, which exemplifies the kind of teamwork that already occurs at that shipyard. I wanted to offer my recognition to that extraordinary work in a very difficult circumstance.

AMENDMENT NO. 2107

I rise in support of the amendment offered by the Senator from Arizona, Senator MCCAIN, in authorizing a very limited drug importation program, whereby Americans can purchase medications from accredited online Canadian pharmacies. I am supporting this amendment, as I have in the past. In fact, we have had broader amendments offered on the floor of the Senate for almost more than a decade with respect to allowing importation of prescriptions from other countries that offer more competitive prices.

I applaud Senator MCCAIN, who obviously has been a very valuable ally in

this effort for many years. But he proposed a very limited approach to address those who have concerns with the idea of importing prescription drugs. I, for one, cannot understand why there is such a fundamental concern about this issue because, first of all, Americans have been facing tremendous increases in prescription drug prices for far too long. I think it is at a point at which Congress should address this issue, and precisely on this particular piece of legislation that is before us today. It could not be more appropriate to have this amendment offered on this legislation.

In 2010, AARP found that retail prices for the most popular brandname drugs increased 41.5 percent, while the Consumer Price Index rose just 13 percent. In other words, the cost of prescription drugs rose more than three times as much as the inflation rate. That is completely unacceptable.

What has occurred as a result of this trend? First of all, American consumers are increasingly choosing to risk living without taking critical medications. According to the Commonwealth Fund, in 2010, 48 million Americans did not fill a prescription due to high costs. That represents an increase of 66 percent since 2001.

If the Senate and the overall Congress were to adopt the McCain amendment, it would allow Americans to purchase safe medications at a lower price than they are available for us in this country. We could begin to turn this disturbing trend around. I know people in Maine deserve access to affordable drug prices. Millions of Americans, and certainly those in Maine, have purchased drugs from Canada safely, at a significant savings over the years. They have had to go to great lengths in order to purchase lower price medications. They have taken bus trips to Canada to purchase that medication because that was the only way they could have access to the prescriptions they so desperately need. The McCain amendment builds on that foundation.

If we look at this first chart, Mr. President, an April 27, 2012, survey comparing average Canadian drug prices against major U.S. retail pharmacy prices, we find the average U.S. price for a 90-day supply of Nexium, which is a common blood thinner, is $560 in America but only $265 in Canada. So Americans are paying twice as much for Nexium as Canadians do. I think that is simply outrageous. Why should American consumers pay twice as much for a medication that so many Americans depend upon?

Here is another example of a drug that is a blood-thinning drug that is also very crucial in this process, and that is Plavix. That costs $585 in the United States versus $398 in Canada for a 90-day supply. So, again, American consumers are paying 50 percent higher costs for the same prescription drugs as Canadians do.

Then let's look at the very popular anticholesterol medication Lipitor. This chart illustrates, again, what Lipitor costs the American consumer. The cost is $478 in the United States as compared to $278 in Canada for a 90-day supply.

So for patients who are already trying to make ends meet in this very difficult economy by rationing their medications, splitting their pills, or even skipping medications entirely, why would we deny them access to safe drug products at these dramatically lower prices? That is why I have cosponsored Senator MCCAIN's amendment. It would allow Americans to import medication from accredited Canadian pharmacies from a list approved by the Secretary of Health and Human Services. These accredited pharmacies must commit to ongoing quality assurance programs and product testing to determine the safety and efficacy of these products.

This amendment is more narrowly focused than even the one that our former colleague Senator Dorgan and I had offered previously. This provides a pathway to a more limited approach for Americans to access affordable medications. In fact, there has been a very recent study conducted by Roger Bate of the American Enterprise Institute entitled ''Unveiling the Mystery of Online Pharmacies: An Audit Study.'' Let me quote from him as to what he discovered:

> If some foreign Web sites sell safe prescription drugs with substantial price discounts, but American consumers are guided to buy from U.S. Web sites only, the FDA could potentially discourage price competition between the U.S. and foreign pharmacies and, thereby, reduce drug affordability within the United States. The danger of reducing price competition depends on whether consumers can distinguish trustworthy Web sites from the vast pool of foreign Web sites.

So here we have the documentation by a very significant study that talks about how Americans can access these affordable medications. We shouldn't be discouraging price competition, as this study illustrates. That is one of the points I have been arguing over the years; that the real problem in this country with respect to prices for prescriptions is that we don't have competition within the industry and competition for those medications.

Americans have learned that citizens in other countries use the very same medications as we do. They are made in the very same plants. Yet they pay less. We talk about injecting greater free market competition in the health care marketplace as a way of achieving greater affordability, and this amendment attempts to address that very issue. As we look at what other countries do, when we are talking about accessing cheaper medications, we know in Canada that is the case, and it is certainly true in other industrialized nations.

I should add, in fact, they pay 35 to 55 percent less for their drugs because of the higher prices Americans pay, which is about $90 billion more for prescription drugs every year than we would otherwise. I think that is totally unacceptable. Why should American consumers be paying 35 to 55 percent more or nearly $90 billion more than consumers in other countries for the very same medications? It simply doesn't make sense.

According to former Pfizer CEO Hank McKinnell—looking at the quote on this chart:

> Competition is good medicine for economies. . . . Name an industry in which competition is allowed to flourish—computers, telecommunications, small package shipping, retailing, entertainment—and I will show you lower prices, higher quality, more innovation, and better customer service. There's nary an exception. Okay, there's one. So far, the health care industry seems immune to the discipline of competition.

When we last considered the legislation I introduced along with former colleague Senator Dorgan, we allowed importation only from Canada, the European Union, Australia, New Zealand, and Japan, and the Congressional Budget Office estimated the Federal Government would save almost $20 billion—$20 billion—if we allowed the importation of those medications. So we know for a fact allowing drug importation generates considerable cost savings to the government, to individuals, and businesses that provide health insurance coverage to their employees.

The bottom line is where nations institute safe, regulated trade in pharmaceuticals they achieve results. When Sweden entered the European Union system of trade, they saw a reduction of 12 to 19 percent in the price of traded drugs. In fact, Europe has had parallel trading for more than 30 years and has never had an incident.

Industries see the advantage in being a part of the global market when it comes to manufacturing costs. For example, according to a Pew study in 2011, the number of prescription drugs made at non-U.S. sites doubled between 2001 and 2008. That means they doubled at a sizable increase with respect to the number of prescription drugs that are made at non-U.S. sites. There are more than 50 plants where our medications are manufactured, and not all of those facilities are even inspected—not even inspected. Yet those are medications we use in this country because they are manufactured at other plants in other countries. As I said, there are more than 50 countries in which we have our prescriptions manufactured.

So let me see if I have this straight. It is fine for some foreign countries to manufacture drugs in their own plants for the U.S. market, ship those drugs here where the American people are given the privilege of paying higher prices than anywhere else in the world, but somehow we can't safely import those very drugs into the United States directly. It simply doesn't make sense.

The American taxpayer is underwriting more than $30 billion of research—basic and applied research—at the National Institutes of Health alone, so consumers in all those other

nations are benefiting from the investments the American taxpayer is making with respect to research. That U.S. research produces these medications and these prescriptions that other nations pay 35 to 55 percent less for than the American consumer. The American taxpayer is paying more for those drugs, as I said, and also paying more of their tax dollars for the research that is ongoing at the National Institutes of Health. It simply doesn't make sense.

With all of the additional profit, industry invests nearly equally in R&D in the United States and in Europe and is increasingly moving research to low-cost Asian countries. So paying the world's highest prices for drugs doesn't ensure us more research, but it decreases our access to drugs. So that is the contradiction that Americans confront each and every day when they are purchasing their medications at a much higher cost than consumers in other countries.

The amendment that is offered by the Senator from Arizona is allowing importation solely from Canada, and it is for online pharmacies based on a list that has been drafted by the Department of Health and Human Services. That is a very prescribed, targeted, limited approach to allowing American consumers to benefit from those lower priced drugs that are offered in Canada.

It is very important we take this step. It is important for American consumers who otherwise are not going to be able to afford these medications when they are paying two to three times more than their counterparts in Canada, for example. The prices are rising five times more than the inflation rate year after year, so the compounding effect is significant and overwhelming for most American consumers and families. So what I hope is we will support the amendment that has been offered by Senator MCCAIN.

Some have suggested that providing support for the McCain amendment will hinder efforts to quickly move on the underlying legislation for the FDA. That concern is certainly not persuasive because the McCain amendment is a very narrowly focused approach. It represents a good-faith effort to find common ground. It has included strong safety-related measures and is done under very limited circumstances so the American consumer can take advantage of the lower prices I have demonstrated today with regard to some of the commonly used drugs, such as the anticholesterol medication Lipitor and the drug-thinning drugs such as Plavix. It is explicitly designed to make it more broadly acceptable to those who might have concerns in taking the approach of drug importation.

We must create a more competitive, more affordable health care system for the American people. The prescription drug market needs competition. Competition will lower prices. For some reason, even though we are underwriting all of the research that benefits consumers in so many other countries, and even though our medications are manufactured at other plants in 50 countries, the American consumers are paying up to 55 percent more than their counterparts around the world. It simply doesn't make sense. In fact, I would suggest it is outrageous.

So that is why I am supporting this amendment. We need to take this limited, modest first step that I think goes a long way to addressing any reservations anyone might have in this Chamber with respect to the issue of importation. I hope we will allow American consumers to benefit from the much lower prices, especially during these very difficult economic times. This is a first step toward a larger system of safe, regulated drug importation.

I commend the Senator from Arizona for offering this amendment, and I hope the Senate will adopt it.

I yield the floor.

The PRESIDING OFFICER (Mr. BROWN of Ohio). The Senator from Iowa.

AMENDMENTS NOS. 2142, AS MODIFIED, 2145, AS MODIFIED, AND 2146, AS MODIFIED EN BLOC

Mr. HARKIN. Mr. President, prior to Senator BINGAMAN bringing up his amendment, I ask unanimous consent that the following amendments be in order and made pending: Leahy No. 2142, as modified, with the changes that are at the desk; Portman No. 2145, as modified, with the changes that are at the desk; and Portman No. 2146, as modified, with the changes that are at the desk.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Iowa [Mr. HARKIN], for himself, Mr. LEAHY, Mr. PORTMAN, Mr. WHITEHOUSE, and Mr. SCHUMER, proposes amendments en bloc numbered 2142, as modified, 2145, as modified, and 2146, as modified.

The amendments, as modified, are as follows:

AMENDMENT NO. 2142, AS MODIFIED

(Purpose: To modify and limit certain exemptions to the Freedom of Information Act)

On page 192, strike line 10 through line 21 and insert the following:

(2) by adding at the end the following:

''(b) ABILITY TO RECEIVE AND PROTECT CONFIDENTIAL INFORMATION OBTAINED FROM FOREIGN GOVERNMENTS.—

''(1) IN GENERAL.—The Secretary shall not be required to disclose under section 552 of title 5, United States Code (commonly referred to as the Freedom of Information Act), or any other provision of law, any information described in subsection (c)(3) obtained from a foreign government agency, if—

''(A) the information is provided or made available to the United States Government voluntarily and on the condition that the information not be released to the public; and

''(B) the information is covered by, and subject to, a certification and written agreement under subsections (c)(1) and (c)(2).

''(2) TIME LIMITATIONS.—The written agreement described in subsection (c)(2) shall specify the time period for which the non-disclosure requirements under paragraph (1) shall apply to the voluntarily disclosed information. The non-disclosure requirements under paragraph (1) shall not apply after the date specified, but all other applicable legal protections, including section 552 of title 5, United States Code and section 319L(e)(1) of the Public Health Service Act, shall continue to apply to such information, as appropriate. If no date is specified in the written agreement, the non-disclosure protections described in paragraph (1) shall not exceed 3 years.

''(3) DISCLOSURES NOT AFFECTED.—Nothing in this section authorizes any official to withhold, or to authorize the withholding of, information from Congress or information required to be disclosed pursuant to an order of a court of the United States.

''(4) PUBLIC INFORMATION.—For purposes of section 552 of title 5, United States Code, this subsection shall be considered a statute described in section 552(b)(3)(B).''.

AMENDMENT NO. 2145, AS MODIFIED

(Purpose: To facilitate the development of recommendations on interoperability standards to inform and facilitate the exchange of prescription information across State lines)

At the end of title XI, add the following:

SEC. 11___. RECOMMENDATIONS ON INTEROPERABILITY STANDARDS.

(a) IN GENERAL.—The Attorney General and the Secretary of Health and Human Services may collaborate to facilitate the development of recommendations on interoperability standards to inform and facilitate the exchange of prescription information across State lines by States receiving grant funds under—

(1) the Harold Rogers Prescription Drug Monitoring Program established under the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2002 (Public Law 107–77; 115 Stat. 748); and

(2) the Controlled Substance Monitoring Program established under section 399O of the Public Health Service Act (42 U.S.C. 280g–3).

(b) REQUIREMENTS.—The Attorney General and the Secretary of Health and Human Services shall consider the following in facilitating the development of recommendations on interoperability of prescription drug monitoring programs under subsection (a)—

(1) open standards that are freely available, without cost and without restriction, in order to promote broad implementation;

(2) the use of exchange intermediaries, or hubs, as necessary to facilitate interstate interoperability by accommodating State-to-hub and direct State-to-State communication;

(3) the support of transmissions that are fully secured as required, using industry standard methods of encryption, to ensure that Protected Health Information and Personally Identifiable Information are not compromised at any point during such transmission; and

(4) access control methodologies to share protected information solely in accordance with State laws and regulations.

(c) REPORT.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Attorney General, in consultation with the Secretary of Health and Human Services, shall submit to the Committee on the Judiciary and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on the Judiciary and the Committee on Energy and Commerce of the House of Representatives a report on enhancing the interoperability of State prescription

monitoring programs with other technologies and databases used for detecting and reducing fraud, diversion, and abuse of prescription drugs.

(2) CONTENTS.—The report required under paragraph (1) shall include—

(A) an assessment of legal, technical, fiscal, privacy, or security challenges that have an impact on interoperability;

(B) a discussion of how State prescription monitoring programs could increase the production and distribution of unsolicited reports to prescribers and dispensers of prescription drugs, law enforcement officials, and health professional licensing agencies, including the enhancement of such reporting through interoperability with other States and relevant technology and databases; and

(C) any recommendations for addressing challenges that impact interoperability of State prescription monitoring programs in order to reduce fraud, diversion, and abuse of prescription drugs.

AMENDMENT NO. 2146, AS MODIFIED

(Purpose: To amend the Controlled Substances Act to place synthetic drugs in Schedule I)

At the end of title XI, insert the following:

Subtitle D—Synthetic Drugs

SECTION 1141. SHORT TITLE.

This subtitle may be cited as the ''Synthetic Drug Abuse Prevention Act of 2012''.

SEC. 1142. ADDITION OF SYNTHETIC DRUGS TO SCHEDULE I OF THE CONTROLLED SUBSTANCES ACT.

(a) CANNABIMIMETIC AGENTS.—Schedule I, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end the following:

''(d)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

''(2) In paragraph (1):

''(A) The term 'cannabimimetic agents' means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

''(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

''(ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

''(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

''(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

''(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

''(B) Such term includes—

''(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP–47,497);

''(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog);

''(iii) 1-pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678);

''(iv) 1-butyl-3-(1-naphthoyl)indole (JWH–073);

''(v) 1-hexyl-3-(1-naphthoyl)indole (JWH–019);

''(vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200);

''(vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250);

''(viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081);

''(ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122);

''(x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398);

''(xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);

''(xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);

''(xiii) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19 and RCS–4);

''(xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8); and

''(xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH–203).''.

(b) OTHER DRUGS.—Schedule I of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended in subsection (c) by adding at the end the following:

''(18) 4-methylmethcathinone (Mephedrone).

''(19) 3,4-methylenedioxypyrovalerone (MDPV).

''(20) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E).

''(21) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D).

''(22) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C).

''(23) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I).

''(24) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2).

''(25) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4).

''(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C–H).

''(27) 2-(2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C–N).

''(28) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P).''.

SEC. 1143. TEMPORARY SCHEDULING TO AVOID IMMINENT HAZARDS TO PUBLIC SAFETY EXPANSION.

Section 201(h)(2) of the Controlled Substances Act (21 U.S.C. 811(h)(2)) is amended—

(1) by striking ''one year'' and inserting ''2 years''; and

(2) by striking ''six months'' and inserting ''1 year''.

SEC. 1144. PROHIBITION ON IMPOSING MANDATORY MINIMUM SENTENCES.

Section 401(b)(1)(C) of the Controlled Substances Act (21 U.S.C. 841(b)(1)(C)) is amended by adding at the end the following: ''Any mandatory minimum term of imprisonment required to be imposed under this subparagraph shall not apply with respect to any controlled substance added to schedule I by the Synthetic Drug Abuse Prevention Act of 2012.''.

SYNTHETIC DRUGS

Mr. LEAHY. Mr. President, I ask to engage in a colloquy with Senator HARKIN.

I thank the Senator from Iowa for his hard work as chairman of the Committee on Health, Education, Labor, and Pensions and, in particular, on the Food and Drug Administration Safety and Innovation Act that the Senate is now considering. I appreciate Senator HARKIN reaching out to me about those amendments to his bill that fall within the jurisdiction of the Judiciary Committee. One of those amendments concerns the issue of synthetic drugs—a major problem that the committee has been addressing.

Mr. HARKIN. Amendment 2146, as modified, filed by Senator PORTMAN, places a number of synthetic drugs within schedule I under the Controlled Substances Act.

Mr. LEAHY. Yes. That amendment is the same in substance as three bills that the Senate Judiciary Committee passed last year—the Combating Dangerous Synthetic Stimulants Act, S. 409; the Combating Designer Drugs Act, S. 839; and the Dangerous Synthetic Drug Control Act, S. 605. It addresses substances commonly known as bath salts and other synthetic drugs that have no legitimate use and can too easily be obtained under current law. Bath salts have resulted in a number of reports of individuals acting violently in the United States, including in Vermont, and have led to injuries to those using them and to others.

Mr. HARKIN. I am glad that those bills and, therefore, the substance of this amendment have already been given careful consideration by the Senate Judiciary Committee. That gives me comfort in including this amendment among those to which the managers of the bill consent.

Mr. LEAHY. I agree. I want to be sure that the amendment to be included will be Senator PORTMAN's amendment that corresponds precisely to the bills that were considered by the Judiciary Committee. Adding chemicals to schedule I of the Controlled Substances Act has serious consequences and is not a step that we should undertake without careful consideration. Do you understand that the consent to include Senator PORTMAN's amendment is not consent to further amend the Controlled Substances Act, that it is limited to these chemicals and matters contained in that amendment, and that have been considered and approved by the Senate Judiciary Committee?

Mr. HARKIN. Absolutely.

Mr. LEAHY. It is unfortunate that the three synthetic drug bills that the Judiciary Committee passed last summer have been unable to move on the Senate floor because they have been held up by one Senator. They have been cleared for Senate passage on the Democratic side for some time.

Mr. HARKIN. It is too bad that so much progress has been blocked by so few in this Congress. I am glad that the Food and Drug Administration Safety and Innovation Act may provide an opportunity to make progress on this important issue.

Mr. LEAHY. I thank the Senator for his assistance on this matter.

Mr. HARKIN. Mr. President, I ask unanimous consent that the following pending amendments be agreed to: Leahy No. 2142, as modified; Portman No. 2145, as modified; and Coburn No. 2131; and that the Coburn amendment No. 2132 be withdrawn.

The PRESIDING OFFICER (Mr. BROWN of Ohio). Is there objection? Without objection, it is so ordered.

AMENDMENT NO. 2142, AS MODIFIED

Mr. LEAHY. Mr. President, I commend the Senate for unanimously adopting my amendment to address Freedom of Information Act, FOIA, concerns with section 708 of the Food and Drug Administration Safety and Innovation Act. I especially thank Senators HARKIN and ENZI—the distinguished Chairman and Ranking Member of the HELP Committee—for working with me to protect the American public's ability to access important health and safety information under FOIA.

My amendment improves the bill by allowing the Food and Drug Administration, FDA, to obtain important information about drug inspections and drug investigations undertaken by foreign governments, while at the same time ensuring that the American public has access to information about potential health and safety dangers. Specifically, the amendment narrows the scope of the FOIA exemption in the original bill to No. 1 cover only information obtained from foreign government agencies and No. 2 clarify that the information to be withheld must be voluntarily provided to the FDA pursuant to a written Memorandum of Understanding. The amendment also preserves the right of the Congress to obtain this information. Lastly, the amendment places a 3 year time limit for withholding information pursuant to the exemption, unless a different time period is specified by the foreign government agency—so that the information will not automatically be shielded from the public indefinitely.

For more than four decades, the Freedom of Information Act has been an indispensible tool for the public to obtain Government information. This law carefully balances the need for the Government to keep some information confidential, with the need to ensure free flow of information in our Democratic society. I am pleased that by unanimously adopting my amendment, the Senate has worked in a bipartisan manner to ensure that this careful balance is maintained regarding FDA drug inspections and investigations.

I thank the many open government and consumer groups—including OpenTheGovernment.org and Public Citizen—that supported this amendment. Again, I also thank and congratulate the lead sponsors of this bill on the passage of this important legislation.

AMENDMENT NO. 2146, AS MODIFIED

Mr. HARKIN. Mr. President, it is my understanding that we are ready to act on the Portman amendment No. 2146, as modified.

The PRESIDING OFFICER. Is there further debate on the amendment? If there is no further debate, the question is on the adoption of the amendment.

The amendment (No. 2146), as modified, was agreed to.

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

The PRESIDING OFFICER. The senior Senator from New Mexico.

AMENDMENT NO. 2111

(Purpose: To provide substantial savings in health care costs to the Federal government and consumers by fostering competition among generic pharmaceutical manufacturers and ensuring that anti-competitive ''pay-for-delay'' settlements between brand-name and generic pharmaceutical manufacturers do not block generic drugs from entering the market)

Mr. BINGAMAN. Mr. President, I call up amendment No. 2111.

The PRESIDING OFFICER. The clerk will report the amendment by number.

The assistant legislative clerk read as follows:

The Senator from New Mexico [Mr. BINGAMAN], for himself, Mr. VITTER, Mr. FRANKEN, Mrs. SHAHEEN, Mr. KOHL, Mr. UDALL of New Mexico, Mr. JOHNSON of South Dakota, Ms. KLOBUCHAR, Mr. MERKLEY, and Mr. SANDERS, proposes an amendment numbered 2111.

Mr. BINGAMAN. I ask unanimous consent that the reading be dispensed with.

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

(The amendment is printed in the RECORD of Thursday, May 17, 2012 under ''Text of Amendments.'')

Mr. BINGAMAN. Mr. President, this amendment is one that is a bipartisan amendment. Senator VITTER is cosponsoring this with me, also Senators FRANKEN, SHAHEEN, KOHL, TOM UDALL, TIM JOHNSON, KLOBUCHAR, MERKLEY, SANDERS, and the Presiding Officer, Senator BROWN.

This amendment addresses the very same issue that the Senator from Maine was talking about; that is, how do we bring down the price of prescription drugs? How do we get competition into the market for prescription drugs?

We have a circumstance today in which an anticompetitive, anticonsumer practice is engaged in, and our amendment will change the law so that practice can no longer be engaged in. The practice I am talking about is the entering into so-called pay-for-delay settlements between brand-name drugs—brand-name pharmaceutical companies and generic manufacturers.

These pay-for-delay settlements have the effect of delaying timely access to generic drugs. These agreements between companies shield billions of dollars in sales each year from effective competition. The pharmaceutical companies benefit from this lack of competition and they do so at the expense of consumers and they do so at the expense of the Federal Government, since the Federal Government is a very large consumer and purchases a substantial amount of prescription drugs for the military and in other ways.

A preliminary estimate from the CBO indicates that this amendment will reduce direct spending by hundreds of millions of dollars at a minimum. Frankly, I believe it will, in fact, save us billions of dollars annually at the Federal Government level. The CBO also indicates that the amendment will reduce the average cost for prescription drugs and lower the cost of health insurance plans.

Early access to generic drugs is a key to saving money in the health care system. Kaiser Family Foundation has found this. They concluded that spending in the United States for prescription drugs reached $259.1 billion in 2010. That is nearly six times as much as we spent on prescription drugs in 1990. Since generic drugs are on average four times less expensive—or another way to put that is one-quarter of the cost of the brand-name alternatives—they can be a very important source for reducing the cost in our health care system. To actually receive these savings, consumers have to have access to these generic drugs and have access to them in a timely manner.

In 1984, Congress passed the bipartisan Hatch-Waxman Act to create market-based incentives for generic pharmaceutical companies to bring their drugs to market as quickly as possible. The purpose of the law was to incentivize the early generic drug competition while preserving incentives for pioneer companies to develop innovative new medicines. Unfortunately, pay-for-delay settlements between brand-name drugs that already have their products in the market and generic pharmaceutical manufacturers who have not yet brought their products to market have become commonplace, and these agreements, these so-called settlements, have stifled competition and delayed access to generic drugs at a significant cost to everyone who is involved in the health care system.

There is a table I want to put up. It relates to three particular drugs, and I will talk about the second two of these drugs because this gives some context to what I am concerned about.

This second drug is Lipitor. Everybody knows about Lipitor. It is a cholesterol-lowering drug. It is familiar to most people. It is the best-selling pharmaceutical ever in the history of the world.

According to a 2008 New York Times report, a pay-for-delay settlement delayed generic entry into that market—the entry of a generic version of Lipitor—by 20 months. The same report stated the generic version of the drug was estimated to sell for less than one-third the cost of the brand-name Lipitor. It pointed out that the brand-named Lipitor had earned $12.7 billion in sales the year before.

According to a letter sent to the FDA Director Hamburg last year from some of my colleagues in the Senate indicating that the Federal Government was spending $2.4 billion a year on

Lipitor, they estimated that bringing a generic version to market would generate somewhere between $4 billion and $6.7 billion in savings annually to people who are purchasing this drug in this country.

The second example is Provigil. This is a sleep disorder drug. Due to the pay-for-delay settlement entered into there, a generic version of Provigil just came to market this year. Had this amendment we are offering as part of this bill been law, generics very likely would have entered the market 6 years ago with the expiration of exclusivity.

The chief executive officer of Cephalon—which is the brand-name manufacturer of Provigil—is quoted as saying:

> We were able to get six more years of patent protection. That's $4 billion in sales that no one expected.

In other words, the Provigil case represents 6 years and millions of dollars of lost savings to consumers, the largest consumer being the U.S. Government and particularly the U.S. military.

I have a chart that relates to the U.S. military's potential savings from this amendment. This translates this into dollars that are being paid out by the U.S. military as part of the defense budget, which we are going to be passing later this year.

Assuming that a generic version of Provigil would have been released in 2006, the Department of Defense alone would have saved $159 million from this one drug between 2006 and 2011. That is over $150 million from a single prescription drug.

If enacted, this amendment would foster more generic competition, would bring generic drugs to the market sooner, and would do so in a manner that is consistent with the original intent of the Hatch-Waxman Act. Passage of the amendment would significantly cut prescription drug costs for American consumers and help reduce the Federal deficit.

Let me also allude to an article on the front page of the New York Times. I know some of my colleagues take exception to the New York Times occasionally, but this is an article entitled ''New Fervor for Cutting Costs Among Hospitals and Insurers.'' The reporter is Reed Abelson. About three paragraphs into the article, he states:

> After years of self-acknowledged profligacy, hospitals, doctors and health insurers say there is a strong effort under way to bring medical costs under control.

I was struck by that phrase ''self-acknowledged profligacy in the health care system.'' I think that is what we have engaged in, in the Congress, frankly, is self-acknowledged profligacy in the health care system. This amendment will help to correct that.

The amendment has the strong support of AARP, of Families USA, Consumer Federation of America, U.S. PIRG, Consumers Union, the Center for Medicare Advocacy, AFL–CIO, AFSME, Walmart, the National Committee to Preserve Social Security and Medicare, among other groups and organizations.

If my colleagues favor competition, this amendment helps to promote competition. If we want to see reduced costs to the taxpayer for health care, then this amendment helps to reduce the cost to the taxpayer. If we want to reduce what patients and hospitals and insurance companies have to pay for prescription drugs, this amendment helps to do that as well.

I think this is something that is long past time we corrected this problem. This is a great opportunity for us to do so. I believe it is one of the first amendments that will be considered on this legislation. I hope my colleagues will put aside whatever other considerations they might have had in the past and go ahead and vote for this correction in Federal law. This is a problem, frankly, that we passed legislation that provided the opportunity—unfortunately. It was not intended. But an unintended consequence of the earlier legislation that we passed, the Hatch-Waxman Act, was to allow this kind of blocking, these kinds of pay-for-delay settlements to be entered into. We can correct that today. I hope very much we will.

I urge my colleagues to support the amendment, and I yield the floor.

Mr. SCHUMER addressed the Chair.

The PRESIDING OFFICER. On whose time is the Senator speaking?

Mr. SCHUMER. I am speaking on the majority's time.

The PRESIDING OFFICER. On the Bingaman amendment?

Mr. SCHUMER. No. I am speaking on the McCain amendment.

The PRESIDING OFFICER. The senior Senator from New York is recognized.

AMENDMENT NO. 2146

Mr. SCHUMER. Mr. President, I am going to speak for a brief moment on the amendment No. 2146 and then on a different issue, which is the reaction of some to the proposal Senator CASEY and I made about Eduardo Saverin and others who renounced their citizenship for tax purposes.

First, on 2146. I am glad this amendment has now finally passed the Senate. It places synthetic drugs on schedule I of the Controlled Substances Act as totally banned substances, which are where they belong.

These synthetic substances are also known as bath salts or, in the case of synthetic marijuana, Spice incense. Synthetic drugs aren't sold on street corners by slingers who keep hidden stashes; instead, these drugs are legal—even though they are dangerous—and can be found in local corner stores across the country. They are as easy to buy as a lollipop or a carton of milk but far more dangerous, even more dangerous than the common illegal drug on which they are based.

By passing this amendment, we finally get these poisonous drugs off our shelves and keep our Nation's youth out of emergency rooms.

I wish to thank Senators KLOBUCHAR and GRASSLEY for working with me on this amendment, as well as Chairman HARKIN and Senator ENZI, Chairman LEAHY, Senator GRASSLEY, and Senator FEINSTEIN for their leadership, and I want to thank Senator HARKIN and ENZI particularly for getting us in this package and Senator PORTMAN for working with us on this amendment.

EDUARDO SAVERIN

On the issue of Eduardo Saverin, last week, Senator CASEY and I introduced the Ex-Patriot Act. It is a bill that makes sure that people that renounce their citizenship for tax purposes do not escape what they owe and cannot come back without repaying all that they avoided paying this great country.

It is a modest proposal, made in response to the regrettable effort by a person named Eduardo Saverin, who renounced his American citizenship to avoid paying even the historically low level of 15 percent on capital gains for the several billion dollars in windfall profit he is set to receive from the Facebook IPO.

Mr. Saverin is no longer involved in the day-to-day running of the company, and it bears mentioning that the current, active leadership of Facebook is comprised of responsible corporate citizens who meet all of their responsibilities and obligations.

Mr. Saverin, on the other hand, has chosen to disown the United States to save some money on his taxes.

Senator CASEY and I have proposed a response. Our bill would bar Saverin—and others like him—from reentering the country. It would also re-impose taxes on investment income earned in the United States even if an expatriate is living abroad.

I believe that the vast majority of Americans, of all parties and persuasions, think that renouncing citizenship in America to avoid taxes is troubling, unwarranted and ungrateful.

It is upsetting, to say the least, when a person who has benefitted so thoroughly from being an American—a person who accessed and enjoyed so many exceptional aspects of American society—just takes the money and runs, rather than doing the right thing and repaying the debt he owes to a nation that nurtured, facilitated and cheered his success.

And I think that the vast majority of Americans are receptive to suggestions for how we can address this kind of unacceptable behavior.

Look, nobody enjoys paying taxes, but Americans know that we would not have a functioning society without them. We argue and debate about the proper rates, and what is fair, and what level will sustain and grow our economy and our middle class.

But I think that most Americans agree that paying a mere 15 percent in capital gains taxes on a sum of $3 billion or $4 billion is not too much to ask a person, especially a person who fled

their own homeland because their native society could not provide a reasonable level of security to their family.

While the real point here is not just about this one case—our bill addresses a small group of evaders over the last decade or so—it is worth pointing out that in this particular case the Saverin family found security here thanks to taxpayer funded cops and stability thanks to a taxpayer funded military, and a world-class university system, like that at Harvard—again underpinned by public support.

And they also found an expansive middle class that would become the market for his product. And a dynamic, entrepreneurial, free market economy that allows for significant accumulation of wealth. And functioning capital markets that were recently saved from the brink of catastrophic collapse through who? The American taxpayer.

And they found a government that invests in research and development, in things like creating the internet, and the web, and GPS, and microprocessors, all of which are necessary precursors to what Saverin and his cohorts created via Facebook.

And let's not forget, a non-corrupt legal system, which decided a case in his favor that made him a billionaire.

Yes, Eduardo Saverin did well by being in America.

And I think that most Americans know full well that what he accomplished was not done in a vacuum and that his success is the also the outgrowth of his participation in an extraordinary American society—a society that we collectively support.

No one gets rich in America on their own. And when people do well in America, they should do well by America.

I believe the vast majority of Americans believe this, too. So when I introduced our legislation I was sure it would garner wide and deep support, and in general, it has.

That is why it is baffling that extreme right wing Republicans, people like Grover Norquist, the de-facto leader of the Republican Party on tax matters, would rush to the defense of a man who is turning his back on America by dodging taxes.

Amazingly, the extreme right-wing echo chamber has made Saverin into a cause célèbre, defending his decision to disown the country as somehow ''heroic''—Their words, not mine.

I was amazed. Just amazed. I took it as a given that citizenship—and all that it implies in terms of loyalty and duty to America—was axiomatic.

But that is no longer the case. Here is just some of what was said.

Forbes said that ''For De-Friending The U.S., Facebook's Eduardo Saverin Is An American Hero.'' An American hero? Renouncing your citizenship now qualifies as heroic for the hard right wing? George Washington was heroic. Rosa Parks was heroic. JOHN MCCAIN and Gabby Giffords are heroic. Navy SEALS are heroic. Eduardo Saverin is not.

National Review's Mario Loyola says, ''It is the foolish and counter-productive tax policies of the left that are chasing Eduardo Saverin to another country. . . .'' I'm sorry. 15 percent capital gains rate on several billion dollars is so onerous that it is chasing him away? I am sure any American worker would love to have that rate.

And if 15 percent is too high, what does Mr. Loyola or Mr. Norquist think the proper capital gains rate should be? Do they think we should have even lower taxes on capital gains, which disproportionately goes to the highest income earners?

What is the proper capital gains rate, Mr. Norquist? Should we make it 10 percent? 5 percent? Or should it be zero?

They won't say. Because if they did, they would be laughed out of town.

The Wall Street Journal says we are ''oppressive and demagogic.''

No. In America, You are free to leave. But if you leave to purposely avoid paying your fair share, then we will attach a consequence to that dodge.

Right wing blog after blog—from the American Thinker to the Daily Caller—echoes that, ''punishing Saverin for tax dodging is un-American.''

Really? Silly me. I thought that renouncing one's citizenship was un-American.

While on right wing radio they ask:

> If it's a more favorable tax haven than you can find elsewhere, why is it automatic that you are unpatriotic? Why is it automatic that you are a coward?

Because, my fellow Americans, when you renounce your nation to fatten your bank account, you are—by definition—being greedy and unpatriotic.

Grover Norquist: says our bill is like fascist Nazi Germany or apartheid South Africa or communist Soviet Union, while in American Thinker we of erecting a ''Berlin Wall.'' And In the Examiner they are accused say we are ''totalitarian.''

The comparisons are absurd on their face and burden on the odious.

The law Mr. Norquist references in Nazi Germany was purely; discriminatory. It targeted a particular race of people—the Jewish people—and—punished them for nothing other than being Jewish and exercising freedom of movement. It was meant to constrain that freedom by forcing Jews to reside inside Germany.

Our proposal targets no single race, creed or class. It doesn't punish you for factors beyond your control, like who your parents were. It applies based on actions you take—namely, disowning the United States to avoid taxes. Our law is not triggered by a wish to travel beyond America's borders, or even reside permanently in a foreign country. It is the act of renouncing one's U.S. citizenship—for the purpose of avoiding taxes—that triggers our bill.

Another right wing opinion piece asks: ''If you leave to protest heavy taxation why must you pay a penalty?''

I am sorry, gentlemen, but Mr. Saverin is not protesting anything If he was protesting, he would stay here, and fight for a lower tax rate—not simply exempt himself and leave others like him to continue paying a rate he considers too high. What he is doing is free-riding on America, dodging paying his fair share, and pocketing the billions from an IPO windfall.

Yet another right wing blog says we are engaged in ''class warfare to vilify people that create wealth-just like the Nazi's did with the Jews.''—I know a thing or two about what Nazi's did—some of my relatives were killed by them—and saying that a person who made their fortune specifically because of the positive elements of American society, in turn, has a responsibility to do right by America is not even on the same planet as comparing to what the Nazis did to the Jews. That comparison is odious, but it is in a bunch of these right-wing blogs.

On and on it goes. The whole torrent of vitriol is absurd. Just absurd.

Mr. Saverin is, in essence, an economic tax dodger.

And once upon a time, the right wing castigated draft dodgers for failing to heed their nation's call. Those who fled the country were vilified by the right wing as cowards, as self-absorbed, as traitors.

Yet, in this case, the exact same kind of unpatriotic, un-American behavior is actually being defended by the extreme right wing.

It is off the deep end.

And when a view this irrational has overtaken one end of the political spectrum, it has serious, negative consequences for our ability to solve our nation's problems.

If those on the other side of the negotiating table are this obsessive on taxes—that they consider their minimization a higher priority than preserving our national identity—then it is no wonder a grand bargain on taxes and spending has been so out of reach.

In the last several years, the far right has disregarded one historically conservative priority after another in favor of an all-consuming obsession with protecting low tax rates for the wealthiest Americans.

First, it was the deficit. The Republicans have for years claimed that deficit reduction was their top priority. But that has since been exposed as a myth.

Every independent economist will tell you that the deficit problem cannot be solved except through both spending cuts and revenue increases. In fact, preserving tax cuts for the very wealthy is counterproductive to the goal of reducing our annual deficits.

Yet the far right marches on in defense of tax cuts for millionaires, deficits be damned.

Last August, our Nation's creditworthiness became a second casualty of the far right's insistence on low taxes for the wealthy. The right wing was so dug in against any reasonable fiscal

compromise that they forced a manufactured crisis over raising the Nation's debt limit. This caused the first-ever downgrade of our Nation's credit rating.

Unbelievably, the far right prioritized millionaire tax breaks over our Nation's full faith and credit.

Despite that unreasonableness, we thought we had finally figured out a way to force the far right to come to grips with the need to deal with revenues. We come up with a mechanism called the sequester that would trigger harsh defense cuts if the Republicans continued to refuse any new revenues.

Surely, if there was one thing conservatives prized as much as tax cuts, it was defense spending, right?

Wrong. As we speak, the far right remains unwilling to cede an inch on revenues, no matter what it means for the Pentagon. The deficit; the Nation's creditworthiness; National security—all of these have taken a backseat to the far right's idolatry on taxes. Now they have gone so far, they have taken this idolatry all the way to its extreme end point by making Eduardo Saverin into their patron saint.

In the name of low taxes for the wealthy, they have lionized an inherently unpatriotic person.

The hero worship of Saverin is Norquist's extreme right wing anti-tax agenda being carried to its logical conclusion. And it is a scary, absurd place where even a tax dodger who renounces America for his own 30 pieces of silver is celebrated as a patriot and an American hero.

It is perverse.

Reasonable Republicans rightly seem wary to embrace taking things this far. House Speaker JOHN BOEHNER labeled Saverin's move ''absolutely outrageous'' and said he would support legislation to stop wealthy ex-pats relocating to avoid taxes.

Others have been quiet, perhaps cowed by fears of being the next target of the right wing echo chamber.

Shouldn't loyalty to America—and the broader responsibilities and duty of citizenship—trump base, non-essential financial self-interest?

Sadly, the answer of the extreme right is no.

The Wall Street Journal attacked the thrust of our proposed legislation as an example of the ''age of envy.'' Well, it is not envy. In fact, I am happy those who intended and invested in Facebook got very rich. Having an idea and succeeding and maybe getting rich off this great idea is the American way. More power to them.

However, what is not the American way is taking a free ride on all the exceptional aspects of American society. What is not the American way is deriving massive advantage from various publicly supported elements of that society and then skipping town when you hit the jackpot. Yes, you are free to leave. You have a right to be selfish—even greedy—when renouncing this Nation.

I understand this will make you more money and there is a rational, simplistic argument to be made in favor of doing it—if the only factor that mattered was always getting richer and all other values were irrelevant. But we Americans have other values too.

America is special for many reasons. It is secure, it offers freedom of expression, it is diverse and tolerant, it is entrepreneurial, and it is economically and culturally dynamic. Looking out for the common good is in our blood. It is a part of our shared history and vision of our Founding Fathers.

We provide for the common defense. We promote the general welfare. We are not just out for ourselves. No. We look to secure the blessings of liberty not just for ourselves but for our posterity. It is this, and so much more, that makes America an exceptional society.

I am appalled by the reaction. I am not appalled by a debate on tax policy. I am appalled by making heroic a man who renounces his citizenship to escape a tax rate, capital gains of 15 percent.

Too often I think every action and dilemma we face is now reduced to a question of whether this means bigger government or smaller government. Since those on the extreme right believe we must have smaller government at all costs, they vehemently oppose all taxes. But sometimes, as with this case and others like it, it is not just about the size of government. It is about doing what is fair and right and just based on your responsibilities as a citizen.

Citizenship is not simply a business decision, it is not just a transaction. Those on the right, such as Grover Norquist, defending this economic draft dodger are saying something very different. They are saying the social contract somehow excludes the accumulation of money. We know we give up certain rights and freedoms to live in a place like America, but we cannot just carry out vigilantism to pursue justice.

So in conclusion, being an American is not a one-way street. There are enormous benefits to being a citizen of our Nation and a member of the amazing society that has spawns. But there are also responsibilities and duties, such as patriotism, service, contributing your fair share, and commitment to community and family.

As we approach critical debates on the matters of taxation and fairness and job creation so critical to keeping America, the greatest Nation on the face of the Earth, I certainly hope it is these values, not glorified self-interest, that drowns out all other values that guide our actions.

Thank you. I yield the floor.

The PRESIDING OFFICER. The senior Senator from Wyoming.

Mr. ENZI. Mr. President, while I agree with much of what the Senator has said, I hope this doesn't encourage other partisan diatribes to come to the floor when we are on a bipartisan bill and trying to solve getting necessary pharmaceuticals to the market as soon as possible. We have a limited time of debate, and we need to stay on the subject. So I hope others are not encouraged to come down to counter anything they may have heard or to make different charges.

We have some time left on Bingaman and some others, but I hope we can move forward on the bill.

I yield the floor to the Chair.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Mr. President, I concur with Senator ENZI on that, to stick to the bill.

I ask unanimous consent, notwithstanding the previous order, the Senate proceed to votes in relation to the following amendments at 12 noon with all other provisions of the previous order remaining in effect: Bingaman amendment No. 2111, Murkowski amendment No. 2108, and Paul amendment No. 2143.

The PRESIDING OFFICER. Is there objection?

Mr. VITTER addressed the Chair.

The PRESIDING OFFICER. The Senator from Louisiana.

Mr. VITTER. Mr. President, reserving the right to object, I will not object. I want to ensure that I will have 10 minutes in support of the Bingaman-Vitter amendment prior to the vote as was promised to me.

The PRESIDING OFFICER. The Senator from Louisiana is notified that there is not 10 minutes remaining in support of that amendment.

Mr. VITTER. Mr. President, may I inquire to the Chair how much time is remaining.

The PRESIDING OFFICER. There are 3 minutes left in support of the Bingaman-Vitter amendment.

Mr. VITTER. Mr. President, I ask unanimous consent that as part of this agreement that I be given 7 minutes before the vote.

The PRESIDING OFFICER. Is there objection?

Mr. HARKIN. Mr. President, I would modify my unanimous consent request to have the vote start at 12:05.

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

The assistant majority leader is recognized.

Mr. DURBIN. Mr. President, I think that accommodation was to allow the Senator from Louisiana for 7 minutes, and I would ask for 5 minutes before the votes begin.

The PRESIDING OFFICER. Without objection, the Senator from Louisiana will be given 7 minutes and the assistant majority leader will be given 5 minutes and the vote will begin at 12:05. Is there objection? Without objection, it is so ordered.

The assistant majority leader.

AMENDMENT NO. 2127

Mr. DURBIN. Mr. President, today we are considering a bill that will improve the FDA's ability to assure the

safety of drugs in our medicine cabinets and medical devices in our hospitals. The FDA is an essential guardian of the public's health and safety. In the past few years, FDA has faced obstacles that call on the agency to adapt and respond to the evolving nature of reviewing, manufacturing, and distributing drugs and devices.

Some of those obstacles and challenges are addressed in the reauthorizations of the Prescription Drug User Fee Act and the Medical Device User Fee Act, which are set to expire at the end of September 2012.

Last fall, I visited Cook Medical's medical device plant in Canton, Illinois, and representatives expressed concern about the amount of time it takes medical devices to be reviewed. The FDA needs sufficient time to review medical devices, in order to ensure their safety and effectiveness. However, inefficiencies and insufficient resources can result in longer review times, which mean patients have to wait longer to benefit from new medical devices.

This bill makes key changes to maintain the safety of devices and preserve our country's leadership in biomedical innovation. The bill will authorize the FDA to collect almost $600 million in user fees over 5 years. The FDA can use these additional resources to help hire and train staff.

Furthermore, the bill makes important improvements by streamlining the review process for devices and increasing communication between the FDA and device manufacturers throughout the review process. These changes to the review of medical devices will not only help innovative device companies get their product to market faster, but will prevent patients from having to wait extra weeks and months to benefit from a new device.

In addition to reauthorizing the Prescription Drug and Medical Device User Fee Acts, this bill also establishes the Drug User Fee Act and Biosimilar User Fee Act, which gives the FAA new authority to collect user fees for generic and biosimilar drugs. Currently the FDA does not collect user fees to support the review of generic drugs, and it takes about 30 months for the agency to review generic drug applications. This extra time reduces access to safe, affordable generic drugs and leaves patients and taxpayers paying the tab for brand-name drugs that lack competition from generics.

Since the first Prescription Drug User Fee Act was enacted in 1992, the FDA began collecting user fees to support the review of applications. The FDA has cut the review time for new drugs by 60%, from 2 years to a little over 1 year. Similarly, the Generic Drug User Fee Act will give the FDA the support it needs to cut the current 30-month review time for generic drugs down to 10 months. This improvement will promote competition in the marketplace and save money by reducing the amount of time patients have to wait for less expensive generic alternatives to brand name drugs. The process of negotiating and drafting this legislation started 18 months ago and the result is a comprehensive bill that improves the safety and quality of drugs and medical devices.

Chairman HARKIN and Senator ENZI have put together a bill that responds to many of these challenges, including one that is of particular interest to me——the national shortage of critical drugs. Between 2006 and 2010 the drug shortage increased 200 percent from 56 to 178 drugs. Currently the drug shortage includes over 200 drugs, like intravenous nutrition supplements, cancer treating drugs, and anesthesia.

Over the past few months, I have held three roundtable discussions at hospitals across Illinois to learn about the drug shortage and how it is affecting providers and patients. From these discussions it is clear that the drug shortage is being felt at most hospitals and those Illinois hospitals, providers, and pharmacists are working around the clock to ensure patients maintain access to drugs and safe treatments.

At Advocate Hospital in Libertyville, a doctor shared that he learned just days before starting a patient on chemotherapy that the drug was not available. Unfortunately, this is a common scenario across the country as doctors learn days before starting a treatment or even once the patient is on the hospital bed that a drug is not available. Pharmacists now spend part of each day scrambling to find drugs or an alternative treatment.

Recently I learned that a young woman on my staff here in D.C. is all too familiar with the drug shortage. She is a smart and hard-working woman who has been taking Concerta to treat her ADD since she was 14. Like most people with severe ADD, she must take her medicine at a certain time every day in order to keep her ADD symptoms from impeding basic life and work responsibilities. And while there are several ADD drugs on the market, each drug works differently and can have different side effects, so switching to a new prescription is not without risk.

Last year, the local CVS where she usually had her prescription filled started telling her they didn't have her drug in stock. She didn't think much of it as she would wake up early and walk to another CVS in the morning where she was usually able to get the prescription. Over time, she grew accustomed to going between these two CVS pharmacies to fill her prescription.

Until one month, when she carried her prescription with her for 3 days and was unable to find a pharmacy with enough Concerta to fill her 30-day prescription.

By the end of day 3, she was out of her supply. She woke up early and rode her bike to four or five CVS pharmacies until she was able to find a pharmacy that could fill her prescription. But by then it was 12 o'clock and past the prescribed time to take the drug.

The shortage of ADD drugs impacts children, adults, parents, and employees across the country. Congress needs to take action to address the drug shortage.

The FDA Safety and Innovation Act builds on Senator KLOBUCHAR's bill with key provisions to curb the national drug shortage. First, the bill requires drug manufacturers to notify the FDA 6 months in advance for certain drug shortages. With this much notice, the FDA can work with manufacturers to try to avoid a shortage and, when necessary, identify alternative sources of the drug to ensure we maintain a supply for patients.

This winter, thanks to open communication between the FDA and drug companies, the FDA successfully avoided a shortage of methotrexate, a vital drug to treat leukemia in children. The FDA collaborated with Illinois-based generic drug manufacturer, Hospira, to increase production of this live-saving drug when another company halted production. Requiring 6 months advance notice of a drug shortage will help the FDA to work with companies to avoid shortages of critical drugs.

Furthermore, the bill requires FDA to enhance the agency's response to shortages and will improve reporting of shortages by allowing third-parties to report drug shortages to the FDA.

This bill also takes steps to improve the safety of drugs and the drug supply chain.

In 2008, serious injuries and 81 deaths were linked to contamination of the crucial blood thinning drug heparin. The source of the contamination was a facility in China that intentionally adulterated the drug. This was a horrible illustration of what happens when adulterated and counterfeit drugs make their way into the drug supply chain and ultimately to patients. This case has also raised serious questions about the global manufacturing practices of drugs and drug ingredients and the FDA's responsibility to protect the drug supply chain.

Since the heparin incident, the global nature of the drug supply chain has only grown. Today 80 percent of active pharmaceutical ingredients are manufactured outside of the United States. This bill improves the safety of our supply chain, both domestically and internationally by requiring foreign manufacturers to register their facilities with the FDA. The bill also places greater responsibility on U.S. drug manufacturers to know their international suppliers and increases penalties for intentionally contaminating or counterfeiting drug. Counterfeit and adulterated drugs can have deadly consequences, yet the penalty for committing these crimes is less than the penalty for selling a counterfeit designer purse.

Currently, the penalty for intentionally counterfeiting or adulterating a drug is no more than 3 years in prison or a $10,000 fine or both.

This bill raises the penalty for intentionally adulterating a drug to no more than 20 years in prison or a $1 million fine or both.

And the penalty for intentionally counterfeiting drugs is raised to no more than 20 years in prison or a $4 million fine or both.

This bill addresses the drug shortage, reduces the review time for medical devices and drugs, improves the pipeline for antibiotics and pediatric drugs, and helps secure the supply chain for prescription drugs.

I would like to thank Chairman HARKIN and Senator ENZI for their extraordinary leadership and hard work on this bill.

The amendment we will face this afternoon is one I am offering relative to dietary supplements. I want to make it clear what this is about.

If someone walked into their neighborhood drugstore and looked at everything on the shelf, here is what they can say: All the prescription drugs the pharmacy has access to have been reviewed by the Food and Drug Administration that they are safe and effective. All of the over-the-counter drugs have been reviewed and registered with the Food and Drug Administration to make certain they are safe and have been precleared before they can be sold. Now when they move back to the vitamin counter, all bets are off. Those are called dietary supplements. They are not subject to the same level of scrutiny, inspection, testing or regulation. It is an entirely different world.

It is understandable that there are those of us who want to be able to walk in and buy vitamins, for example, without a prescription. That is our right as Americans. But we also want to make sure that whatever is on the shelf at the pharmacy is not dangerous or at least we know it is there.

There are between 55,000 and 75,000 dietary supplements in America. We don't know the exact number. They include the obvious, vitamins and minerals, but they also go further. They include energy drinks. Ever heard of the 5-Hour Energy Drink, Monster Energy Drink? Those are not sold as colas, sodas, or beverages. They are sold as dietary supplements. Why? Because there is no regulation in terms of their contents.

We had a sad story I told on the Senate floor 2 days ago, with the family in the gallery, about a 16-year-old girl from Hagerstown, MD, who drank two Monster Energy Drinks within a 24-hour period and went into cardiac arrest. It was too much for her heart. She died. That was a dietary supplement.

My amendment says if they want to sell a dietary supplement in the United States, they have to do one basic thing: They have to go to the Food and Drug Administration and say: This is the name of my company. This is the name of my product and the ingredients in it. And here is a copy of the label. That is it.

So is it important that we know this? There will be 1,000 new products bought and sold in the United States as dietary supplements every year. Just in case we think knowing the dietary supplement facility company has been registered is enough, hang on tight. These dietary supplements are coming from all over the world. Sadly, a lot of them turn out to be dangerous.

In 2009 the FDA announced that Super Slim, a dietary supplement manufactured in China, contained the pharmaceutical ingredient sibutramine, which is no longer available in the United States and found to increase the risk of heart attack or stroke. If the manufacturers had registered this dietary supplement so we knew the ingredient, we could protect American consumers.

The same thing was true in 2001. Another Chinese-based weight-loss ingredient, aristolochic acid, was found to cause kidney damage and to be a potent carcinogen. Isn't it important for us to know this? Is it too much to ask the dietary supplement companies to go to the FDA and at least register their products before they put them on the shelves across America? Don't American families have the right to scrutiny and at least some basic knowledge of the sale of these products?

The industry is against this. They don't want to report it. They basically say: It is none of your business. We will sell what we want to sell, and that is the way it will be. If we want to volunteer the information, so be it. But we don't want to be required to disclose the information.

There are groups that see it differently. I ask unanimous consent to have printed in the RECORD letters that support my amendment. The Center for Science and Public Interest and the Consumers Union are in support of this amendment.

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

CENTER FOR SCIENCE IN THE PUBLIC INTEREST,
Washington, DC, May 24, 2012.

Senator DICK DURBIN,
Attn.: Binta Beard, U.S. Senate, Washington, DC.

DEAR SENATOR DURBIN: The Center for Science in the Public Interest is pleased that you are introducing an amendment to the Food, Drug, and Cosmetic Act that would help improve public confidence in dietary supplements. Supplements are poorly tested, may be contaminated, can sometimes interact with pharmaceuticals, and are marketed with more hype than just about any other consumer product. Your amendment would do the minimum to protect both consumers and conscientious companies: require disclosure to the Food and Drug Administration of all ingredients, build a repository of labels, and require registration with the FDA. Much more really should be done to assure safety and efficacy, but we hope your amendment will receive widespread support.

Sincerely,

MICHAEL F. JACOBSON,
Ph.D., Executive Director.

MAY 21, 2012.

Senator RICHARD J. DURBIN,
U.S. Senate, Hart Senate Office Building, Washington, DC.

DEAR SENATOR DURBIN: Consumers Union applauds your efforts to strengthen dietary supplement safety by requiring manufacturers to register their products with the Food and Drug Administration (FDA). Specifically, your proposed amendment to the Food and Drug Administration Safety and Innovation Act (S. 3187) would require manufacturers to provide the FDA with accurate and up-to-date information regarding each dietary supplement product they manufacture, a list of ingredients included in those products, and a copy of the product labels.

Although many dietary supplements on the market may be safe and healthful, there are numerous ingredients that may pose significant dangers to consumers. Some supplement ingredients could, for example, interact with prescription drugs to produce dangerous side effects. Others can change the effectiveness of prescription drugs. Still others could be generally safe for most consumers, but have hazardous health effects for certain population subgroups, such as pregnant women or children.

Dietary supplement manufacturers are currently subject to limited registration requirements as food-processing facilities. However, these entities are not required to register their products with the FDA, in order to facilitate timely action in the event of a safety alert. As noted by the U.S. Government Accountability Office (GAO) in its 2009 report, FDA ''lacks complete information on the names and location of dietary supplement firms within the agency's jurisdiction,'' and does not have a comprehensive database of products currently being sold in the marketplace, and the ingredients they contain. This leaves the FDA without adequate marketplace information, should it need to take prompt or immediate action regarding supplement ingredients that are dangerous or found to be adulterated.

Requiring manufacturers to submit a list of products sold, product ingredients, and product labels to FDA on a regular basis would ensure that the agency can appropriately assess potential safety issues and quickly respond as they arise. The FDA's post-marketing surveillance of dietary supplements will be much more effective if the FDA has accurate, timely information about supplement products currently available in the U.S. marketplace.

Consumers Union believes this amendment will advance the safety of dietary supplements for consumers. We thank you for taking on this critically important issue, and look forward to working with you to support the amendment.

Sincerely,

CHUCK BELL,
Programs Director Consumers Union.

IOANA RUSU,
Regulatory Counsel Consumers Union.

Mr. DURBIN. I ask my colleagues when this vote comes before us, before we have another death in America from a dietary supplement from China, India, Mexico, or even in the United States, shouldn't we require the most basic information so we know the name of the company, the ingredients in the product, and what the label looks like?

The FDA has asked for this information. They asked expressly for this information. To say it is a burden on them, they already asked for it.

I ask my colleagues when this amendment comes up later this afternoon that they support this in the best interest of protecting American families and consumers.

I yield the floor.

The PRESIDING OFFICER (Mrs. HAGAN). The Senator from Louisiana.

AMENDMENT NO. 211

Mr. VITTER. Madam President, I rise to strongly support the upcoming Bingaman-Vitter amendment, which is basically an amendment form that Bingaman-Vitter Fair Generics Act would stop an escalating trend in the drug industry which has pay-for-delay deals between a generic manufacturer and a big pharmaceutical manufacturer.

Over the last several years we have seen a huge increase, and we have seen this trend grow from modest to a raging trend, and it is anticompetitive. It is pay-for-delay deals in which the brand-name drug dealer pays off or settles with the first-to-file generic drugmaker, often restricting generic market entry for years into the future.

As prescription drug prices explode, they put real pressure and burdens on many Americans' budgets because they are making medications that should be more affordable in terms of coming onto the market. They are postponing those drugs, paying for the delay, and holding them off the market longer and longer.

The FTC has compiled data and made clear that this trend is happening, and the FTC, an official government agency, said:

> The continued trends of record numbers of brands and generics resolving patent litigation prior to a final court decision [yields] significant numbers of such settlements potentially involving pay-for-delay.

Those were the FTC's words.

In 2004 the FTC had identified zero of those sorts of pay-for-delay deals. In 2006 it was up to 14. In 2011 it doubled to 28. Clearly it is a big trend. That is ''28 final settlements (that) contain both compensation to the generic manufacturer and a restriction on the generic manufacturer's ability to market its product.''

This fair generics bill, through this amendment, fixes the problem. That was the intent of the original Hatch-Waxman language, but there was a loophole that has been exploited in this pay-for-delay deal because the first filer is granted exclusivity even if the first filer is paid off and settles and doesn't pursue its ability to enter the market.

The Fair Generics Act would fix that, and it would basically outlaw that sort of marketing of generics. It would realign and reaffirm the incentive and reward not just for filing first but for successfully challenging and invalidating a patent. So we would move the first filing exclusivity to a reward for filing and also successfully invalidating a patent.

It is a realistic proposal. It would allow the first filer to follow through on that filing. It would encourage it, but also if that is not going to happen, it would allow subsequent filers to litigate and validate the patent and thereby gain ability to enter the marketplace. I really think this was the intent of Hatch-Waxman.

Unfortunately, there is a loophole that has been exploited in Hatch-Waxman that has led to these serious pay-for delay cases. Again, this is an escalating trend that is still growing. I have no doubt that when we get the number for 2012, it is going to be significantly above the 2011 number of 28.

So to simplify it, if the first filer does not enter into a settlement with the restricted and delayed market entry date and if it does diligently challenge and invalidate a patent, nothing changes under present law. The current 6-month market exclusivity reward remains. So that incentive, that reward absolutely remains. However, if that doesn't happen and the first filer just wants to settle or park its filing and is generic, a subsequent filer would have the ability to step up and challenge the patent and, if it won, it would have market access.

This solution provides more litigation certainty. We propose basically a use-it-or-lose-it statute for the brand name to sue the generic within the 45-day window. Current law provides a brand manufacturer a 30-month stay if they sue the generic within the 45-day window but still allows a suit after.

So, again, I believe this is a reasonable and measured approach. This is not as Draconian or dramatic an approach as other proposals in the Senate. I believe this is the middle ground, and I believe this honors and gets us back to the original intent on this subject of Hatch-Waxman. But it is a measured response to this escalating trend that we clearly see, that the FTC has objectively identified and measured—a so-called pay-for-delay arrangement.

In conclusion, the goal of Hatch-Waxman was to bring generics to the market more quickly. This approach, the FAIR Generics Act, will do that. There are anticompetitive deals that are being struck more and more often—pay for delay—and they are becoming much more prevalent, and they are hurting American families.

The mega-lobbyist pharmaceutical industry, of course, opposes this reform because, quite frankly, those pay-for-delay deals are a way to buy more exclusivity and keep generics off the market longer. But that is not in the interests of the consumer. It is time to stand up to them. It is time to have some courage, to stand up to Big Pharma and say: We are going to preserve your exclusivity for developing a drug, but we are not going to let you buy off generics and unfairly extend that time period. We are going to let generics come to market in a reasonable time. We are going to create incentives to make sure that happens.

I urge all of my colleagues to support that proposal, which is embodied in the Bingaman-Vitter amendment, the FAIR Generics Act.

I yield the floor.

The PRESIDING OFFICER. There is now 2 minutes of debate equally divided on the Bingaman amendment.

Mr. HARKIN. Madam President, first I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The yeas and nays are ordered.

The Senator from New Mexico.

Mr. BINGAMAN. Madam President, I thank Senator VITTER for his comments and for his strong support of this amendment. I thank all of the other cosponsors of the legislation.

If we are interested in promoting competition in the health care field so that we can keep prices down, then we need to support this amendment. That is exactly what this does.

Under our law in this country, we provide exclusive rights to a company that develops a drug to sell that drug during the time the patent is in effect. But what we are concerned with here is that after that patent is no longer valid, companies are still extending their exclusivity, extending their time when they don't have any competition by entering into these agreements. So we think they can settle their disputes—we don't have a problem there—but they cannot keep other generic manufacturers from coming to the market who also have demonstrated the invalidity of a patent.

If we are worried about the cost of health care to the Federal Government—the Federal Government is paying too much for prescription drugs because of this flaw in the Hatch-Waxman Act that we are trying to correct. If we are worried about keeping prices down for hospitals, insurance companies, and consumers, this amendment will help to do that.

I urge my colleagues to support the amendment.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Madam President, I rise today to oppose the amendment addressing the patent settlements for generic claims.

I am sympathetic to the intent of the sponsors of this amendment. I believe that some drug patent settlements may be improper and could be unfairly increasing drug prices for consumers. If that is in fact happening, we should stop the bad settlements and encourage the ones that work.

The problem with this amendment, however, is that its scope is much broader and could lead to unintended consequences that could harm consumers and increase costs. That is why I must oppose it. The amendment uses a machete when a scalpel might solve the problem. Not all patent settlements are abusive. They do not all lead to higher costs. In fact, some settlements can actually expedite generic drugs coming to market. According to

one recent study by RBC Capital Markets, patent settlements helped expedite 24 of the 37 most recent generic drug approvals.

The amendment would allow competing generic manufacturers, in certain cases, to share the 180 days of exclusivity provided under the drug patent law known as Hatch-Waxman. This period of exclusivity was intended to create a market incentive for generic manufacturers to be the first to file a generic drug application with FDA.

The amendment is intended to discourage generic manufacturers from reaching settlements with brand manufacturers to delay generic competition. Unfortunately, it may also have the unintended consequence of discouraging generic competition generally.

The Hatch-Waxman statute, which first established our current system of brand and generic drug approvals, was a careful compromise of competing interests. It struck a balance between encouraging research and development of new cures and promoting competition to lower costs. By all accounts, this law has been a success. Our Nation leads the world in the creation of new drugs and therapies that improve the lives of countless patients across the world. At the same time, generic drugs have promoted competition and lowered costs to American patients. According to one recent estimate, generic drugs have saved the American health care system over $930 billion over the last decade.

This amendment would disrupt that system and reduce the incentives that currently encourage manufacturers to file generic drug applications with the FDA. Allowing competitors to share the 180 days of exclusivity will undermine the market incentives for manufacturers to make such filings. It will also create uncertainty about whether generic manufacturers will ultimately be able to recoup their investments and could mean that there will be fewer generic drugs.

That is why the generic drug manufacturers oppose this amendment. While I genuinely appreciate the desire to prevent abusive settlements, I believe that we must be very careful in disrupting a system that has worked so well for patients and consumers.

We should hold hearings in the HELP Committee to hear from all of the stakeholders who have a role in this system. We need to learn how any proposal will impact the incentives to encourage competition. We also need to learn how any proposed solutions will affect settlements and patent litigation.

This is clearly an important and very complex issue, but this amendment could have serious and detrimental consequences for patients. This is why I would urge my colleagues to oppose this amendment.

I yield the floor.

The PRESIDING OFFICER. The question is on agreeing to the amendment.

The yeas and nays have been ordered. This is a 60-vote threshold vote.

The clerk will call the roll.

The assistant bill clerk called the roll.

Mr. DURBIN. I announce that the Senator from Connecticut (Mr. BLUMENTHAL) and the Senator from Maryland (Ms. MIKULSKI) are necessarily absent.

Mr. KYL. The following Senators are necessarily absent: the Senator from Idaho (Mr. CRAPO), the Senator from Texas (Mrs. HUTCHISON), and the Senator from Illinois (Mr. KIRK).

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

The result was announced—yeas 28, nays 67, as follows:

[Rollcall Vote No. 105 Leg.]

YEAS—28

Akaka	Inouye	Schumer
Bingaman	Johnson (SD)	Shaheen
Boxer	Klobuchar	Snowe
Brown (OH)	Kohl	Udall (CO)
Cardin	Levin	Udall (NM)
Conrad	McCain	Vitter
Durbin	Merkley	Webb
Feinstein	Pryor	Whitehouse
Franken	Reed	
Gillibrand	Sanders	

NAYS—67

Alexander	Graham	Moran
Ayotte	Grassley	Murkowski
Barrasso	Hagan	Murray
Baucus	Harkin	Nelson (NE)
Begich	Hatch	Nelson (FL)
Bennet	Heller	Paul
Blunt	Hoeven	Portman
Boozman	Inhofe	Reid
Brown (MA)	Isakson	Risch
Burr	Johanns	Roberts
Cantwell	Johnson (WI)	Rockefeller
Carper	Kerry	Rubio
Casey	Kyl	Sessions
Chambliss	Landrieu	Shelby
Coats	Lautenberg	Stabenow
Coburn	Leahy	Tester
Cochran	Lee	Thune
Collins	Lieberman	Toomey
Coons	Lugar	Warner
Corker	Manchin	Wicker
Cornyn	McCaskill	Wyden
DeMint	McConnell	
Enzi	Menendez	

NOT VOTING—5

Blumenthal	Hutchison	Mikulski
Crapo	Kirk	

The PRESIDING OFFICER. Under the previous order requiring 60 votes for the adoption of this amendment, the amendment is rejected.

AMENDMENT NO. 2108

Mr. HARKIN. Madam President, I inquire what the next vote would be on?

The PRESIDING OFFICER. The Murkowski amendment No. 2108.

Mr. HARKIN. Madam President, I ask that that vote be a 10-minute vote.

The PRESIDING OFFICER. That is already the order.

There are now 2 minutes equally divided.

Ms. MURKOWSKI. Madam President, I ask for support of the amendment that is before us. This is an amendment that will actually strengthen the role of NOAA as the Federal agency that has oversight over our fisheries.

Currently the FDA is considering an application for a genetically engineered fish, a fish that takes DNA from one salmon and an ell pout to accelerate the growth unnaturally. The FDA is not looking at labeling this fish. The FDA is not considering the environmental impact of escapement on this fish into the marine environment.

What we are asking for with this amendment is as the FDA proceeds in its process that the agency that has oversight of our fisheries be allowed to participate and weigh in as to whether there are any environmental consequences that may come about as a consequence of a release into a marine environment.

This is a situation where people have a right to know about the quality of their fish, where it comes from, what it is made of. What I am asking is for the agency that has oversight of our fisheries to have a role in this process. I urge Members to support the amendment.

The PRESIDING OFFICER. The majority leader.

Mr. REID. Madam President, the time, as usual, did not run as quickly as we wanted. I ask unanimous consent that we only have two votes prior to lunch today, and that the next vote start at 5 minutes until 2 today after we complete this vote.

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

The Senator from Kansas.

Mr. HARKIN. Regular order, please.

The PRESIDING OFFICER. For what purpose does the Senator seek recognition?

Mr. ROBERTS. Madam President, I rise in opposition to speak for 1 minute.

The PRESIDING OFFICER. There is 1 minute in opposition. The Senator is recognized.

Mr. ROBERTS. Madam President, I fear this legislation would insert Congress in the scientific process of approving applications that we have entrusted to the FDA. This application has been pending at FDA for over 15 years. We should allow the FDA to complete their scientific review of the product and not interfere with the ongoing reviews.

We have a science-based system that allows for complete review. We should allow that process to continue. This amendment sets up a two-tiered, two-agency approval system. That is not good. We know the FDA has already conferred with NOAA regarding the pending application.

Basically, Members of the Senate should not put on lab coats and tell the FDA to approve or deny the pending application. We should allow them to act on the statutory authority that is given to them. I reluctantly oppose the amendment of my colleague from Alaska.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KERRY. Madam President, this would be the first time Congress has ever interfered in an FDA-based, science-based approval process. If we open that, we would be opening an extraordinary can of worms.

I urge my colleagues to oppose this amendment.

The PRESIDING OFFICER. The question is on agreeing to the amendment.

Mr. MERKLEY. Madam President, 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 bill clerk called the roll.

Mr. DURBIN. I announce the Senator from Connecticut (Mr. BLUMENTHAL) is necessarily absent.

Mr. KYL. The following Senators are necessarily absent: the Senator from Idaho (Mr. CRAPO), the Senator from Texas (Mrs. HUTCHISON), and the Senator from Illinois (Mr. KIRK).

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

The result was announced—yeas 46, nays 50, as follows:

[Rollcall Vote No. 106 Leg.]

YEAS—46

Akaka	Graham	Reid
Ayotte	Johnson (SD)	Rockefeller
Baucus	Landrieu	Sanders
Begich	Lautenberg	Schumer
Bennet	Leahy	Shaheen
Bingaman	Levin	Snowe
Boxer	Lieberman	Stabenow
Cantwell	Manchin	Tester
Cardin	Menendez	Udall (CO)
Coburn	Merkley	Udall (NM)
Cochran	Mikulski	Warner
Collins	Murkowski	Whitehouse
Conrad	Murray	Wicker
Durbin	Nelson (FL)	Wyden
Feinstein	Portman	
Gillibrand	Reed	

NAYS—50

Alexander	Grassley	McCain
Barrasso	Hagan	McCaskill
Blunt	Harkin	McConnell
Boozman	Hatch	Moran
Brown (MA)	Heller	Nelson (NE)
Brown (OH)	Hoeven	Paul
Burr	Inhofe	Pryor
Carper	Inouye	Risch
Casey	Isakson	Roberts
Chambliss	Johanns	Rubio
Coats	Johnson (WI)	Sessions
Coons	Kerry	Shelby
Corker	Klobuchar	Thune
Cornyn	Kohl	Toomey
DeMint	Kyl	Vitter
Enzi	Lee	Webb
Franken	Lugar	

NOT VOTING—4

Blumenthal	Hutchison
Crapo	Kirk

The amendment (No. 2108) was rejected.

The PRESIDING OFFICER. Under the previous order requiring 60 votes for the adoption of the amendment, the amendment is rejected.

The Senator from Tennessee.

Mr. CORKER. Madam President, I understand I have 3 or 4 minutes to speak about the GAIN Act.

The PRESIDING OFFICER. How much time does the Senator wish to speak?

Mr. CORKER. About 3 or 4 minutes.

The PRESIDING OFFICER. On an amendment or on the bill?

Mr. CORKER. On the bill.

Mr. HARKIN. Madam President, parliamentary inquiry.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. There is a lot of commotion going on. I want to know where the time is coming from for the Senator from Tennessee.

The PRESIDING OFFICER. The Senator said he was speaking on the bill.

Mr. HARKIN. Madam President, how much time is left on the bill?

The PRESIDING OFFICER. The Senator from Iowa controls 15 minutes, and the Senator from Wyoming controls 22 minutes.

Mr. HARKIN. How much time does the Senator from Tennessee need?

Mr. CORKER. Three minutes.

Mr. HARKIN. OK, that is fine.

Mr. ENZI. Madam President, I yield 3 minutes to the Senator from Tennessee.

Mr. HARKIN. I will, too, if he needs it.

Mr. CORKER. Madam President, I rise to thank both the majority and minority leaders of the bill for their great effort. I am pleased to speak about a provision in the FDA Safety Innovation Act that addresses a growing public threat in Tennessee and Connecticut and across the Nation.

Several months ago, Senator BLUMENTHAL and I introduced the GAIN Act, which is a bipartisan provision that provides a meaningful market incentive and reduces regulatory burdens to encourage development of new antibiotics that will help save lives and reduce health care costs.

Drug-resistant bacteria, or ''superbugs'' as we call them, are becoming harder to treat because we lack new antibiotics capable of combating these infections. Not only do these infections take a toll on patients and their families, but they also run up health care spending to the tune of $35 billion to $45 billion annually.

It is crucial that these new antibiotics are discovered in order to stay ahead of the growing trend of drug resistance. Drug discoveries do not happen overnight, so we must act now to ensure that we have lifesaving medications when we need them.

The GAIN Act is a straightforward, commonsense bill that provides market incentives to encourage innovation without putting Federal dollars at stake, and it is included in this FDA reauthorization. Antibiotic resistance is a growing issue that we need to address now to properly prepare for the future.

Dr. William Evans, director and CEO of St. Jude's Hospital in Tennessee, wrote a letter supporting this bill, which says:

> We don't want to find ourselves in a situation in which we have been able to save a child's life after a cancer diagnosis only to lose them to an untreatable multi-drug resistant infection.

I thank Senator BLUMENTHAL from Connecticut for his leadership on this bill. I especially thank Senators HARKIN and ENZI for working with us the way they have to include this provision in the FDA Safety and Innovation Act.

I think I have stayed within my time limit.

I yield the floor.

The PRESIDING OFFICER. Who yields time?

The Senator from Wyoming.

Mr. ENZI. Madam President, I yield 5 minutes to the Senator from Ohio.

The PRESIDING OFFICER. The Senator from Ohio.

AMENDMENTS NOS. 2145 AND 2146

Mr. PORTMAN. Madam President, I thank the ranking member and congratulate him for the good work today on this legislation.

There are a couple of amendments that are part of the bill I want to speak about. First is on prescription drug abuse—a problem we all face as representatives of our States. I particularly thank Senator WHITEHOUSE for his partnership on this important bill.

In the last decade, unfortunately, prescription drug abuse has reached epidemic proportions in States such as Ohio, and in so many other States around the country. In doing so, it has devastated the lives of so many individuals but also the well-being of our communities, and of course affected their families, affected our economy, and it has caused a big spike in crimes, including theft, as addicts look for ways to support their addictions. This crime, of course, has doubly strained law enforcement, which has already had to contend with the increase in drug trafficking with constrained budgets. It has also served as a gateway to other drug use, including heroin use, which tends to be less expensive and causes additional public health challenges.

Amazingly, since 2007, drug overdoses have now moved ahead of car accidents as the leading cause of accidental death in my home State of Ohio. Again, we have seen this, unfortunately, too often around the country. We have had record levels of hepatitis C infection from needle sharing. In one county on the Ohio River, in southern Ohio, 10 percent of the babies born in 2010 had drugs in their system.

The good news is progress is being made in places such as Scioto County and around the country thanks to the good work of health professionals, law enforcement, local, State, and Federal officials, along with community groups, families, schools, churches, and others. But they need some help. More work needs to be done, and one critical tool they are looking for in the fight against prescription drug abuse is a better way to monitor prescription drug use. There are databases around the country called prescription drug monitoring programs. They allow States to monitor and track the dispensing of prescription drug medications by health care providers to be able to identify and stop the abuse of people getting prescriptions for these drugs in various different doctors' offices and in what have been called pill mills. Preliminary research has shown monitoring programs are highly effective in stemming the tide of abuse. That is why 48 States and 1 territory

now have them, with 41 of them operational.

There is a problem, however. Different States' monitoring programs can't communicate with one another, so one State doesn't know what the other State is doing, and drug trafficking is an interstate problem. This is especially true in places such as Scioto County in southern Ohio, right across the river from Kentucky and bordering West Virginia. We want these States to be able to work together, and that is why Senator WHITEHOUSE and I have offered this amendment, No. 2145, as a Federal solution to providing a framework for monitoring programs to participate in data sharing across State lines.

This amendment also supports collaboration between the Department of Health and Human Services and the Bureau of Justice Assistance in order to further their research to assess challenges that have an impact on States' interoperability.

Some have called for a national monitoring program—one Federal program. I don't think that is necessary. I don't think it will work as well. A lot of States have programs that are working extremely well and they have put a lot of money into them. There are differing protected health standards State by State. So rather than trying to federalize it, our amendment gets these disparate programs to work together securely, reliably, and efficiently without undermining or jeopardizing the State's autonomy in this area. States should remain free to establish laws that determine user eligibility and reporting requirements. So this amendment is to help, again, give these communities the tools they need to fight this prescription drug abuse.

Finally, I would say that our amendment has no effect on direct spending or revenues over the 10-year period.

The other amendment I want to mention also has to do with substance abuse—about the dangers of what we unfortunately all here in this Chamber have heard about—and that is synthetic drug abuse, including K2 Spice, bath salts, and herbal incense. Today we have an opportunity to do something about this problem. Let's prohibit these drugs from getting into the hands of our children, our service men and women, and others.

This amendment addresses the growing use and misuse of synthetic drugs by placing 15 cannabinoids, 2 stimulants, and 9 hallucinogens in Schedule I to expose those who manufacture, distribute, possess, import, and export synthetic drugs without proper authority to the full spectrum of criminal, civil, and administrative penalties, sanctions, and regulatory controls.

I want to give special thanks to the people who led this effort over the years—Senators GRASSLEY, SCHUMER, and KLOBUCHAR. They have worked hard on this issue, and we are all pleased this is part of the underlying legislation. It was Senator GRASSLEY, as well as the folks from the Community Anti-Drug Coalition, who originally introduced me to the prevalence of designer drugs. I was told of the story of David Mitchell Rozga and many others who have suffered, and of some of the deaths that have occurred around the country.

This amendment, again, would have no significant effect on direct spending or revenues over a 10-year period and is a good, commonsense approach to trying to get our hands around this issue and help the constituents we represent and help our communities fight to stem this particular substance abuse that is affecting us all.

Madam President, I yield the remainder of my time, and I yield the floor.

Mr. HARKIN. Madam President, if I may inquire of the Senator how much time she wishes.

Mrs. HAGAN. I would request 6 minutes.

Mr. HARKIN. I yield 6 minutes off the bill.

The PRESIDING OFFICER (Mrs. MCCASKILL). The Senator from North Carolina.

Mrs. HAGAN. First, Madam President, I do want to applaud the hard work of the Senate HELP Committee chairman TOM HARKIN and the ranking member Senator MIKE ENZI. This bill is truly one of the most bipartisan efforts I have had the opportunity to be a part of in the 3 years I have served in the Senate. It ought to be a reminder that, yes, when we work together across the aisle, the Senate can get things done.

I am particularly proud to support this bill because of what it will mean for patients who are suffering with diseases, who do not have access to adequate treatments, or who do not have access to any treatment at all. This bill we are voting on includes key provisions of the TREAT Act—the Transforming the Regulatory Environment to Accelerate Access to Treatments Act—which I introduced in February. These important provisions will expedite the review of treatments for serious or life-threatening diseases without compromising the FDA's already high standards for safety and effectiveness.

I introduced the TREAT Act after meeting with a family whose child suffered from spinal muscular atrophy or SMA. This is an incurable neuromuscular disease and is the leading genetic cause of infant deaths. Of course, that family was not alone. There are 30 million Americans suffering from rare diseases, and I have had the honor to meet a number of them. Their stories are both heartbreaking and inspiring.

When I visited the North Carolina Children's Hospital last month, I met with Megan and Jarrod Hendren of Lumberton, NC, whose 13-month-old twins Logan and Lucas suffer from Gaucher's disease. This disease is a painful and potentially debilitating metabolic disorder for which currently there is no cure.

I also met with 8-year-old Ashley Burnette from Raleigh, who is resilient and wise beyond her years, but who is suffering from neuroblastoma.

For the families and patients like these, suffering from these rare diseases for which there are no approved medications, medical advances cannot come fast enough. There are so many rare diseases, but fewer than 250 have FDA-approved therapies. The provisions of the TREAT Act that have been included in this bill take great steps toward resolving the problem.

There is currently a pathway at the FDA to expedite the review of drugs for illnesses that are serious or life-threatening and for which there is no adequate treatment. This is called the Accelerated approval pathway. Since the early 1990s, it has been successfully used to advance treatments for patients with HIV and cancer by leaps and bounds. However, it has not been applied regularly or consistently to the review of drugs to treat other diseases.

This inconsistency is why I introduced the TREAT Act. My bill will broaden the application of the accelerated approval pathway beyond HIV/AIDS and cancer to a wider range of diseases, with a particular focus on rare diseases. That is why my proposal enjoys broad support from patient advocates, including the National Organization of Rare Diseases, Us Against Alzheimers, Parkinson's Action Network, the Huntington's Disease Society of America, and many more.

By providing for consistent application, we will help the FDA implement these provisions, assist drug sponsors to navigate the approval process, and, hopefully, bring safe and effective treatments more rapidly to the patients who need them.

I am also proud to have played a critical role in the legislation that led to the negotiations of the first biosimilars user fee agreement, which is also included in the bill before us. Last Congress, we passed the Biologics Price Competition and Innovation Act to facilitate the introduction of lower cost alternatives to biologic drugs, while ensuring continued research and development into innovative biologics which can save or improve the lives of millions of Americans.

The user fees negotiated by the industry and the FDA will provide the necessary funding for the review of these critical therapies. The biosimilars industry is in the earliest stages of development, and the biosimilars user fee agreement will help facilitate this industry's growth.

In addition, the FDA Safety and Innovation Act provides the necessary regulatory updates to keep pace with the rapid innovations of the biopharmaceutical industry. This is imperative for creating jobs in States such as mine—in North Carolina—and maintaining America's competitive edge in the global economy.

Companies with footprints in North Carolina are partnering with our world-class universities to improve the health of people all across the globe

every day by researching, discovering, and developing lifesaving treatments for those suffering from these devastating diseases.

Passing the FDA Safety and Innovation Act for States such as North Carolina, and for our Nation, to remain global leaders is important. It is especially important if we are to help attract the jobs of the future.

The American public also expects the FDA to be the world's gold standard when it comes to ensuring the supply, the safety, and the integrity of our drug supply. By sending the FDA Safety and Innovation Act to the President's desk, we will establish a clear and effective pathway for turning ideas into cures and cures into treatments. And we will have shown the foresight and flexibility required to maintain our country's position at the top of the medical treatment and device industries.

I thank the Chair and I urge my colleagues to join in supporting the FDA Safety and Innovation Act.

I yield the floor.

Ms. MIKULSKI. Madam President, I rise in opposition to the McCain amendment No. 2107. I appreciate the intent of Senator MCCAIN to make lower cost drugs available to the American people, but I have many flashing lights about this amendment. I bring this from knowledge of being both on the Intelligence Committee and also in working with the FBI as the chair of the Subcommittee on Commerce, Justice, and Science.

This amendment allows individuals to import FDA approved drugs from Canada. It sounds great, but we don't know if the drug was made in Canada. No HHS Secretary has been able to demonstrate that importation will be safe. It is ironic that some faux populists who oppose a public option, who oppose allowing Medicare to negotiate drug prices, support importing price controls from Canada. This amendment doesn't guarantee cost savings for consumers, Medicare, Medicaid, or insurers.

I oppose this amendment for four reasons. First, it is a budget buster. Enforcing this will take enormous amounts of resources, and the amendment doesn't give the FDA the human resources, the financial resources, or the technological resources to ensure the safety of these drugs for U.S. consumers. It doesn't give FDA the resources to inspect and certify the brick-and-mortar and Internet-based Canadian pharmacies, nor does it give FDA the resources to verify that these pharmacies comply with Canada's laws. We all know that FDA needs more money to carry out its existing responsibilities overseas and domestically. The agency doesn't need another unfunded mandate.

The second reason I oppose this amendment is because I am concerned about organized crime and counterfeiting. We have a history of phony drugs coming from rogue Web sites. We cannot be sure that the drugs coming from Canada are not a counterfeit, lethal drug. There is no guarantee that these drugs originate from the legitimate supply chain. Where there is compelling, compassionate human need, there is greed. Where there is greed, there are scams and schemes. In this case, the scams and schemes can be lethal.

The third reason I oppose this amendment is that it doesn't exempt biologics. Biologics are different from chemical drugs. There is no way to ensure that the supply chain remains intact and that the product that reaches your doorstep will be effective. Because biologics tend to be more expensive than chemical drugs, criminals will make more money by counterfeiting them.

The final reason I oppose this amendment is because it doesn't guarantee that the drug you buy will be bioequivalent to the FDA-approved drug. How will consumers be assured that the drug they buy online is metabolized the same way? Also, what guarantee is there that the packaging and labeling will be identical?

We have examples of awful things that have happened. Interpol and the United States have seized millions of counterfeit pills. These drugs were made in unsanitary conditions and were deadly and ineffective. Remember the contaminated Heparin from China that killed over 150 people. Then there was cough syrup made from antifreeze instead of glycerin. Seventy-eight people died. There are also the ineffective drugs that may not kill you but certainly won't improve your health. I could list more, but I urge my colleagues to go talk to the FDA, FBI, and Customs and Border Protection and hear firsthand what they have experienced.

Counterfeiting is a real threat. It is a matter of life and death. We have to make affordable drugs in our own country, and we did so by closing the doughnut hole in health reform. Today we are doing so again. The FDA user fee reauthorization before us creates the first ever generic drug user fee program. It will speed generic drug entry into the U.S. market so that consumers get safe FDA approved drugs more quickly and cheaply.

If you want safety, then defeat the McCain amendment.

Mr. BENNET. Mr. President, I come to the floor today to support the goal of my friend and colleague from New Mexico of delivering lower cost medicines to Americans. But, unfortunately, I cannot support his underlying amendment, No. 2111 to S. 3187. I agree that we should increase access to generic drugs wherever we can, and I agree that the path to market for generic products is fraught with legal challenges. But I have several concerns about the amendment. First, as convoluted as it seems, the Hatch-Waxman law that created the pathway to bring generic drugs to market has been a tremendous success in doing just that. Eighty percent of the drugs on the market now are generic, and over the last decade consumers have saved $931 billion on their drug costs as a result. There is clearly a balance in the system, and mechanisms within that system are working to bring generics to market.

As I understand it, a key element of generic entry into the market is the incentive to challenge brand-name patents. The underlying amendment changes the key incentive for generic manufacturers—the 180 days of market exclusivity. The amendment allows late filers to now share in the exclusivity, significantly reducing the incentive for companies to file early and ensuring that products get to market as quickly as possible. Generic manufacturers have a limited window for market advantage, and it is the revenues gained during this incentive period that fuel additional product development. There is a balance here. If we need to adjust that balance, I think it needs to be done in a broader context. We need to be sure that any changes that we might make do not disrupt the balance and inadvertently harm consumers.

While other aspects of the amendment are well-meaning, they may also have unintended consequences. I look forward to continuing the dialog on this issue with my colleague and others as we all work collectively to provide lower cost medicines to our constituents while maintaining an appropriate incentive for companies to innovate and develop the therapies that patients need.

Mr. HARKIN. 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. HARKIN. 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. HARKIN. Madam President, I suggest the absence of a quorum, and I ask unanimous consent that the time during the quorum call be taken off of the Burr amendment and be equally divided on both sides.

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

The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. CARPER. 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. CARPER. I ask unanimous consent to be recognized for 10 minutes and that the time be taken from the Burr amendment and equally divided.

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

AMENDMENT NO. 2131

Mr. CARPER. Madam President, we have three counties in Delaware. The

southernmost county is called Sussex County. Several years ago, I was privileged to visit a Methodist Church there and speak as a lay speaker to try to encourage people to become mentors.

The minister that day was a great old guy, Reverend Reynolds. He is now deceased, but he said to me that day these words, and I have never forgotten them. He said, ''The main thing is to keep the main thing the main thing.''

That is what he said. ''The main thing is to keep the main thing the main thing.''

At first I wasn't sure what he was talking about, but the more I thought about it I thought: Boy, this guy is smart. And if I am smart, I will keep the main thing the main thing.

For us in the Senate and in Congress, the main thing for the voters of this country is they want us to work together—well, maybe the two main things are they want us to work together—they want Democrats and Republicans to work together—and they want us to get things done. One of the things they want us to get done is to create what I call a nurturing environment for job creation and job preservation. They want us to do things that are going to help encourage the creation of jobs and the preservation of jobs.

Little known to a lot of folks across the country, we actually have been doing some of that in the Senate for much of this year, and we have worked productively across party lines to pass a series of bills that I think do help create a more nurturing environment for job preservation and job creation.

Just a couple examples, if I could: One, the reauthorization of the Federal Aviation Administration to establish a new source of additional revenues to modernize and update airports across the country, to bring the air traffic control system of our country into the 21st century where we had kind of an analogue system, and to bring it into the digital age.

Patent reform was another significant step forward earlier this year, where we said enough of this patent patrol—people who come in after someone has filed for a patent and say: Oh, no, that was my idea, and just botch things up and drag things out in the courts. Under patent reform legislation, if you are first to file, you are first to file, and that is your patent. Also provided in the same legislation are the resources needed in the Patent Office to more expeditiously process patent applicants.

Free-trade agreements. One of our roles as the government is to try to make sure we have access to foreign markets. If our goods and services are being closed out in those foreign markets, then we have to open them up. We agreed by a broad bipartisan proposal this year—three of them, actually, three free-trade agreements—one with South Korea, one with Colombia, one with Panama negotiated originally by the George W. Bush administration and embraced by the Obama administration, which is now the law of the land, to make sure when businesses have the opportunity to export, the barriers that have maybe kept them out in the past are knocked down or eliminated, and to make sure if American businesses need financing and help to finance their exports, that they have that kind of help through the Export-Import Bank, which we have reauthorized and extended into the future.

Another one that we worked on this year together, a bipartisan bill and supported by the President, is something called the JOBS Act. What it is all about is trying to make sure companies have better access to capital, and if a small or medium privately held company wants to go public, to make sure they can do it through something called an IPO onramp as opposed to just trying to jump into it and get it done all at once. Or for companies that want to stay privately held, for them to be capped at 1964 levels, 500 shareholders, to say they can go up to 1,000, 2,000 shareholders to enable them to have that access to capital to continue to grow and to create jobs.

Other examples of bipartisan legislation we worked on, in one case the Transportation bill—land transportation: roads, highways, bridges, and transit—we passed a good bill in the Senate, paid for, to help over the next couple of years to meet our transportation needs and make sure the 3 million people who are working on transportation and transit projects across the country don't basically get laid off in a month or two. We passed a good bill. I give a lot of credit to Senators BOXER and INHOFE for helping to lead the bipartisan approach.

Also, 7 or 8 million jobs depend on the Postal Service. The Postal Service is in tough straits, running out of money and losing $125 million a day. We are hoping that the House of Representatives will pass the bill—they need to—so we can go to conference and help fix that problem. But there is good bipartisan legislation here to effect positively 7 or 8 million jobs that depend on the Postal Service. All that stuff, in terms of the American people wanting us to work together, and we have been. Those are just a couple examples.

In terms of actually doing things that help create jobs and preserve jobs, every one of the items I just mentioned does create a more nurturing environment for job creation and job preservation. In the coming weeks, we also want to work on agricultural legislation—a bipartisan bill, again, out of the Agriculture Committee that will save billions of dollars on the deficit side. It will also help to strengthen our agricultural economy.

We need to get to work on a national flood insurance update, and that legislation helps to bolster the home building industry in this country which is struggling, as we know, and we have the opportunity for those things that are on our to-do list, to get them done.

Today the Senate is considering another bipartisan piece of legislation, as we know, the Food and Drug Administration Safety and Innovation Act, affectionately known by its acronym. I don't like acronyms, but I love this one. It is called PDUFA. So it is the FDA and how we make sure the FDA has the resources they need to do their job. As the other bills passed by the Senate I just talked about, this bill helps create a more nurturing environment for those businesses to thrive. Those businesses include the pharmaceutical business and businesses that make and sell medical devices. But just as important, this bill helps to ensure that Americans get access to lifesaving medications and medical devices that are developed in this country as soon and as safely as possible.

This bill reflects a strong bipartisan, bicameral effort, for which Chairman HARKIN and ranking member MIKE ENZI deserve enormous praise, and I praise them even though they are not in the Chamber right now. They have done great work, and I thank them and their staffs for bringing it to this point today.

The legislation builds upon the successful current user fee programs. For a number of years, the companies have paid a user fee if they want the FDA to approve a drug or medical device, and we are making progress to actually have more resources for the FDA to do this than we used to. But they need some additional help, and this legislation would do that, paid for by the industries that are seeking the consideration of their new pharmaceuticals and their new medical devices.

The legislation also adds important new user fees for generic and biological drugs. The user fees are paid, again, by the prescription drug and medical device industries to help cover the FDA's costs for reviewing new drugs and medical devices.

What this means is safer drugs and a speedier process to bring new and less expensive drugs and medical devices to markets for consumers, and I think it is a win-win for just about everybody.

As a result of the FDA legislation affectionately known as PDUFA, the FDA's drug review times have already been cut in half. That is good. If these user fees, these user programs are not reauthorized, though, the FDA would have to lay off, I am told, about 2,000 employees, which would put them back in the ditch, if you will, and begin to delay approval of new drugs. We don't want to see that happen. That would threaten patent access to new therapies, as well as pharmaceutical and medical device industry jobs, and America's global leadership in biomedical innovation.

This bill also makes medicines safer for millions of children, improves the FDA's tools to police the global drug supply chain, and reduces the risk of drug shortages. There are a number of amendments that are being offered to the bill—we have voted on a couple of

those—and one of the amendments that we will be voting on, I believe, a little later this afternoon is legislation that would, in my view, weaken or contaminate our country's supply of prescription drugs and put our patients and our health care system at risk.

Some of my colleagues have proposed to include a measure in this bill that ostensibly would lower prescription drug prices. This amendment, in my view, however, is not without unintended consequences, and we always have to be careful of those.

The PRESIDING OFFICER. The Senator's time has expired.

Mr. CARPER. I ask unanimous consent for 3 more minutes equally divided.

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

Mr. CARPER. Unfortunately, it would open our borders to increased numbers of contaminated and adulterated drugs.

The proposal to import drugs from Canada would allow drugs to be imported wholesale, often from illegal Internet pharmacies with no protection against abuse or contamination.

Also, though this measure is supposed to be about importing drugs from Canada, in truth it would allow drugs to come from countries that don't have the kind of strong inspection and policing of prescription drugs that we have in the United States.

Instead of going down that road, we should work to increase the FDA's abilities to protect and regulate our drug supply. While doing so, we should reject any proposals to import drugs from Canada that undermine our ability to ensure that prescription drugs are safe and effective.

One last thing I want to mention is there is an amendment that is going to be offered today—or maybe already has been, but I am going to mention this anyway—that deals with generic drugs and concern about the ability for larger pharmaceutical companies to work with and pay off, buy out the generic drug companies so they don't bring their generic version of the name-brand drug to market. I just want to say that we need to be careful what we are doing here.

I came out of the Navy and came to this Congress in 1983 as a freshman Congressman. In 1982, 20 percent of the prescriptions being filled in this country were generic drugs. This year, 80 percent of the medicines or prescriptions that are being filled are generic. One of the well-intentioned amendments to have been offered today is one that says we are not making enough progress toward allowing the generics to grow. Say that again?

We have gone from 20 percent generic penetration in 1982 to, today, 80 percent. I would suggest that we should declare victory, and as time goes by, even that 80 percent will become 85 percent or 90 percent. But we have come a long way. As a result of that, people who need to buy medicine can find a generic version of almost any medicine that is being sold in this country. I think the system is working just fine, and we ought to allow it to continue to work.

In closing, the main thing is the main thing. The main thing is to keep the main thing the main thing.

For us, the main thing is to work together. We are in a whole host of ways—including under the great leadership of Senator HARKIN and Senator ENZI—working to make sure our pharmaceutical industry is vibrantly strong, the medical device industry is vitally strong, but also that patients are not disadvantaged, that they are actually advantaged by all of that.

So responding to folks in Delaware and Iowa and across the country, we are working together. We are not just working together on a couple of things but on a whole host of things, a whole litany of provisions and laws and proposals that do what: help us to create a more nurturing environment for job creation and job preservation. That is a good thing. That is a very good thing.

I thank Senator HARKIN for giving me a chance to say a few words and for the great work that he and Senator ENZI have done. I am happy to follow their leadership here today.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Madam President, I appreciate the remarks made by my good friend from Delaware. I thank him and his staff for their input on this bill. Again, this bill is the work of a lot of different people, and I want to thank the Senator from Delaware for helping us get to the point where we have a good consensus bill.

Madam President, is there any time remaining on the Burr amendment?

The PRESIDING OFFICER. There is no time remaining on the Burr amendment.

Mr. HARKIN. Madam President, I yield 6 minutes off of the McCain amendment, on our side, to the Senator from New Jersey.

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

AMENDMENT NO. 2107

Mr. LAUTENBERG. Madam President, I rise to speak against amendment No. 2107, the one that talks about pharmaceutical products, medicines. We know how important the prescription medicines are in improving health in this country and the need to make sure those drugs are safe and affordable. Prescription drugs have brought great advances in health outcomes. Just look at how much longer people are living. Over the past century, life expectancy increased from 49 years to 77 years. We know that beneficial drugs need to be more affordable and more readily available. But allowing drugs to enter into the United States from other countries is not the answer.

The Department of Health and Human Services found that importing prescription drugs might save 1 to 2 percent on their prescription drugs—and I am not describing that as insignificant—but these are modest savings compared to what the outcome might be.

Importing risky prescription drugs from other countries could cause more health problems, more suffering, and in the final analysis, more expensive treatments. Americans buy medicine to lower their cholesterol, fight cancer, prevent heart disease. Some of these have had remarkable effects. Heart disease is much less threatening. It is still a dangerous disease but much less than it was years ago. Imagine what would happen to a mother or a child if they were relying on imported drugs only to find out that the drugs were unsafe. We need to be absolutely certain that we are not putting Americans' lives at risk.

That is why I am opposing amendment No. 2107, the McCain amendment, which would allow potentially unsafe prescription drugs to be shipped across our border, directly into the medicine cabinets of homes throughout America. Instead of safeguarding American patients, this amendment could bring potentially dangerous and ineffective drugs from Canada. I say that because, though Canadian drugs may seem safe, we already know that drugs that claim to be from Canada are not always reliable. They are not worth the risk. An FDA investigation found that 85 percent of drugs imported from Canadian Internet pharmacies were actually from 27 other countries. Many of these were pure counterfeit.

The Senate already recognized the danger that imported drugs pose to Americans. On five previous occasions, this Chamber has asked the Department of Health and Human Services to certify that importation will not put people at risk. The Secretary still has not been able to confirm that imported drugs would be safe.

I wish to make another observation. I find it kind of amusing to watch Republican colleagues talk about how wonderful the Canadian health system is. Last I checked, Canada's health care system is socialized medicine. During the health care reform debate these same colleagues were decrying the Canadian system as a horrible socialist experiment. My colleagues need to make up their minds. Do they prefer socialized medicine? If so, it comes with some risks.

I am proud that many of our country's drugs originate in the State of New Jersey, commonly known as the Medicine Chest State. In fact, there are over 46,000 highly skilled people in my home State working to produce life-saving drugs. It would be wrong to undercut the hard work of these trained New Jerseyans, only to put Americans in danger.

Right now the drugs in our country are safe and effective, as we have seen by the results. Thanks to Senator HARKIN and Senator ENZI, this bill will even make our drugs more safe. Americans deserve real peace of mind. When

they open the pill bottle and swallow their medicine, they have to know the product is safe and effective.

I urge my colleagues to support keeping medicine in our country safe and affordable. I urge the drug companies, the medicine companies, to do whatever they can to make drugs, medicines, more available at cheaper prices. I urge my colleagues to vote against amendment No. 2107.

I yield the floor.

Mr. HARKIN. Madam President, I yield 6 minutes to the Senator from West Virginia, again off the opposition to the McCain amendment time.

The PRESIDING OFFICER. The Senator from West Virginia is recognized.

Mr. MANCHIN. Madam President, I wish to say to the chairman that I appreciate his hard work on this bill, a very important piece of legislation.

I would like to address an issue that touches all of us: Democrats and Republicans, rich and poor, young and old, West Virginians and New Yorkers.

As you know, the prescription drug epidemic is destroying communities across this nation, wreaking havoc on our education system, devastating our workforce and our economy, and tearing our families apart.

Prescription drug abuse is the fastest growing drug problem in the United States, and it is claiming the lives of thousands of Americans every year. According to a report issued by the Centers for Disease Control in November, the death toll from overdoses of prescription painkillers has more than tripled in the past decade. More than 40 people die every day—every single day—from overdoses involving narcotic pain relievers. These prescription painkillers kill more Americans than heroin and cocaine combined.

It's especially tough in my home state of West Virginia, which has the highest rate of drug overdose deaths in the country. Nearly 90 percent of those deaths are linked to prescription drug abuse.

For months now, I have been going out and listening to the stories of so many people in my State—law enforcement, business owners, school teachers, pastors, and especially the children who ask for help getting their parents off the stuff. So I worked with all of them to offer an amendment to this bill that would make it harder for anyone to abuse prescription drugs. That bipartisan amendment was submitted on behalf of the countless West Virginians and Americans whose lives have been cut short by drug abuse and the families who are picking up the pieces, and it is on their behalf that I thank my colleagues in the Senate for passing it unanimously.

Last night I was so moved and encouraged to see the Members of the U.S. Senate come together across party lines and unanimously approve that measure, to take a serious step to fight this prescription drug epidemic. I strongly urge our friends in the House to do the same, and the President to sign this important bill.

This measure is not the work of just one person, however. I would like to thank the cosponsors of this bill, who all believe so strongly in it: Senator MARK KIRK of Illinois, Senator KIRSTEN GILLIBRAND of New York, Senator CHUCK SCHUMER of New York and, of course, Senator JAY ROCKEFELLER of my home State of West Virginia.

I also thank Governor Earl Ray Tomblin and Congressman NICK RAHALL for their tireless work on this issue, along with Congressman VERN BUCHANAN of Florida, who is doing excellent work to end pill mills. As we all know, last night's vote gives this amendment a solid step forward, but there is much work remaining to give our communities the right tools to fight this epidemic.

That's because all too often, we all hear stories like this one, which the Ohio County Substance Abuse Prevention Coalition in my State shared with me.

> A young boy was injured and was prescribed prescription pain killers containing hydrocodone. After the injury he began using the opiates with the other teens in school. They began by taking pills and eventually by graduation, snorting the pills on a daily basis. One day he was convinced by a friend to try IV use. He was married and was able to hold down a job until he began using IV. His wife was addicted to pain killers and their child was born addicted to drugs. He wanted more than anything to be a hard-working father and husband. He wanted to live and to amend his past behaviors. He completed treatment but eventually began using pain killers again. This man in his mid-twenties overdosed and died.

Think about it. This young man was snorting pills by high school graduation and dead in his mid-20s. Unfortunately, that story is more common than we would all like to believe.

A 2012 study by the National Institute on Drug Abuse found that 8 percent of high school seniors had admitted to abusing Vicodin in the past year. The Centers for Disease Control has found that about 12 million Americans have reported non-medical use of prescription painkillers in the past year.

Unlike many illegal drugs, prescription drugs are not produced in basement labs or smuggled across the border—they are found in our own medicine cabinets and are often prescribed for medically necessary reasons. And that makes it much easier for people to become addicted or abuse these medications.

In 2010 alone, pharmacies dispensed the equivalent of 42 tons of pure hydrocodone—that is enough to give every man, woman and child in the United States 24 Vicodin pills.

The fact is, that number is just too high. People are getting these pills because it is just too easy.

That is why this amendment would make it harder to get addictive prescription drugs, by moving them to a more restrictive category in our official drug classification system.

Practically, this means that patients would need an original prescription for refills and pills would have to be stored more securely.

Let me me close by sharing a few more personal stories about this problem—stories that show on a human level the urgency we need to put a stop to prescription drug abuse and why I am committed to this fight.

This is a problem that hits very close to home in my office. A member of my staff, a very bright young girl from Wyoming County who is doing very good work has lost three friends to drug abuse, all in their 20s. Theirs were lives full of promise, but they were tragically cut short by drug abuse.

In the past 7 years, more than 120 people have died from drug overdoses in Wyoming County alone, including 41 in 2011 and 12 just this year.

I visited Wyoming County in October to speak with a group of students at Oceana Middle School who are working very hard to take on the drug abuse crisis in their community.

These students were part of a letter writing campaign, organized by the faith-based group ''One Voice,'' which works to help addicts and their families. I want to share with you a few excerpts from some of these letters:

> ''My town, Oceana, has an issue about drugs. I write this letter to you because I hope that you can do something about it. In 2006, my godmother died of an overdose. She was the only person I could talk to. Drugs make people act in bad ways and if something doesn't happen about them then our town will be in worse shape.

I will give just one more example:

> I am 13 years old and I am a student at Oceana Middle School. I have witnessed drug deals, prostitution and homeless people in our town. I have medicine I take for ADHD and here recently some of my meds were stolen. I will graduate high school in 7 years. If nothing is done about these issues it'll be worse in the future.

I visited with these students in person. They want a better life for their parents, their siblings, their friends, their communities—and themselves. They are willing to fight, and they are asking for our help.

The amendment that passed last night with unanimous bipartisan support is a good step toward reaching their dream, and I offer my heartfelt thanks to my colleagues on behalf of all the people in West Virginia who have been affected by prescription drug abuse. And I urge my colleagues in the House to support this measure and the President to sign it—for the good of all the 12-year-old girls who are asking us to help get their daddies off this stuff.

The PRESIDING OFFICER. The time of the Senator has expired.

Mr. MANCHIN. I would like to say to both chairmen on both sides of the aisle, thank you for legislation that is much needed. Thank you for an amendment agreed upon, voted on unanimously, and accepted last night. This will go a long way to fight drug abuse in America and save countless children's lives. I thank both Senators so much.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Madam President, how much time remains on the McCain opposition?

The PRESIDING OFFICER. There is 3 minutes.

Mr. HARKIN. Madam President, I yield myself that time and a couple of minutes off the bill.

The PRESIDING OFFICER. The Senator is recognized.

Mr. HARKIN. Madam President, I wish Senators to know that we will start voting here in 9 or 10 minutes, and these will be 10-minute votes.

The first vote will be on the amendment offered by the Senator from Kentucky, Mr. PAUL, followed by Senator MCCAIN's amendment, Senator SANDERS' amendment, Senator DURBIN's amendment, and then final passage.

By an earlier consent, all of those votes will be 10-minute votes. I wanted to make sure that people knew what the lay of the land was here.

We are rapidly approaching the final passage of this bill. We have had great cooperation from all Senators on both sides in moving this legislation forward here on the floor. We have had good debates. They have not been drawn out endlessly, but we have had good debates and a good airing of the amendments on the bill. I thank all Senators for that, and hopefully we can move rapidly to wrap up this bill and move on.

This bill is the product of 18 months of very hard work by Senator ENZI and all of the Senators on our committee on both sides of the aisle. It is a true compromise and bipartisan bill. As I mentioned earlier, it has the support of a broad spectrum of stakeholders, from the pharmaceutical companies to pharmacists to consumer organizations, across the broad spectrum who support this bill, and it is necessary that we get it done. That is why we have urged everyone to expeditiously get this done before the break period coming up for Memorial Day so the Food and Drug Administration won't have to start sending pink slips out to people this summer, and so there will not be any disruptions. It will allow them to get on with the business of making sure we get drugs and devices to patients expeditiously but safely, making sure our drugs and our devices are safe.

It is a good bill, and it is the result of a lot of hard work by a lot of people, so I hope we can move these amendments rapidly and move to final passage this afternoon.

I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Madam President, I ask unanimous consent that when we begin the next vote, Senator PAUL, who has 7 minutes left on his item, be given 2 minutes so he may explain his bill in exchange for those 7 minutes.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

The Senator from Iowa.

Mr. HARKIN. Madam President, I yield myself as much time as I may consume off the bill.

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

AMENDMENT NO. 2143

Mr. HARKIN. Madam President, we are rapidly approaching a vote on the Paul amendment, and I know the Senator wants to have a couple of minutes to speak on that.

I rise in opposition to the Paul amendment. I oppose it for several reasons. Perhaps the most important reason is that this is a drug bill. This bill deals with drugs and devices. It does not deal with food. We dealt with dietary supplements and vitamins and things such as that in the food safety bill that we passed 2 years ago and that bill, again, was a consensus bill that has been through the committee structure. We brought it to the floor and had a lot of debate on it. We made modifications at that time to the whole area of vitamins, minerals, and supplements, and that is the proper place to address it, not on a bill such as this. This bill is a bill on drugs, not on supplements and food, so that is the most important reason.

I will make that same argument on the Durbin amendment. That should not be here because this is a drug bill.

On substance, I would say this bill kind of turns food law on its head. It would allow supplements to be sold with claims to cure any disease, such as AIDS or cancer, without any kind of FDA review whatsoever. I take a backseat to no one in terms of my support for the vitamin, mineral, and supplement industry and their products. Senator HATCH and I were the two people who put through the DSHEA bill, the Dietary Supplementary Health and Education Act in 1994. If I might say, we have sort of been protectors of it in working to make sure it has been implemented correctly since that time.

But the Paul amendment would go way too far. It is not consensus policy. In fact, it is strongly opposed by even the dietary supplement industry. I would note that the Natural Products Association, United Natural Products Alliance, and the Council on Responsible Nutrition, all three are big umbrella groups that oppose the Paul amendment. This would open this industry to snake oil salesmen.

Again, those of us who want to make sure people have unfettered access to safe products and to good, nutritious vitamins, minerals, and supplements, the last thing we want to see is people in their garages mixing it up and selling it as snake oil. This is not good for America, it is not good for people who want to take vitamins and supplements and minerals for their own health. It would throw this thing open and turn the clock back 50 years or more where anybody could make any claim they want and the FDA would have no way of reviewing it whatsoever.

I will move to table the amendment at the appropriate time, but I urge all Senators to oppose the Paul amendment.

I yield the floor.

The PRESIDING OFFICER. Who yields time?

Mr. ENZI. Madam President, I yield the Senator from Kentucky the time he is already entitled to.

The PRESIDING OFFICER. The Senator from Kentucky is recognized for 2 minutes under the previous order.

Mr. PAUL. My amendment is to rein in the FDA. I believe they have gotten overzealous in their duties. They do have important duties, but I think they have gotten overblown. My amendment has three parts.

First, it attempts to stop the FDA's overzealous regulation of vitamins, foods, and supplements by codifying the first amendment prohibition on prior restraint. What this means is the first amendment says we cannot restrain speech before it happens. This amendment also helps to make explicit that commercial speech is speech and should be protected.

Under current rules, the FDA prevents even the manufacturer of prune juice from saying that prune juice relieves constipation. I think that is an FDA that has gotten a little bit out of hand. I think that vitamin supplement manufacturers and distributors should be allowed to give us information and that the buyers should be allowed to review that information in making decisions about the product and that this speech should not be restricted.

Second, my amendment says the FDA doesn't need to be carrying weapons. I don't need to see bureaucrats carrying automatic weapons. If there are police officers necessary in the operation of their duties, I would rather have the FBI. The FDA does not need to be sending armed agents to the Amish farms to arrest a farmer for selling milk from the cow.

Third, my amendment fixes what needs to be fixed in a lot of regulatory crimes. We need to add in the component of mens rea. Mens rea means that when a person commits a crime and they put that person in jail, they have to prove that person had a guilty mind and had intent to commit a crime. So we add two words. If they are going to accuse a person of a crime, it has to be knowing and willful. These are very simple words, but they change the burden of the government. If the government is going to accuse a person of the crime, they need to know this. If Congress is going to criminalize conduct at a Federal level, as it does in the FDA Act, then the least we can do is add in the mens rea requirement.

Thank you. I urge support for my amendment.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Madam President, I move to table the amendment by the Senator from Kentucky and ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The question is agreeing to the motion.

The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from Hawaii (Mr. AKAKA), the Senator from Connecticut (Mr. BLUMENTHAL), the Senator from California (Mrs. BOXER), and the Senator from Michigan (Ms. STABENOW) are necessarily absent.

Mr. KYL. The following Senators are necessarily absent: the Senator from Nevada (Mr. HELLER), the Senator from Texas (Mrs. HUTCHISON), and the Senator from Illinois (Mr. KIRK).

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

The result was announced—yeas 78, nays 15, as follows:

[Rollcall Vote No. 107 Leg.]

YEAS—78

Alexander	Graham	Mikulski
Barrasso	Grassley	Moran
Baucus	Hagan	Murkowski
Begich	Harkin	Murray
Bennet	Hatch	Nelson (NE)
Bingaman	Hoeven	Nelson (FL)
Blunt	Inhofe	Portman
Brown (MA)	Inouye	Pryor
Brown (OH)	Isakson	Reed
Burr	Johnson (SD)	Reid
Cantwell	Kerry	Roberts
Cardin	Klobuchar	Rockefeller
Carper	Kohl	Rubio
Casey	Kyl	Sanders
Chambliss	Landrieu	Schumer
Coats	Lautenberg	Sessions
Cochran	Leahy	Shaheen
Collins	Levin	Shelby
Conrad	Lieberman	Snowe
Coons	Lugar	Tester
Corker	Manchin	Udall (CO)
Durbin	McCain	Udall (NM)
Enzi	McCaskill	Warner
Feinstein	McConnell	Webb
Franken	Menendez	Whitehouse
Gillibrand	Merkley	Wyden

NAYS—15

Ayotte	DeMint	Risch
Boozman	Johanns	Thune
Coburn	Johnson (WI)	Toomey
Cornyn	Lee	Vitter
Crapo	Paul	Wicker

NOT VOTING—7

Akaka	Heller	Stabenow
Blumenthal	Hutchison	
Boxer	Kirk	

The motion was agreed to.

AMENDMENT NO. 2107

The PRESIDING OFFICER. Under the previous order, there will now be 2 minutes of debate equally divided prior to a vote in relation to amendment No. 2107, offered by the Senator from Arizona, Mr. MCCAIN.

Who wishes the floor?

The Senator from Arizona.

Mr. MCCAIN. Mr. President, this amendment is a simple one. It creates a safe individual drug importation program only from approved Canadian pharmacies, overseen by the Secretary of Health and Human Services.

In a normal world, this would probably require a voice vote. But what we are about to see is the incredible influence of the special interests, particularly PhRMA, here in Washington, where people who cannot afford it will have to make a choice between eating and medicine. They will not be allowed to purchase a medication at less than half the price, many times, than they will in American pharmacies in Canada.

So what you are about to see is the reason for the cynicism the American people have about the way we do business in Washington. PhRMA—one of the most powerful lobbies in Washington—will exert its influence again at the expense of average low-income Americans who will, again, have to choose between medication and eating.

The PRESIDING OFFICER. The Senator from New Jersey.

Mr. MENENDEZ. Mr. President, it is not the special interests that have caused the Senate countless times to reject this policy. It is an amendment that puts Americans at risk, undermines the FDA's authority, and would have a devastating ripple effect throughout the country's drug supply by allowing foreign pharmaceuticals into the country.

It is not simply about Canada. The Canadians themselves have said they cannot be expected to monitor all the drugs coming through Canada and into our country, and all the Web-based opportunities would allow untraceable drugs to come through Canada into the United States.

This is about the health and security of the American people. That is why time after time the Senate has rejected it. It is why it should be rejected once again.

The PRESIDING OFFICER. The majority leader.

Mr. REID. Mr. President, I have had, during this short period of time, four different Senators come to me and say: Please hold the votes to 10 minutes, with the 5-minute penalty. So we are going to do that. A number of Senators already missed votes today. We are going to cut those votes off. If you are not here, there is no excuse. These votes have been scheduled since yesterday. So we are going to turn in these votes exactly at 15 minutes. The clerks understand that. If a Senator is late, they are late.

The PRESIDING OFFICER. Under the previous order, this amendment is subject to a 60-vote threshold. The question is on agreeing to the amendment.

The yeas and nays have been ordered.

The clerk will call the roll.

The bill clerk called the roll.

Mr. DURBIN. I announce that the Senator from Connecticut (Mr. BLUMENTHAL) is necessarily absent.

Mr. KYL. The following Senators are necessarily absent: the Senator from Texas (Mrs. HUTCHISON) and the Senator from Illinois (Mr. KIRK).

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

The result was announced—yeas 43, nays 54, as follows:

[Rollcall Vote No. 108 Leg.]

YEAS—43

Begich	Boozman	Brown (OH)
Bingaman	Boxer	Cardin
Collins	Levin	Shaheen
Conrad	McCain	Shelby
DeMint	McCaskill	Snowe
Feinstein	Merkley	Stabenow
Franken	Murkowski	Thune
Graham	Nelson (NE)	Toomey
Grassley	Nelson (FL)	Udall (NM)
Heller	Paul	Vitter
Johnson (SD)	Pryor	Webb
Klobuchar	Reed	Whitehouse
Kohl	Rockefeller	Wyden
Leahy	Sanders	
Lee	Sessions	

NAYS—54

Akaka	Cornyn	Lieberman
Alexander	Crapo	Lugar
Ayotte	Durbin	Manchin
Barrasso	Enzi	McConnell
Baucus	Gillibrand	Menendez
Bennet	Hagan	Mikulski
Blunt	Harkin	Moran
Brown (MA)	Hatch	Murray
Burr	Hoeven	Portman
Cantwell	Inhofe	Reid
Carper	Inouye	Risch
Casey	Isakson	Roberts
Chambliss	Johanns	Rubio
Coats	Johnson (WI)	Schumer
Coburn	Kerry	Tester
Cochran	Kyl	Udall (CO)
Coons	Landrieu	Warner
Corker	Lautenberg	Wicker

NOT VOTING—3

Blumenthal	Hutchison	Kirk

The PRESIDING OFFICER. Under the previous order requiring 60 votes for the adoption of this amendment, the amendment is rejected.

AMENDMENT NO. 2109

Under the previous order, there will now be 2 minutes of debate equally divided prior to a vote in relation to amendment No. 2109, offered by the Senator from Vermont, Mr. SANDERS.

Mr. SANDERS. Mr. President, this amendment is supported by Public Citizen, U.S. PIRG, the National Committee to Preserve Social Security and Medicare, and the National Women's Health Network.

In the United States, we pay by far the highest prices in the world for prescription drugs—much higher than Canada, much higher than Europe. There are a number of reasons for that. One of the reasons is the widespread fraud, systemic fraud being perpetrated on the American people by virtually every major drug company in this country.

In the last few years, companies such as Abbott, Pfizer, Johnson & Johnson, Merck, GlaxoSmithKline, and many others combined have paid billions of dollars in fines because they are ripping off Medicare, they are ripping off Medicaid, and they are ripping off the American consumer. It is high time we said that fraud cannot be perpetrated as a business model by some of the major corporations in this country.

I ask for a ''yes'' vote.

The PRESIDING OFFICER. The Senator from Wyoming

Mr. ENZI. Mr. President, I would oppose this amendment. We do need to combat health care fraud, but this amendment goes too far in several aspects. First and most important, it would discourage any settlement agreements. People would fight it to the death if they are going to lose their exclusivity.

Second, as drafted, the amendment would require companies to forfeit exclusivity anytime there is a civil or criminal liability under the Federal Food, Drug, and Cosmetic Act. It is disproportionate. This could be triggered by a misdemeanor. In addition, such liability may not reflect fraud. The amendment would discourage the development of new cures for patients. If manufactures know they could lose exclusivity for even minor infractions, they will not invest the millions of dollars necessary to create new lifesaving therapies for patients.

I ask that the Senate oppose the amendment.

I yield the floor.

The PRESIDING OFFICER. All time has expired.

Under the previous order, this amendment is subject to a 60-vote threshold for adoption.

The question is on agreeing to the amendment.

Mr. HARKIN. 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 assistant bill clerk called the roll.

Mr. DURBIN. I announce that the Senator from Connecticut (Mr. BLUMENTHAL) is necessarily absent.

Mr. KYL. The following Senators are necessarily absent: the Senator from Texas (Mrs. HUTCHISON) and the Senator from Illinois (Mr. KIRK).

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

The result was announced—yeas 9, nays 88, as follows:

[Rollcall Vote No. 109 Leg.]

YEAS—9

Bennet	Franken	Sanders
Brown (OH)	Levin	Schumer
Durbin	McCain	Whitehouse

NAYS—88

Akaka	Graham	Murkowski
Alexander	Grassley	Murray
Ayotte	Hagan	Nelson (NE)
Barrasso	Harkin	Nelson (FL)
Baucus	Hatch	Paul
Begich	Heller	Portman
Bingaman	Hoeven	Pryor
Blunt	Inhofe	Reed
Boozman	Inouye	Reid
Boxer	Isakson	Risch
Brown (MA)	Johanns	Roberts
Burr	Johnson (SD)	Rockefeller
Cantwell	Johnson (WI)	Rubio
Cardin	Kerry	Sessions
Carper	Klobuchar	Shaheen
Casey	Kohl	Shelby
Chambliss	Kyl	Snowe
Coats	Landrieu	Stabenow
Coburn	Lautenberg	Tester
Cochran	Leahy	Thune
Collins	Lee	Toomey
Conrad	Lieberman	Udall (CO)
Coons	Lugar	Udall (NM)
Corker	Manchin	Vitter
Cornyn	McCaskill	Warner
Crapo	McConnell	Webb
DeMint	Menendez	Wicker
Enzi	Merkley	Wyden
Feinstein	Mikulski	
Gillibrand	Moran	

NOT VOTING—3

Blumenthal	Hutchison	Kirk

The PRESIDING OFFICER. Under the previous order requiring 60 votes for the adoption of the amendment, the amendment is rejected.

The Senator from North Carolina.

AMENDMENT NO. 2130 WITHDRAWN

Mr. BURR. Mr. President, I ask unanimous consent to withdraw the Burr amendment No. 2130.

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

Mr. BURR. I thank the Chair.

AMENDMENT NO. 2127

The PRESIDING OFFICER. Under the previous order, there will now be 2 minutes of debate equally divided prior to a vote in relation to amendment No. 2127, offered by the Senator from Illinois, Mr. DURBIN.

Mr. DURBIN. Mr. President, this is a very simple amendment. If you go into the drugstore and look at the prescription drugs, every one of them has been registered with the FDA. The over-the-counter drugs have all been registered. When you go to the dietary supplement section, there is no requirement under the law for the company selling those products to register the name of the product, the ingredients of it, or a copy of the label.

The GAO did a study in 2009, and the FDA said we need this information to protect American consumers. From what? One of them is an example on this chart. This is a Chinese product that was imported into the United States, put up for sale, and then we discovered that one of the ingredients was life-threatening. It was never registered with the FDA, and there was no disclosure of its ingredients.

If you want to sell from the counters in America, shouldn't you be required, whether you are from China, India, Mexico, or anywhere in the United States, to register your product, the ingredients in it, and a copy of the label? The FDA says they need this information to keep America safe.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Mr. President, first of all, this is a drug and device bill, not a food bill. We addressed food issues in the food safety bill 2 years ago. That doesn't solve the problem Senator DURBIN talked about. This bill is a very delicate balance. We have worked on this for 18 months. Stakeholders all over the country, consumers, the pharmaceutical industry, and pharmacists all support this bill. This would upset that delicate balance.

I say to the Senator that every supplement has a label, the ingredients, and the potency, by law, on every single item sold as a supplement. This is a drug bill, not a food bill.

The PRESIDING OFFICER. The Senator from Utah.

Mr. HATCH. Mr. President, I strongly oppose this amendment. I will be voting to table it, and I encourage my colleagues to do the same. It would impose another layer of regulations on an industry that already has a workable regulatory framework. It is totally unnecessary, and it will only increase costs for those who use dietary supplements.

I wish to make a few points clear.

First, HHS already has authority to impose an immediate ban on any dietary supplement that poses imminent hazard to public health.

Second, four previous FDA Commissioners and a former Deputy Commissioner agree that DSHEA already provides sufficient oversight of this industry. This amendment would strap the FDA with a huge burden at a time when the agency is already struggling to perform its current core responsibilities.

Third, it unnecessarily expands registration requirements without adding any additional consumer protections.

All this amendment does is penalize good companies, while doing nothing to go after the bad.

In the end, as a result of this amendment, consumers will suffer by paying higher prices for their supplements.

This amendment is bad for the FDA and bad for consumers. The Senate should reject it.

We already have a regulatory framework under DSHEA that works. A new intrusive regulatory regime is totally unnecessary. I urge my colleagues to vote with me to table this amendment.

Mr. DURBIN. Mr. President, I ask unanimous consent to have the same amount of time given on the other side.

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

Mr. DURBIN. Mr. President, the FDA asked for this knowledge and information. What am I asking them to disclose? The name of the product, the ingredients of it, and a copy of the label. If a Chinese manufacturer wants to sell a dietary supplement in Des Moines, IA, shouldn't they have to report to the FDA the name of the product and its ingredients? It is not required by law now. Let's give the FDA this extra information to keep Americans safe.

Mr. HARKIN. Madam President, I move to table the Durbin amendment, and I ask for the yeas and nays.

The PRESIDING OFFICER (Mrs. HAGAN). Is there a sufficient second?

There is a sufficient second.

The question is on agreeing to the motion.

The clerk will call the roll.

The bill clerk called the roll.

Mr. DURBIN. I announce that the Senator from Connecticut (Mr. BLUMENTHAL) is necessarily absent.

Mr. KYL. The following Senators are necessarily absent: the Senator from Texas (Mrs. HUTCHISON) and the Senator from Illinois (Mr. KIRK).

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

The result was announced—yeas 77, nays 20, as follows:

[Rollcall Vote No. 110 Leg.]

YEAS—77

Akaka	Barrasso	Blunt
Alexander	Begich	Boozman
Ayotte	Bennet	Brown (MA)

Brown (OH)	Inhofe	Nelson (NE)
Burr	Inouye	Nelson (FL)
Cantwell	Isakson	Paul
Carper	Johanns	Portman
Casey	Johnson (SD)	Risch
Chambliss	Johnson (WI)	Roberts
Coats	Kerry	Rubio
Coburn	Kohl	Sessions
Cochran	Kyl	Shaheen
Collins	Landrieu	Shelby
Coons	Lee	Snowe
Corker	Levin	Stabenow
Cornyn	Lieberman	Tester
Crapo	Lugar	Thune
DeMint	Manchin	Toomey
Enzi	McCain	Udall (CO)
Graham	McConnell	Udall (NM)
Grassley	Menendez	Vitter
Hagan	Merkley	Warner
Harkin	Mikulski	Whitehouse
Hatch	Moran	Wicker
Heller	Murkowski	Wyden
Hoeven	Murray	

NAYS—20

Baucus	Franken	Reed
Bingaman	Gillibrand	Reid
Boxer	Klobuchar	Rockefeller
Cardin	Lautenberg	Sanders
Conrad	Leahy	Schumer
Durbin	McCaskill	Webb
Feinstein	Pryor	

NOT VOTING—3

Blumenthal	Hutchison	Kirk

The motion was agreed to.

Mr. HARKIN. Madam 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.

PRESCRIPTION DRUG INFORMATION

Mrs. GILLIBRAND. Madam President, earlier this week I introduced the Cody Miller Initiative for Safe Prescriptions Act. The legislation would require the Food and Drug Administration to issue regulations to ensure patients receive timely, consistent, and accurate information with their prescription drugs. The legislation would ensure patient medication information is regularly updated as new information becomes available and ensure that common information is applied consistently across similar products. Most importantly, the legislation would ensure patients are kept up to date about potential adverse side effects and dangerous drug interactions.

Mr. HARKIN. I applaud the work of the Senator from New York on this legislation and share her commitment to ensuring patients receive standardized and accurate information about their prescription drugs. While verbal counseling by a pharmacist is still critical, the patient medication information is also an important resource to help patients use medications safely.

Mrs. GILLIBRAND. I appreciate the Chairman's support and hope to work with him to advance this legislation. I also hope he will join me in calling on the FDA to use its existing authority to ensure patient medication information is uniform, accurate, and up-to-date. The FDA is currently engaged in efforts to revise the patient education materials that are distributed to patients. However, the FDA's current plan falls short of ensuring that consumers will receive unbiased and accurate information about their prescription drugs. It also fails to ensure that patient medication information is consistent for identical or similar products.

Mr. HARKIN. I agree we need to take steps to improve the information patients receive and look forward to working with the Senator on this issue.

ACCELERATED PATIENT ACCESS

Mrs. HAGAN. Section 901 of the managers' amendment to S. 3187, Enhancement of Accelerated Patient Access to New Medical Treatments states that an accelerated approval under section 506(b) of the Federal Food, Drug, and Cosmetic Act is subject to certain limitations, including the requirement that the sponsor conduct appropriate postapproval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit. Does the lack of an explicit reference to postapproval validation of surrogate endpoints, as described in current law, in any way restrict the Secretary's existing authority to require such validation postapproval?

Mr. HARKIN. The managers' amendment to 3187 revises section 506(b), removing the explicit language in current law requiring postapproval validation of surrogate endpoints. However, this is not intended to restrict the Secretary's current ability to require such validation postapproval, if appropriate. Equally important, the change likewise is not intended to suggest that any such validation should now occur prior to approval under section 506(b). Rather, in keeping with current practice, the bill's new language continues to permit the Secretary to require postapproval studies to verify the effect on the surrogate endpoint or predicted clinical outcome, i.e., verification of the predicted clinical benefit. In addition, it continues to allow the Secretary to withdraw an accelerated approval if the required studies fail to verify and describe the predicted effect.

Mr. ENZI. To receive accelerated approval, the managers' amendment requires that FDA determine that a surrogate or clinical endpoint is reasonably likely to be predictive of an effect on clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality as of the time of granting accelerated approval and the standards under section 505(c) of the FDCA or section 351(a) of the Public Health Service Act are met. In meeting such a requirement, it is appropriate for the Secretary to seek data and information to show that the surrogate or clinical endpoint is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

I would just like to reiterate that nothing in these amendments to section 506(b) is intended to alter the FDA's historical practice of utilizing unvalidated surrogates to grant accelerated approval in appropriate cases or its practice of granting traditional approval under section 505(b) based on validated surrogates in appropriate cases.

Mr. LEAHY. Madam President, Senator MANCHIN's amendment, amendment 2151 to the Food and Drug Administration Safety and Innovation Act, seeks to address the problem of prescription opiate drugs by tightening restrictions on hydrocodone. Opiate prescription drugs like hydrocodone have been a tremendous and growing problem in Vermont, as they have in West Virginia. I thank Senator MANCHIN for working with me to make the amendment better.

The scourge of prescription drug abuse has had a devastating effect in communities across the country. I heard about the lives destroyed by this epidemic and the violence and other ills it has brought with it in several hearings in Vermont in recent years. Senator MANCHIN's amendment seeks to make it more difficult for prescription drugs to get into the hands of those who would abuse them by requiring prescriptions more comprehensively and by restricting storage and transportation. I hope these steps will be helpful.

I am glad Senator MANCHIN was willing to work with me to modify the amendment so that it did not cause as many sentencing increases, and particularly to eliminate what would have been a new mandatory minimum sentence. Those who work on the problem of prescription drugs every day have not identified a lack of adequate criminal sentences to be part of the problem, so a significant change in the sentencing scheme was not needed or intended.

Indeed, the proliferation of severe sentences for drug offenses and of mandatory minimum sentences in particular is a large part of what has led to the serious problem we face now in having too many people in prison for too long. These sentences have contributed to the runaway prison costs that are so crippling to Federal and State budgets.

Overwhelming prison costs take resources away from programs focusing on drug prevention, drug treatment, and strong law enforcement, all of which are more effective in helping communities take on prescription drug problems than are lengthy sentences. I am glad that we could work to ensure that this amendment would help to address our prescription drug problem without contributing to the overincarceration of drug offenders.

I know some doctors in Vermont and elsewhere continue to have concerns about the effect this amendment will have on getting prescriptions to those who need them. I hope we can continue working together to ensure that we tackle the difficult problem of prescription drug addiction without hindering crucial medical care.

I thank Senator MANCHIN for his leadership on this issue.

Mr. REED. Madam President, I am pleased that last night, my amendment, No. 2126, which would ensure that there are no future delays on the

implementation of new sunscreen labeling and testing standards, was adopted as part of the Food and Drug Administration Safety and Innovation Act.

Because sunscreens have been considered a cosmetic, they have largely avoided government oversight and the FDA hasn't changed its recommendations for sunscreen standards in over 30 years.

However, last June, after years of prodding by our former colleague Senator Dodd, me, and others, the FDA finally acted.

The agency finalized comprehensive new sunscreen regulations that were scheduled to go into effect on June 18, just a few weeks from now and in time for summer. Indeed, this was considered a victory for families across the country that spend more time outdoors and under the sun's harmful UVA and UVB rays during the summer months.

But just 2 weeks ago, the FDA announced it is now giving the industry an extra 6 months to make changes, meaning the standards will take effect in mid-December instead of this summer.

For too long the FDA has allowed manufacturers to get away with inaccurate claims about sun protection. My amendment will protect against any future delays and ensure the new sunscreen safety and labeling standards go into effect no later than the end of this year.

I am pleased that the Environmental Working Group supports this amendment, and the Consumer Health Care Products Association, which represents sunscreen manufacturers, has agreed to the amendment's inclusion in this bill. Finally, the Congressional Budget Office has informed me that my amendment would not result in any additional cost to the Federal government.

I thank Chairman HARKIN and Senator ENZI for reviewing this amendment and including it in this FDA reauthorization bill.

Mr. LEVIN. Madam President, I will support final passage of the Food and Drug Administration Safety and Innovation Act which will reauthorize the user fee agreements that govern the fees paid by the pharmaceutical and medical device industries to the Food and Drug Administration, FDA, to expedite the drug and device approval process.

These fees are an important funding source that provides the FDA with resources necessary to ensure potentially lifesaving drugs and medical devices can be reviewed and ultimately brought to market quickly and safely. I understand this legislation is the product of a tremendous amount of work by the chairman and ranking member of the HELP Committee, in conjunction with various stakeholders, and enjoys broad support from industry, the FDA, and consumer groups.

For the first time, this bill will also create new user fee agreements for generic drug manufacturers; manufacturers of biologics; and would make permanent the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. These two laws together help improve the safety and efficacy of pharmaceuticals for children.

Of particular interest, the bill aims to address drug shortages by requiring all manufactures of certain drugs to provide advance notification of possible supply disruptions and any permanent discontinuance of these products to the Health and Human Services Secretary. In addition, it will also require HHS to establish a task force to address possible drug shortages and will grant the secretary the authority to expedite the inspection and review process of substitute products that could mitigate a shortage.

The bill will allow the FDA to continue to collect fees from pharmaceutical manufacturers and medical device manufacturers through 2017. I am pleased to join with colleagues from both sides of the aisle in voting in favor of this important legislation.

Ms. MIKULSKI. Madam President, I applaud the effort underway between the FDA and industry to develop a transitional pathway for the regulation of emerging diagnostic tests. In addition, I am pleased that the FDA expressed its commitment to work with industry on this important initiative in the MDUFA III commitment letter.

Many new diagnostic tests serve as the missing link to improved health care through better detection, treatment, and monitoring of disease. Thus, it is critical for public health that FDA's premarket review system for diagnostics be modernized in a manner that supports advances in the sciences and promotes patient access.

I look forward to developments with respect to the agency's plans to develop a transitional in vitro diagnostics pathway and steps taken related to its implementation.

I also wish to talk about two massively important laws that work to ensure that medications used in children are tested and labeled correctly—the Best Pharmaceuticals for Children Act, known as BPCA, and the Pediatric Research Equity Act, known as PREA.

Taken together, these two laws encourage and require drug companies to study their products in children. They have been hugely successful in ensuring that physicians and parents have information needed to best treat our Nation's children.

Most drugs on the market have never been tested in children, largely because manufacturers face economic, mechanical, ethical, and legal obstacles that work to discourage pediatric testing.

With respect to economic obstacles, the pediatric drug marketplace is generally small, with little economic incentive for manufacturers to commit resources to testing in children when they could just test in the much larger adult population.

With respect to mechanical obstacles, young children often cannot swallow pills. This presents a challenge for drug manufacturers, who often then have to develop alternate formulations, such as liquids or chewable tablets. Finally, even for adults, ethical and legal requirements for participation in a clinical trial are incredibly complex and challenging. Trying to recruit children for trials is even more difficult. Parents don't want their kids used in experiments, and drug companies face added liability concerns.

We understand these challenges, but doctors still must treat children—many with serious and life-threatening conditions. And, too often, doctors are forced to prescribe drugs that have never been studied in kids. So in 2002 and 2003 Congress passed laws that serve as a carrot and stick to generate more pediatric drug information. We passed the Pediatric Research Equity Act, which requires safety and efficacy studies in children for all new drugs. For drugs that were on the market before PREA was enacted, the law allows FDA to go back and mandate child studies where appropriate.

We also passed the Best Pharmaceuticals for Children Act, which rewards drug companies with 6 months additional exclusivity if they complete additional pediatric testing requested by FDA.

As a result of BPCA and PREA, over 425 drug labels have been revised with important pediatric information. Before BPCA and PREA, more than 80 percent of drugs used in kids were used off-label without data on safety and efficacy. Today, that number has been reduced to approximately 50 percent. New pediatric studies conducted as result of BPCA and PREA have resulted in new dosing information, new indications of use, new safety information, and new data on effectiveness in children.

The Food and Drug Administration Safety and Innovation Act removes the 5-year sunsets for BPCA and PREA, giving biopharmaceutical companies a more predictable regulatory path and providing certainty that these programs will still be up and running when companies complete their pediatric trials.

This bill also makes important pediatric information publicly available. The last reauthorization of BPCA and PREA ensured that certain pediatric studies were made publicly available but did not ensure the availability of pre-2007 studies. This bill ensures that pediatric studies conducted between 2002 and 2007, which resulted in a labeling change, are made publicly available for physicians, researchers, and parents.

Finally, this bill gives FDA new tools to ensure that studies required by PREA are completed on time, unless there is an appropriate reason for delay.

Children are not small adults. They have different medical needs. The only way to improve the health of current and future generations of children is to

better understand how drugs work in pediatric populations. We need to help doctors by getting them more information so that treatment of pediatric diseases is less of a guessing game and more of an informed practice. I believe these two pediatric programs have been incredibly successful, and I am very encouraged by the improvements we make in the bill before us today.

Finally Madam President, I wish to talk about the safety of our Nation's prescription drug supply. Today, there are many challenges and obstacles facing our families—from trying to find or keep a job, to figuring out how to pay off crushing student loans, to obtaining affordable health insurance. One thing that our families shouldn't have to worry about is whether the drug they are taking or whether the drug their loved one is taking to cure or treat an illness is going to harm them instead of help them.

When the modern FDA was first established in 1938, most of our medical products were developed and manufactured within our own borders. That is no longer the case. Nearly 40 percent of drugs Americans rely upon are made outside our borders. About 80 percent of the active ingredients used in drugs made in the United States come from 150 other countries. The increased globalization of our drug industry, coupled with the fact that we have not given our Federal agencies additional authorities to keep pace, has created great challenges for FDA and industry and great danger to patients in need.

Where there is need, there is greed. Where there is greed, there is scam and schemes. In this case, we know that increased globalization and insufficient authorities to regulate at a Federal level has created a dangerous opportunity for bad actors to take advantage. And they have taken advantage—from adulteration, to counterfeiting, to cargo theft, to manufacturing drugs in unsanitary conditions, to mislabeled products. We have seen it all in recent years and the consequences have been deadly.

In recent years, a highly toxic solvent, known as DEG, added to fever medicine, cough syrup, and teething products resulted in the deaths of children and adults in Panama, Haiti, and Nigeria.

In 2007, pet food adulterated with melamine and acid sickened several thousand pets in the United States. Melamine and acid was added to infant formula in China, poisoning and killing six babies and sickening 300,000 others.

In 2008, contaminated Heparin from China killed and sickened hundreds across the United States.

In 2003, more than $20 million in illegally imported and counterfeit Lipitor was sold throughout the United States.

In 2009, an estimated 46 drug cargo thefts occurred, valued at $184 million.

Many stolen drugs are then improperly stored or handled before being sold back to consumers, putting patients at risk. For instance, stolen insulin was reintroduced into the drug supply and caused adverse events in patients because it had not been refrigerated. I could go on and on with examples of how counterfeit, adulterated, and stolen drugs have sickened and killed people and animals worldwide.

But, I am encouraged by the bill before us today. The FDA Safety and Innovation Act takes a number of important steps to improve the safety of our Nation's drug supply. For instance, this legislation requires every foreign establishment engaged in the manufacture of a drug or device imported into the United States, to electronically register with the FDA.

Under current law, there are no requirements governing how often FDA must inspect foreign facilities. The bill before us requires FDA to set up a risk-based inspection frequency to ensure that we are getting in there and inspecting facilities that pose the greatest risks.

This legislation gives the Secretary of Homeland Security the authority to refuse admission into the United States any drug or ingredient if it was manufactured, processed, packed, or held at an establishment that has refused or delayed inspection by FDA.

This bill requires drug manufacturers and wholesalers to notify the FDA if they become aware that their drug has been counterfeited or has been stolen or lost in substantial quantities.

Finally, this bill increases penalties for bad actors who knowingly adulterate or counterfeit drugs.

In developing this legislation, the question we had to ask was this: Does the Federal agency tasked with ensuring the safety of our Nation's drugs have the resources and authorities necessary to do their job and protect the public health? The answer was no. But I believe the new authorities contained in the FDA Safety and Innovation Act—which we developed on a bipartisan basis in the Senate HELP committee—will help us ensure that the next time we ask this question, the answer will be yes.

Mr. DURBIN. Madam President, today, we are considering a bill that will improve the FDA's ability to assure the safety of drugs in our medicine cabinets and medical devices in our hospitals.

The FDA is an essential guardian of the public's health and safety.

In the past few years, FDA has faced obstacles that call on the agency to adapt and respond to the evolving nature of reviewing, manufacturing, and distributing drugs and devices.

Some of those obstacles and challenges are addressed in the reauthorizations of the Prescription Drug User Fee Act and the Medical Device User Fee Act, which are set to expire at the end of September 2012.

Last fall, I visited Cook Medical's medical device plant in Canton, IL, and representatives expressed concern about the amount of time it takes medical devices to be reviewed.

FDA needs sufficient time to review medical devices in order to ensure their safety and effectiveness. However, inefficiencies and insufficient resources can result in longer review times, which means patients have to wait longer to benefit from new medical devices.

This bill makes key changes to maintain the safety of devices and preserve our country's leadership in biomedical innovation.

The bill will authorize the FDA to collect almost $600 million in user fees over 5 years. FDA can use these additional resources to help hire and train staff.

Furthermore, the bill makes important improvements by streamlining the review process for devices and increasing communication between the FDA and device manufacturers throughout the review process.

These changes to the review of medical devices will not only help innovative device companies get their product to market faster but will prevent patients from having to wait extra weeks and months to benefit from a new device.

In addition to reauthorizing the Prescription Drug and Medical Device User Fee Acts, this bill also establishes the Generic Drug User Fee Act and Biosimilar User Fee Act, which give FDA new authority to collect user fees for generic and biosimilar drugs.

Currently the FDA does not collect user fees to support the review of generic drugs, and it takes about 30 months for the agency to review generic drug applications. This extra time reduces access to safe, affordable generic drugs and leaves patients and taxpayers paying the tab for brand-name drugs that lack competition from generics.

Since the first Prescription Drug User Fee Act was enacted in 1992, the FDA began collecting user fees to support the review of applications.

FDA has cut the review time for new drugs by 60 percent, from 2 years to a little over 1 year.

Similarly, the Generic Drug User Fee Act will give FDA the support it needs to cut the current 30-month review time for generic drugs down to 10 months.

This improvement will promote competition in the marketplace and save money by reducing the amount of time patients have to wait for less expensive generic alternatives to brand-name drugs.

The process of negotiating and drafting this legislation started 18 months ago, and the result is a comprehensive bill that improves the safety and quality of drugs and medical devices.

Chairman HARKIN and Senator ENZI have put together a bill that responds to many of these challenges, including one that is of particular interest to me—the national shortage of critical drugs.

Between 2006 and 2010 the drug shortage increased 200 percent—from 56 to

178 drugs. Currently the drug shortage includes over 200 drugs, such as intravenous nutrition supplements, cancer treating drugs, and anesthesia.

Over the past few months, I have held three roundtable discussions at hospitals across Illinois to learn about the drug shortage and how it is affecting providers and patients. From these discussions it is clear that the drug shortage is being felt at most hospitals, and those Illinois hospitals, providers, and pharmacists are working around the clock to ensure patients maintain access to drugs and safe treatments.

At Advocate Hospital in Libertyville, a doctor shared that he learned just days before starting a patient on chemotherapy that the drug was not available. Unfortunately, this is a common scenario across the country as doctors learn days before starting a treatment or even once the patient is on the hospital bed that a drug is not available.

Pharmacists now spend part of each day scrambling to find drugs or an alternative treatment.

I recently learned that a young woman on my staff here in DC is all too familiar with the drug shortage. She is a smart and hardworking woman who has been taking Concerta to treat her ADD since she was 14. Like most people with severe ADD, she must take her medicine at a certain time every day in order to keep their ADD symptoms from impeding basic life and work responsibilities. And while there are several ADD drugs on the market, each drug works differently and can have different side effects, so switching to a new prescription is not without risk.

Last year, the local CVS where she usually had her prescription filled started telling her they didn't have her drug in stock. She didn't think much of it, as she would wake up early and walk to another CVS in the morning where she was usually able to get the prescription.

Over time, she grew accustomed to going between these two CVS pharmacies to fill her prescription until one month when she carried her prescription with her for 3 days and was unable to find a pharmacy with enough Concerta to fill her 30-day prescription. By the end of day 3, she was out of her supply. She woke up early and rode her bike to four or five CVS pharmacies until she was able to find a pharmacy that could fill her prescription. But by then it was 12 o'clock and past the prescribed time to take the drug.

The shortage of ADD drugs impacts children, adults, parents, and employees across the country.

Congress must take action to address the drug shortage.

The FDA Safety and Innovation Act builds on Senator KLOBUCHAR's bill, with key provisions to curb the national drug shortage.

First, the bill requires drug manufacturers to notify the FDA 6 months in advance for certain drug shortages.

With this much notice, the FDA can work with manufacturers to try to avoid a shortage and, when necessary, identify alternative sources of the drug to ensure we maintain a supply for patients.

This winter, thanks to open communication between the FDA and drug companies, the FDA successfully avoided a shortage of methotrexate, a vital drug to treat leukemia with children.

FDA collaborated with Illinois-based generic drug manufacturer Hospira to increase production of this lifesaving drug when another company halted production.

Requiring 6 months' advance notice of a drug shortage will help the FDA to work with companies to avoid shortages of critical drugs.

Furthermore, the bill requires FDA to enhance the agency's response to shortages and will improve reporting of shortages by allowing third parties to report drug shortages to the FDA.

This bill also takes steps to improve the safety of drugs and the drug supply chain.

In 2008, serious injuries and 81 deaths were linked to contamination of the crucial blood thinning drug heparin. The source of the contamination was a facility in China that intentionally adulterated the drug. This was a horrible illustration of what happens when adulterated and counterfeit drugs make their way into the drug supply chain and ultimately to patients.

This case has also raised serious questions about the global manufacturing practices of drugs and drug ingredients and the FDA's responsibility to protect the drug supply chain. Since the heparin incident, the global nature of the drug supply chain has only grown. Today, 80 percent of active pharmaceutical ingredients are manufactured outside of the United States.

This bill improves the safety of our supply chain both domestically and internationally by requiring foreign manufacturers to register their facilities with the FDA.

The bill also places greater responsibility on U.S. drug manufacturers to know their international suppliers and increases penalties for intentionally contaminating or counterfeiting drugs.

Counterfeit and adulterated drugs can have deadly consequences, yet the penalty for committing these crimes is less than the penalty for selling a counterfeit designer purse. Currently, the penalty for intentionally counterfeiting or adulterating a drug is no more than 3 ears in prison or a $10,000 fine or both. This bill raises the penalty for intentionally adulterating a drug to no more than 20 years in prison or a $1 million fine or both. And the penalty for intentionally counterfeiting drugs is raised to no more than 20 years in prison or a $4 million fine or both.

This bill addresses the drug shortage, reduces the review time for medical devices and drugs, improves the pipeline for antibiotics and pediatric drugs, and helps secure the supply chain for prescription drugs.

I thank Chairman HARKIN and Senator ENZI for their extraordinary leadership and hard work on this bill.

The PRESIDING OFFICER. The question is on the engrossment and the third reading of the bill.

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

The PRESIDING OFFICER. Under the previous order, there will now be 2 minutes of debate equally divided prior to a vote on passage of the bill, as amended.

The Senator from Iowa.

Mr. HARKIN. Madam President, we have all put in a lot of work and benefited greatly by the constructive ideas and efforts of all the Members of this body. I sincerely thank all my colleagues, especially Senator ENZI, for their hard work on this must-pass legislation.

This excellent bill is a shining example of what we can achieve when we all work together. Now we must keep our promise to patients and the biomedical industry and pass this critical bill.

Today, with one vote, we can reauthorize the essential FDA's user fee agreements, systematically modernize FDA's medical product authority, and help to boost American innovation and ensure that patients have access to the therapies they need.

So I urge my colleagues to join in this bipartisan spirit of cooperation and pass this important legislation, the FDA Safety and Innovation Act.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Madam President, the chairman has said it well. We appreciate the bipartisan spirit in which people have participated, especially in committee for a year and a half, working out amendments, working out ideas, and coming up with a bill that had a good consensus.

I appreciate the action on the Senate floor, the people who were willing to do time limits on their amendments, and how quickly we have gotten through the votes.

I particularly want to thank the chairman for the way he has handled this in committee and the process since then. We had a couple of issues that were outstanding and those got worked out.

I also want to thank the staffs on both sides. Their dedication for a year and a half is what made this happen, and we have some outstanding staff on both sides. Every member of the committee and every committee member's staff helped on this one, and that makes a difference. So I ask everyone to support the bill.

I yield the floor.

The PRESIDING OFFICER. The question is, Shall the bill pass?

Mr. HARKIN. Madam President, I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The clerk will call the roll.

The assistant bill clerk called the roll.

Mr. DURBIN. I announce that the Senator from Connecticut (Mr. BLUMENTHAL) is necessarily absent.

Mr. KYL. The following Senators are necessarily absent: the Senator from Texas (Mrs. HUTCHISON) and the Senator from Illinois (Mr. KIRK).

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

The result was announced—yeas 96, nays 1, as follows:

[Rollcall Vote No. 111 Leg.]

YEAS—96

Akaka	Franken	Mikulski
Alexander	Gillibrand	Moran
Ayotte	Graham	Murkowski
Barrasso	Grassley	Murray
Baucus	Hagan	Nelson (NE)
Begich	Harkin	Nelson (FL)
Bennet	Hatch	Paul
Bingaman	Heller	Portman
Blunt	Hoeven	Pryor
Boozman	Inhofe	Reed
Boxer	Inouye	Reid
Brown (MA)	Isakson	Risch
Brown (OH)	Johanns	Roberts
Burr	Johnson (SD)	Rockefeller
Cantwell	Johnson (WI)	Rubio
Cardin	Kerry	Schumer
Carper	Klobuchar	Sessions
Casey	Kohl	Shaheen
Chambliss	Kyl	Shelby
Coats	Landrieu	Snowe
Coburn	Lautenberg	Stabenow
Cochran	Leahy	Tester
Collins	Lee	Thune
Conrad	Levin	Toomey
Coons	Lieberman	Udall (CO)
Corker	Lugar	Udall (NM)
Cornyn	Manchin	Vitter
Crapo	McCain	Warner
DeMint	McCaskill	Webb
Durbin	McConnell	Whitehouse
Enzi	Menendez	Wicker
Feinstein	Merkley	Wyden

NAYS—1

Sanders

NOT VOTING—3

Blumenthal	Hutchison	Kirk

The bill (S. 3187), as amended, was passed, as follows:

S. 3187

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 Safety and Innovation Act''.

SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.

(a) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents; references in Act.

TITLE I—FEES RELATING TO DRUGS

Sec. 101. Short title; finding.
Sec. 102. Definitions.
Sec. 103. Authority to assess and use drug fees.
Sec. 104. Reauthorization; reporting requirements.
Sec. 105. Sunset dates.
Sec. 106. Effective date.
Sec. 107. Savings clause.

TITLE II—FEES RELATING TO DEVICES

Sec. 201. Short title; findings.
Sec. 202. Definitions.
Sec. 203. Authority to assess and use device fees.
Sec. 204. Reauthorization; reporting requirements.
Sec. 205. Savings clause.
Sec. 206. Effective date.
Sec. 207. Sunset dates.
Sec. 208. Streamlined hiring authority to support activities related to the process for the review of device applications.

TITLE III—FEES RELATING TO GENERIC DRUGS

Sec. 301. Short title.
Sec. 302. Authority to assess and use human generic drug fees.
Sec. 303. Reauthorization; reporting requirements.
Sec. 304. Sunset dates.
Sec. 305. Effective date.
Sec. 306. Amendment with respect to misbranding.
Sec. 307. Streamlined hiring authority of the Food and Drug Administration to support activities related to human generic drugs.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

Sec. 401. Short title; finding.
Sec. 402. Fees relating to biosimilar biological products.
Sec. 403. Reauthorization; reporting requirements.
Sec. 404. Sunset dates.
Sec. 405. Effective date.
Sec. 406. Savings clause.
Sec. 407. Conforming amendment.

TITLE V—PEDIATRIC DRUGS AND DEVICES

Sec. 501. Permanence.
Sec. 502. Written requests.
Sec. 503. Communication with Pediatric Review Committee.
Sec. 504. Access to data.
Sec. 505. Ensuring the completion of pediatric studies.
Sec. 506. Pediatric study plans.
Sec. 507. Reauthorizations.
Sec. 508. Report.
Sec. 509. Technical amendments.
Sec. 510. Relationship between pediatric labeling and new clinical investigation exclusivity.
Sec. 511. Pediatric rare diseases.

TITLE VI—MEDICAL DEVICE REGULATORY IMPROVEMENTS

Sec. 601. Reclassification procedures.
Sec. 602. Condition of approval studies.
Sec. 603. Postmarket surveillance.
Sec. 604. Sentinel.
Sec. 605. Recalls.
Sec. 606. Clinical holds on investigational device exemptions.
Sec. 607. Unique device identifier.
Sec. 608. Clarification of least burdensome standard.
Sec. 609. Custom devices.
Sec. 610. Agency documentation and review of certain decisions regarding devices.
Sec. 611. Good guidance practices relating to devices.
Sec. 612. Modification of de novo application process.
Sec. 613. Humanitarian device exemptions.
Sec. 614. Reauthorization of third-party review and inspections.
Sec. 615. 510(k) device modifications.
Sec. 616. Health information technology.

TITLE VII—DRUG SUPPLY CHAIN

Subtitle A—Drug Supply Chain

Sec. 701. Registration of domestic drug establishments.
Sec. 702. Registration of foreign establishments.
Sec. 703. Identification of drug excipient information with product listing.
Sec. 704. Electronic system for registration and listing.
Sec. 705. Risk-based inspection frequency.
Sec. 706. Records for inspection.
Sec. 707. Failure to allow foreign inspection.
Sec. 708. Exchange of information.
Sec. 709. Enhancing the safety and quality of the drug supply.
Sec. 710. Accreditation of third-party auditors for drug establishments.
Sec. 711. Standards for admission of imported drugs.
Sec. 712. Notification.
Sec. 713. Protection against intentional adulteration.
Sec. 714. Enhanced criminal penalty for counterfeiting drugs.
Sec. 715. Extraterritorial jurisdiction.
Sec. 716. Compliance with international agreements.

Subtitle B—Pharmaceutical Distribution Integrity

Sec. 721. Short title.
Sec. 722. Securing the pharmaceutical distribution supply chain.
Sec. 723. Independent assessment.

TITLE VIII—GENERATING ANTIBIOTIC INCENTIVES NOW

Sec. 801. Extension of exclusivity period for drugs.
Sec. 802. Priority review.
Sec. 803. Fast track product.
Sec. 804. GAO study.
Sec. 805. Clinical trials.
Sec. 806. Regulatory certainty and predictability.

TITLE IX—DRUG APPROVAL AND PATIENT ACCESS

Sec. 901. Enhancement of accelerated patient access to new medical treatments.
Sec. 902. Breakthrough therapies.
Sec. 903. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments.
Sec. 904. Accessibility of information on prescription drug container labels by visually-impaired and blind consumers.
Sec. 905. Risk-benefit framework.
Sec. 906. Independent study on medical innovation inducement model.
Sec. 907. Orphan product grants program.
Sec. 908. Reporting of inclusion of demographic subgroups in clinical trials and data analysis in applications for drugs, biologics, and devices.

TITLE X—DRUG SHORTAGES

Sec. 1001. Drug shortages.

TITLE XI—OTHER PROVISIONS

Subtitle A—Reauthorizations

Sec. 1101. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.
Sec. 1102. Reauthorization of the Critical Path Public-Private Partnerships.

Subtitle B—Medical Gas Product Regulation

Sec. 1111. Regulation of medical gas products.
Sec. 1112. Regulations.
Sec. 1113. Applicability.

Subtitle C—Miscellaneous Provisions

Sec. 1121. Advisory committee conflicts of interest.
Sec. 1122. Guidance document regarding product promotion using the Internet.
Sec. 1123. Electronic submission of applications.
Sec. 1124. Combating prescription drug abuse.
Sec. 1125. Tanning bed labeling.

Sec. 1126. Optimizing global clinical trials.
Sec. 1127. Advancing regulatory science to promote public health innovation.
Sec. 1128. Information technology.
Sec. 1129. Reporting requirements.
Sec. 1130. Strategic integrated management plan.
Sec. 1131. Drug development and testing.
Sec. 1132. Patient participation in medical product discussions.
Sec. 1133. Nanotechnology regulatory science program.
Sec. 1134. Online pharmacy report to Congress.
Sec. 1135. Medication and device errors.
Sec. 1136. Compliance provision.
Sec. 1137. Ensuring adequate information regarding pharmaceuticals for all populations, particularly underrepresented subpopulations, including racial subgroups.
Sec. 1138. Report on small businesses.
Sec. 1139. Protections for the commissioned corps of the public health service act.
Sec. 1140. Regulations on clinical trial registration; GAO Study of clinical trial registration and reporting requirements.
Sec. 1141. Hydrocodone amendment.
Sec. 1142. Compliance date for rule relating to sunscreen drug products for over-the-counter human use.
Sec. 1143. Recommendations on interoperability standards.

Subtitle D—Synthetic Drugs

Sec. 1151. Short title.
Sec. 1152. Addition of synthetic drugs to schedule I of the Controlled Substances Act.
Sec. 1153. Temporary scheduling to avoid imminent hazards to public safety expansion.
Sec. 1154. Prohibition on imposing mandatory minimum sentences.

(b) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

TITLE I—FEES RELATING TO DRUGS

SEC. 101. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Prescription Drug User Fee Amendments of 2012''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services 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.

SEC. 102. DEFINITIONS.

Paragraph (7) of section 735 (21 U.S.C. 379g) is amended, in the matter preceding subparagraph (A), by striking ''incurred''.

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

Section 736 (21 U.S.C. 379h) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking ''fiscal year 2008'' and inserting ''fiscal year 2013'';

(B) in paragraph (1), in clauses (i) and (ii) of subparagraph (A), by striking ''subsection (c)(5)'' each place such term appears and inserting ''subsection (c)(4)'';

(C) in the matter following clause (ii) in paragraph (2)(A)—

(i) by striking ''subsection (c)(5)'' and inserting ''subsection (c)(4)''; and

(ii) by striking ''payable on or before October 1 of each year'' and inserting ''due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section''; and

(D) in paragraph (3)—

(i) in subparagraph (A)—

(I) by striking ''subsection (c)(5)'' and inserting ''subsection (c)(4)''; and

(II) by striking ''payable on or before October 1 of each year.'' and inserting ''due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section.''; and

(ii) by amending subparagraph (B) to read as follows:

''(B) EXCEPTION.—A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is—

''(i) identified on the list compiled under section 505(j)(7) with a potency described in terms of per 100 mL;

''(ii) the same product as another product that—

''(I) was approved under an application filed under section 505(b) or 505(j); and

''(II) is not in the list of discontinued products compiled under section 505(j)(7);

''(iii) the same product as another product that was approved under an abbreviated application filed under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997); or

''(iv) the same product as another product that was approved under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.'';

(2) in subsection (b)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking ''fiscal years 2008 through 2012'' and inserting ''fiscal years 2013 through 2017'';

(ii) in subparagraph (A), by striking ''$392,783,000; and'' and inserting ''$693,099,000;''; and

(iii) by striking subparagraph (B) and inserting the following:

''(B) the dollar amount equal to the inflation adjustment for fiscal year 2013 (as determined under paragraph (3)(A)); and

''(C) the dollar amount equal to the workload adjustment for fiscal year 2013 (as determined under paragraph (3)(B)).''; and

(B) by striking paragraphs (3) and (4) and inserting the following:

''(3) FISCAL YEAR 2013 INFLATION AND WORKLOAD ADJUSTMENTS.—For purposes of paragraph (1), the dollar amount of the inflation and workload adjustments for fiscal year 2013 shall be determined as follows:

''(A) INFLATION ADJUSTMENT.—The inflation adjustment for fiscal year 2013 shall be the sum of—

''(i) $652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(B); and

''(ii) $652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(C).

''(B) WORKLOAD ADJUSTMENT.—Subject to subparagraph (C), the workload adjustment for fiscal 2013 shall be—

''(i) $652,709,000 plus the amount of the inflation adjustment calculated under subparagraph (A); multiplied by

''(ii) the amount (if any) by which a percentage workload adjustment for fiscal year 2013, as determined using the methodology described in subsection (c)(2)(A), would exceed the percentage workload adjustment (as so determined) for fiscal year 2012, if both such adjustment percentages were calculated using the 5-year base period consisting of fiscal years 2003 through 2007.

''(C) LIMITATION.—Under no circumstances shall the adjustment under subparagraph (B) result in fee revenues for fiscal year 2013 that are less than the sum of the amount under paragraph (1)(A) and the amount under paragraph (1)(B).'';

(3) by striking subsection (c) and inserting the following:

''(c) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of—

''(A) one;

''(B) the average annual percent 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 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years; and

''(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data, multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year under this paragraph shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this paragraph.

''(2) WORKLOAD ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, after the fee revenues established in subsection (b) 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 for the process for the review of human drug applications. With respect to such adjustment:

''(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph), efficacy supplements, and manufacturing supplements submitted to the Secretary, and the change in the total number of active commercial investigational new drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available. The Secretary shall publish in the Federal Register

the fee revenues and fees resulting from the adjustment and the supporting methodologies.

''(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the sum of the amount under subsection (b)(1)(A) and the amount under subsection (b)(1)(B), as adjusted for inflation under paragraph (1).

''(C) The Secretary shall contract with an independent accounting or consulting firm to periodically review the adequacy of the adjustment and publish the results of those reviews. The first review shall be conducted and published by the end of fiscal year 2013 (to examine the performance of the adjustment since fiscal year 2009), and the second review shall be conducted and published by the end of fiscal year 2015 (to examine the continued performance of the adjustment). The reports shall evaluate whether the adjustment reasonably represents actual changes in workload volume and complexity and present options to discontinue, retain, or modify any elements of the adjustment. The reports shall be published for public comment. After review of the reports and receipt of public comments, the Secretary shall, if warranted, adopt appropriate changes to the methodology. If the Secretary adopts changes to the methodology based on the first report, the changes shall be effective for the first fiscal year for which fees are set after the Secretary adopts such changes and each subsequent fiscal year.

''(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2017, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1) and (2), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of fiscal year 2018. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2017. If the Secretary has carryover balances for such process in excess of 3 months of such operating reserves, the adjustment under this paragraph shall not be made.

''(4) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, application, product, and establishment fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

''(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.''; and

(4) in subsection (g)—

(A) in paragraph (1), by striking ''Fees authorized'' and inserting ''Subject to paragraph (2)(C), fees authorized'';

(B) in paragraph (2)—

(i) in subparagraph (A)—

(I) in clause (i), by striking ''shall be retained'' and inserting ''subject to subparagraph (C), shall be collected and available''; and

(II) in clause (ii), by striking ''shall only be collected and available'' and inserting ''shall be available''; and

(ii) by adding at the end the following new subparagraph:

''(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.'';

(C) in paragraph (3), by striking ''fiscal years 2008 through 2012'' and inserting ''fiscal years 2013 through 2017''; and

(D) in paragraph (4)—

(i) by striking ''fiscal years 2008 through 2010'' and inserting ''fiscal years 2013 through 2015'';

(ii) by striking ''fiscal year 2011'' and inserting ''fiscal year 2016'';

(iii) by striking ''fiscal years 2008 though 2011'' and inserting ''fiscal years 2013 through 2016''; and

(iv) by striking ''fiscal year 2012'' and inserting ''fiscal year 2017''.

SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 736B (21 U.S.C. 379h–2) is amended—

(1) by amending subsection (a) to read as follows:

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report under this subsection 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) in subsection (b), by striking ''2008'' and inserting ''2013''; and

(3) in subsection (d), by striking ''2012'' each place it appears and inserting ''2017''.

SEC. 105. SUNSET DATES.

(a) AUTHORIZATION.—Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g; 379h) shall cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.—Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) shall cease to be effective January 31, 2018.

(c) PREVIOUS SUNSET PROVISION.—Section 106 of the Prescription Drug User Fee Amendments of 2007 (Title I of Public Law 110–85) is repealed.

(d) TECHNICAL CLARIFICATIONS.—

(1) Effective September 30, 2007, section 509 of the Prescription Drug User Fee Amendments Act of 2002 (Title V of Public Law 107–188) is repealed.

(2) Effective September 30, 2002, section 107 of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115) is repealed.

(3) Effective September 30, 1997, section 105 of the Prescription Drug User Fee Act of 1992 (Public Law 102–571) is repealed.

SEC. 106. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later, except that fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all human drug applications received on or after October 1, 2012, regardless of the date of the enactment of this Act.

SEC. 107. SAVINGS CLAUSE.

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 the 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, 2007, but before October 1, 2012, 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 2012.

TITLE II—FEES RELATING TO DEVICES

SEC. 201. SHORT TITLE; FINDINGS.

(a) SHORT TITLE.—This title may be cited as the ''Medical Device User Fee Amendments of 2012''.

(b) FINDINGS.—The Congress finds that the fees authorized under the amendments made by this title will 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 part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act in the letters from the Secretary of Health and Human Services 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.

SEC. 202. DEFINITIONS.

Section 737 (21 U.S.C. 379i) is amended—

(1) in paragraph (9), by striking ''incurred'' after ''expenses'';

(2) in paragraph (10), by striking ''October 2001'' and inserting ''October 2011''; and

(3) in paragraph (13), by striking ''is required to register'' and all that follows through the end of paragraph (13) and inserting the following: ''is registered (or is required to register) with the Secretary under section 510 because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device.''.

SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—Section 738(a) (21 U.S.C. 379j(a)) is amended—

(1) in paragraph (1), by striking ''fiscal year 2008'' and inserting ''fiscal year 2013'';

(2) in paragraph (2)(A)—

(A) in the matter preceding clause (i)—

(i) by striking ''subsections (d) and (e)'' and inserting ''subsections (d), (e), and (f)'';

(ii) by striking ''October 1, 2002'' and inserting ''October 1, 2012''; and

(iii) by striking ''subsection (c)(1)'' and inserting ''subsection (c)''; and

(B) in clause (viii), by striking ''1.84'' and inserting ''2''; and

(3) in paragraph (3)—

(A) in subparagraph (A)—

(i) by inserting ''and subsection (f)'' after ''subparagraph (B)''; and

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

(B) in subparagraph (C), by striking ''initial registration'' and all that follows through ''section 510.'' and inserting ''later of—

''(i) the initial or annual registration (as applicable) of the establishment under section 510; or

''(ii) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.''.

(b) FEE AMOUNTS.—Section 738(b) (21 U.S.C. 379j(b)) is amended to read as follows:

''(b) FEE AMOUNTS.—

''(1) IN GENERAL.—Subject to subsections (c), (d), (e), (f), and (i), for each of fiscal years 2013 through 2017, fees under subsection (a) shall be derived from the base fee amounts specified in paragraph (2), to generate the total revenue amounts specified in paragraph (3).

''(2) BASE FEE AMOUNTS.—For purposes of paragraph (1), the base fee amounts specified in this paragraph are as follows:

''Fee Type	Fiscal Year 2013	Fiscal Year 2014	Fiscal Year 2015	Fiscal Year 2016	Fiscal Year 2017
Premarket Application	$248,000	$252,960	$258,019	$263,180	$268,443
Establishment Registration	$2,575	$3,200	$3,750	$3,872	$3,872

''(3) TOTAL REVENUE AMOUNTS.—For purposes of paragraph (1), the total revenue amounts specified in this paragraph are as follows:

''(A) $97,722,301 for fiscal year 2013.

''(B) $112,580,497 for fiscal year 2014.

''(C) $125,767,107 for fiscal year 2015.

''(D) $129,339,949 for fiscal year 2016.

''(E) $130,184,348 for fiscal year 2017.''.

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section 738(c) (21 U.S.C. 379j(c)) is amended—

(1) in the subsection heading, by inserting ''; ADJUSTMENTS'' after ''SETTING'';

(2) by striking paragraphs (1) and (2);

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

(4) by inserting before paragraph (4), as so redesignated, the following:

''(1) IN GENERAL.—The Secretary shall, 60 days before the start of each fiscal year after September 30, 2012, establish fees under subsection (a), based on amounts specified under subsection (b) and the adjustments provided under this subsection, and publish such fees, and the rationale for any adjustments to such fees, in the Federal Register.

''(2) INFLATION ADJUSTMENTS.—

''(A) ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—For fiscal year 2014 and each subsequent fiscal year, the Secretary shall adjust the total revenue amount specified in subsection (b)(3) for such fiscal year by multiplying such amount by the applicable inflation adjustment under subparagraph (B) for such year.

''(B) APPLICABLE INFLATION ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—The applicable inflation adjustment for a fiscal year is—

''(i) for fiscal year 2014, the base inflation adjustment under subparagraph (C) for such fiscal year; and

''(ii) for fiscal year 2015 and each subsequent fiscal year, the product of—

''(I) the base inflation adjustment under subparagraph (C) for such fiscal year; and

''(II) the product of the base inflation adjustment under subparagraph (C) for each of the fiscal years preceding such fiscal year, beginning with fiscal year 2014.

''(C) BASE INFLATION ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—

''(i) IN GENERAL.—Subject to further adjustment under clause (ii), the base inflation adjustment for a fiscal year is the sum of one plus—

''(I) the average annual percent 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 3 years of the preceding 4 fiscal years, multiplied by 0.60; and

''(II) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by 0.40.

''(ii) LIMITATIONS.—For purposes of subparagraph (B), if the base inflation adjustment for a fiscal year under clause (i)—

''(I) is less than 1, such adjustment shall be considered to be equal to 1; or

''(II) is greater than 1.04, such adjustment shall be considered to be equal to 1.04.

''(D) ADJUSTMENT TO BASE FEE AMOUNTS.—For each of fiscal years 2014 through 2017, the base fee amounts specified in subsection (b)(2) shall be adjusted as needed, on a uniform proportionate basis, to generate the total revenue amounts under subsection (b)(3), as adjusted for inflation under subparagraph (A).

''(3) VOLUME-BASED ADJUSTMENTS TO ESTABLISHMENT REGISTRATION BASE FEES.—For each of fiscal years 2014 through 2017, after the base fee amounts specified in subsection (b)(2) are adjusted under paragraph (2)(D), the base establishment registration fee amounts specified in such subsection shall be further adjusted, as the Secretary estimates is necessary in order for total fee collections for such fiscal year to generate the total revenue amounts, as adjusted under paragraph (2).''.

(d) FEE WAIVER OR REDUCTION.—Section 738 (21 U.S.C. 379j) is amended by—

(1) redesignating subsections (f) through (k) as subsections (g) through (l), respectively; and

(2) by inserting after subsection (e) the following new subsection:

''(f) FEE WAIVER OR REDUCTION.—

''(1) IN GENERAL.—The Secretary may, at the Secretary's sole discretion, grant a waiver or reduction of fees under subsection (a)(2) or (a)(3) if the Secretary finds that such waiver or reduction is in the interest of public health.

''(2) LIMITATION.—The sum of all fee waivers or reductions granted by the Secretary in any fiscal year under paragraph (1) shall not exceed 2 percent of the total fee revenue amounts established for such year under subsection (c).

''(3) DURATION.—The authority provided by this subsection terminates October 1, 2017.''.

(e) CONDITIONS.—Section 738(h)(1)(A) (21 U.S.C. 379j(h)(1)(A)), as redesignated by subsection (d)(1), is amended by striking ''$205,720,000'' and inserting ''$280,587,000''.

(f) CREDITING AND AVAILABILITY OF FEES.—Section 738(i) (21 U.S.C. 379j(i)), as redesignated by subsection (d)(1), is amended—

(1) in paragraph (1), by striking ''Fees authorized'' and inserting ''Subject to paragraph (2)(C), fees authorized'';

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''shall be retained'' and inserting ''subject to subparagraph (C), shall be collected and available''; and

(ii) in clause (ii)—

(I) by striking ''collected and'' after ''shall only be''; and

(II) by striking ''fiscal year 2002'' and inserting ''fiscal year 2009''; and

(B) by adding at the end, the following:

''(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.'';

(3) by amending paragraph (3) to read as follows:

''(3) AUTHORIZATIONS OF APPROPRIATIONS.—For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount specified under subsection (b)(3) for the fiscal year, as adjusted under subsection (c) and, for fiscal year 2017 only, as further adjusted under paragraph (4).''; and

(4) in paragraph (4)—

(A) by striking ''fiscal years 2008, 2009, and 2010'' and inserting ''fiscal years 2013, 2014, and 2015'';

(B) by striking ''fiscal year 2011'' and inserting ''fiscal year 2016'';

(C) by striking ''June 30, 2011'' and inserting ''June 30, 2016'';

(D) by striking ''the amount of fees specified in aggregate in'' and inserting ''the cumulative amount appropriated pursuant to'';

(E) by striking ''aggregate amount in'' before ''excess shall be credited''; and

(F) by striking ''fiscal year 2012'' and inserting ''fiscal year 2017''.

(g) CONFORMING AMENDMENT.—Section 515(c)(4)(A) (21 U.S.C. 360e(c)(4)(A)) is amended by striking ''738(g)'' and inserting ''738(h)''.

SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) REAUTHORIZATION.—Section 738A(b) (21 U.S.C. 379j–1(b)) is amended—

(1) in paragraph (1), by striking ''2012'' and inserting ''2017''; and

(2) in paragraph (5), by striking ''2012'' and inserting ''2017''.

(b) REPORTS.—Section 738A(a) (21 U.S.C. 379j–1(a)) is amended—

(1) by striking ''2008 through 2012'' each place it appears and inserting ''2013 through 2017''; and

(2) by striking ''section 201(c) of the Food and Drug Administration Amendments Act of 2007'' and inserting ''section 201(b) of the Medical Device User Fee Amendments of 2012''.

SEC. 205. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to submissions described in section 738(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (as in effect as of such day) that on or after October 1, 2007, but before October 1, 2012, 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 2013.

SEC. 206. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for submissions described in section 738(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act received on or after October 1, 2012, regardless of the date of the enactment of this Act.

SEC. 207. SUNSET DATES.

(a) AUTHORIZATIONS.—Sections 737 and 738 (21 U.S.C. 739i; 739j) shall cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.—Section 738A (21 U.S.C. 739j–1) shall cease to be effective January 31, 2018.

(c) PREVIOUS SUNSET PROVISION.—Section 217 of the Medical Device User Fee Amendments of 2007 (Title II of Public Law 110–85) is repealed.

(d) TECHNICAL CLARIFICATION.—Effective September 30, 2007, section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107– 250) is repealed.

SEC. 208. STREAMLINED HIRING AUTHORITY TO SUPPORT ACTIVITIES RELATED TO THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS.

Subchapter A of chapter VII (21 U.S.C. 371 et seq.) is amended by inserting after section 713 the following new section:

"SEC. 714. STREAMLINED HIRING AUTHORITY.

''(a) IN GENERAL.—In addition to any other personnel authorities under other provisions of law, the Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, appoint employees to positions in the Food and Drug Administration to perform, administer, or support activities described in subsection (b), if the Secretary determines that such appointments are needed to achieve the objectives specified in subsection (c).

''(b) ACTIVITIES DESCRIBED.—The activities described in this subsection are activities under this Act related to the process for the review of device applications (as defined in section 737(8)).

''(c) OBJECTIVES SPECIFIED.—The objectives specified in this subsection are with respect to the activities under subsection (b), the goals referred to in section 738A(a)(1).

''(d) INTERNAL CONTROLS.—The Secretary shall institute appropriate internal controls for appointments under this section.

''(e) SUNSET.—The authority to appoint employees under this section shall terminate on the date that is three years after the date of enactment of this section.''.

TITLE III—FEES RELATING TO GENERIC DRUGS

SEC. 301. SHORT TITLE.

(a) SHORT TITLE.—This title may be cited as the ''Generic Drug User Fee Amendments of 2012''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to human generic drug activities, as set forth in the goals identified for purposes of part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services 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.

SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

"PART 7—FEES RELATING TO GENERIC DRUGS

"SEC. 744A. DEFINITIONS.

''For purposes of this part:

''(1) The term 'abbreviated new drug application'—

''(A) means an application submitted under section 505(j), an abbreviated application submitted under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997), or an abbreviated new drug application submitted pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984; and

''(B) does not include an application for a positron emission tomography drug.

''(2) The term 'active pharmaceutical ingredient' means—

''(A) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended—

''(i) to be used as a component of a drug; and

''(ii) to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or

''(B) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture described in subparagraph (A).

''(3) The term 'adjustment factor' means a factor applicable to a fiscal year that is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2011.

''(4) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control, both of the business entities.

''(5)(A) The term 'facility'—

''(i) means a business or other entity—

''(I) under one management, either direct or indirect; and

''(II) at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form; and

''(ii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: repackaging, relabeling, or testing.

''(B) For purposes of subparagraph (A), separate buildings within close proximity are considered to be at one geographic location or address if the activities in them are—

''(i) closely related to the same business enterprise;

''(ii) under the supervision of the same local management; and

''(iii) capable of being inspected by the Food and Drug Administration during a single inspection.

''(C) If a business or other entity would meet the definition of a facility under this paragraph but for being under multiple management, the business or other entity is deemed to constitute multiple facilities, one per management entity, for purposes of this paragraph.

''(6) The term 'finished dosage form' means—

''(A) a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;

''(B) a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or

''(C) any combination of an active pharmaceutical ingredient with another component of a drug product for purposes of production of a drug product described in subparagraph (A) or (B).

''(7) The term 'generic drug submission' means an abbreviated new drug application, an amendment to an abbreviated new drug application, or a prior approval supplement to an abbreviated new drug application.

''(8) The term 'human generic drug activities' means the following activities of the Secretary associated with generic drugs and inspection of facilities associated with generic drugs:

''(A) The activities necessary for the review of generic drug submissions, including review of drug master files referenced in such submissions.

''(B) The issuance of—

''(i) approval letters which approve abbreviated new drug applications or supplements to such applications; or

''(ii) complete response letters which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

''(C) The issuance of letters related to Type II active pharmaceutical drug master files which—

''(i) set forth in detail the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies; or

''(ii) document that no deficiencies need to be addressed.

''(D) Inspections related to generic drugs.

''(E) Monitoring of research conducted in connection with the review of generic drug submissions and drug master files.

''(F) Postmarket safety activities with respect to drugs approved under abbreviated new drug applications or supplements, including the following activities:

''(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.

''(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

''(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies) insofar as those activities relate to abbreviated new drug applications.

''(v) Carrying out section 505(k)(5) (relating to adverse-event reports and postmarket safety activities).

''(G) Regulatory science activities related to generic drugs.

''(9) The term 'positron emission tomography drug' has the meaning given to the term 'compounded positron emission tomography drug' in section 201(ii), except that paragraph (1)(B) of such section shall not apply.

''(10) The term 'prior approval supplement' means a request to the Secretary to approve a change in the drug substance, drug product, production process, quality controls, equipment, or facilities covered by an approved abbreviated new drug application when that change has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

''(11) The term 'resources allocated for human generic drug activities' means the expenses 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 and employees 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; and

''(D) collecting fees under subsection (a) and accounting for resources allocated for

the review of abbreviated new drug applications and supplements and inspection related to generic drugs.

''(12) The term 'Type II active pharmaceutical ingredient drug master file' means a submission of information to the Secretary by a person that intends to authorize the Food and Drug Administration to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.

''SEC. 744B. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

''(a) TYPES OF FEES.—Beginning in fiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

''(1) ONE-TIME BACKLOG FEE FOR ABBREVIATED NEW DRUG APPLICATIONS PENDING ON OCTOBER 1, 2012.—

''(A) IN GENERAL.—Each person that owns an abbreviated new drug application that is pending on October 1, 2012, and that has not received a tentative approval prior to that date, shall be subject to a fee for each such application, as calculated under subparagraph (B).

''(B) METHOD OF FEE AMOUNT CALCULATION.—The amount of each one-time backlog fee shall be calculated by dividing $50,000,000 by the total number of abbreviated new drug applications pending on October 1, 2012, that have not received a tentative approval as of that date.

''(C) NOTICE.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the fee required by subparagraph (A).

''(D) FEE DUE DATE.—The fee required by subparagraph (A) shall be due no later than 30 calendar days after the date of the publication of the notice specified in subparagraph (C).

''(2) DRUG MASTER FILE FEE.—

''(A) IN GENERAL.—Each person that owns a Type II active pharmaceutical ingredient drug master file that is referenced on or after October 1, 2012, in a generic drug submission by any initial letter of authorization shall be subject to a drug master file fee.

''(B) ONE-TIME PAYMENT.—If a person has paid a drug master file fee for a Type II active pharmaceutical ingredient drug master file, the person shall not be required to pay a subsequent drug master file fee when that Type II active pharmaceutical ingredient drug master file is subsequently referenced in generic drug submissions.

''(C) NOTICE.—

''(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the drug master file fee for fiscal year 2013.

''(ii) FISCAL YEAR 2014 THROUGH 2017.—Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall publish in the Federal Register the amount of the drug master file fee established by this paragraph for such fiscal year.

''(D) AVAILABILITY FOR REFERENCE.—

''(i) IN GENERAL.—Subject to subsection (g)(2)(C), for a generic drug submission to reference a Type II active pharmaceutical ingredient drug master file, the drug master file must be deemed available for reference by the Secretary.

''(ii) CONDITIONS.—A drug master file shall be deemed available for reference by the Secretary if—

''(I) the person that owns a Type II active pharmaceutical ingredient drug master file has paid the fee required under subparagraph (A) within 20 calendar days after the applicable due date under subparagraph (E); and

''(II) the drug master file has not failed an initial completeness assessment by the Secretary, in accordance with criteria to be published by the Secretary.

''(iii) LIST.—The Secretary shall make publicly available on the Internet Web site of the Food and Drug Administration a list of the drug master file numbers that correspond to drug master files that have successfully undergone an initial completeness assessment, in accordance with criteria to be published by the Secretary, and are available for reference.

''(E) FEE DUE DATE.—

''(i) IN GENERAL.—Subject to clause (ii), a drug master file fee shall be due no later than the date on which the first generic drug submission is submitted that references the associated Type II active pharmaceutical ingredient drug master file.

''(ii) LIMITATION.—No fee shall be due under subparagraph (A) for a fiscal year until the later of—

''(I) 30 calendar days after publication of the notice provided for in clause (i) or (ii) of subparagraph (C), as applicable; or

''(II) 30 calendar days after the date of enactment of an appropriations Act providing for the collection and obligation of fees under this section.

''(3) ABBREVIATED NEW DRUG APPLICATION AND PRIOR APPROVAL SUPPLEMENT FILING FEE.—

''(A) IN GENERAL.—Each applicant that submits, on or after October 1, 2012, an abbreviated new drug application or a prior approval supplement to an abbreviated new drug application shall be subject to a fee for each such submission in the amount established under subsection (d).

''(B) NOTICE.—

''(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the fees under subparagraph (A) for fiscal year 2013.

''(ii) FISCAL YEARS 2014 THROUGH 2017.—Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

''(C) FEE DUE DATE.—

''(i) IN GENERAL.—Except as provided in clause (ii), the fees required by subparagraphs (A) and (F) shall be due no later than the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies.

''(ii) SPECIAL RULE FOR 2013.—For fiscal year 2013, such fees shall be due on the later of—

''(I) the date on which the fee is due under clause (i);

''(II) 30 calendar days after publication of the notice referred to in subparagraph (B)(i); or

''(III) if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of submission of the application or prior approval supplement for which the fees under subparagraphs (A) and (F) apply, 30 calendar days after the date that such an appropriations Act is enacted.

''(D) REFUND OF FEE IF ABBREVIATED NEW DRUG APPLICATION IS NOT CONSIDERED TO HAVE BEEN RECEIVED.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any abbreviated new drug application or prior approval supplement to an abbreviated new drug application that the Secretary considers not to have been received within the meaning of section 505(j)(5)(A) for a cause other than failure to pay fees.

''(E) FEE FOR AN APPLICATION THE SECRETARY CONSIDERS NOT TO HAVE BEEN RECEIVED, OR THAT HAS BEEN WITHDRAWN.—An abbreviated new drug application or prior approval supplement that was submitted on or after October 1, 2012, and that the Secretary considers not to have been received, or that has been withdrawn, shall, upon resubmission of the application or a subsequent new submission following the applicant's withdrawal of the application, be subject to a full fee under subparagraph (A).

''(F) ADDITIONAL FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—An applicant that submits a generic drug submission on or after October 1, 2012, shall pay a fee, in the amount determined under subsection (d)(3), in addition to the fee required under subparagraph (A), if—

''(i) such submission contains information concerning the manufacture of an active pharmaceutical ingredient at a facility by means other than reference by a letter of authorization to a Type II active pharmaceutical drug master file; and

''(ii) a fee in the amount equal to the drug master file fee established in paragraph (2) has not been previously paid with respect to such information.

''(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

''(A) IN GENERAL.—Facilities identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce a finished dosage form of a human generic drug or an active pharmaceutical ingredient contained in a human generic drug shall be subject to fees as follows:

''(i) GENERIC DRUG FACILITY.—Each person that owns a facility which is identified or intended to be identified in at least one generic drug submission that is pending or approved to produce one or more finished dosage forms of a human generic drug shall be assessed an annual fee for each such facility.

''(ii) ACTIVE PHARMACEUTICAL INGREDIENT FACILITY.—Each person that owns a facility which produces, or which is pending review to produce, one or more active pharmaceutical ingredients identified, or intended to be identified, in at least one generic drug submission that is pending or approved or in a Type II active pharmaceutical ingredient drug master file referenced in such a generic drug submission, shall be assessed an annual fee for each such facility.

''(iii) FACILITIES PRODUCING BOTH ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED DOSAGE FORMS.—Each person that owns a facility identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce both one or more finished dosage forms subject to clause (i) and one or more active pharmaceutical ingredients subject to clause (ii) shall be subject to fees under both such clauses for that facility.

''(B) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (d).

''(C) NOTICE.—

''(i) FISCAL YEAR 2013.—For fiscal year 2013, the Secretary shall publish in the Federal Register a notice announcing the amount of the fees provided for in subparagraph (A) within the timeframe specified in subsection (d)(1)(B).

''(ii) FISCAL YEARS 2014 THROUGH 2017.—Within the timeframe specified in subsection (d)(2), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

''(D) FEE DUE DATE.—

''(i) FISCAL YEAR 2013.—For fiscal year 2013, the fees under subparagraph (A) shall be due on the later of—

''(I) not later than 45 days after the publication of the notice under subparagraph (B); or

''(II) if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of the publication of such notice, 30 days after the date that such an appropriations Act is enacted.

''(ii) FISCAL YEARS 2014 THROUGH 2017.—For each of fiscal years 2014 through 2017, the fees under subparagraph (A) for such fiscal year shall be due on the later of—

''(I) the first business day on or after October 1 of each such year; or

''(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year.

''(5) DATE OF SUBMISSION.—For purposes of this Act, a generic drug submission or Type II pharmaceutical master file is deemed to be 'submitted' to the Food and Drug Administration—

''(A) if it is submitted via a Food and Drug Administration electronic gateway, on the day when transmission to that electronic gateway is completed, except that a submission or master file that arrives on a weekend, Federal holiday, or day when the Food and Drug Administration office that will review that submission is not otherwise open for business shall be deemed to be submitted on the next day when that office is open for business; or

''(B) if it is submitted in physical media form, on the day it arrives at the appropriate designated document room of the Food and Drug Administration.

''(b) FEE REVENUE AMOUNTS.—

''(1) IN GENERAL.—

''(A) FISCAL YEAR 2013.—For fiscal year 2013, fees under subsection (a) shall be established to generate a total estimated revenue amount under such subsection of $299,000,000. Of that amount—

''(i) $50,000,000 shall be generated by the one-time backlog fee for generic drug applications pending on October 1, 2012, established in subsection (a)(1); and

''(ii) $249,000,000 shall be generated by the fees under paragraphs (2) through (4) of subsection (a).

''(B) FISCAL YEARS 2014 THROUGH 2017.—For each of the fiscal years 2014 through 2017, fees under paragraphs (2) through (4) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to $299,000,000, as adjusted pursuant to subsection (c).

''(2) TYPES OF FEES.—In establishing fees under paragraph (1) to generate the revenue amounts specified in paragraph (1)(A)(ii) for fiscal year 2013 and paragraph (1)(B) for each of fiscal years 2014 through 2017, such fees shall be derived from the fees under paragraphs (2) through (4) of subsection (a) as follows:

''(A) 6 percent shall be derived from fees under subsection (a)(2) (relating to drug master files).

''(B) 24 percent shall be derived from fees under subsection (a)(3) (relating to abbreviated new drug applications and supplements). The amount of a fee for a prior approval supplement shall be half the amount of the fee for an abbreviated new drug application.

''(C) 56 percent shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than $15,000 and not more than $30,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States, including its territories and possessions, and those located outside of the United States and its territories and possessions.

''(D) 14 percent shall be derived from fees under subsection (a)(4)(A)(ii) (relating to active pharmaceutical ingredient facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than $15,000 and not more than $30,000 higher than the amount of the fee for a facility located in the United States, including its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States and its territories and possessions and those located outside of the United States and its territories and possessions.

''(c) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by an amount equal to the sum of—

''(A) one;

''(B) the average annual percent 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 3 years of the preceding 4 fiscal years multiplied by the proportion of personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years; and

''(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year under this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this subsection.

''(2) FINAL YEAR ADJUSTMENT.—For fiscal year 2017, the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for the first 3 months of fiscal year 2018. Such fees may only be used in fiscal year 2018. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2017. If the Secretary has carryover balances for such activities in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

''(d) ANNUAL FEE SETTING.—

''(1) FISCAL YEAR 2013.—For fiscal year 2013—

''(A) the Secretary shall establish, by October 31, 2012, the one-time generic drug backlog fee for generic drug applications pending on October 1, 2012, the drug master file fee, the abbreviated new drug application fee, and the prior approval supplement fee under subsection (a), based on the revenue amounts established under subsection (b); and

''(B) the Secretary shall establish, not later than 45 days after the date to comply with the requirement for identification of facilities in subsection (f)(2), the generic drug facility fee and active pharmaceutical ingredient facility fee under subsection (a) based on the revenue amounts established under subsection (b).

''(2) FISCAL YEARS 2014 THROUGH 2017.—Not more than 60 days before the first day of each of fiscal years 2014 through 2017, the Secretary shall establish the drug master file fee, the abbreviated new drug application fee, the prior approval supplement fee, the generic drug facility fee, and the active pharmaceutical ingredient facility fee under subsection (a) for such fiscal year, based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).

''(3) FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—In establishing the fees under paragraphs (1) and (2), the amount of the fee under subsection (a)(3)(F) shall be determined by multiplying—

''(A) the sum of—

''(i) the total number of such active pharmaceutical ingredients in such submission; and

''(ii) for each such ingredient that is manufactured at more than one such facility, the total number of such additional facilities; and

''(B) the amount equal to the drug master file fee established in subsection (a)(2) for such submission.

''(e) LIMIT.—The total amount of fees charged, as adjusted under subsection (c), for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for human generic drug activities.

''(f) IDENTIFICATION OF FACILITIES.—

''(1) PUBLICATION OF NOTICE; DEADLINE FOR COMPLIANCE.—Not later than October 1, 2012, the Secretary shall publish in the Federal Register a notice requiring each person that owns a facility described in subsection (a)(4)(A), or a site or organization required to be identified by paragraph (4), to submit to the Secretary information on the identity of each such facility, site, or organization. The notice required by this paragraph shall specify the type of information to be submitted and the means and format for submission of such information.

''(2) REQUIRED SUBMISSION OF FACILITY IDENTIFICATION.—Each person that owns a facility described in subsection (a)(4)(A) or a site or organization required to be identified by paragraph (4) shall submit to the Secretary the information required under this subsection each year. Such information shall—

''(A) for fiscal year 2013, be submitted not later than 60 days after the publication of the notice under paragraph (1); and

''(B) for each subsequent fiscal year, be submitted, updated, or reconfirmed on or before June 1 of the previous year.

''(3) CONTENTS OF NOTICE.—At a minimum, the submission required by paragraph (2) shall include for each such facility—

''(A) identification of a facility identified or intended to be identified in an approved or pending generic drug submission;

''(B) whether the facility manufactures active pharmaceutical ingredients or finished dosage forms, or both;

''(C) whether or not the facility is located within the United States and its territories and possessions;

''(D) whether the facility manufactures positron emission tomography drugs solely, or in addition to other drugs; and

''(E) whether the facility manufactures drugs that are not generic drugs.

''(4) CERTAIN SITES AND ORGANIZATIONS.—

''(A) IN GENERAL.—Any person that owns or operates a site or organization described in

subparagraph (B) shall submit to the Secretary information concerning the ownership, name, and address of the site or organization.

''(B) SITES AND ORGANIZATIONS.—A site or organization is described in this subparagraph if it is identified in a generic drug submission and is—

''(i) a site in which a bioanalytical study is conducted;

''(ii) a clinical research organization;

''(iii) a contract analytical testing site; or

''(iv) a contract repackager site.

''(C) NOTICE.—The Secretary may, by notice published in the Federal Register, specify the means and format for submission of the information under subparagraph (A) and may specify, as necessary for purposes of this section, any additional information to be submitted.

''(D) INSPECTION AUTHORITY.—The Secretary's inspection authority under section 704(a)(1) shall extend to all such sites and organizations.

''(g) EFFECT OF FAILURE TO PAY FEES.—

''(1) GENERIC DRUG BACKLOG FEE.—Failure to pay the fee under subsection (a)(1) shall result in the Secretary placing the person that owns the abbreviated new drug application subject to that fee on an arrears list, such that no new abbreviated new drug applications or supplement submitted on or after October 1, 2012, from that person, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

''(2) DRUG MASTER FILE FEE.—

''(A) Failure to pay the fee under subsection (a)(2) within 20 calendar days after the applicable due date under subparagraph (E) of such subsection (as described in subsection (a)(2)(D)(ii)(I)) shall result in the Type II active pharmaceutical ingredient drug master file not being deemed available for reference.

''(B)(i) Any generic drug submission submitted on or after October 1, 2012, that references, by a letter of authorization, a Type II active pharmaceutical ingredient drug master file that has not been deemed available for reference shall not be received within the meaning of section 505(j)(5)(A) unless the condition specified in clause (ii) is met.

''(ii) The condition specified in this clause is that the fee established under subsection (a)(2) has been paid within 20 calendar days of the Secretary providing the notification to the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the drug master file fee as specified in subparagraph (C).

''(C)(i) If an abbreviated new drug application or supplement to an abbreviated new drug application references a Type II active pharmaceutical ingredient drug master file for which a fee under subsection (a)(2)(A) has not been paid by the applicable date under subsection (a)(2)(E), the Secretary shall notify the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the applicable fee.

''(ii) If such fee is not paid within 20 calendar days of the Secretary providing the notification, the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of 505(j)(5)(A).

''(3) ABBREVIATED NEW DRUG APPLICATION FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—Failure to pay a fee under subparagraph (A) or (F) of subsection (a)(3) within 20 calendar days of the applicable due date under subparagraph (C) of such subsection shall result in the abbreviated new drug application or the prior approval supplement to an abbreviated new drug application not being received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

''(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

''(A) IN GENERAL.—Failure to pay the fee under subsection (a)(4) within 20 calendar days of the due date as specified in subparagraph (D) of such subsection shall result in the following:

''(i) The Secretary shall place the facility on a publicly available arrears list, such that no new abbreviated new drug application or supplement submitted on or after October 1, 2012, from the person that is responsible for paying such fee, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A).

''(ii) Any new generic drug submission submitted on or after October 1, 2012, that references such a facility shall not be received, within the meaning of section 505(j)(5)(A) if the outstanding facility fee is not paid within 20 calendar days of the Secretary providing the notification to the sponsor of the failure of the owner of the facility to pay the facility fee under subsection (a)(4)(C).

''(iii) All drugs or active pharmaceutical ingredients manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 502(aa).

''(B) APPLICATION OF PENALTIES.—The penalties under this paragraph shall apply until the fee established by subsection (a)(4) is paid or the facility is removed from all generic drug submissions that refer to the facility.

''(C) NONRECEIVAL FOR NONPAYMENT.—

''(i) NOTICE.—If an abbreviated new drug application or supplement to an abbreviated new drug application submitted on or after October 1, 2012, references a facility for which a facility fee has not been paid by the applicable date under subsection (a)(4)(C), the Secretary shall notify the sponsor of the generic drug submission of the failure of the owner of the facility to pay the facility fee.

''(ii) NONRECEIVAL.—If the facility fee is not paid within 20 calendar days of the Secretary providing the notification under clause (i), the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of section 505(j)(5)(A).

''(h) LIMITATIONS.—

''(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2012, unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor (as defined in section 744A) applicable to the fiscal year involved.

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for Type II active pharmaceutical ingredient drug master files, abbreviated new drug applications and prior approval supplements, and generic drug facilities and active pharmaceutical ingredient facilities at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

''(i) 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, subject to paragraph (2). 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 human generic drug activities.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—The fees authorized by this section—

''(i) subject to subparagraphs (C) and (D), shall be collected and available 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

''(ii) shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of human generic drug activities (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activities), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $97,000,000 multiplied by the adjustment factor, as defined in section 744A(3), applicable to the fiscal year involved.

''(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for human generic activities are not more than 10 percent below the level specified in such subparagraph.

''(C) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2013 for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013, may be collected and shall be credited to such account and remain available until expended.

''(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2013), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted under subsection (c), if applicable, or as otherwise affected under paragraph (2) of this subsection.

''(j) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar 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.

''(k) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in human generic drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(1) POSITRON EMISSION TOMOGRAPHY DRUGS.—

''(1) EXEMPTION FROM FEES.—Submission of an application for a positron emission tomography drug or active pharmaceutical ingredient for a positron emission tomography drug shall not require the payment of any fee under this section. Facilities that solely produce positron emission tomography drugs shall not be required to pay a facility fee as established in subsection (a)(4).

''(2) IDENTIFICATION REQUIREMENT.—Facilities that produce positron emission tomography drugs or active pharmaceutical ingredients of such drugs are required to be identified pursuant to subsection (f).

''(m) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under this section, a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

''(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—An abbreviated new drug application that is not considered to be received within the meaning of section 505(j)(5)(A) because of failure to pay an applicable fee under this provision within the time period specified in subsection (g) shall be deemed not to have been 'substantially complete' on the date of its submission within the meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbreviated new drug application that is not substantially complete on the date of its submission solely because of failure to pay an applicable fee under the preceding sentence shall be deemed substantially complete and received within the meaning of section 505(j)(5)(A) as of the date such applicable fee is received.''.

SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 7 of subchapter C of chapter VII, as added by section 302 of this Act, is amended by inserting after section 744B the following:

''SEC. 744C. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

''(b) FISCAL REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of 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 such fiscal year.

''(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

''(d) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for human generic drug activities for the first 5 fiscal years after fiscal year 2017, 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 generic drug industry.

''(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the generic drug industry on the reauthorization of this part, the Secretary shall—

''(A) publish a notice in the Federal Register requesting public input on the reauthorization;

''(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

''(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

''(D) publish the comments on the Food and Drug Administration's Internet Web site.

''(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the generic drug industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

''(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the generic drug 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.

''(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), 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.

''(6) MINUTES OF NEGOTIATION MEETINGS.—

''(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the generic drug industry.

''(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.''.

SEC. 304. SUNSET DATES.

(a) AUTHORIZATION.—The amendments made by section 302 cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.—The amendments made by section 303 cease to be effective January 31, 2018.

SEC. 305. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this title, whichever is later, except that fees under section 302 shall be assessed for all human generic drug submissions and Type II active pharmaceutical drug master files received on or after October 1, 2012, regardless of the date of enactment of this title.

SEC. 306. AMENDMENT WITH RESPECT TO MISBRANDING.

Section 502 (21 U.S.C. 352) is amended by adding at the end the following:

''(aa) If it is a drug, or an active pharmaceutical ingredient, and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744A(a)(4) or for which identifying information required by section 744B(f) has not been submitted, or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility.''.

SEC. 307. STREAMLINED HIRING AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION TO SUPPORT ACTIVITIES RELATED TO HUMAN GENERIC DRUGS.

Section 714 of the Federal Food, Drug, and Cosmetic Act, as added by section 208, is amended—

(1) in subsection (b)—

(A) by striking ''are activities'' and inserting ''are—

''(1) activities'';

(B) by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(2) activities under this Act related to human generic drug activities (as defined in section 744A).''; and

(2) by amending subsection (c) to read as follows:

''(c) OBJECTIVES SPECIFIED.—The objectives specified in this subsection are—

''(1) with respect to the activities under subsection (b)(1), the goals referred to in section 738A(a)(1); and

''(2) with respect to the activities under subsection (b)(2), the performance goals with respect to section 744A (regarding assessment and use of human generic drug fees), as set forth in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2012.''.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 401. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Biosimilar User Fee Act of 2012''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services 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.

SEC. 402. FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS.

Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by inserting after part 7, as added by title III of this Act, the following:

"PART 8—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

"SEC. 744G. DEFINITIONS.

''For purposes of this part:

''(1) The term 'adjustment factor' applicable to a fiscal year that is the Consumer Price Index for all urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items) of the preceding fiscal year divided by such Index for September 2011.

''(2) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control, both of the business entities.

''(3) The term 'biosimilar biological product' means a product for which a biosimilar biological product application has been approved.

''(4)(A) Subject to subparagraph (B), the term 'biosimilar biological product application' means an application for licensure of a biological product under section 351(k) of the Public Health Service Act.

''(B) Such term does not include—

''(i) a supplement to such an application;

''(ii) an application filed under section 351(k) of the Public Health Service Act that cites as the reference product a bovine blood product for topical application licensed before September 1, 1992, or a large volume parenteral drug product approved before such date;

''(iii) an application filed under section 351(k) of the Public Health Service Act with respect to—

''(I) whole blood or a blood component for transfusion;

''(II) an allergenic extract product;

''(III) an in vitro diagnostic biological product; or

''(IV) a biological product for further manufacturing use only; or

''(iv) an application for licensure under section 351(k) of the Public Health Service Act that is submitted by a State or Federal Government entity for a product that is not distributed commercially.

''(5) The term 'biosimilar biological product development meeting' means any meeting, other than a biosimilar initial advisory meeting, regarding the content of a development program, including a proposed design for, or data from, a study intended to support a biosimilar biological product application.

''(6) The term 'biosimilar biological product development program' means the program under this part for expediting the process for the review of submissions in connection with biosimilar biological product development.

''(7)(A) The term 'biosimilar biological product establishment' means a foreign or domestic place of business—

''(i) that is at one general physical location consisting of one or more buildings, all of which are within five miles of each other; and

''(ii) at which one or more biosimilar biological products are manufactured in final dosage form.

''(B) For purposes of subparagraph (A)(ii), the term 'manufactured' does not include packaging.

''(8) The term 'biosimilar initial advisory meeting'—

''(A) means a meeting, if requested, that is limited to—

''(i) a general discussion regarding whether licensure under section 351(k) of the Public Health Service Act may be feasible for a particular product; and

''(ii) if so, general advice on the expected content of the development program; and

''(B) does not include any meeting that involves substantive review of summary data or full study reports.

''(9) The term 'costs of resources allocated for the process for the review of biosimilar biological product applications' means the expenses in connection with the process for the review of biosimilar biological product applications 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; and

''(D) collecting fees under section 744H and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

''(10) The term 'final dosage form' means, with respect to a biosimilar biological product, a finished dosage form which is approved for administration to a patient without substantial further manufacturing (such as lyophilized products before reconstitution).

''(11) The term 'financial hold'—

''(A) means an order issued by the Secretary to prohibit the sponsor of a clinical investigation from continuing the investigation if the Secretary determines that the investigation is intended to support a biosimilar biological product application and the sponsor has failed to pay any fee for the product required under subparagraph (A), (B), or (D) of section 744H(a)(1); and

''(B) does not mean that any of the bases for a 'clinical hold' under section 505(i)(3) have been determined by the Secretary to exist concerning the investigation.

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

''(13) The term 'process for the review of biosimilar biological product applications' means the following activities of the Secretary with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements:

''(A) The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

''(B) Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or which set forth in detail the specific deficiencies in such applications, and where appropriate, the actions necessary to place such applications in condition for approval.

''(C) The inspection of biosimilar biological product establishments and other facilities undertaken as part of the Secretary's review of pending biosimilar biological product applications and supplements.

''(D) Activities necessary for the release of lots of biosimilar biological products under section 351(k) of the Public Health Service Act.

''(E) Monitoring of research conducted in connection with the review of biosimilar biological product applications.

''(F) Postmarket safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities:

''(i) Collecting, developing, and reviewing safety information on biosimilar biological products, including adverse-event reports.

''(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

''(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

''(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies).

''(v) Carrying out section 505(k)(5) (relating to adverse-event reports and postmarket safety activities).

''(14) The term 'supplement' means a request to the Secretary to approve a change in a biosimilar biological product application which has been approved, including a supplement requesting that the Secretary determine that the biosimilar biological product meets the standards for interchangeability described in section 351(k)(4) of the Public Health Service Act.

"SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES.

''(a) TYPES OF FEES.—Beginning in fiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

''(1) BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

''(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

''(i) IN GENERAL.—Each person that submits to the Secretary a meeting request described under clause (ii) or a clinical protocol for an investigational new drug protocol described under clause (iii) shall pay for the product named in the meeting request or the investigational new drug application the initial biosimilar biological product development fee established under subsection (b)(1)(A).

''(ii) MEETING REQUEST.—The meeting request described in this clause is a request for a biosimilar biological product development meeting for a product.

''(iii) CLINICAL PROTOCOL FOR IND.—A clinical protocol for an investigational new drug protocol described in this clause is a clinical protocol consistent with the provisions of section 505(i), including any regulations promulgated under section 505(i), (referred to in this section as 'investigational new drug application') describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for a product.

''(iv) DUE DATE.—The initial biosimilar biological product development fee shall be due by the earlier of the following:

''(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

''(II) The date of submission of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application.

''(v) TRANSITION RULE.—Each person that has submitted an investigational new drug application prior to the date of enactment of the Biosimilars User Fee Act of 2012 shall pay the initial biosimilar biological product development fee by the earlier of the following:

''(I) Not later than 60 days after the date of the enactment of the Biosimilars User Fee Act of 2012, if the Secretary determines that the investigational new drug application describes an investigation that is intended to

support a biosimilar biological product application.

''(II) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

''(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

''(i) IN GENERAL.—A person that pays an initial biosimilar biological product development fee for a product shall pay for such product, beginning in the fiscal year following the fiscal year in which the initial biosimilar biological product development fee was paid, an annual fee established under subsection (b)(1)(B) for biosimilar biological product development (referred to in this section as 'annual biosimilar biological product development fee').

''(ii) DUE DATE.—The annual biosimilar biological product development program fee for each fiscal year will be due on the later of—

''(I) the first business day on or after October 1 of each such year; or

''(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

''(iii) EXCEPTION.—The annual biosimilar development program fee for each fiscal year will be due on the date specified in clause (ii), unless the person has—

''(I) submitted a marketing application for the biological product that was accepted for filing; or

''(II) discontinued participation in the biosimilar biological product development program for the product under subparagraph (C).

''(C) DISCONTINUATION OF FEE OBLIGATION.—A person may discontinue participation in the biosimilar biological product development program for a product effective October 1 of a fiscal year by, not later than August 1 of the preceding fiscal year—

''(i) if no investigational new drug application concerning the product has been submitted, submitting to the Secretary a written declaration that the person has no present intention of further developing the product as a biosimilar biological product; or

''(ii) if an investigational new drug application concerning the product has been submitted, by withdrawing the investigational new drug application in accordance with part 312 of title 21, Code of Federal Regulations (or any successor regulations).

''(D) REACTIVATION FEE.—

''(i) IN GENERAL.—A person that has discontinued participation in the biosimilar biological product development program for a product under subparagraph (C) shall pay a fee (referred to in this section as 'reactivation fee') by the earlier of the following:

''(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued).

''(II) Upon the date of submission (after the date on which such participation was discontinued) of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for that product.

''(ii) APPLICATION OF ANNUAL FEE.—A person that pays a reactivation fee for a product shall pay for such product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B).

''(E) EFFECT OF FAILURE TO PAY BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

''(i) NO BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT MEETINGS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting relating to the product for which fees are owed.

''(ii) NO RECEIPT OF INVESTIGATIONAL NEW DRUG APPLICATIONS.—Except in extraordinary circumstances, the Secretary shall not consider an investigational new drug application to have been received under section 505(i)(2) if—

''(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

''(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

''(iii) FINANCIAL HOLD.—Notwithstanding section 505(i)(2), except in extraordinary circumstances, the Secretary shall prohibit the sponsor of a clinical investigation from continuing the investigation if—

''(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

''(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee for the product as required under subparagraph (D).

''(iv) NO ACCEPTANCE OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS OR SUPPLEMENTS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), any biosimilar biological product application or supplement submitted by that person shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.

''(F) LIMITS REGARDING BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

''(i) NO REFUNDS.—The Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or any reactivation fee paid under subparagraph (D).

''(ii) NO WAIVERS, EXEMPTIONS, OR REDUCTIONS.—The Secretary shall not grant a waiver, exemption, or reduction of any initial or annual biosimilar biological product development fee due or payable under subparagraph (A) or (B), or any reactivation fee due or payable under subparagraph (D).

''(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION AND SUPPLEMENT FEE.—

''(A) IN GENERAL.—Each person that submits, on or after October 1, 2012, a biosimilar biological product application or a supplement shall be subject to the following fees:

''(i) A fee for a biosimilar biological product application that is equal to—

''(I) the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application; minus

''(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for the product that is the subject of the application.

''(ii) A fee for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required, that is equal to—

''(I) half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application; minus

''(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

''(iii) A fee for a supplement for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required, that is equal to half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application.

''(B) REDUCTION IN FEES.—Notwithstanding section 404 of the Biosimilars User Fee Act of 2012, any person who pays a fee under subparagraph (A), (B), or (D) of paragraph (1) for a product before October 1, 2017, but submits a biosimilar biological product application for that product after such date, shall be entitled to the reduction of any biosimilar biological product application fees that may be assessed at the time when such biosimilar biological product application is submitted, by the cumulative amount of fees paid under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

''(C) PAYMENT DUE DATE.—Any fee required by subparagraph (A) shall be due upon submission of the application or supplement for which such fee applies.

''(D) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If a biosimilar biological product application or supplement was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a biosimilar biological product application or a supplement for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

''(E) REFUND OF APPLICATION FEE IF APPLICATION REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under this paragraph for any application or supplement which is refused for filing or withdrawn without a waiver before filing.

''(F) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A biosimilar biological product application or supplement that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived under subsection (c).

''(3) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (E), each person that is named as the applicant in a biosimilar biological product application shall be assessed an annual fee established under subsection (b)(1)(E) for each biosimilar biological product establishment that is listed in the approved biosimilar biological product application as an establishment that manufactures the biosimilar biological product named in such application.

''(B) ASSESSMENT IN FISCAL YEARS.—The establishment fee shall be assessed in each fiscal year for which the biosimilar biological product named in the application is assessed a fee under paragraph (4) unless the biosimilar biological product establishment listed in the application does not engage in the manufacture of the biosimilar biological product during such fiscal year.

''(C) DUE DATE.—The establishment fee for a fiscal year shall be due on the later of—

''(i) the first business day on or after October 1 of such fiscal year; or

''(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section.

''(D) APPLICATION TO ESTABLISHMENT.—

''(i) Each biosimilar biological product establishment shall be assessed only one fee

per biosimilar biological product establishment, notwithstanding the number of biosimilar biological products manufactured at the establishment, subject to clause (ii).

''(ii) In the event an establishment is listed in a biosimilar biological product application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose biosimilar biological products are manufactured by the establishment during the fiscal year and assessed biosimilar biological product fees under paragraph (4).

''(E) EXCEPTION FOR NEW PRODUCTS.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a biosimilar biological product at an establishment listed in its biosimilar biological product application—

''(i) that did not manufacture the biosimilar biological product in the previous fiscal year; and

''(ii) for which the full biosimilar biological product establishment fee has been assessed in the fiscal year at a time before manufacture of the biosimilar biological product was begun,

the applicant shall not be assessed a share of the biosimilar biological product establishment fee for the fiscal year in which the manufacture of the product began.

''(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

''(A) IN GENERAL.—Each person who is named as the applicant in a biosimilar biological product application shall pay for each such biosimilar biological product the annual fee established under subsection (b)(1)(F).

''(B) DUE DATE.—The biosimilar biological product fee for a fiscal year shall be due on the later of—

''(i) the first business day on or after October 1 of each such year; or

''(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

''(C) ONE FEE PER PRODUCT PER YEAR.—The biosimilar biological product fee shall be paid only once for each product for each fiscal year.

''(b) FEE SETTING AND AMOUNTS.—

''(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, the fees under subsection (a). Except as provided in subsection (c), such fees shall be in the following amounts:

''(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The initial biosimilar biological product development fee under subsection (a)(1)(A) for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

''(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The annual biosimilar biological product development fee under subsection (a)(1)(B) for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

''(C) REACTIVATION FEE.—The reactivation fee under subsection (a)(1)(D) for a fiscal year shall be equal to 20 percent of the amount of the fee established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

''(D) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—The biosimilar biological product application fee under subsection (a)(2) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

''(E) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—The biosimilar biological product establishment fee under subsection (a)(3) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug establishment for that fiscal year.

''(F) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—The biosimilar biological product fee under subsection (a)(4) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug product for that fiscal year.

''(2) LIMIT.—The total amount of fees charged for a fiscal year under this section may not exceed the total amount for such fiscal year of the costs of resources allocated for the process for the review of biosimilar biological product applications.

''(c) APPLICATION FEE WAIVER FOR SMALL BUSINESS.—

''(1) WAIVER OF APPLICATION FEE.—The Secretary shall grant to a person who is named in a biosimilar biological product application a waiver from the application fee assessed to that person under subsection (a)(2)(A) for the first biosimilar biological product application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

''(A) application fees for all subsequent biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business; and

''(B) all supplement fees for all supplements to biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business.

''(2) CONSIDERATIONS.—In determining whether to grant a waiver of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

''(3) SMALL BUSINESS DEFINED.—In this subsection, the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates, and does not have a drug product that has been approved under a human drug application (as defined in section 735) or a biosimilar biological product application (as defined in section 744G(4)) and introduced or delivered for introduction into interstate commerce.

''(d) EFFECT OF FAILURE TO PAY FEES.—A biosimilar biological product application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

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

''(1) IN GENERAL.—Subject to paragraph (2), 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 review of biosimilar biological product applications.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available 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.

''(B) USE OF FEES AND LIMITATION.—The fees authorized by this section shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of the process for the review of biosimilar biological product applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $20,000,000, multiplied by the adjustment factor applicable to the fiscal year involved.

''(C) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2013, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013 may be collected and shall be credited to such account and remain available until expended.

''(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2013), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.

''(f) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) 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) WRITTEN REQUESTS FOR WAIVERS AND REFUNDS.—To qualify for consideration for a waiver under subsection (c), or for a refund of any fee collected in accordance with subsection (a)(2)(A), a person shall submit to the Secretary a written request for such waiver or refund not later than 180 days after such fee is due.

''(h) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of biosimilar biological product applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.''.

SEC. 403. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 8 of subchapter C of chapter VII, as added by section 402, is further amended by inserting after section 744H the following:

''SEC. 744I. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 401(b) of the Biosimilar User Fee Act of 2012 during such fiscal year

and the future plans of the Food and Drug Administration for meeting such 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 biosimilar biological product applications and supplements in the cohort.

''(b) FISCAL REPORT.—Not later than 120 days after the end of fiscal year 2013 and each subsequent fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of 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 such fiscal year.

''(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

''(d) STUDY.—

''(1) IN GENERAL.—The Secretary shall contract with an independent accounting or consulting firm to study the workload volume and full costs associated with the process for the review of biosimilar biological product applications.

''(2) INTERIM RESULTS.—Not later than June 1, 2015, the Secretary shall publish, for public comment, interim results of the study described under paragraph (1).

''(3) FINAL RESULTS.—Not later than September 30, 2016, the Secretary shall publish, for public comment, the final results of the study described under paragraph (1).

''(e) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for the process for the review of biosimilar biological product applications for the first 5 fiscal years after fiscal year 2017, 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, 2017, the Secretary shall transmit to the 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.''.

SEC. 404. SUNSET DATES.

(a) AUTHORIZATION.—The amendment made by section 402 shall cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.—The amendment made by section 403 shall cease to be effective January 31, 2018.

SEC. 405. EFFECTIVE DATE.

(a) IN GENERAL.—Except as provided under subsection (b), the amendments made by this title shall take effect on the later of—

(1) October 1, 2012; or

(2) the date of the enactment of this title.

(b) EXCEPTION.—Fees under part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as added by this title, shall be assessed for all biosimilar biological product applications received on or after October 1, 2012, regardless of the date of the enactment of this title.

SEC. 406. SAVINGS CLAUSE.

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 the 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 were accepted by the Food and Drug Administration for filing on or after October 1, 2007, but before October 1, 2012, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2013.

SEC. 407. CONFORMING AMENDMENT.

Section 735(1)(B) (21 U.S.C. 379g(1)(B)) is amended by striking ''or (k)''.

TITLE V—PEDIATRIC DRUGS AND DEVICES

SEC. 501. PERMANENCE.

(a) PEDIATRIC STUDIES OF DRUGS.—Subsection (q) of section 505A (21 U.S.C. 355a) is amended—

(1) in the subsection heading, by striking ''SUNSET'' and inserting ''PERMANENCE'';

(2) in paragraph (1), by striking ''on or before October 1, 2012,''; and

(3) in paragraph (2), by striking ''on or before October 1, 2012,''.

(b) RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.—Section 505B (21 U.S.C. 355c) is amended—

(1) by striking subsection (m); and

(2) by redesignating subsection (n) as subsection (m).

SEC. 502. WRITTEN REQUESTS.

(a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Subsection (h) of section 505A (21 U.S.C. 355a) is amended to read as follows:

''(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Exclusivity under this section shall only be granted for the completion of a study or studies that are the subject of a written request and for which reports are submitted and accepted in accordance with subsection (d)(3). Written requests under this section may consist of a study or studies required under section 505B.''.

(b) PUBLIC HEALTH SERVICE ACT.—Section 351(m)(1) of the Public Health Service Act (42 U.S.C. 262(m)(1)) is amended by striking ''(f), (i), (j), (k), (l), (p), and (q)'' and inserting ''(f), (h), (i), (j), (k), (l), (n), and (p)''.

SEC. 503. COMMUNICATION WITH PEDIATRIC REVIEW COMMITTEE.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this title as the ''Secretary'') shall issue internal standard operating procedures that provide for the review by the internal review committee established under section 505C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355d) of any significant modifications to initial pediatric study plans, agreed initial pediatric study plans, and written requests under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c). Such internal standard operating procedures shall be made publicly available on the Internet website of the Food and Drug Administration.

SEC. 504. ACCESS TO DATA.

Not later than 3 years after the date of enactment of this Act, the Secretary shall make available to the public, including through posting on the Internet website of the Food and Drug Administration, the medical, statistical, and clinical pharmacology reviews of, and corresponding written requests issued to an applicant, sponsor, or holder for, pediatric studies submitted between January 4, 2002 and September 27, 2007 under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) for which 6 months of market exclusivity was granted and that resulted in a labeling change. The Secretary shall make public the information described in the preceding sentence in a manner consistent with how the Secretary releases information under section 505A(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(k)).

SEC. 505. ENSURING THE COMPLETION OF PEDIATRIC STUDIES.

(a) EXTENSION OF DEADLINE FOR DEFERRED STUDIES.—Section 505B (21 U.S.C. 355c) is amended—

(1) in subsection (a)(3)—

(A) by redesignating subparagraph (B) as subparagraph (C);

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

''(B) DEFERRAL EXTENSION.—

''(i) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may grant an extension of a deferral approved under subparagraph (A) for submission of some or all assessments required under paragraph (1) if—

''(I) the Secretary determines that the conditions described in subclause (II) or (III) of subparagraph (A)(i) continue to be met; and

''(II) the applicant submits a new timeline under subparagraph (A)(ii)(IV) and any significant updates to the information required under subparagraph (A)(ii).

''(ii) TIMING AND INFORMATION.—If the deferral extension under this subparagraph is requested by the applicant, the applicant shall submit the deferral extension request containing the information described in this subparagraph not less than 90 days prior to the date that the deferral would expire. The Secretary shall respond to such request not later than 45 days after the receipt of such letter. If the Secretary grants such an extension, the specified date shall be the extended date. The sponsor of the required assessment under paragraph (1) shall not be issued a letter described in subsection (d) unless the specified or extended date of submission for such required studies has passed or if the request for an extension is pending. For a deferral that has expired prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act or that will expire prior to 270 days after the date of enactment of such Act, a deferral extension shall be requested by an applicant not later than 180 days after the date of enactment of such Act. The Secretary shall respond to any such request as soon as practicable, but not later than 1 year after the date of enactment of such Act. Nothing in this clause shall prevent the Secretary from updating the status of a study or studies publicly if components of such study or studies are late or delayed.''; and

(C) in subparagraph (C), as so redesignated—

(i) in clause (i), by adding at the end the following:

''(III) Projected completion date for pediatric studies.

''(IV) The reason or reasons why a deferral or deferral extension continues to be necessary.''; and

(ii) in clause (ii)—

(I) by inserting '', as well as the date of each deferral or deferral extension, as applicable,'' after ''clause (i)''; and

(II) by inserting ''not later than 90 days after submission to the Secretary or with the next routine quarterly update'' after ''Administration''; and

(2) in subsection (f)—

(A) in the subsection heading, by inserting ''DEFERRAL EXTENSIONS,'' after ''DEFERRALS,'';

(B) in paragraph (1), by inserting '', deferral extension,'' after ''deferral''; and

(C) in paragraph (4)—

(i) in the paragraph heading, by inserting ''DEFERRAL EXTENSIONS,'' after ''DEFERRALS,''; and

(ii) by inserting '', deferral extensions,'' after ''deferrals''.

(b) TRACKING OF EXTENSIONS; ANNUAL INFORMATION.—Section 505B(f)(6)(D) (21 U.S.C. 355c(f)(6)(D)) is amended to read as follows:

''(D) aggregated on an annual basis—

''(i) the total number of deferrals and deferral extensions requested and granted under this section and, if granted, the reasons for each such deferral or deferral extension;

''(ii) the timeline for completion of the assessments; and

''(iii) the number of assessments completed and pending;''.

(c) ACTION ON FAILURE TO COMPLETE STUDIES.—

(1) ISSUANCE OF LETTER.—Subsection (d) of section 505B (21 U.S.C. 355c) is amended to read as follows:

''(d) SUBMISSION OF ASSESSMENTS.—If a person fails to submit a required assessment described in subsection (a)(2), fails to meet the applicable requirements in subsection (a)(3), or fails to submit a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b), the following shall apply:

''(1) Beginning 270 days after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall issue a non-compliance letter to such person informing them of such failure to submit or meet the requirements of the applicable subsection. Such letter shall require the person to respond in writing within 45 calendar days of issuance of such letter. Such response may include the person's request for a deferral extension if applicable. Such letter and the person's written response to such letter shall be made publicly available on the Internet Web site of the Food and Drug Administration 60 calendar days after issuance, with redactions for any trade secrets and confidential commercial information. If the Secretary determines that the letter was issued in error, the requirements of this paragraph shall not apply.

''(2) The drug or biological product that is the subject of an assessment described in subsection (a)(2), applicable requirements in subsection (a)(3), or request for approval of a pediatric formulation, may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303), but such failure shall not be the basis for a proceeding—

''(A) to withdraw approval for a drug under section 505(e); or

''(B) to revoke the license for a biological product under section 351 of the Public Health Service Act.''.

(2) TRACKING OF LETTERS ISSUED.—Subparagraph (D) of section 505B(f)(6) (21 U.S.C. 355c(f)(6)), as amended by subsection (b), is further amended—

(A) in clause (ii), by striking ''; and'' and inserting a semicolon;

(B) in clause (iii), by adding ''and'' at the end; and

(C) by adding at the end the following:

''(iv) the number of postmarket non-compliance letters issued pursuant to subsection (d), and the recipients of such letters;''.

SEC. 506. PEDIATRIC STUDY PLANS.

(a) IN GENERAL.—Subsection (e) of section 505B (21 U.S.C. 355c) is amended to read as follows:

''(e) PEDIATRIC STUDY PLANS.—

''(1) IN GENERAL.—An applicant subject to subsection (a) shall submit to the Secretary an initial pediatric study plan prior to the submission of the assessments described under subsection (a)(2).

''(2) TIMING; CONTENT; MEETING.—

''(A) TIMING.—An applicant shall submit an initial pediatric study plan to the Secretary not later than 60 calendar days after the date of the end of phase II meeting or such other equivalent time agreed upon between the Secretary and the applicant. Nothing in this paragraph shall preclude the Secretary from accepting the submission of an initial pediatric study plan earlier than the date described under the preceding sentence.

''(B) CONTENT OF INITIAL PLAN.—The initial pediatric study plan shall include—

''(i) an outline of the pediatric study or studies that the applicant plans to conduct (including, to the extent practicable study objectives and design, age groups, relevant endpoints, and statistical approach);

''(ii) any request for a deferral, partial waiver, or waiver under this section, if applicable, along with any supporting information; and

''(iii) other information specified in the regulations promulgated under paragraph (4).

''(C) MEETING.—The Secretary—

''(i) shall meet with the applicant to discuss the initial pediatric study plan as soon as practicable, but not later than 90 calendar days after the receipt of such plan under subparagraph (A);

''(ii) may determine that a written response to the initial pediatric study plan is sufficient to communicate comments on the initial pediatric study plan, and that no meeting is necessary; and

''(iii) if the Secretary determines that no meeting is necessary, shall so notify the applicant and provide written comments of the Secretary as soon as practicable, but not later than 90 calendar days after the receipt of the initial pediatric study plan.

''(3) AGREED INITIAL PEDIATRIC STUDY PLAN.—Not later than 90 calendar days following the meeting under paragraph (2)(C)(i) or the receipt of a written response from the Secretary under paragraph (2)(C)(iii), the applicant shall document agreement on the initial pediatric study plan in a submission to the Secretary marked 'Agreed Initial Pediatric Study Plan', and the Secretary shall confirm such agreement to the applicant in writing not later than 30 calendar days of receipt of such agreed initial pediatric study plan.

''(4) DEFERRAL AND WAIVER.—If the agreed initial pediatric study plan contains a request from the applicant for a deferral, partial waiver, or waiver under this section, the written confirmation under paragraph (3) shall include a recommendation from the Secretary as to whether such request meets the standards under paragraphs (3) or (4) of subsection (a).

''(5) AMENDMENTS TO THE PLAN.—At the initiative of the Secretary or the applicant, the agreed initial pediatric study plan may be amended at any time. The requirements of paragraph (2)(C) shall apply to any such proposed amendment in the same manner and to the same extent as such requirements apply to an initial pediatric study plan under paragraph (1). The requirements of paragraphs (3) and (4) shall apply to any agreement resulting from such proposed amendment in the same manner and to the same extent as such requirements apply to an agreed initial pediatric study plan.

''(6) INTERNAL COMMITTEE.—The Secretary shall consult the internal committee under section 505C on the review of the initial pediatric study plan, agreed initial pediatric plan, and any significant amendments to such plans.

''(7) REQUIRED RULEMAKING.—Not later than 1 year after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall promulgate proposed regulations and issue proposed guidance to implement the provisions of this subsection.''.

(b) CONFORMING AMENDMENTS.—Section 505B (21 U.S.C. 355c)is amended—

(1) by amending subclause (II) of subsection (a)(3)(A)(ii) to read as follows:

''(II) a pediatric study plan as described in subsection (e);''; and

(2) in subsection (f)—

(A) in the subsection heading, by striking ''PEDIATRIC PLANS,'' and inserting ''PEDIATRIC STUDY PLANS,'';

(B) in paragraph (1), by striking ''all pediatric plans'' and inserting ''initial pediatric study plans, agreed initial pediatric study plans,''; and

(C) in paragraph (4)—

(i) in the paragraph heading, by striking ''PEDIATRIC PLANS,'' and inserting ''PEDIATRIC STUDY PLANS,''; and

(ii) by striking ''pediatric plans'' and inserting ''initial pediatric study plans, agreed initial pediatric study plans,''.

(c) EFFECTIVE DATES.—

(1) PEDIATRIC STUDY PLANS.—Subsection (e) of section 505B of the Federal Food, Drug, and Cosmetic Act (other than paragraph (4) of such subsection), as amended by subsection (a), shall take effect 180 days after the date of enactment of this Act, without regard to whether the Secretary has promulgated final regulations under paragraph (4) of such subsection by such date.

(2) CONFORMING AMENDMENTS.—The amendments made by subsection (b) shall take effect 180 days after the date of enactment of this Act.

SEC. 507. REAUTHORIZATIONS.

(a) PEDIATRIC ADVISORY COMMITTEE.—Section 14(d) of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by striking ''Notwithstanding section 14 of the Federal Advisory Committee Act, the advisory committee shall continue to operate during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007'' and inserting ''Section 14 of the Federal Advisory Committee Act shall not apply to the advisory committee''.

(b) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.—Section 15(a)(3) of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by striking ''during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007'' and inserting ''for the duration of the operation of the Oncologic Drugs Advisory Committee''.

(c) HUMANITARIAN DEVICE EXEMPTION EXTENSION.—Section 520(m)(6)(A)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is amended by striking ''2012'' and inserting ''2017''.

(d) DEMONSTRATION GRANTS TO IMPROVE PEDIATRIC DEVICE AVAILABILITY.—Section 305(e) of Pediatric Medical Device Safety and Improvement Act (Public Law 110–85; 42 U.S.C. 282 note)) is amended by striking ''$6,000,000 for each of fiscal years 2008 through 2012'' and inserting ''$4,500,000 for each of fiscal years 2013 through 2017''.

(e) PROGRAM FOR PEDIATRIC STUDY OF DRUGS IN PHSA.—Section 409I(e)(1) of the Public Health Service Act (42 U.S.C. 284m(e)(1)) is amended by striking ''to carry out this section'' and all that follows through the end of paragraph (1) and inserting ''to carry out this section $25,000,000 for each of fiscal years 2012 through 2017.''.

SEC. 508. REPORT.

(a) IN GENERAL.—Not later than October 31, 2016, and at the end of each subsequent 5-year period, the Secretary shall submit to Congress a report that evaluates the effectiveness of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) and section 409I of the Public Health Service Act (42 U.S.C. 284m) in ensuring that medicines used by children are tested in pediatric populations and properly labeled for use in children.

(b) CONTENTS.—The report under subsection (a) shall include—

(1) the number and importance of drugs and biological products for children for which studies have been requested or required (as of the date of such report) under 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) and section 409I of the Public Health Service Act (42 U.S.C. 284m), including—

(A) the number of labeling changes made to drugs and biological products pursuant to such sections since the date of enactment of this Act; and

(B) the importance of such drugs and biological products in the improvement of the health of children;

(2) the number of required studies under such section 505B that have not met the initial deadline provided under such section, including—

(A) the number of deferrals and deferral extensions granted and the reasons such extensions were granted;

(B) the number of waivers and partial waivers granted; and

(C) the number of letters issued under subsection (d) of such section 505B;

(3) the number of written requests issued, declined, and referred to the National Institutes of Health under such section 505A since the date of enactment of this Act (including the reasons for such declination), and a description and status of referrals made under subsection (n) of such section 505A;

(4) the number of proposed pediatric study plans submitted and agreed to as identified in the marketing application under such section 505B;

(5) any labeling changes recommended by the Pediatric Advisory Committee as a result of the review by such Committee of adverse events reports;

(6) the number and current status of pediatric postmarketing requirements;

(7) the number and importance of drugs and biological products for children that are not being tested for use in pediatric populations, notwithstanding the existence of the programs under such sections 505A and 505B and section 409I of the Public Health Service Act;

(8) the possible reasons for the lack of testing reported under paragraph (7);

(9) the number of drugs and biological products for which testing is being done (as of the date of the report) and for which a labeling change is required under the programs described in paragraph (7), including—

(A) the date labeling changes are made;

(B) which labeling changes required the use of the dispute resolution process; and

(C) for labeling changes that required such dispute resolution process, a description of—

(i) the disputes;

(ii) the recommendations of the Pediatric Advisory Committee; and

(iii) the outcomes of such process; and

(D) an assessment of the effectiveness in improving information about pediatric uses of drugs and biological products;

(10)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonatal population (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); and

(B) the results of such efforts;

(11)(A) the number and importance of drugs and biological products for children with cancer that are being tested as a result of the programs described in paragraph (7); and

(B) any recommendations for modifications to such programs that would lead to new and better therapies for children with cancer, including a detailed rationale for each recommendation;

(12) an assessment of progress made in addressing the recommendations and findings of any prior report issued by the Comptroller General, the Institute of Medicine, or the Secretary regarding the topics addressed in the report under this section, including with respect to—

(A) improving public access to information from pediatric studies conducted under such sections 505A and 505B; and

(B) improving the timeliness of pediatric studies and pediatric study planning under such sections 505A and 505B;

(13) any recommendations for modification to the programs that would improve pediatric drug research and increase pediatric labeling of drugs and biological products; and

(14) an assessment of the successes of and limitations to studying drugs for rare diseases under such sections 505A and 505B.

(c) CONSULTATION ON RECOMMENDATIONS.—At least 180 days before the report is due under subsection (a), and no sooner than 4 years after the date of enactment of this Act, the Secretary shall consult with representatives of patient groups, including pediatric patient groups, consumer groups, regulated industry, scientific and medical communities, academia, and other interested parties to obtain any recommendations or information relevant to the effectiveness of the programs described in subsection (b)(7), including suggestions for modifications to such programs.

SEC. 509. TECHNICAL AMENDMENTS.

(a) PEDIATRIC STUDIES OF DRUGS IN FFDCA.—Section 505A (21 U.S.C. 355a) is amended—

(1) in subsection (k)(2), by striking ''subsection (f)(3)(F)'' and inserting ''subsection (f)(6)(F)'';

(2) in subsection (n)—

(A) in the subsection heading, by striking ''COMPLETED'' and inserting ''SUBMITTED''; and

(B) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking ''have not been completed'' and inserting ''have not been submitted by the date specified in the written request issued or if the applicant or holder does not agree to the request'';

(ii) in subparagraph (A)—

(I) in the first sentence, by inserting '', or for which a period of exclusivity eligible for extension under subsection (b)(1) or (c)(1) of this section or under subsection (m)(2) or (m)(3) of section 351 of the Public Health Service Act has not ended'' after ''expired''; and

(II) by striking ''Prior to'' and all that follows through the period at the end; and

(iii) in subparagraph (B), by striking ''no listed patents or has 1 or more listed patents that have expired,'' and inserting ''no unexpired listed patents and for which no unexpired periods of exclusivity eligible for extension under subsection (b)(1) or (c)(1) of this section or under subsection (m)(2) or (m)(3) of section 351 of the Public Health Service Act apply,''; and

(3) in subsection (o)(2), by amendment subparagraph (B) to read as follows:

''(B) a statement of any appropriate pediatric contraindications, warnings, precautions, or other information that the Secretary considers necessary to assure safe use.''.

(b) RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PROJECTS IN FFDCA.—Section 505B (21 U.S.C. 355c) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by inserting ''for a drug'' after ''(or supplement to an application)'';

(ii) in subparagraph (A), by striking ''for a'' and inserting '', including, with respect to a drug, an application (or supplement to an application) for a'';

(iii) in subparagraph (B), by striking ''for a'' and inserting '', including, with respect to a drug, an application (or supplement to an application) for a''; and

(iv) in the matter following subparagraph (B), by inserting ''(or supplement)'' after ''application''; and

(B) in paragraph (4)(C)—

(i) in the first sentence, by inserting ''partial'' before ''waiver is granted''; and

(ii) in the second sentence, by striking ''either a full or'' and inserting ''such a'';

(2) in subsection (b)(1), in the matter preceding subparagraph (A), by striking ''After providing notice'' and all that follows through ''studies), the'' and inserting ''The'';

(3) in subsection (g)—

(A) in paragraph (1)(A), by inserting ''that receives a priority review or 330 days after the date of the submission of an application or supplement that receives a standard review'' after ''after the date of the submission of the application or supplement''; and

(B) in paragraph (2), by striking ''the label of such product'' and inserting ''the labeling of such product''; and

(4) in subsection (h)(1)—

(A) by inserting ''an application (or supplement to an application) that contains'' after ''date of submission of''; and

(B) by inserting '', if the application (or supplement) receives a priority review, or not later than 330 days after the date of submission of an application (or supplement to an application) that contains a pediatric assessment under this section, if the application (or supplement) receives a standard review,'' after ''under this section,''.

(c) INTERNAL REVIEW COMMITTEE.—The heading of section 505C (21 U.S.C. 355d) is amended by inserting ''**AND DEFERRAL EXTENSIONS**'' after ''**DEFERRALS**''.

(d) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—Section 409I(c) of the Public Health Service Act (42 U.S.C. 284m(c)) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by inserting ''or section 351(m) of this Act,'' after ''Cosmetic Act,'';

(B) in subparagraph (A)(i), by inserting ''or section 351(k) of this Act'' after ''Cosmetic Act''; and

(C) by amending subparagraph (B) to read as follows:

''(B) there remains no patent listed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, and every three-year and five-year period referred to in subsection (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act, or applicable twelve-year period referred to in section 351(k)(7) of this Act, and any seven-year period referred to in section 527 of the Federal Food, Drug, and Cosmetic Act has ended for at least one form of the drug; and''; and

(2) in paragraph (2)—

(A) in the paragraph heading, by striking ''FOR DRUGS LACKING EXCLUSIVITY''; and

(B) by striking ''under section 505 of the Federal Food, Drug, and Cosmetic Act''; and

(C) by striking ''505A of such Act'' and inserting ''505A of the Federal Food, Drug, and Cosmetic Act or section 351(m) of this Act''.

(e) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC ADVISORY COMMITTEE.—Section 15(a) of the Best Pharmaceuticals for Children Act (Public Law 107–109), as amended by section 502(e) of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85), is amended in paragraph (1)(D), by striking ''section 505B(f)'' and inserting '' 'section 505C' ''.

(f) FOUNDATION OF 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 ''for which the Secretary issues a certification in the affirmative under section 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act''.

(g) APPLICATION.—Notwithstanding any provision of section 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) stating that a provision applies beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007 or the date of the enactment of the Pediatric Research Equity Act of 2007, any amendment made by this title to such a provision applies beginning on the date of the enactment of this Act.

SEC. 510. RELATIONSHIP BETWEEN PEDIATRIC LABELING AND NEW CLINICAL INVESTIGATION EXCLUSIVITY.

(a) IN GENERAL.—Section 505 (21 U.S.C. 351) is amended by adding at the end the following:

''(w) RELATIONSHIP BETWEEN PEDIATRIC LABELING AND NEW CLINICAL INVESTIGATION EXCLUSIVITY.—The period of market exclusivity described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) shall not apply to a pediatric study conducted under section 505A or 505B that results, pursuant to section 505B(g)(2), in the inclusion in the labeling of the product a determination that the product is not indicated for use in pediatric populations or subpopulations or information indicating that the results of a study were inconclusive or did not demonstrate that the product is safe or effective in pediatric populations or subpopulations.''.

(b) PEDIATRIC STUDIES OF DRUGS.—Section 505A(m) (21 U.S.C. 355a(m)) is amended—

(1) by striking ''(m) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 505(j).—If a'' and all that follows through the end of the matter that precedes paragraph (1) and inserting the following:

''(m) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICATION OR SUPPLEMENT UNDER SUBSECTION (C) OR (J) OF SECTION 505.—

''(1) 180-DAY EXCLUSIVITY PERIOD.—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month exclusivity period under this section, so that the applicant for approval of a drug under section 505(j) entitled to the 180-day period under that section loses a portion of the 180-day period to which the applicant is entitled for the drug, the 180-day period shall be extended from—'';

(2) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B) and moving such subparagraphs, as so redesignated, 2 ems to the right; and

(3) by adding at the end the following:

''(2) 3-YEAR EXCLUSIVITY PERIOD.—The 3-year period of exclusivity under clauses (iii) and (iv) of subsection 505(c)(3)(E) and clauses (iii) and (iv) of subsection 505(j)(5)(F) are not available for approval of applications or supplements to applications based on reports of pediatric studies conducted under sections 505A or 505B that resulted, pursuant to section 505A(j) or 505B(g)(2), in the inclusion in the labeling of the product a determination that the product is not indicated for use in pediatric populations or subpopulations or information indicating that the results of an assessment were inconclusive or did not demonstrate that the product is safe or effective in pediatric populations or subpopulation.''.

(c) PROMPT APPROVAL OF DRUGS.—Section 505A(o) (21 U.S.C. 355a(o)) is amended—

(1) in the heading, by striking ''SECTION 505(J)'' and inserting ''SUBSECTIONS (C) AND (J) OF SECTION 505'';

(2) in paragraph (1), by striking ''under section 505(j)'' and inserting ''under subsection (b)(2), (c), or (j) of section 505'';

(3) in paragraph (2), in the matter preceding subparagraph (A), by inserting ''clauses (iii) and (iv) of section 505(c)(3)(E) or'' after ''Notwithstanding''; and

(4) in paragraph (3)—

(A) in subparagraph (B), by inserting ''that differ from adult formulations'' before the semicolon at the end; and

(B) in subparagraph (C)—

(i) by striking ''under section 505(j)'' and inserting ''under subsection (c) or (j) of section 505''; and

(ii) by inserting ''clauses (iii) or (iv) of section 505(c)(3)(E) or'' after ''exclusivity under''.

SEC. 511. PEDIATRIC RARE DISEASES.

(a) PUBLIC MEETING.—Not later than 18 months after the date of enactment of this Act, the Secretary shall hold a public meeting to discuss ways to encourage and accelerate the development of new therapies for pediatric rare diseases.

(b) REPORT.—Not later than 180 days after the date of the public meeting under subsection (a), the Secretary shall issue a report that includes a strategic plan for encouraging and accelerating the development of new therapies for treating pediatric rare diseases.

TITLE VI—MEDICAL DEVICE REGULATORY IMPROVEMENTS

SEC. 601. RECLASSIFICATION PROCEDURES.

(a) CLASSIFICATION CHANGES.—

(1) IN GENERAL.—Section 513(e)(1) (21 U.S.C. 360c(e)(1)) is amended to read as follows:

''(e)(1)(A) Based on new information respecting a device, the Secretary may, upon the initiative of the Secretary or upon petition of an interested person, change the classification of such device, and revoke, on account of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device, by administrative order published in the Federal Register following publication of a proposed reclassification order in the Federal Register, a meeting of a device classification panel described in subsection (b), and consideration of comments to a public docket, notwithstanding subchapter II of Chapter 5 of title 5 of the United States Code. An order under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such device.

''(B) Authority to issue such administrative order shall not be delegated below the Commissioner. The Commissioner shall issue such an order as proposed by the Director of the Center for Devices and Radiological Health unless the Commissioner, in consultation with the Office of the Secretary of Health and Human Services, concludes that the order exceeds the legal authority of the Food and Drug Administration or that the order would be lawful, but unlikely to advance the public health.''.

(2) TECHNICAL AND CONFORMING AMENDMENTS.—

(A) Section 513(e)(2) (21 U.S.C. 360c(e)(2)) is amended by striking ''regulation promulgated'' and inserting ''an order issued''.

(B) Section 514(a)(1) (21 U.S.C. 360d(a)(1)) is amended by striking ''under a regulation under section 513(e) but such regulation'' and inserting ''under an administrative order under section 513(e) (or a regulation promulgated under such section prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act) but such order (or regulation)'';

(C) Section 517(a)(1) (21 U.S.C. 360g(a)(1)) is amended by striking ''or changing the classification of a device to class I'' and inserting '', an administrative order changing the classification of a device to class I,''.

(3) DEVICES RECLASSIFIED PRIOR TO THE DATE OF ENACTMENT OF THIS ACT.—

(A) IN GENERAL.—The amendments made by this subsection shall have no effect on a regulation promulgated with respect to the classification of a device under section 513(e) of the Federal Food, Drug, and Cosmetic Act prior to the date of enactment of this Act.

(B) APPLICABILITY OF OTHER PROVISIONS.—In the case of a device reclassified under section 513(e) of the Federal Food, Drug, and Cosmetic Act by regulation prior to the date of enactment of this Act, section 517(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g(a)(1)) shall apply to such regulation promulgated under section 513(e) of such Act with respect to such device in the same manner such section 517(a)(1) applies to an administrative order issued with respect to a device reclassified after the date of enactment of this Act.

(b) DEVICES MARKETED BEFORE MAY 28, 1976.—

(1) PREMARKET APPROVAL.—Section 515 (21 U.S.C. 360e) is amended—

(A) in subsection (a), by striking ''regulation promulgated under subsection (b)'' and inserting ''an order issued under subsection (b) (or a regulation promulgated under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act)'';

(B) in subsection (b)—

(i) in paragraph (1)—

(I) in the heading, by striking ''Regulation'' and inserting ''Order''; and

(II) in the matter following subparagraph (B)—

(aa) by striking ''by regulation, promulgated in accordance with this subsection'' and inserting ''by administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, United States Code''; and

(bb) by adding at the end the following:

''Authority to issue such administrative order shall not be delegated below the Commissioner. Before publishing such administrative order, the Commissioner shall consult with the Office of the Secretary. The Commissioner shall issue such an order as proposed by the Director of the Center for Devices and Radiological Health unless the Commissioner, in consultation with the Office of the Secretary, concludes that the order exceeds the legal authority of the Food and Drug Administration or that the order would be lawful, but unlikely to advance the public health.'';

(ii) in paragraph (2)—

(I) by striking subparagraph (B); and

(II) in subparagraph (A)—

(aa) by striking ''(2)(A) A proceeding for the promulgation of a regulation under paragraph (1) respecting a device shall be initiated by the publication in the Federal Register of a notice of proposed rulemaking. Such notice shall contain—'' and inserting ''(2) A proposed order required under paragraph (1) shall contain—'';

(bb) by redesignating clauses (i) through (iv) as subparagraphs (A) through (D), respectively;

(cc) in subparagraph (A), as so redesignated, by striking ''regulation'' and inserting ''order''; and

(dd) in subparagraph (C), as so redesignated, by striking ''regulation'' and inserting ''order'';

(iii) in paragraph (3)—

(I) by striking ''proposed regulation'' each place such term appears and inserting ''proposed order'';

(II) by striking ''paragraph (2) and after'' and inserting ''paragraph (2),'';

(III) by inserting ''and a meeting of a device classification panel described in section 513(b),'' after ''such proposed regulation and findings,'';

(IV) by striking ''(A) promulgate such regulation'' and inserting ''(A) issue an administrative order under paragraph (1)'';

(V) by striking ''paragraph (2)(A)(ii)'' and inserting ''paragraph (2)(B)''; and

(VI) by striking ''promulgation of the regulation'' and inserting ''issuance of the administrative order''; and

(iv) by striking paragraph (4); and

(C) in subsection (i)—

(i) in paragraph (2)—

(I) in the matter preceding subparagraph (A)—

(aa) by striking ''December 1, 1995'' and inserting ''the date that is 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act''; and

(bb) by striking ''publish a regulation in the Federal Register'' and inserting ''issue an administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, United States Code,'';

(II) in subparagraph (B), by striking ''final regulation has been promulgated under section 515(b)'' and inserting ''administrative order has been issued under subsection (b) (or no regulation has been promulgated under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act)'';

(III) in the matter following subparagraph (B), by striking ''regulation requires'' and inserting ''administrative order issued under this paragraph requires''; and

(IV) by striking the third and fourth sentences; and

(ii) in paragraph (3)—

(I) by striking ''regulation requiring'' each place such term appears and inserting ''order requiring''; and

(II) by striking ''promulgation of a section 515(b) regulation'' and inserting ''issuance of an administrative order under subsection (b)''.

(2) TECHNICAL AND CONFORMING AMENDMENTS.—Section 501(f) (21 U.S.C. 351(f)) is amended—

(A) in subparagraph (1)(A)—

(i) in subclause (i), by striking ''a regulation promulgated'' and inserting ''an order issued''; and

(ii) in subclause (ii), by striking ''promulgation of such regulation'' and inserting ''issuance of such order'';

(B) in subparagraph (2)(B)—

(i) by striking ''a regulation promulgated'' and inserting ''an order issued''; and

(ii) by striking ''promulgation of such regulation'' and inserting ''issuance of such order''; and

(C) by adding at the end the following:

''(3) In the case of a device with respect to which a regulation was promulgated under section 515(b) prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act, a reference in this subsection to an order issued under section 515(b) shall be deemed to include such regulation.''.

(3) APPROVAL BY REGULATION PRIOR TO THE DATE OF ENACTMENT OF THIS ACT.—The amendments made by this subsection shall have no effect on a regulation that was promulgated prior to the date of enactment of this Act requiring that a device have an approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) of an application for premarket approval.

(c) REPORTING.—The Secretary of Health and Human Services shall annually post on the Internet website of the Food and Drug Administration—

(1) the number and type of class I and class II devices reclassified as class II or class III in the previous calendar year under section 513(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(e)(1));

(2) the number and type of class II and class III devices reclassified as class I or class II in the previous calendar year under such section 513(e)(1); and

(3) the number and type of devices reclassified in the previous calendar year under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e).

SEC. 602. CONDITION OF APPROVAL STUDIES.

Section 515(d)(1)(B)(ii) (21 U.S.C. 360e(d)(1)(B)(ii)) is amended—

(1) by striking ''(ii)'' and inserting ''(ii)(I)''; and

(2) by adding at the end the following:

''(II) An order approving an application for a device may require as a condition to such approval that the applicant conduct a postmarket study regarding the device.''.

SEC. 603. POSTMARKET SURVEILLANCE.

Section 522 (21 U.S.C. 360l) is amended—

(1) in subsection (a)(1)(A), in the matter preceding clause (i), by inserting '', at the time of approval or clearance of a device or at any time thereafter,'' after ''by order''; and

(2) in subsection (b)(1), by inserting ''The manufacturer shall commence surveillance under this section not later than 15 months after the day on which the Secretary issues an order under this section.'' after the second sentence.

SEC. 604. SENTINEL.

Section 519 (21 U.S.C. 360i) is amended by adding at the end the following:

''(h) INCLUSION OF DEVICES IN THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

''(1) IN GENERAL.—

''(A) APPLICATION TO DEVICES.—The Secretary shall amend the procedures established and maintained under clauses (i), (ii), (iii), and (v) of section 505(k)(3)(C) in order to expand the postmarket risk identification and analysis system established under such section to include and apply to devices.

''(B) EXCEPTION.—Subclause (II) of clause (i) of section 505(k)(3)(C) shall not apply to devices.

''(C) CLARIFICATION.—With respect to devices, the private sector health-related electronic data provided under section 505(k)(3)(C)(i)(III)(bb) may include medical device utilization data, health insurance claims data, and procedure and device registries.

''(2) DATA.—In expanding the system as described in paragraph (1)(A), the Secretary shall use relevant data with respect to devices cleared under section 510(k) or approved under section 515, including claims data, patient survey data, and any other data deemed appropriate by the Secretary.

''(3) STAKEHOLDER INPUT.—To help ensure effective implementation of the system described in paragraph (1)(A), the Secretary shall engage outside stakeholders in development of the system through a public hearing, advisory committee meeting, public docket, or other like public measures, as appropriate.

''(4) VOLUNTARY SURVEYS.—Chapter 35 of title 44, United States Code, shall not apply to the collection of voluntary information from health care providers, such as voluntary surveys or questionnaires, initiated by the Secretary for purposes of postmarket risk identification for devices.''.

SEC. 605. RECALLS.

(a) ASSESSMENT OF DEVICE RECALL INFORMATION.—

(1) IN GENERAL.—

(A) ASSESSMENT PROGRAM.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall enhance the Food and Drug Administration's recall program to routinely and systematically assess—

(i) information submitted to the Secretary pursuant to a device recall order under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)); and

(ii) information required to be reported to the Secretary regarding a correction or removal of a device under section 519(g) of such Act (21 U.S.C. 360i(g)).

(B) USE.—The Secretary shall use the assessment of information described under subparagraph (A) to proactively identify strategies for mitigating health risks presented by defective or unsafe devices.

(2) DESIGN.—The program under paragraph (1) shall, at a minimum, identify—

(A) trends in the numbers and types of device recalls;

(B) the types of devices in each device class that are most frequently recalled;

(C) the causes of device recalls; and

(D) any other information as the Secretary determines appropriate.

(b) AUDIT CHECK PROCEDURES.—The Secretary shall clarify procedures for conducting device recall audit checks to improve the ability of investigators to perform these checks in a consistent manner.

(c) ASSESSMENT CRITERIA.—The Secretary shall develop explicit criteria for assessing whether a person subject to a recall order under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)) or to a requirement under section 519(g) of such Act (21 U.S.C. 360i(g)) has performed an effective recall under such section 518(e) or an effective correction or removal action under such section 519(g), respectively.

(d) TERMINATION OF RECALLS.—The Secretary shall document the basis for the termination by the Food and Drug Administration of—

(1) an individual device recall ordered under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)); and

(2) any correction or removal action for which a report is required to be submitted to the Secretary under section 519(g) of such Act (21 U.S.C. 360i(g)).

SEC. 606. CLINICAL HOLDS ON INVESTIGATIONAL DEVICE EXEMPTIONS.

Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

''(8)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a 'clinical hold') if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

''(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is a determination that—

''(i) the device involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the device, the design of the clinical investigation, the condition for which the device is to be investigated, and the health status of the subjects involved; or

''(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish.

''(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.''.

SEC. 607. UNIQUE DEVICE IDENTIFIER.

Section 519(f) (21 U.S.C. 360i(f)) is amended—

(1) by striking ''The Secretary shall promulgate'' and inserting ''Not later than December 31, 2012, the Secretary shall issue proposed''; and

(2) by adding at the end the following: ''The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized.''.

SEC. 608. CLARIFICATION OF LEAST BURDENSOME STANDARD.

(a) PREMARKET APPROVAL.—Section 513(a)(3)(D) (21 U.S.C. 360c(a)(3)(D)) is amended—

(1) by redesignating clause (iii) as clause (v); and

(2) by inserting after clause (ii) the following:

''(iii) For purposes of clause (ii), the term 'necessary' means the minimum required information that would support a determination by the Secretary that an application provides reasonable assurance of the effectiveness of the device.

''(iv) Nothing in this subparagraph shall alter the criteria for evaluating an application for premarket approval of a device.''.

(b) PREMARKET NOTIFICATION UNDER SECTION 510(K).—Section 513(i)(1)(D) (21 U.S.C. 360c(i)(1)(D)) is amended—

(1) by striking ''(D) Whenever'' and inserting ''(D)(i) Whenever''; and

(2) by adding at the end the following:

''(ii) For purposes of clause (i), the term 'necessary' means the minimum required information that would support a determination of substantial equivalence between a new device and a predicate device.

''(iii) Nothing in this subparagraph shall alter the standard for determining substantial equivalence between a new device and a predicate device.''.

SEC. 609. CUSTOM DEVICES.

Section 520(b) (21 U.S.C. 360j(b)) is amended to read as follows:

''(b) CUSTOM DEVICES.—

''(1) IN GENERAL.—The requirements of sections 514 and 515 shall not apply to a device that—

''(A) is created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing);

''(B) in order to comply with an order described in subparagraph (A), necessarily deviates from an otherwise applicable performance standard under section 514 or requirement under section 515;

''(C) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;

''(D) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat;

''(E)(i) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated); or

''(ii) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated);

''(F) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs described in clause (i) or (ii) of subparagraph (E); and

''(G) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

''(2) LIMITATIONS.—Paragraph (1) shall apply to a device only if—

''(A) such device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on such device would be impractical;

''(B) production of such device under paragraph (1) is limited to no more than 5 units per year of a particular device type, provided that such replication otherwise complies with this section; and

''(C) the manufacturer of such device created or modified as described in paragraph (1) notifies the Secretary on an annual basis, in a manner prescribed by the Secretary, of the manufacture of such device.

''(3) EXCEPTION.—Paragraph (1) shall not apply to oral facial devices.

''(4) GUIDANCE.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue final guidance on replication of multiple devices described in paragraph (2)(B).''.

SEC. 610. AGENCY DOCUMENTATION AND REVIEW OF CERTAIN DECISIONS REGARDING DEVICES.

Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 517 the following:

''SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF CERTAIN DECISIONS REGARDING DEVICES.

''(a) DOCUMENTATION OF RATIONALE FOR DENIAL.—If the Secretary renders a final decision to deny clearance of a premarket notification under section 510(k) or approval of a premarket application under section 515, or when the Secretary disapproves an application for an investigational exemption under 520(g), the written correspondence to the applicant communicating that decision shall provide a substantive summary of the scientific and regulatory rationale for the decision.

''(b) REVIEW OF DENIAL.—

''(1) IN GENERAL.—A person who has submitted a report under section 510(k), an application under section 515, or an application for an exemption under section 520(g) and for whom clearance of the report or approval of the application is denied may request a supervisory review of the decision to deny such clearance or approval. Such review shall be conducted by an individual at the organizational level above the organization level at which the decision to deny the clearance of the report or approval of the application is made.

''(2) SUBMISSION OF REQUEST.—A person requesting a supervisory review under paragraph (1) shall submit such request to the Secretary not later than 30 days after such denial and shall indicate in the request whether such person seeks an in-person meeting or a teleconference review.

''(3) TIMEFRAME.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall schedule an in-person or teleconference review, if so requested, not later than 30 days after such request is made. The Secretary shall issue a decision to the person requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a person who requests an in-person meeting or teleconference, 30 days after such meeting or teleconference.

''(B) EXCEPTION.—Subparagraph (A) shall not apply in cases that involve consultation with experts outside of the Food and Drug Administration, or in cases in which the sponsor seeks to introduce evidence not already in the administrative record at the time the denial decision was made.''.

SEC. 611. GOOD GUIDANCE PRACTICES RELATING TO DEVICES.

Subparagraph (C) of section 701(h)(1) (21 U.S.C. 371(h)(1)) is amended—

(1) by striking ''(C) For guidance documents'' and inserting ''(C)(i) For guidance documents''; and

(2) by adding at the end the following:

''(ii) With respect to devices, if a notice to industry guidance letter, a notice to industry advisory letter, or any similar notice sets forth initial interpretations of a regulation or policy or sets forth changes in interpretation or policy, such notice shall be treated as a guidance document for purposes of this subparagraph.''.

SEC. 612. MODIFICATION OF DE NOVO APPLICATION PROCESS.

(a) IN GENERAL.—Section 513(f)(2) (21 U.S.C. 360c(f)(2)) is amended—

(1) by redesignating subparagraphs (B) and (C) as subparagraphs (C) and (D), respectively;

(2) by amending subparagraph (A) to read as follows:

''(A) In the case of a type of device that has not previously been classified under this Act, a person may do one of the following:

''(i) Submit a report under section 510(k), and, if the device is classified into class III under paragraph (1), such person may request, not later than 30 days after receiving

written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

''(ii) Submit a request for initial classification of the device under this subparagraph, if the person declares that there is no legally marketed device upon which to base a substantial equivalence determination as that term is defined in subsection (i). Subject to subparagraph (B), the Secretary shall classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device and shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such assurance. Requests under this clause shall be subject to the electronic copy requirements of section 745A(b).'';

(3) by inserting after subparagraph (A) the following:

''(B) The Secretary may decline to undertake a classification request submitted under clause (2)(A)(ii) if the Secretary identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence under paragraph (1), or when the Secretary determines that the device submitted is not of low-moderate risk or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.'';

and

(4) in subparagraph (C), as so redesignated—

(A) in clause (i), by striking ''Not later than 60 days after the date of the submission of the request under subparagraph (A),'' and inserting ''Not later than 120 days after the date of the submission of the request under subparagraph (A)(i) or 150 days after the date of the submission of the request under subparagraph (A)(ii),''; and

(B) in clause (ii), by inserting ''or is classified in'' after ''remains in''.

(b) GAO REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall complete a study and submit to Congress a report on the effectiveness of the review pathway under section 513(f)(2)(A) of the Federal Food, Drug, and Cosmetic Act, as amended by this Act.

(c) CONFORMING AMENDMENT.—Section 513(f)(1)(B) (21 U.S.C. 360c(f)(1)(B)) is amended by inserting ''a request under paragraph (2) or'' after ''response to''.

SEC. 613. HUMANITARIAN DEVICE EXEMPTIONS.

(a) IN GENERAL.—Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (6)—

(A) in subparagraph (A)—

(i) by striking clause (i) and inserting the following:

''(i) The device with respect to which the exemption is granted—

''(I) 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; or

''(II) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.''; and

(ii) by striking clause (ii) and inserting the following:

''(ii) During any calendar year, the number of such devices distributed during that year under each exemption granted under this subsection does not exceed the annual distribution number for such device. In this paragraph, the term 'annual distribution number' means the number of such devices reasonably needed to treat, diagnose, or cure a population of 4,000 individuals in the United States. The Secretary shall determine the annual distribution number when the Secretary grants such exemption.''; and

(B) by amending subparagraph (C) to read as follows:

''(C) A person may petition the Secretary to modify the annual distribution number determined by the Secretary under subparagraph (A)(ii) with respect to a device if additional information arises, and the Secretary may modify such annual distribution number.'';

(2) in paragraph (7), by striking ''regarding a device'' and inserting ''regarding a device described in paragraph (6)(A)(i)(I)''; and

(3) in paragraph (8), by striking ''of all devices described in paragraph (6)'' and inserting ''of all devices described in paragraph (6)(A)(i)(I)''.

(b) APPLICABILITY TO EXISTING DEVICES.—A sponsor of a device for which an exemption was approved under paragraph (2) of section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) before the date of enactment of this Act may seek a determination under subclause (I) or (II) of section 520(m)(6)(A)(i) (as amended by subsection (a)). If the Secretary of Health and Human Services determines that such subclause (I) or (II) applies with respect to a device, clauses (ii), (iii), and (iv) of subparagraph (A) and subparagraphs (B), (C), (D), and (E) of paragraph (6) of such section 520(m) shall apply to such device, and the Secretary shall determine the annual distribution number for purposes of clause (ii) of such subparagraph (A) when making the determination under this subsection.

(c) REPORT.—Not later than January 1, 2017, the Comptroller General of the United States shall submit to Congress a report that evaluates and describes—

(1) the effectiveness of the amendments made by subsection (a) in stimulating innovation with respect to medical devices, including any favorable or adverse impact on pediatric device development;

(2) the impact of such amendments on pediatric device approvals for devices that received a humanitarian use designation under section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) prior to the date of enactment of this Act;

(3) the status of public and private insurance coverage of devices granted an exemption under paragraph (2) of such section 520(m) (as amended by subsection (a)) and costs to patients of such devices;

(4) the impact that paragraph (4) of such section 520(m) has had on access to and insurance coverage of devices granted an exemption under paragraph (2) of such section 520(m); and

(5) the effect of the amendments made by subsection (a) on patients described in such section 520(m).

SEC. 614. REAUTHORIZATION OF THIRD-PARTY REVIEW AND INSPECTIONS.

(a) THIRD PARTY REVIEW.—Section 523(c) (21 U.S.C. 360m(c)) is amended by striking ''2012'' and inserting ''2017''.

(b) THIRD PARTY INSPECTIONS.—Section 704(g)(11) (21 U.S.C. 374(g)(11)) is amended by striking ''2012'' and inserting ''2017''.

SEC. 615. 510(K) DEVICE MODIFICATIONS.

Having acknowledged to Congress potential unintended consequences that may result from the implementation of the Food and Drug Administration guidance entitled ''Guidance for Industry and FDA Staff—510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device'', the Secretary of Health and Human Services shall withdraw such guidance promptly and ensure that, before any future guidance document on this issue is made final, affected stakeholders are provided with an opportunity to comment.

SEC. 616. HEALTH INFORMATION TECHNOLOGY.

(a) LIMITATION.—Notwithstanding any other provision of law, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may issue final guidance on medical mobile applications only after the requirements under subsections (b) and (c) are met.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary, in consultation with the Commissioner of Food and Drugs, the National Coordinator for Health Information Technology, and the Chairman of the Federal Communications Commission, 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 contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to medical device regulation and health information technology software, including mobile applications, that promotes innovation and protects patient safety.

(c) WORKING GROUP.—

(1) IN GENERAL.—In carrying out subsection (b), the Secretary shall convene a working group of external stakeholders and experts to provide appropriate input on the strategy and recommendations required for the report under subsection (b).

(2) REPRESENTATIVES.—The Secretary shall determine the number of representatives participating in the working group, and shall ensure that the working group is geographically diverse and includes representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise, as determined by the Secretary.

(3) OTHER REQUIREMENTS.—

(A) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the working group under this section.

(B) FFDCA ADVISORY COMMITTEES.—The requirements for advisory committees under section 712 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d–1), as amended by section 1121, shall not apply to the working group under this section.

TITLE VII—DRUG SUPPLY CHAIN

Subtitle A—Drug Supply Chain

SEC. 701. REGISTRATION OF DOMESTIC DRUG ESTABLISHMENTS.

Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (b)—

(A) in paragraph (1), by striking ''On or before'' and all that follows through the period at the end and inserting the following: ''During the period beginning on October 1 and ending on 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 drug or drugs shall register with the Secretary—

''(A) the name of such person, places of business of such person, all such establishments, the unique facility identifier of each such establishment, and a point of contact e-mail address; and

''(B) the name and place of business of each importer that takes physical possession of and supplies a drug (other than an excipient) to such person, including all establishments of each such drug importer, the unique facility identifier of each such drug importer establishment, and a point of contact e-mail address for each such drug importer.''; and

(B) by adding at the end the following:

''(3) The Secretary may specify the unique facility identifier system that shall be used by registrants under paragraph (1).''; and

(2) in subsection (c), by striking ''with the Secretary his name, place of business, and such establishment'' and inserting ''with the Secretary—

''(1) with respect to drugs, the information described under subsection (b)(1); and

''(2) with respect to devices, the information described under subsection (b)(2).''.

SEC. 702. REGISTRATION OF FOREIGN ESTABLISHMENTS.

(a) ENFORCEMENT OF REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 502(o) (21 U.S.C. 352(o)) is amended by striking ''in any State''.

(b) REGISTRATION OF FOREIGN DRUG ESTABLISHMENTS.—Section 510(i) (U.S.C. 360(i)) is amended—

(1) in paragraph (1)—

(A) by amending the matter preceding subparagraph (A) to read as follows: ''Every person who owns or operates any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—'';

(B) by amending subparagraph (A) to read as follows:

''(A) upon first engaging in any such activity, immediately submit a registration to the Secretary that includes—

''(i) with respect to drugs, the name and place of business of such person, all such establishments, the unique facility identifier of each such establishment, a point of contact e-mail address, the name of the United States agent of each such establishment, the name and place of business of each drug importer with which such person conducts business to import or offer to import drugs into the United States, including all establishments of each such drug importer, the unique facility identifier of each such establishment, and a point of contact e-mail address for each such drug importer; and

''(ii) with respect to devices, 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; and''; and

(C) by amending subparagraph (B) to read as follows:

''(B) each establishment subject to the requirements of subparagraph (A) shall thereafter register with the Secretary during the period beginning on October 1 and ending on December 31 of each year.''; and

(2) by adding at the end the following:

''(4) The Secretary may specify the unique facility identifier system that shall be used by registrants under paragraph (1) with respect to drugs.''.

SEC. 703. IDENTIFICATION OF DRUG EXCIPIENT INFORMATION WITH PRODUCT LISTING.

Section 510(j)(1) (21 U.S.C. 360(j)(1)) is amended—

(1) in subparagraph (C), by striking ''; and'' and inserting a semicolon;

(2) in subparagraph (D), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(E) in the case of a drug contained in the applicable list, the name and place of business of each manufacturer of an excipient of the listed drug with which the person listing the drug conducts business, including all establishments used in the production of such excipient, the unique facility identifier of each such establishment, and a point of contact e-mail address for each such excipient manufacturer.''.

SEC. 704. ELECTRONIC SYSTEM FOR REGISTRATION AND LISTING.

Section 510(p) (21 U.S.C. 360(p)) is amended—

(1) by striking ''(p) Registrations and listings'' and inserting the following:

''(p) ELECTRONIC REGISTRATION AND LISTING.—

''(1) IN GENERAL.—Registration and listing''; and

(2) by adding at the end the following:

''(2) ELECTRONIC DATABASE.—Not later than 2 years after the Secretary specifies a unique facility identifier system under subsections (b) and (i), the Secretary shall maintain an electronic database, which shall not be subject to inspection under subsection (f), populated with the information submitted as described under paragraph (1) that—

''(A) enables personnel of the Food and Drug Administration to search the database by any field of information submitted in a registration described under paragraph (1), or combination of such fields; and

''(B) uses the unique facility identifier system to link with other relevant databases within the Food and Drug Administration, including the database for submission of information under section 801(r).

''(3) RISK-BASED INFORMATION AND COORDINATION.—The Secretary shall ensure the accuracy and coordination of relevant Food and Drug Administration databases in order to identify and inform risk-based inspections under section 510(h).''.

SEC. 705. RISK-BASED INSPECTION FREQUENCY.

Section 510(h) (21 U.S.C. 360(h)) is amended to read as follows:

''(h) INSPECTIONS.—

''(1) IN GENERAL.—Every establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 704.

''(2) BIENNIAL INSPECTIONS FOR DEVICES.—Every establishment described in paragraph (1), in any State, that is engaged in the manufacture, propagation, compounding, or processing of a device or devices classified in class II or III shall be so inspected by one or more officers or employees duly designated by the Secretary, or by persons accredited to conduct inspections under section 704(g), at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter.

''(3) RISK-BASED SCHEDULE FOR DRUGS.—The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect establishments described in paragraph (1) that are engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs (referred to in this subsection as 'drug establishments') in accordance with a risk-based schedule established by the Secretary.

''(4) RISK FACTORS.—In establishing the risk-based scheduled under paragraph (3), the Secretary shall inspect establishments according to the known safety risks of such establishments, which shall be based on the following factors:

''(A) The compliance history of the establishment.

''(B) The record, history, and nature of recalls linked to the establishment.

''(C) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment.

''(D) The certifications described under sections 801(r) and 809 for the establishment.

''(E) Whether the establishment has been inspected in the preceding 4-year period.

''(F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

''(5) EFFECT OF STATUS.—In determining the risk associated with an establishment for purposes of establishing a risk-based schedule under paragraph (3), the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed by such establishment are drugs described in section 503(b).

''(6) ANNUAL REPORT ON INSPECTIONS OF ESTABLISHMENTS.—Not later than February 1 of each year, the Secretary shall submit a report to Congress regarding—

''(A)(i) the number of domestic and foreign establishments registered pursuant to this section in the previous fiscal year; and

''(ii) the number of such domestic establishments and the number of such foreign establishments that the Secretary inspected in the previous fiscal year;

''(B) with respect to establishments that manufacture, prepare, propagate, compound, or process an active ingredient of a drug, a finished drug product, or an excipient of a drug, the number of each such type of establishment; and

''(C) the percentage of the budget of the Food and Drug Administration used to fund the inspections described under subparagraph (A).

''(7) PUBLIC AVAILABILITY OF ANNUAL REPORTS.—The Secretary shall make the report required under paragraph (6) available to the public on the Internet Web site of the Food and Drug Administration.''.

SEC. 706. RECORDS FOR INSPECTION.

Section 704(a) (21 U.S.C. 374(a)) is amended by adding at the end the following:

''(4)(A) Any records or other information that the Secretary is entitled to inspect under this section from a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug shall, upon the request of the Secretary, be provided to the Secretary by such person within a reasonable time frame, within reasonable limits and in a reasonable manner, and in electronic form, at the expense of such person. The Secretary's request shall include a clear description of the records requested.

''(B) Upon receipt of the records requested under subparagraph (A), the Secretary shall provide to the person confirmation of the receipt of such records.

''(C) Nothing in this paragraph supplants the authority of the Secretary to conduct inspections otherwise permitted under this Act in order to ensure compliance by an establishment with this Act.''.

SEC. 707. FAILURE TO ALLOW FOREIGN INSPECTION.

Section 801(a) (21 U.S.C. 381(a)) is amended by adding at the end the following: ''Notwithstanding any other provision of this subsection, the Secretary of Homeland Security shall, upon request from the Secretary of

Health and Human Services refuse to admit into the United States any article if the article was manufactured, prepared, propagated, compounded, processed, or held at an establishment that has refused to permit the Secretary of Health and Human Services to enter or inspect the establishment in the same manner and to the same extent as the Secretary may inspect establishments under section 704.''.

SEC. 708. EXCHANGE OF INFORMATION.

Section 708 (21 U.S.C. 379) is amended—

(1) by striking ''CONFIDENTIAL INFORMATION'' and all that follows through ''The Secretary'' and inserting **''CONFIDENTIAL INFORMATION.**

''(a) CONTRACTORS.—The Secretary''; and

(2) by adding at the end the following:

''(b) ABILITY TO RECEIVE AND PROTECT CONFIDENTIAL INFORMATION OBTAINED FROM FOREIGN GOVERNMENTS.—

''(1) IN GENERAL.—The Secretary shall not be required to disclose under section 552 of title 5, United States Code (commonly referred to as the Freedom of Information Act), or any other provision of law, any information described in subsection (c)(3) obtained from a foreign government agency, if—

''(A) the information is provided or made available to the United States Government voluntarily and on the condition that the information not be released to the public; and

''(B) the information is covered by, and subject to, a certification and written agreement under subsections (c)(1) and (c)(2).

''(2) TIME LIMITATIONS.—The written agreement described in subsection (c)(2) shall specify the time period for which the non-disclosure requirements under paragraph (1) shall apply to the voluntarily disclosed information. The non-disclosure requirements under paragraph (1) shall not apply after the date specified, but all other applicable legal protections, including section 552 of title 5, United States Code and section 319L(e)(1) of the Public Health Service Act, shall continue to apply to such information, as appropriate. If no date is specified in the written agreement, the non-disclosure protections described in paragraph (1) shall not exceed 3 years.

''(3) DISCLOSURES NOT AFFECTED.—Nothing in this section authorizes any official to withhold, or to authorize the withholding of, information from Congress or information required to be disclosed pursuant to an order of a court of the United States.

''(4) PUBLIC INFORMATION.—For purposes of section 552 of title 5, United States Code, this subsection shall be considered a statute described in section 552(b)(3)(B).

''(c) AUTHORITY TO ENTER INTO MEMORANDA OF UNDERSTANDING FOR PURPOSES OF INFORMATION EXCHANGE.—The Secretary may enter into written agreements regarding the exchange of information referenced in section 301(j) subject to the following criteria:

''(1) CERTIFICATION.—The Secretary may only enter into written agreements under this subsection with foreign governments that the Secretary has certified as having the authority and demonstrated ability to protect trade secret information from disclosure. Responsibility for this certification shall not be delegated to any officer or employee other than the Commissioner.

''(2) WRITTEN AGREEMENT.—The written agreement under this subsection shall include a commitment by the foreign government to protect information exchanged under this subsection from disclosure unless and until the sponsor gives written permission for disclosure or the Secretary makes a declaration of a public health emergency pursuant to section 319 of the Public Health Service Act that is relevant to the information.

''(3) INFORMATION EXCHANGE.—The Secretary may provide to a foreign government that has been certified under paragraph (1) and that has executed a written agreement under paragraph (2) information referenced in section 301(j) in the following circumstances:

''(A) Information concerning the inspection of a facility may be provided if—

''(i) the Secretary reasonably believes, or that the written agreement described in paragraph (2) establishes, that the government has authority to otherwise obtain such information; and

''(ii) the written agreement executed under paragraph (2) limits the recipient's use of the information to the recipient's civil regulatory purposes.

''(B) Information not described in subparagraph (A) may be provided as part of an investigation, or to alert the foreign government to the potential need for an investigation, if the Secretary has reasonable grounds to believe that a drug has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

''(4) EFFECT OF SUBSECTION.—Nothing in this subsection affects the ability of the Secretary to enter into any written agreement authorized by other provisions of law to share confidential information.''.

SEC. 709. ENHANCING THE SAFETY AND QUALITY OF THE DRUG SUPPLY.

Section 501 (21 U.S.C. 351) is amended by adding at the end the following flush text:

''For purposes of subsection (a)(2)(B), the term 'current good manufacturing practice' includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.''.

SEC. 710. ACCREDITATION OF THIRD-PARTY AUDITORS FOR DRUG ESTABLISHMENTS.

(a) IN GENERAL.—Chapter VIII (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

''SEC. 809. ACCREDITATION OF THIRD-PARTY AUDITORS FOR DRUG ESTABLISHMENTS.

''(a) DEFINITIONS.—In this section:

''(1) ACCREDITATION BODY.—The term 'accreditation body' means an authority that performs accreditation of third-party auditors.

''(2) ACCREDITED THIRD-PARTY AUDITOR.—The term 'accredited third-party auditor' means a third-party auditor (which may be an individual) accredited by an accreditation body to conduct drug safety and quality audits.

''(3) AUDIT AGENT.—The term 'audit agent' means an individual who is an employee or agent of an accredited third-party auditor and, although not individually accredited, is qualified to conduct drug safety and quality audits on behalf of an accredited third-party auditor.

''(4) CONSULTATIVE AUDIT.—The term 'consultative audit' means an audit of an eligible entity intended for internal purposes only to determine whether an establishment is in compliance with the provisions of this Act and applicable industry practices, or any other such service.

''(5) DRUG SAFETY AND QUALITY AUDIT.—The term 'drug safety and quality audit'—

''(A) means an audit of an eligible entity to certify that the eligible entity meets the requirements of this Act applicable to drugs, including the requirements of section 501 with respect to drugs; and

''(B) is not a consultative audit.

''(6) ELIGIBLE ENTITY.—The term 'eligible entity' means an entity, including a foreign drug establishment registered under section 510(c), in the drug supply chain that chooses to be audited by an accredited third-party auditor or the audit agent of such accredited third-party auditor.

''(7) THIRD-PARTY AUDITOR.—The term 'third-party auditor' means a foreign government, agency of a foreign government or any other third party (which may be an individual), as the Secretary determines appropriate in accordance with the criteria described in subsection (c)(1), that is eligible to be considered for accreditation to conduct drug safety and quality audits.

''(b) ACCREDITATION SYSTEM.—

''(1) RECOGNITION OF ACCREDITATION BODIES.—

''(A) IN GENERAL.—Not later than 2 years after date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall establish a system for the recognition of accreditation bodies that accredit third-party auditors to conduct drug safety and quality audits.

''(B) DIRECT ACCREDITATION.—

''(i) IN GENERAL.—If, by the date that is 2 years after the date of establishment of the system described in subparagraph (A), the Secretary has not identified and recognized an accreditation body to meet the requirements of this section, the Secretary may directly accredit third-party auditors.

''(ii) CERTAIN DIRECT ACCREDITATIONS.—Notwithstanding subparagraph (A) or clause (i), the Secretary may directly accredit any foreign government or any agency of a foreign government as a third-party auditor at any time after the date of enactment of the Food and Drug Administration Safety and Innovation Act.

''(2) NOTIFICATION.—Each accreditation body recognized by the Secretary shall submit to the Secretary—

''(A) a list of all accredited third-party auditors accredited by such body (including the name, contact information, and scope and duration of accreditation for each such auditor), and the audit agents of such auditors; and

''(B) updated lists as needed to ensure the list held by the Secretary is accurate.

''(3) REVOCATION OF RECOGNITION AS AN ACCREDITATION BODY.—The Secretary shall promptly revoke, after the opportunity for an informal hearing, the recognition of any accreditation body found not to be in compliance with the requirements of this section.

''(4) REINSTATEMENT.—The Secretary shall establish procedures to reinstate recognition of an accreditation body if the Secretary determines, based on evidence presented by such accreditation body, that revocation was inappropriate or that the body meets the requirements for recognition under this section.

''(5) MODEL ACCREDITATION STANDARDS.—

''(A) IN GENERAL.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall develop model standards, including standards for drug safety and quality audit results, reports, and certifications, and each recognized accreditation body shall ensure that third-party auditors and audit agents of such auditors meet such standards in order to qualify such third-party auditors as accredited third-party auditors under this section.

''(B) CONTENT.—The standards developed under subparagraph (A) may—

''(i) include a description of required standards relating to the training procedures, competency, management responsibilities, quality control, and conflict of interest requirements of accredited third-party auditors; and

''(ii) set forth procedures for the periodic renewal of the accreditation of accredited third-party auditors.

''(C) REQUIREMENT TO PROVIDE RESULTS AND REPORTS TO THE SECRETARY.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) may not accredit a third-party auditor unless such third-party auditor agrees to provide to the Secretary, upon request, the results and reports of any drug safety and quality audit conducted pursuant to the accreditation provided under this section.

''(6) DISCLOSURE.—The Secretary shall maintain on the Internet Web site of the Food and Drug Administration a list of recognized accreditation bodies and accredited third-party auditors under this section.

''(c) ACCREDITED THIRD-PARTY AUDITORS.—

''(1) REQUIREMENTS FOR ACCREDITATION AS A THIRD-PARTY AUDITOR.—

''(A) FOREIGN GOVERNMENTS.—Prior to accrediting a foreign government or an agency of a foreign government as an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) shall perform such reviews and audits of drug safety programs, systems, and standards of the government or agency of the government as the Secretary deems necessary, including requirements under the standards developed under subsection (b)(5), to determine that the foreign government or agency of the foreign government is capable of adequately ensuring that eligible entities or drugs certified by such government or agency meet the requirements of this Act.

''(B) OTHER THIRD PARTIES.—Prior to accrediting any other third party to be an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) shall perform such reviews and audits of the training and qualifications of audit agents used by that party and conduct such reviews of internal systems and such other investigation of the party as the Secretary deems necessary, including requirements under the standards developed under subsection (b)(5), to determine that the third-party auditor is capable of adequately ensuring that an eligible entity or drug certified by such third-party auditor meets the requirements of this Act.

''(2) USE OF AUDIT AGENTS.—An accredited third-party auditor may conduct drug safety and quality audits and may employ or use audit agents to conduct drug safety and quality audits, but must ensure that such audit agents comply with all requirements the Secretary deems necessary, including requirements under paragraph (1) and subsection (b)(5).

''(3) REVOCATION OF ACCREDITATION.—

''(A) IN GENERAL.—The Secretary shall promptly revoke, after the opportunity for an informal hearing, the accreditation of an accredited third-party auditor—

''(i) if, following an evaluation, the Secretary finds that the accredited third-party auditor is not in compliance with the requirements of this section; or

''(ii) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to determine compliance with the requirements set forth in this section.

''(B) ADDITIONAL BASIS FOR REVOCATION OF ACCREDITATION.—The Secretary may revoke accreditation from an accredited third-party auditor in the case that such third-party auditor is accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(3) is revoked, if the Secretary determines that there is good cause for the revocation of accreditation.

''(4) REACCREDITATION.—The Secretary shall establish procedures to reinstate the accreditation of a third-party auditor for which accreditation has been revoked under paragraph (3)—

''(A) if the Secretary determines, based on evidence presented, that—

''(i) the third-party auditor satisfies the requirements of this section; and

''(ii) adequate grounds for revocation no longer exist; and

''(B) in the case of a third-party auditor accredited by an accreditation body for which recognition as an accreditation body is revoked under subsection (b)(3)—

''(i) if the third-party auditor becomes accredited not later than 1 year after revocation of accreditation under paragraph (3), through direct accreditation under subsection (b)(1)(B), or by an accreditation body in good standing; or

''(ii) under such other conditions as the Secretary may require.

''(5) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICE.—

''(A) IN GENERAL.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) may not accredit a third-party auditor unless such third-party auditor agrees to issue a written and, as appropriate, electronic, document or certification, as the Secretary may require under this Act, regarding compliance with section 501. The Secretary may consider any such document or certification to satisfy requirements under section 801(r) and to target inspection resources under section 510(h).

''(B) REQUIREMENTS FOR ISSUING CERTIFICATION.—

''(i) IN GENERAL.—An accredited third-party auditor shall issue a drug certification described in subparagraph (A) only after conducting a drug safety and quality audit and such other activities that may be necessary to establish compliance with the provisions of section 501.

''(ii) PROVISION OF CERTIFICATION.—Only an accredited third-party auditor or the Secretary may provide a drug certification described in subparagraph (A).

''(C) RECORDS.—Following any accreditation of a third-party auditor, the Secretary may, at any time, require the accredited third-party auditor or any audit agent of such auditor to submit to the Secretary a drug safety and quality audit report and such other reports or documents required as part of the drug safety and quality audit process, for any eligible entity for which the accredited third-party auditor or audit agent of such auditor performed a drug safety and quality audit. The Secretary may require documentation that the eligible entity is in compliance with any applicable registration requirements.

''(D) LIMITATION.—The requirement under subparagraph (C) shall not include any report or other documents resulting from a consultative audit, except that the Secretary may access the results of a consultative audit in accordance with section 704.

''(E) DECLARATION OF AUDIT TYPE.—Before an accredited third-party auditor begins any audit or provides any consultative service to an eligible entity, both the accredited third-party auditor and eligible entity shall establish in writing whether the audit is intended to be a drug safety and quality audit. Any audit, inspection, or consultative service of any type provided by an accredited third-party auditor on behalf of an eligible entity shall be presumed to be a drug safety and quality audit in the absence of such a written agreement. Once a drug safety and quality audit is initiated, it shall be subject to the requirements of this section, and no person may withhold from the Secretary any document subject to subparagraph (C) on the grounds that the audit was a consultative audit or otherwise not a drug safety and quality audit.

''(F) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary under section 704.

''(6) REQUIREMENTS REGARDING SERIOUS RISKS TO THE PUBLIC HEALTH.—If, at any time during a drug safety and quality audit, an accredited third-party auditor or an audit agent of such auditor discovers a condition that could cause or contribute to a serious risk to the public health, such auditor shall immediately notify the Secretary of—

''(A) the identity and location of the eligible entity subject to the drug safety and quality audit; and

''(B) such condition.

''(7) LIMITATIONS.—

''(A) IN GENERAL.—An audit agent of an accredited third-party auditor may not perform a drug safety and quality audit of an eligible entity if such audit agent has performed a drug safety and quality audit or consultative audit of such eligible entity during the previous 13-month period.

''(B) WAIVER.—The Secretary may waive the application of subparagraph (A) if the Secretary determines that there is insufficient access to accredited third-party auditors in a country or region or that the use of the same audit agent or accredited third-party auditor is otherwise necessary.

''(8) CONFLICTS OF INTEREST.—

''(A) ACCREDITATION BODIES.—A recognized accreditation body shall—

''(i) not be owned, managed, or controlled by any person that owns or operates a third-party auditor to be accredited by such body;

''(ii) in carrying out accreditation of third-party auditors under this section, have procedures to ensure against the use of any officer or employee of such body that has a financial conflict of interest regarding a third-party auditor to be accredited by such body; and

''(iii) annually make available to the Secretary disclosures of the extent to which such body and the officers and employees of such body have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

''(B) ACCREDITED THIRD-PARTY AUDITORS.—An accredited third-party auditor shall—

''(i) not be owned, managed, or controlled by any person that owns or operates an eligible entity to be certified by such auditor;

''(ii) in carrying out drug safety and quality audits of eligible entities under this section, have procedures to ensure against the use of any officer or employee of such auditor that has a financial conflict of interest regarding an eligible entity to be certified by such auditor; and

''(iii) annually make available to the Secretary disclosures of the extent to which such auditor and the officers and employees of such auditor have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

''(C) AUDIT AGENTS.—An audit agent shall—

''(i) not own or operate an eligible entity to be audited by such agent;

''(ii) in carrying out audits of eligible entities under this section, have procedures to ensure that such agent does not have a financial conflict of interest regarding an eligible entity to be audited by such agent; and

''(iii) annually make available to the Secretary disclosures of the extent to which such agent has maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

''(d) FALSE STATEMENTS.—Any statement or representation made—

''(1) by an employee or agent of an eligible entity to an accredited third-party auditor or audit agent; or

''(2) by an accreditation body, accredited third-party auditor, or audit agent of such auditor to the Secretary, shall be subject to section 1001 of title 18, United States Code.

''(e) MONITORING.—To ensure compliance with the requirements of this section, the Secretary—

''(1) shall periodically, or at least once every 4 years, reevaluate the accreditation bodies described in subsection (b)(1);

''(2) shall periodically, or at least once every 4 years, evaluate the performance of each accredited third-party auditor, through the review of regulatory audit reports by such auditors, the compliance history as available of eligible entities certified by such auditors, and any other measures deemed necessary by the Secretary;

''(3) may at any time, conduct an onsite audit of any eligible entity certified by an accredited third-party auditor, with or without the auditor present; and

''(4) shall take any other measures deemed necessary by the Secretary.

''(f) EFFECT OF AUDIT.—The results of a drug safety and quality audit by an accredited third-party auditor under this section—

''(1) may be used by the eligible entity—

''(A) as documentation of compliance with section 501(a)(2)(B) or section 801(r); and

''(B) for other purposes as determined appropriate by the Secretary; and

''(2) shall be used by the Secretary in establishing the risk-based inspection schedules under section 510(h).

''(g) COSTS.—

''(1) AUTHORIZED FEES OF SECRETARY.—The Secretary may assess fees on accreditation bodies and accredited third-party auditors in such an amount necessary to establish and administer the recognition and accreditation program under this section. The Secretary may require accredited third-party auditors and audit agents to reimburse the Food and Drug Administration for the work performed to carry out this section. The Secretary shall not generate surplus revenue from such a reimbursement mechanism. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to remain available until expended.

''(2) AUTHORIZED FEES FOR RECOGNIZED ACCREDITATION BODIES.—An accreditation body recognized by the Secretary under subsection (b) may assess a reasonable fee to accredit third-party auditors.

''(h) LIMITATIONS.—

''(1) NO EFFECT ON SECTION 704 INSPECTIONS.—The drug safety and quality audits performed under this section shall not be considered inspections under section 704.

''(2) NO EFFECT ON INSPECTION AUTHORITY.—Nothing in this section affects the authority of the Secretary to inspect any eligible entity pursuant to this Act.

''(i) REGULATIONS.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this section.

''(2) PROCEDURE.—In promulgating the regulations implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the effective date of the regulation.

''(3) CONTENT.—Such regulations shall include—

''(A) requirements that, to the extent practicable, drug safety and quality audits performed under this section be unannounced;

''(B) a structure to decrease the potential for conflicts of interest, including timing and public disclosure, for fees paid by eligible entities to accredited third-party auditors; and

''(C) appropriate limits on financial affiliations between an accredited third-party auditor or audit agents of such auditor and any person that owns or operates an eligible entity to be audited by such auditor, as described in subparagraphs (A) and (B).

''(4) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2).''.

(b) REPORT ON ACCREDITED THIRD-PARTY AUDITORS.—Not later than January 20, 2017, the Comptroller General of the United States shall submit to Congress a report that addresses the following, with respect to the period beginning on the date of implementation of section 809 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) and ending on the date of such report:

(1) The extent to which drug safety and quality audits completed by accredited third-party auditors under such section 809 are being used by the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') in establishing or applying the risk-based inspection schedules under section 510(h) of such Act (as amended by section 705).

(2) The extent to which drug safety and quality audits completed by accredited third-party auditors or agents are assisting the Food and Drug Administration in evaluating compliance with sections 501(a)(2)(B) of such Act (21 U.S.C. 351(a)(2)(B)) and 801(r) of such Act (as added by section 711).

(3) Whether the Secretary has been able to access drug safety and quality audit reports completed by accredited third-party auditors under such section 809.

(4) Whether accredited third-party auditors accredited under such section 809 have adhered to the conflict of interest provisions set forth in such section.

(5) The extent to which the Secretary has audited recognized accreditation bodies or accredited third-party auditors to ensure compliance with the requirements of such section 809.

(6) The number of waivers under subsection (c)(7)(B) of such section 809 issued during the most recent 12-month period and the official justification by the Secretary for each determination that there was insufficient access to an accredited third-party auditor.

(7) The number of times a manufacturer has used the same accredited third-party auditor for 2 or more consecutive drug safety and quality audits under such section 809.

(8) Recommendations to Congress regarding the accreditation program under such section 809, including whether Congress should continue, modify, or terminate the program.

SEC. 711. STANDARDS FOR ADMISSION OF IMPORTED DRUGS.

Section 801 (21 U.S.C. 381) is amended—

(1) in subsection (o), by striking ''drug or''; and

(2) by adding at the end the following:

''(r)(1) The Secretary may require, as a condition of granting admission to a drug imported or offered for import into the United States, that the importer electronically submit information demonstrating that the drug complies with applicable requirements of this Act.

''(2) The information described under paragraph (1) may include—

''(A) information demonstrating the regulatory status of the drug, such as the new drug application, abbreviated new drug application, or investigational new drug or drug master file number;

''(B) facility information, such as proof of registration and the unique facility identifier;

''(C) indication of compliance with current good manufacturing practice, testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations; and

''(D) any other information deemed necessary and appropriate by the Secretary to assess compliance of the article being offered for import.

''(3) Information requirements referred to in paragraph (2)(C) may, at the discretion of the Secretary, be satisfied—

''(A) by certifications from accredited third parties, as described under section 809;

''(B) through representation by a foreign government, if such inspection is conducted using standards and practices as determined appropriate by the Secretary; or

''(C) other appropriate documentation or evidence as described by the Secretary.

''(4)(A) Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this subsection. Such requirements shall be appropriate for the type of import, such as whether the drug is for import into the United States for use in preclinical research or in a clinical investigation under an investigational new drug exemption under 505(i).

''(B) In promulgating the regulations implementing this subsection, the Secretary shall—

''(i) issue a notice of proposed rulemaking that includes the proposed regulation;

''(ii) provide a period of not less than 60 days for comments on the proposed regulation; and

''(iii) publish the final regulation not less than 30 days before the effective date of the regulation.

''(C) Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this subsection only as described in subparagraph (B).''.

SEC. 712. NOTIFICATION.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(aaa) The failure to notify the Secretary in violation of section 568.''.

(b) NOTIFICATION.—

(1) IN GENERAL.—Subchapter E of chapter V (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

''SEC. 568. NOTIFICATION.

''(a) NOTIFICATION TO SECRETARY.—With respect to a drug, the Secretary may require notification to the Secretary by a covered person if the covered person knows—

''(1) of a substantial loss or theft of such drug; or

''(2) that such drug—

''(A) has been or is being counterfeited; and

''(B)(i) is a counterfeit product in commerce in the United States; or

''(ii) is offered for import into the United States.

''(b) MANNER OF NOTIFICATION.—Notification under this section shall be made in a reasonable time, in such reasonable manner, and by such reasonable means as the Secretary may require by regulation or specify in guidance.

''(c) DEFINITION.—In this section, the term 'covered person' means—

''(1) a person who is required to register under section 510 with respect to an establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug; or

''(2) a person engaged in the wholesale distribution (as defined in section 503(e)(3)(B)) of a drug.''.

(2) APPLICABILITY.—Notifications under section 568 of the Federal Food, Drug, and Cosmetic Act (as added by paragraph (1)) apply to losses, thefts, or counterfeiting, as described in subsection (a) of such section 568, that occur on or after the date of enactment of this Act.

SEC. 713. PROTECTION AGAINST INTENTIONAL ADULTERATION.

Section 303(b) (21 U.S.C. 333(b)) is amended by adding at the end the following:

''(7) Notwithstanding subsection (a)(2), any person that knowingly and intentionally adulterates a drug such that the drug is adulterated under subsection (a)(1), (b), (c), or (d) of section 501 and has a reasonable probability of causing serious adverse health consequences or death to humans or animals shall be imprisoned for not more than 20 years or fined not more than $1,000,000, or both.''.

SEC. 714. ENHANCED CRIMINAL PENALTY FOR COUNTERFEITING DRUGS.

(a) FFDCA.—Section 303(b) (21 U.S.C. 333(b)), as amended by section 713, is further amended by adding at the end the following:

''(8) Notwithstanding subsection (a)(2), any person who knowingly and intentionally violates section 301(i) shall be imprisoned for not more than 20 years or fined not more than $4,000,000 or both.''.

(b) TITLE 18.—Section 2320(b) of title 18, United States Code, is amended—

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

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

''(2) COUNTERFEIT DRUGS.—

''(A) IN GENERAL.—Whoever commits an offense under subsection (a) with respect to a drug (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) shall—

''(i) if an individual, be fined not more than $4,000,000, imprisoned not more than 20 years, or both; and

''(ii) if a person other than an individual, be fined not more than $10,000,000.

''(B) MULTIPLE OFFENSES.—In the case of an offense by a person under this paragraph that occurs after that person is convicted of another offense under this paragraph, the person convicted—

''(i) if an individual, shall be fined not more than $8,000,000, imprisoned not more than 20 years, or both; and

''(ii) if other than an individual, shall be fined not more than $20,000,000.''.

(c) SENTENCING.—

(1) DIRECTIVE TO SENTENCING COMMISSION.—Pursuant to its authority under section 994(p) of title 28, United States Code, and in accordance with this section, the United States Sentencing Commission shall review and amend, if appropriate, its guidelines and its policy statements applicable to persons convicted of an offense described in section 2320(b)(2) of title 18, United States Code, as amended by subsection (b), in order to reflect the intent of Congress that such penalties be increased in comparison to those currently provided by the guidelines and policy statements.

(2) REQUIREMENTS.—In carrying out this subsection, the Commission shall—

(A) ensure that the sentencing guidelines and policy statements reflect the intent of Congress that the guidelines and policy statements reflect the serious nature of the offenses described in paragraph (1) and the need for an effective deterrent and appropriate punishment to prevent such offenses;

(B) consider the extent to which the guidelines may or may not appropriately account for the potential and actual harm to the public resulting from the offense;

(C) assure reasonable consistency with other relevant directives and with other sentencing guidelines;

(D) account for any additional aggravating or mitigating circumstances that might justify exceptions to the generally applicable sentencing ranges;

(E) make any necessary conforming changes to the sentencing guidelines; and

(F) assure that the guidelines adequately meet the purposes of sentencing as set forth in section 3553(a)(2) of title 18, United States Code.

SEC. 715. EXTRATERRITORIAL JURISDICTION.

Chapter III (21 U.S.C. 331 et seq.) is amended by adding at the end the following:

''SEC. 311. EXTRATERRITORIAL JURISDICTION.

''There is extraterritorial jurisdiction over any violation of this Act relating to any article regulated under this Act if such article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.''.

SEC. 716. COMPLIANCE WITH INTERNATIONAL AGREEMENTS.

Nothing in this title (or an amendment made by this title) shall be construed in a manner inconsistent with the obligations of the United States under the Agreement Establishing the World Trade Organization, or any other treaty or international agreement to which the United States is a party.

Subtitle B—Pharmaceutical Distribution Integrity

SEC. 721. SHORT TITLE.

This subtitle may be referred to as the ''Securing Pharmaceutical Distribution Integrity to Protect the Public Health Act of 2012'' or the ''Securing Pharmaceutical Distribution Integrity Act of 2012''.

SEC. 722. SECURING THE PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter H—Pharmaceutical Distribution Integrity

''SEC. 581. DEFINITIONS.

''In this subchapter:

''(1) DATA CARRIER.—The term 'data carrier' means a machine-readable graphic that is intended to be affixed to, or imprinted upon, an individual saleable unit and a homogeneous case of product. The data carrier shall comply with a form and format developed by a widely recognized international standards development organization to ensure interoperability among distribution chain participants.

''(2) INDIVIDUAL SALEABLE UNIT.—The term 'individual saleable unit' means the smallest container of product put into interstate commerce by the manufacturer that is intended by the manufacturer for individual sale to a pharmacy or other dispenser of such product.

''(3) PRODUCT.—The term 'product' means a finished drug subject to section 503(b)(1).

''(4) PRODUCT TRACING.—The term 'product tracing' means—

''(A) identifying the immediate previous source and immediate subsequent recipient of a product in wholesale distribution at the lot level where a change of ownership of such product has occurred between non-affiliated entities, except as otherwise described in this subchapter;

''(B) identifying the immediate subsequent recipient of the product at the lot level when a manufacturer or repackager introduces such product into interstate commerce;

''(C) identifying that manufacturer and dispenser of a product at the lot level when a manufacturer ships a product at the lot level, without regard to the change in ownership involving the wholesale distributor; and

''(D) identifying the immediate previous source of a product at the lot level for dispensers.

''(5) RXTEC.—The term 'RxTEC' means a data carrier that includes the standardized numerical identifier (SNI), the lot number, and the expiration date of a product. The standard data carrier RxTEC shall be a 2D data matrix barcode affixed to each individual saleable unit of a product and a linear or 2D data matrix barcode on a homogenous case of a product. Such information shall be both machine readable and human readable.

''(6) SUSPECT PRODUCT.—The term 'suspect product' means a product that, based on credible evidence—

''(A) is potentially counterfeit, diverted, or stolen;

''(B) is reasonably likely to be intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; or

''(C) appears otherwise unfit for distribution such that the product would result in serious adverse health consequence or death to humans.

''(7) VERIFICATION.—The term 'verification' means the process of determining whether a product has the standardized numerical identifier or lot number, consistent with section 582, and expiration date assigned by the manufacturer, or the repackager as applicable, and identifying whether a product has the appearance of being a counterfeit, diverted, or stolen product, or a product otherwise unfit for distribution. Verification of the RxTEC data may occur by using either a human-readable, machine-readable, or other method such as through purchase records or invoices.

''SEC. 582. ENSURING THE SAFETY OF THE PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN THROUGH THE ESTABLISHMENT OF AN RXTEC SYSTEM.

''(a) MANUFACTURER REQUIREMENTS.—

''(1) PRODUCT TRACING.—A manufacturer, not later than 4½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) apply RxTEC to the individual saleable units and homogeneous case of all products intended to be introduced into interstate commerce;

''(B) maintain change of ownership and transaction information, including RxTEC data that associate unit and lot level data for each individual saleable unit of product and homogenous case introduced in interstate commerce; and

''(C) maintain, where a change of ownership has occurred between non-affiliated entities or, in the case of a return from the immediate previous source, change of ownership and transaction information relating to a product, including—

''(i) RxTEC data;

''(ii) the business name and address of the immediate previous source, if applicable, and the immediate subsequent recipient of the product;

''(iii) the proprietary or established name or names of the product;

''(iv) the National Drug Code number of the product;

''(v) container size;

''(vi) number of containers;

''(vii) the lot number or numbers of the product; and

''(viii) the date of the transaction;

''(D) provide the following change of ownership and trans action information to the

immediate subsequent recipient of such product—

''(i) the proprietary or established name or names of the product;

''(ii) the National Drug Code number of the product;

''(iii) container size;

''(iv) number of containers;

''(v) the lot number or numbers of the product; and

''(vi) a signed statement that the manufacturer did not knowingly and intentionally adulterate or knowingly and intentionally counterfeit such product; and

''(E) upon request by the Secretary, other appropriate Federal official, or State official, in the event of a recall or as determined necessary by the Secretary, or such other Federal or State official, to investigate a suspect product, provide in a reasonable time and in a reasonable manner—

''(i) RxTEC data by lot; and

''(ii) change of ownership and transaction information pursuant to subparagraphs (C) and (D) necessary to identify the immediate previous source or immediate subsequent recipient of such product, as applicable.

''(2) VERIFICATION REQUIREMENTS.—A manufacturer, not later than 4½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) utilize RxTEC data at the lot level, as part of ongoing activities to significantly minimize or prevent the incidences of a suspect product in the pharmaceutical distribution supply chain, as applicable and appropriate, which—

''(i) may include responding to an alert regarding a suspect product from a trading partner or the Secretary, routine monitoring of a suspect product at the lot level while such product is in the possession of the manufacturer, and checking inventory for a suspect product at the request of a trading partner or the Secretary in case of returns; and

''(ii) shall take into consideration—

''(I) the likelihood that a particular product has a high potential risk with respect to pharmaceutical distribution supply chain security;

''(II) the history and severity of incidences of counterfeit, diversion, and theft of such product;

''(III) the point in the pharmaceutical distribution supply chain where counterfeit, diversion, or theft has occurred or is most likely to occur;

''(IV) the likelihood that such activities will reduce the possibility of the counterfeit, diversion, and theft of such product;

''(V) whether the product could mitigate or prevent a drug shortage as defined in section 506C; and

''(VI) any guidance the Secretary issues regarding high-risk scenarios that could increase the risk of a suspect product entering the pharmaceutical distribution supply chain; and

''(B) conduct unit level verification upon the request of a licensed or registered repackager, wholesale distributor, dispenser, or the Secretary, regarding such product.

''(3) NOTIFICATION OF PRODUCT REMOVAL.—

''(A) IN GENERAL.—Not later than 4½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a manufacturer, upon confirming that a product does not have the standardized numerical identifier or lot number, consistent with this section, and expiration date assigned by the manufacturer, or has the appearance of being a counterfeit, diverted, or stolen product, or a product otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans, shall—

''(i) promptly notify the Secretary and impacted trading partners, as applicable and appropriate; and

''(ii) take steps to remove such product from the pharmaceutical distribution supply chain.

''(B) REDISTRIBUTION.—Any product subject to a notification under this subsection may not be redistributed as a saleable product unless the manufacturer, in consultation with the Secretary, determines such product may reenter the pharmaceutical distribution supply chain.

''(4) LIMITATION.—Nothing in this section shall require a manufacturer to aggregate unit level data to cases or pallets.

''(b) REPACKAGER REQUIREMENTS.—

''(1) PRODUCT TRACING.—A repackager, not later than 5½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) apply RxTEC to the individual saleable unit and the homogenous case of all product intended to be introduced into interstate commerce;

''(B) maintain change of ownership and transaction information, including RxTEC data, that associate unit and lot level data for each individual saleable unit of product and each homogenous case of product introduced in interstate commerce, including RxTEC data received for such products and for which a repackager applies a new RxTEC;

''(C) receive only products encoded with RxTEC data from a licensed or registered manufacturer or wholesaler;

''(D) maintain, where a change of ownership has occurred between non-affiliated entities in wholesale distribution, change of ownership and transaction information relating to a product, including—

''(i) RxTEC data;

''(ii) the business name and address of the immediate previous source and the immediate subsequent recipient of the product;

''(iii) the proprietary or established name or names of the product;

''(iv) the National Drug Code number of the product;

''(v) container size;

''(vi) number of containers;

''(vii) the lot number or numbers of the product; and

''(viii) the date of the transaction;

''(E) provide the following change of ownership and transaction information to the immediate subsequent recipient of such product—

''(i) the proprietary or established name or names of the product;

''(ii) the National Drug Code number of the product;

''(iii) container size;

''(iv) number of containers;

''(v) the lot number or numbers of the product; and

''(vi) a signed statement that the repackager—

''(I) is licensed or registered;

''(II) received the product from a manufacturer that is licensed or registered;

''(III) received a signed statement from the manufacturer of such product consistent with subsection (a)(1)(D)(vi); and

''(IV) did not knowingly and intentionally adulterate or knowingly and intentionally counterfeit such product; and

''(F) upon request by the Secretary, other appropriate Federal official, or State official, in the event of a recall, or as determined necessary by the Secretary or such other Federal or State official to investigate a suspect product, provide in a reasonable time and in a reasonable manner—

''(i) RxTEC data by lot; and

''(ii) change of ownership and transaction information pursuant to subparagraph (C) or (E) necessary to identify the immediate previous source or the immediate subsequent recipient of such product, as applicable.

''(2) VERIFICATION REQUIREMENTS.—A repackager, not later than 5½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) utilize RxTEC data at the lot level, as part of ongoing activities to significantly minimize or prevent the incidences of suspect product in the pharmaceutical distribution supply chain, as applicable and appropriate, which—

''(i) may include—

''(I) responding to alerts regarding a suspect product from a trading partner or the Secretary, routine monitoring of a suspect product at the lot level while such product is in the possession of the repackager; and

''(II) checking inventory for a suspect product at the request of a trading partner or the Secretary in the case of returns; and

''(ii) shall take into consideration—

''(I) the likelihood that a particular product has a high potential risk with respect to pharmaceutical distribution supply chain security;

''(II) the history and severity of incidences of counterfeit, diversion, and theft of such product;

''(III) the point in the pharmaceutical distribution supply chain where counterfeit, diversion, and theft has occurred or is most likely to occur;

''(IV) the likelihood that such activities will reduce the possibility of counterfeit, diversion, and theft of such product;

''(V) whether the product could mitigate or prevent a drug shortage as defined in section 506C; and

''(VI) any guidance the Secretary issues regarding high-risk scenarios that could increase the risk of a suspect product entering the pharmaceutical distribution supply chain; and

''(B) conduct unit level verification upon the request of a licensed or registered manufacturer, wholesale distributor, dispenser, or the Secretary, regarding such product.

''(3) NOTIFICATION AND PRODUCT REMOVAL.—

''(A) IN GENERAL.—Not later than 5½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a repackager, upon confirming that a product does not have the standardized numerical identifier or lot number, consistent with this section, and expiration date assigned by the manufacturer, or has the appearance of being a counterfeit, diverted, or stolen product, or a product otherwise unfit for distribution such that it would result in serious adverse health consequences or death to humans, shall—

''(i) promptly notify the Secretary and impacted trading partners, as applicable and appropriate; and

''(ii) take steps to remove such product from the pharmaceutical distribution supply chain.

''(B) REDISTRIBUTION.—Any product subject to a notification under this subsection may not be redistributed as a saleable product unless the repackager, in consultation with the Secretary, and manufacturer as applicable, determines such product may reenter the pharmaceutical distribution supply chain.

''(4) LIMITATION.—Nothing in this section shall require a repackager to aggregate unit level data to cases or pallets.

''(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

''(1) PRODUCT TRACING REQUIREMENTS.—A wholesale distributor engaged in wholesale distribution, not later than 6½ years after

the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) receive only products encoded with RxTEC from a licensed or registered manufacturer, wholesaler, or repackager;

''(B) maintain, in wholesale distribution where a change of ownership has occurred between non-affiliated entities, change of ownership and transaction information, including—

''(i) RxTEC data by lot;

''(ii) the business name and address of the immediate previous source and the immediate subsequent recipient of the product;

''(iii) the proprietary or established name or names of the product;

''(iv) the National Drug Code number of the product;

''(v) container size;

''(vi) number of containers;

''(vii) the lot number or numbers of the product; and

''(viii) the date of the transaction;

''(C) provide the following change of ownership and transaction information to the immediate subsequent recipient of such product—

''(i) the proprietary or established name or names of the product;

''(ii) the National Drug Code number of the product;

''(iii) container size;

''(iv) number of containers;

''(v) the lot number or numbers of the product;

''(vi) the date of the transaction; and

''(vii) a signed statement that the wholesale distributor—

''(I) is licensed or registered;

''(II) received the product from a registered or licensed manufacturer, repackager, or wholesale distributor, as applicable;

''(III) received a signed statement from the immediate subsequent recipient of such product that such trading partner did not knowingly and intentionally adulterate or knowingly and intentionally counterfeit such product; and

''(IV) did not knowingly and intentionally adulterate or knowingly and intentionally counterfeit such product; and

''(D) upon request by the Secretary, other appropriate Federal official, or State official, in the event of a recall, return, or as determined necessary by the Secretary, or such other Federal or State official, to investigate a suspect product, provide in a reasonable time and in a reasonable manner—

''(i) RxTEC data by lot; and

''(ii) change of ownership and transaction information pursuant to subparagraphs (B) and (C), as necessary to identify the immediate previous source or the immediate subsequent recipient of such product.

''(2) VERIFICATION REQUIREMENTS.—

''(A) IN GENERAL.—A wholesale distributor engaged in wholesale distribution, not later than 6½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(i) utilize RxTEC data at the lot level, as part of ongoing activities to significantly minimize or prevent the incidence of suspect product in the pharmaceutical distribution supply chain, as applicable and appropriate, which—

''(I) may include responding to an alert regarding a suspect product from a trading partner or the Secretary, routine monitoring of a suspect product at the lot level while such product is in the possession of the wholesale distributor, and checking inventory for a suspect product at the request of a trading partner or the Secretary; and

''(II) shall take into consideration—

''(aa) the likelihood that a particular product has a high potential risk with respect to pharmaceutical distribution supply chain security;

''(bb) the history and severity of incidences of counterfeit, diversion, and theft of such product;

''(cc) the point in the pharmaceutical distribution supply chain where counterfeit, diversion, and theft has occurred or is most likely to occur;

''(dd) the likelihood that such activities will reduce the possibility of counterfeit, diversion, and theft of such product;

''(ee) whether the product could mitigate or prevent a drug shortage as defined in section 506C; and

''(ff) any guidance the Secretary issues regarding high-risk scenarios that could increase the risk of suspect product entering the pharmaceutical distribution supply chain;

''(ii) conduct lot-level verification in the event of a recall, including upon the request of a licensed or registered manufacturer, repackager, dispenser, or the Secretary, regarding such product and recall;

''(iii) conduct verification of a returned product to validate the return at the lot level for a sealed homogenous case of such product or at the individual saleable unit of such product if the unit is not in a sealed homogenous case; and

''(iv) conduct unit level verification of a suspect product—

''(I) upon the request of a licensed or registered manufacturer, repackager, wholesaler, dispenser, or the Secretary, regarding such product; or

''(II) upon the determination that a product is a suspect product.

''(B) LIMITATION.—Nothing in this paragraph shall require a wholesale distributor to verify product at the unit level except as required under clauses (iii) and (iv) of subparagraph (A).

''(3) NOTIFICATION AND PRODUCT REMOVAL.—

''(A) IN GENERAL.—Not later than 6½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a wholesale distributor, upon confirming that a product does not have the standardized numerical identifier or lot number, consistent with this section, and expiration date assigned by the manufacturer, or has the appearance of being a counterfeit, diverted, or stolen product, or a product otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans, shall—

''(i) promptly notify the Secretary and impacted trading partners, as applicable and appropriate; and

''(ii) take steps to remove such product from the pharmaceutical distribution supply chain.

''(B) REDISTRIBUTION.—Any product subject to a notification under this subsection may not be redistributed as a saleable product unless the wholesaler, in consultation with the Secretary, and manufacturer or repackager as applicable, determines such product may reenter the pharmaceutical distribution supply chain.

''(C) CONFIDENTIAL DATA.—A wholesale distributor may confidentially maintain RxTEC data for a direct trading partner and provide access to such information to such trading partner in lieu of data transmission, if mutually agreed upon by such trading partners.

''(d) DISPENSER REQUIREMENTS.—

''(1) PRODUCT TRACING REQUIREMENTS.—A dispenser, not later than 7½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) receive product only from a licensed or registered manufacturer, repackager, or wholesale distributor;

''(B) receive only products encoded with RxTEC lot level data from a manufacturer, repackager, or wholesale distributor selling the drug product to the dispenser;

''(C) maintain RxTEC lot level data or allow the wholesale distributor to confidentially maintain and store the RxTEC lot level data sufficient to identify the product provided to the dispenser from the immediate previous source where a change of ownership has occurred between non-affiliated entities (if such arrangement is mutually agreed upon by the dispenser and the wholesale distributor);

''(D) use the RxTEC lot level data maintained by the dispenser or maintained by the wholesale distributor on behalf of the dispenser (if such arrangement is mutually agreed upon by the dispenser and the wholesale distributor), as necessary to respond to a request from the Secretary in the event of a suspect product or recall;

''(E) maintain lot level data upon change of ownership between non-affiliated entities and for recalled product; and

''(F) for investigation purposes only, and upon request by the Secretary, other appropriate Federal official, or State official, for the purpose of investigating a suspect or recalled product, provide the RxTEC data by lot and the immediate previous source or immediate subsequent receipt of the suspect or recalled product, as applicable.

''(2) VERIFICATION REQUIREMENTS.—Not later than 7½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a dispenser shall be required to conduct lot level verification of suspect product only.

''(3) NOTIFICATION AND PRODUCT REMOVAL.—

''(A) IN GENERAL.—Not later than 7½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a dispenser, upon confirming that a product is a suspect product or a product otherwise unfit for distribution, shall—

''(i) promptly notify the Secretary and impacted trading partners, as applicable and appropriate; and

''(ii) take steps to remove such product from the pharmaceutical distribution supply chain.

''(B) REDISTRIBUTION.—Any product subject to a notification under this paragraph may not be redistributed as a saleable product unless the dispenser, in consultation with the Secretary, and manufacturer, repackager, or wholesaler as applicable, determines such product may reenter the pharmaceutical distribution supply chain.

''(C) LIMITATIONS.—Nothing in this section shall—

''(i) require a dispenser to verify product at the unit level; or

''(ii) require a dispenser to adopt specific technologies or business systems for compliance with this section.

''(e) ENSURING FLEXIBILITY.—The requirements under this section shall—

''(1) require the maintenance and transmission only of information that is reasonably available and appropriate;

''(2) be based on current scientific and technological capabilities and shall neither require nor restrict the use of additional data carrier technologies;

''(3) not prescribe or proscribe specific technologies or systems for the maintenance and transmission of data other than the standard data carrier for RxTEC or specific methods of verification;

''(4) not require a record of the complete previous distribution history of the drug from the point of origin of such drug;

''(5) take into consideration whether the public health benefits of imposing any additional regulations outweigh the cost of compliance with such requirements;

''(6) be scale-appropriate and practicable for entities of varying sizes and capabilities;

''(7) with respect to cost and recordkeeping burdens, not require the creation and maintenance of duplicative records where the information is contained in other company records kept in the normal course of business;

''(8) to the extent practicable, not require specific business systems for compliance with such requirements;

''(9) include a process by which the Secretary may issue a waiver of such regulations for an individual entity if the Secretary determines that such requirements would result in an economic hardship or for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act; and

''(10) include a process by which the Secretary may determine exceptions to the standard data carrier RxTEC requirement if a drug is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with this section.

''(f) REGULATIONS AND GUIDANCE.—

''(1) IN GENERAL.—The Secretary may issue guidance consistent with this section regarding the circumstances surrounding suspect product and verification practices.

''(2) PROCEDURE.—The Secretary, in promulgating any regulation pursuant to this section, shall—

''(A) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the effective date of the regulation.

''(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2).

''(g) STANDARDS.—The Secretary shall, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale distributors, dispensers, and other supply chain stakeholders, prioritize and develop standards for the interoperable exchange of ownership and transaction information for tracking and tracing prescription drugs.''.

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by section 712, is further amended by inserting at the end the following:

''(bbb) The violation of any requirement under section 582.''.

(c) SMALL ENTITY COMPLIANCE GUIDE.—Not later than 180 days after enactment of this Act, the Secretary of Health and Human Services (referred to in this title as the ''Secretary'') shall issue a compliance guide setting forth in plain language the requirements under section 582 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), in order to assist small entities in complying with such section.

(d) LIMITATIONS.—

(1) SAVINGS CLAUSE.—Nothing in this subtitle or the amendments made by this subtitle shall preempt any State or local law or regulation.

(2) EFFECT ON CALIFORNIA LAW.—Notwithstanding any other provision of Federal or State law, including any provision of this subtitle or of subchapter H of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), such subchapter H shall not trigger California Business and Professions Code, section 4034.1.

(3) EFFECTIVE DATE.—Subsection (c) and the amendments made by subsections (a) and (b) shall take effect on January 1, 2022, or on the date on which Congress enacts a law providing for express preemption of any State law regulating the distribution of drugs, whichever is later.

SEC. 723. INDEPENDENT ASSESSMENT.

(a) IN GENERAL.—The Secretary shall contract with a private, independent consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to conduct a comprehensive assessment of the process for the review of drug applications under subsections (b) and (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b), (j)) and subsections (a) and (k) of section 351 of the Public Health Service Act (42 U.S.C. 262(a), (k)). The assessment shall address the premarket review process of drugs by the Food and Drug Administration, using an assessment framework that draws from appropriate quality system standards, including management responsibility, documents controls and records management, and corrective and preventive action.

(b) PARTICIPATION.—Representatives of the Food and Drug Administration and manufacturers of drugs subject to user fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.) shall participate in a comprehensive assessment of the process for the review of drug applications under section 505 of the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act. The assessment shall be conducted in phases.

(c) FIRST CONTRACT.—The Secretary shall award the contract for the first assessment under this section not later than March 31, 2013. Such contractor shall evaluate the implementation of recommendations and publish a written assessment not later than February 1, 2016.

(d) FINDINGS AND RECOMMENDATIONS.—

(1) IN GENERAL.—The Secretary shall publish the findings and recommendations under this section that are likely to have a significant impact on review times not later than 6 months after the contract is awarded. Final comprehensive findings and recommendations shall be published not later than 1 year after the contract is awarded.

(2) IMPLEMENTATION PLAN.—The Food and Drug Administration shall publish an implementation plan not later than 6 months after the date of receipt of each set of recommendation.

(e) SCOPE OF ASSESSMENT.—The assessment under this section shall include the following:

(1) Identification of process improvements and best practices for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards.

(2) Analysis of elements of the review process that consume or save time to facilitate a more efficient process. Such analysis shall include—

(A) consideration of root causes for inefficiencies that may affect review performance and total time to decision;

(B) recommended actions to correct any failures to meet user fee program goals; and

(C) consideration of the impact of combination products on the review process.

(3) Assessment of methods and controls of the Food and Drug Administration for collecting and reporting information on premarket review process resource use and performance.

(4) Assessment of effectiveness of the reviewer training program of the Food and Drug Administration.

(5) Recommendations for ongoing periodic assessments and any additional, more detailed or focused assessments.

(f) REQUIREMENTS.—The Secretary shall—

(1) analyze the recommendations for improvement opportunities identified in the assessment, develop and implement a corrective action plan, and ensure it effectiveness;

(2) incorporate the findings and recommendations of the contractors, as appropriate, into the management of the premarket review program of the Food and Drug Administration; and

(3) incorporate the results of the assessment in a Good Review Management Practices guidance document, which shall include initial and ongoing training of Food and Drug Administration staff, and periodic audits of compliance with the guidance.

TITLE VIII—GENERATING ANTIBIOTIC INCENTIVES NOW

SEC. 801. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 505D the following:

''SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS.

''(a) EXTENSION.—If the Secretary approves an application pursuant to section 505 for a drug that has been designated as a qualified infectious disease product under subsection (d), the 4- and 5-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, or the 7-year period described in section 527, as applicable, shall be extended by 5 years.

''(b) RELATION TO PEDIATRIC EXCLUSIVITY.—Any extension under subsection (a) of a period shall be in addition to any extension of the period under section 505A with respect to the drug.

''(c) LIMITATIONS.—Subsection (a) does not apply to the approval of—

''(1) a supplement to an application under section 505(b) for any qualified infectious disease product for which an extension described in subsection (a) is in effect or has expired;

''(2) a subsequent application filed with respect to a product approved under section 505 for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

''(3) an application for a product that is not approved for the use for which it received a designation under subsection (d).

''(d) DESIGNATION.—

''(1) IN GENERAL.—The manufacturer or sponsor of a drug may request the Secretary to designate a drug as a qualified infectious disease product at any time before the submission of an application under section 505(b) for such drug. The Secretary shall, not later than 60 days after the submission of such a request, determine whether the drug is a qualified infectious disease product.

''(2) LIMITATION.—Except as provided in paragraph (3), a designation under this subsection shall not be withdrawn for any reason, including modifications to the list of qualifying pathogens under subsection (f)(2)(C).

''(3) REVOCATION OF DESIGNATION.—The Secretary may revoke a designation of a drug as a qualified infectious disease product if the

Secretary finds that the request for such designation contained an untrue statement of material fact.

''(e) REGULATIONS.—

''(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this section.

''(2) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the effective date of the regulation.

''(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2), except that the Secretary may issue interim guidance for sponsors seeking designation under subsection (d) prior to the promulgation of such regulations.

''(4) DESIGNATION PRIOR TO REGULATIONS.—The Secretary may designate drugs as qualified infectious disease products under subsection (d) prior to the promulgation of regulations under this subsection.

''(f) QUALIFYING PATHOGEN.—

''(1) DEFINITION.—In this section, the term 'qualifying pathogen' means a pathogen identified and listed by the Secretary under paragraph (2) that has the potential to pose a serious threat to public health, such as—

''(A) resistant gram positive pathogens, including methicillin-resistant Staphylococcus aureus, vancomycin-resistant Staphylococcus aureus, and vancomycin-resistant enterococcus;

''(B) multi-drug resistant gram negative bacteria, including Acinetobacter, Klebsiella, Pseudomonas, and E. coli species;

''(C) multi-drug resistant tuberculosis; and

''(D) Clostridium difficile.

''(2) LIST OF QUALIFYING PATHOGENS.—

''(A) IN GENERAL.—The Secretary shall establish and maintain a list of qualifying pathogens, and shall make public the methodology for developing such list.

''(B) CONSIDERATIONS.—In establishing and maintaining the list of pathogens described under this section the Secretary shall—

''(i) consider—

''(I) the impact on the public health due to drug-resistant organisms in humans;

''(II) the rate of growth of drug-resistant organisms in humans;

''(III) the increase in resistance rates in humans; and

''(IV) the morbidity and mortality in humans; and

''(ii) consult with experts in infectious diseases and antibiotic resistance, including the Centers for Disease Control and Prevention, the Food and Drug Administration, medical professionals, and the clinical research community.

''(C) REVIEW.—Every 5 years, or more often as needed, the Secretary shall review, provide modifications to, and publish the list of qualifying pathogens under subparagraph (A) and shall by regulation revise the list as necessary, in accordance with subsection (e).

''(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term 'qualified infectious disease product' means an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by—

''(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

''(2) qualifying pathogens listed by the Secretary under subsection (f).''.

(b) APPLICATION.—Section 505E of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to a drug that is first approved under section 505(c) of such Act (21 U.S.C. 355(c)) on or after the date of the enactment of this Act.

SEC. 802. PRIORITY REVIEW.

(a) AMENDMENT.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 524 the following:

''SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.

''If the Secretary designates a drug under section 505E(d) as a qualified infectious disease product, then the Secretary shall give priority review to any application submitted for approval for such drug under section 505(b).''.

(b) APPLICATION.—Section 524A of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to an application that is submitted under section 505(b) of such Act (21 U.S.C. 355(b)) on or after the date of the enactment of this Act.

SEC. 803. FAST TRACK PRODUCT.

Section 506(a)(1) (21 U.S.C. 356(a)(1)), as amended by section 901(b), is amended by inserting '', or if the Secretary designates the drug as a qualified infectious disease product under section 505E(d)'' before the period at the end of the first sentence.

SEC. 804. GAO STUDY.

(a) IN GENERAL.—The Comptroller General of the United States shall—

(1) conduct a study—

(A) on the need for, and public health impact of, incentives to encourage the research, development, and marketing of qualified infectious disease biological products and antifungal products; and

(B) consistent with trade and confidentiality data protections, assessing, for all antibacterial and antifungal drugs, including biological products, the average or aggregate—

(i) costs of all clinical trials for each phase;

(ii) percentage of success or failure at each phase of clinical trials; and

(iii) public versus private funding levels of the trials for each phase; and

(2) not later than 1 year after the date of enactment of this Act, submit a report to Congress on the results of such study, including any recommendations of the Comptroller General on appropriate incentives for addressing such need.

(b) CONTENTS.—The part of the study described in subsection (a)(1)(A) shall include—

(1) an assessment of any underlying regulatory issues related to qualified infectious disease products, including qualified infectious disease biological products;

(2) an assessment of the management by the Food and Drug Administration of the review of qualified infectious disease products, including qualified infectious disease biological products and the regulatory certainty of related regulatory pathways for such products;

(3) a description of any regulatory impediments to the clinical development of new qualified infectious disease products, including qualified infectious disease biological products, and the efforts of the Food and Drug Administration to address such impediments; and

(4) recommendations with respect to—

(A) improving the review and predictability of regulatory pathways for such products; and

(B) overcoming any regulatory impediments identified in paragraph (3).

(c) DEFINITIONS.—In this section:

(1) The term ''biological product'' has the meaning given to such term in section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) The term ''qualified infectious disease biological product'' means a biological product intended to treat a serious or life-threatening infection described in section 505E(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 801.

(3) The term ''qualified infectious disease product'' has the meaning given such term in section 505E(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 801.

SEC. 805. CLINICAL TRIALS.

(a) REVIEW AND REVISION OF GUIDANCE DOCUMENTS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall review and, as appropriate, revise not fewer than 3 guidance documents per year, which shall include—

(A) reviewing the guidance documents of the Food and Drug Administration for the conduct of clinical trials with respect to antibacterial and antifungal drugs; and

(B) as appropriate, revising such guidance documents to reflect developments in scientific and medical information and technology and to ensure clarity regarding the procedures and requirements for approval of antibacterial and antifungal drugs under chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.).

(2) ISSUES FOR REVIEW.—At a minimum, the review under paragraph (1) shall address the appropriate animal models of infection, in vitro techniques, valid micro-biological surrogate markers, the use of non-inferiority versus superiority trials, trial enrollment, data requirements, and appropriate delta values for non-inferiority trials.

(3) RULE OF CONSTRUCTION.—Except to the extent to which the Secretary makes revisions under paragraph (1)(B), nothing in this section shall be construed to repeal or otherwise effect the guidance documents of the Food and Drug Administration.

(b) RECOMMENDATIONS FOR INVESTIGATIONS.—

(1) REQUEST.—The sponsor of a drug intended to be designated as a qualified infectious disease product may request that the Secretary provide written recommendations for nonclinical and clinical investigations which the Secretary believes may be necessary to be conducted with the drug before such drug may be approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in treating, detecting, preventing, or identifying a qualifying pathogen, as defined in section 505E of such Act.

(2) RECOMMENDATIONS.—If the Secretary has reason to believe that a drug for which a request is made under this subsection is a qualified infectious disease product, the Secretary shall provide the person making the request written recommendations for the nonclinical and clinical investigations which the Secretary believes, on the basis of information available to the Secretary at the time of the request, would be necessary for approval under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) of such drug for the use described in paragraph (1).

(c) GAO STUDY.—Not later than January 1, 2016, the Comptroller General of the United States shall submit to Congress a report—

(1) regarding the review and revision of the clinical trial guidance documents required under subsection (a) and the impact such review and revision has had on the review and approval of qualified infectious disease products;

(2) assessing—

(A) the effectiveness of the results-oriented metrics managers employ to ensure that reviewers of such products are familiar with, and consistently applying, clinical trial guidance documents; and

(B) the predictability of related regulatory pathways and review;

(3) identifying any outstanding regulatory impediments to the clinical development of qualified infectious disease products;

(4) reporting on the progress the Food and Drug Administration has made in addressing the impediments identified under paragraph (3); and

(5) containing recommendations regarding how to improve the review of, and regulatory pathway for, such products.

(d) QUALIFIED INFECTIOUS DISEASE PRODUCT.—For purposes of this section, the term ''qualified infectious disease product'' has the meaning given such term in section 505E(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 801.

SEC. 806. REGULATORY CERTAINTY AND PREDICTABILITY.

(a) INITIAL STRATEGY AND IMPLEMENTATION PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall submit to Congress a strategy and implementation plan with respect to the requirements of this Act. The strategy and implementation plan shall include—

(1) a description of the regulatory challenges to clinical development, approval, and licensure of qualified infectious disease products;

(2) the regulatory and scientific priorities of the Secretary with respect to such challenges; and

(3) the steps the Secretary will take to ensure regulatory certainty and predictability with respect to qualified infectious disease products, including steps the Secretary will take to ensure managers and reviewers are familiar with related regulatory pathways, requirements of the Food and Drug Administration, guidance documents related to such products, and applying such requirements consistently.

(b) SUBSEQUENT REPORT.—Not later than 3 years after the date of enactment of this Act, the Secretary shall submit to Congress a report on—

(1) the progress made toward the priorities identified under subsection (a)(2);

(2) the number of qualified infectious disease products that have been submitted for approval or licensure on or after the date of enactment of this Act;

(3) a list of qualified infectious disease products with information on the types of exclusivity granted for each product, consistent with the information published under section 505(j)(7)(A)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)(A)(iii));

(4) the number of such qualified infectious disease products and that have been approved or licensed on or after the date of enactment of this Act; and

(5) the number of calendar days it took for the approval or licensure of the qualified infectious disease products approved or licensed on or after the date of enactment of this Act.

(c) QUALIFIED INFECTIOUS DISEASE PRODUCT.—For purposes of this section, the term ''qualified infectious disease product'' has the meaning given such term in section 505E(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 801.

TITLE IX—DRUG APPROVAL AND PATIENT ACCESS

SEC. 901. ENHANCEMENT OF ACCELERATED PATIENT ACCESS TO NEW MEDICAL TREATMENTS.

(a) FINDINGS; SENSE OF CONGRESS.—

(1) FINDINGS.—Congress finds as follows:

(A) The Food and Drug Administration (referred to in this section as the ''FDA'') serves a critical role in helping to assure that new medicines are safe and effective. Regulatory innovation is 1 element of the Nation's strategy to address serious and life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs.

(B) During the 2 decades following the establishment of the accelerated approval mechanism, advances in medical sciences, including genomics, molecular biology, and bioinformatics, have provided an unprecedented understanding of the underlying biological mechanism and pathogenesis of disease. A new generation of modern, targeted medicines is under development to treat serious and life-threatening diseases, some applying drug development strategies based on biomarkers or pharmacogenomics, predictive toxicology, clinical trial enrichment techniques, and novel clinical trial designs, such as adaptive clinical trials.

(C) As a result of these remarkable scientific and medical advances, the FDA should be encouraged to implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions, including those for rare diseases or conditions, using a broad range of surrogate or clinical endpoints and modern scientific tools earlier in the drug development cycle when appropriate. This may result in fewer, smaller, or shorter clinical trials for the intended patient population or targeted subpopulation without compromising or altering the high standards of the FDA for the approval of drugs.

(D) Patients benefit from expedited access to safe and effective innovative therapies to treat unmet medical needs for serious or life-threatening diseases or conditions.

(E) For these reasons, the statutory authority in effect on the day before the date of enactment of this Act governing expedited approval of drugs for serious or life-threatening diseases or conditions should be amended in order to enhance the authority of the FDA to consider appropriate scientific data, methods, and tools, and to expedite development and access to novel treatments for patients with a broad range of serious or life-threatening diseases or conditions.

(2) SENSE OF CONGRESS.—It is the sense of Congress that the Food and Drug Administration should apply the accelerated approval and fast track provisions set forth in section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), as amended by this section, to help expedite the development and availability to patients of treatments for serious or life-threatening diseases or conditions while maintaining safety and effectiveness standards for such treatments.

(b) EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.—Section 506 (21 U.S.C. 356) is amended to read as follows:

''SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

''(a) DESIGNATION OF DRUG AS FAST TRACK PRODUCT.—

''(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. (In this section, such a drug is referred to as a 'fast track product'.)

''(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

''(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

''(b) ACCELERATED APPROVAL OF A DRUG FOR A SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION, INCLUDING A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—

''(A) ACCELERATED APPROVAL.—The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product, under section 505(c) or section 351(a) of the Public Health Service Act upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. The approval described in the preceding sentence is referred to in this section as 'accelerated approval'.

''(B) EVIDENCE.—The evidence to support that an endpoint is reasonably likely to predict clinical benefit under subparagraph (A) may include epidemiological, pathophysiological, therapeutic, pharmacologic, or other evidence developed using biomarkers, for example, or other scientific methods or tools.

''(2) LIMITATION.—Approval of a product under this subsection may be subject to 1 or both of the following requirements:

''(A) That the sponsor conduct appropriate post-approval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

''(B) That the sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

''(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

''(A) the sponsor fails to conduct any required post-approval study of the drug with due diligence;

''(B) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the

product fails to verify and describe such effect or benefit;

''(C) other evidence demonstrates that the product is not safe or effective under the conditions of use; or

''(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

''(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

''(A) provides a schedule for submission of information necessary to make the application complete; and

''(B) pays any fee that may be required under section 736.

''(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

''(d) AWARENESS EFFORTS.—The Secretary shall—

''(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to accelerated approval and fast track products; and

''(2) establish a program to encourage the development of surrogate and clinical endpoints, including biomarkers, and other scientific methods and tools that can assist the Secretary in determining whether the evidence submitted in an application is reasonably likely to predict clinical benefit for serious or life-threatening conditions for which significant unmet medical needs exist.

''(e) CONSTRUCTION.—

''(1) PURPOSE.—The amendments made by the Food and Drug Administration Safety and Innovation Act to this section are intended to encourage the Secretary to utilize innovative and flexible approaches to the assessment of products under accelerated approval for treatments for patients with serious or life-threatening diseases or conditions and unmet medical needs.

''(2) CONSTRUCTION.—Nothing in this section shall be construed to alter the standards of evidence under subsection (c) or (d) of section 505 (including the substantial evidence standard in section 505(d)) of this Act or under section 351(a) of the Public Health Service Act. Such sections and standards of evidence apply to the review and approval of products under this section, including whether a product is safe and effective. Nothing in this section alters the ability of the Secretary to rely on evidence that does not come from adequate and well-controlled investigations for the purpose of determining whether an endpoint is reasonably likely to predict clinical benefit as described in subsection (b)(1)(B).''.

(c) GUIDANCE; AMENDED REGULATIONS.—

(1) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue draft guidance to implement the amendments made by this section. In developing such guidance, the Secretary shall specifically consider issues arising under the accelerated approval and fast track processes under section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), for drugs designated for a rare disease or condition under section 526 of such Act (21 U.S.C. 360bb) and shall also consider any unique issues associated with very rare diseases.

(2) FINAL GUIDANCE.—Not later than 1 year after the issuance of draft guidance under paragraph (1), and after an opportunity for public comment, the Secretary shall issue final guidance.

(3) CONFORMING CHANGES.—The Secretary shall issue, as necessary, conforming amendments to the applicable regulations under title 21, Code of Federal Regulations, governing accelerated approval.

(4) NO EFFECT OF INACTION ON REQUESTS.—If the Secretary fails to issue final guidance or amended regulations as required by this subsection, such failure shall not preclude the review of, or action on, a request for designation or an application for approval submitted pursuant to section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b).

(d) INDEPENDENT REVIEW.—The Secretary may, in conjunction with other planned reviews, contract with an independent entity with expertise in assessing the quality and efficiency of biopharmaceutical development and regulatory review programs to evaluate the Food and Drug Administration's application of the processes described in section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), and the impact of such processes on the development and timely availability of innovative treatments for patients suffering from serious or life-threatening conditions. Any such evaluation shall include consultation with regulated industries, patient advocacy and disease research foundations, and relevant academic medical centers.

SEC. 902. BREAKTHROUGH THERAPIES.

(a) IN GENERAL.—Section 506 (21 U.S.C. 356), as amended by section 901, is further amended—

(1) by redesignating subsections (a) through (c) as subsections (b) through (d), respectively;

(2) by redesignating subsection (d) as subsection (f);

(3) by inserting before subsection (b), as so redesignated, the following:

''(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH THERAPY.—

''(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of such drug if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. (In this section, such a drug is referred to as a 'breakthrough therapy'.)

''(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a breakthrough therapy. A request for the designation may be made concurrently with, or at any time after, the submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

''(3) DESIGNATION.—

''(A) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a breakthrough therapy and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

''(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

''(i) holding meetings with the sponsor and the review team throughout the development of the drug;

''(ii) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the non-clinical and clinical data necessary for approval is as efficient as practicable;

''(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

''(iv) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

''(v) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.'';

(4) in subsection (f)(1), as so redesignated, by striking ''applicable to accelerated approval'' and inserting ''applicable to breakthrough therapies, accelerated approval, and''; and

(5) by adding at the end the following:

''(g) REPORT.—Beginning in fiscal year 2013, the Secretary shall annually 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, and make publicly available, with respect to this section for the previous fiscal year—

''(1) the number of drugs for which a sponsor requested designation as a breakthrough therapy;

''(2) the number of products designated as a breakthrough therapy; and

''(3) for each product designated as a breakthrough therapy, a summary of the actions taken under subsection (a)(3).''.

(b) GUIDANCE; AMENDED REGULATIONS.—

(1) IN GENERAL.—

(A) GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue draft guidance on implementing the requirements with respect to breakthrough therapies, as set forth in section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)), as amended by this section. The Secretary shall issue final guidance not later than 1 year after the close of the comment period for the draft guidance.

(B) AMENDED REGULATIONS.—

(i) IN GENERAL.—If the Secretary determines that it is necessary to amend the regulations under title 21, Code of Federal Regulations in order to implement the amendments made by this section to section 506(a) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall amend such regulations not later than 2 years after the date of enactment of this Act.

(ii) PROCEDURE.—In amending regulations under clause (i), the Secretary shall—

(I) issue a notice of proposed rulemaking that includes the proposed regulation;

(II) provide a period of not less than 60 days for comments on the proposed regulation; and

(III) publish the final regulation not less than 30 days before the effective date of the regulation.

(iii) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing the amendments made by section only as described in clause (ii).

(2) REQUIREMENTS.—Guidance issued under this section shall—

(A) specify the process and criteria by which the Secretary makes a designation under section 506(a)(3) of the Federal Food, Drug, and Cosmetic Act; and

(B) specify the actions the Secretary shall take to expedite the development and review of a breakthrough therapy pursuant to such designation under such section 506(a)(3), including updating good review management practices to reflect breakthrough therapies.

(c) INDEPENDENT REVIEW.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States, in consultation with appropriate experts, shall assess the manner by which the Food and Drug Administration has applied the processes described in section 506(a) of the Federal Food, Drug, and Cosmetic Act, as amended by this section, and the impact of such processes on the development and timely availability of innovative treatments for patients affected by serious or life-threatening conditions. Such assessment shall be made publicly available upon completion.

(d) CONFORMING AMENDMENTS.—Section 506B(e) (21 U.S.C. 356b) is amended by striking ''section 506(b)(2)(A)'' each place such term appears and inserting ''section 506(c)(2)(A)''.

SEC. 903. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by section 712, is further amended by adding at the end the following:

''SEC. 569. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

''(a) IN GENERAL.—For the purpose of promoting the efficiency of and informing the review by the Food and Drug Administration of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, the following shall apply:

''(1) CONSULTATION WITH STAKEHOLDERS.—Consistent with sections X.C and IX.E.4 of the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, as referenced in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012, the Secretary shall ensure that opportunities exist, at a time the Secretary determines appropriate, for consultations with stakeholders on the topics described in subsection (c).

''(2) CONSULTATION WITH EXTERNAL EXPERTS.—The Secretary shall develop and maintain a list of external experts who, because of their special expertise, are qualified to provide advice on rare disease issues, including topics described in subsection (c). The Secretary may, when appropriate to address a specific regulatory question, consult such external experts on issues related to the review of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, including the topics described in subsection (c), when such consultation is necessary because the Secretary lacks specific scientific, medical, or technical expertise necessary for the performance of its regulatory responsibilities and the necessary expertise can be provided by the external experts.

''(b) EXTERNAL EXPERTS.—For purposes of subsection (a)(2), external experts are those who possess scientific or medical training that the Secretary lacks with respect to one or more rare diseases.

''(c) TOPICS FOR CONSULTATION.—Topics for consultation pursuant to this section may include—

''(1) rare diseases;

''(2) the severity of rare diseases;

''(3) the unmet medical need associated with rare diseases;

''(4) the willingness and ability of individuals with a rare disease to participate in clinical trials;

''(5) an assessment of the benefits and risks of therapies to treat rare diseases;

''(6) the general design of clinical trials for rare disease populations and subpopulations; and

''(7) demographics and the clinical description of patient populations.

''(d) CLASSIFICATION AS SPECIAL GOVERNMENT EMPLOYEES.—The external experts who are consulted under this section may be considered special government employees, as defined under section 202 of title 18, United States Code.

''(e) PROTECTION OF PROPRIETARY INFORMATION.—Nothing in this section shall be construed to alter the protections offered by laws, regulations, and policies governing disclosure of confidential commercial or trade secret information, and any other information exempt from disclosure pursuant to section 552(b) of title 5, United States Code, as such provisions would be applied to consultation with individuals and organizations prior to the date of enactment of this section.

''(f) OTHER CONSULTATION.—Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals and organizations as authorized prior to the date of enactment of this section.

''(g) NO RIGHT OR OBLIGATION.—Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder. Nothing in this section shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012. Nothing in this section is intended to increase the number of review cycles as in effect before the date of enactment of this section.''.

SEC. 904. ACCESSIBILITY OF INFORMATION ON PRESCRIPTION DRUG CONTAINER LABELS BY VISUALLY-IMPAIRED AND BLIND CONSUMERS.

(a) ESTABLISHMENT OF WORKING GROUP.—

(1) IN GENERAL.—The Architectural and Transportation Barriers Compliance Board (referred to in this section as the ''Access Board'') shall convene a stakeholder working group (referred to in this section as the ''working group'') to develop best practices on access to information on prescription drug container labels for individuals who are blind or visually impaired.

(2) MEMBERS.—The working group shall be comprised of representatives of national organizations representing blind and visually-impaired individuals, national organizations representing the elderly, and industry groups representing stakeholders, including retail, mail order, and independent community pharmacies, who would be impacted by such best practices. Representation within the working group shall be divided equally between consumer and industry advocates.

(3) BEST PRACTICES.—

(A) IN GENERAL.—The working group shall develop, not later than 1 year after the date of the enactment of this Act, best practices for pharmacies to ensure that blind and visually-impaired individuals have safe, consistent, reliable, and independent access to the information on prescription drug container labels.

(B) PUBLIC AVAILABILITY.—The best practices developed under subparagraph (A) may be made publicly available, including through the Internet websites of the working group participant organizations, and through other means, in a manner that provides access to interested individuals, including individuals with disabilities.

(C) LIMITATIONS.—The best practices developed under subparagraph (A) shall not be construed as accessibility guidelines or standards of the Access Board, and shall not confer any rights or impose any obligations on working group participants or other persons. Nothing in this section shall be construed to limit or condition any right, obligation, or remedy available under the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.) or any other Federal or State law requiring effective communication, barrier removal, or nondiscrimination on the basis of disability.

(4) CONSIDERATIONS.—In developing and issuing the best practices under paragraph (3)(A), the working group shall consider—

(A) the use of—

(i) Braille;

(ii) auditory means, such as—

(I) ''talking bottles'' that provide audible container label information;

(II) digital voice recorders attached to the prescription drug container; and

(III) radio frequency identification tags;

(iii) enhanced visual means, such as—

(I) large font labels or large font ''duplicate'' labels that are affixed or matched to a prescription drug container;

(II) high-contrast printing; and

(III) sans-serf font; and

(iv) other relevant alternatives as determined by the working group;

(B) whether there are technical, financial, manpower, or other factors unique to pharmacies with 20 or fewer retail locations which may pose significant challenges to the adoption of the best practices; and

(C) such other factors as the working group determines to be appropriate.

(5) INFORMATION CAMPAIGN.—Upon completion of development of the best practices under subsection (a)(3), the National Council on Disability, in consultation with the working group, shall conduct an informational and educational campaign designed to inform individuals with disabilities, pharmacists, and the public about such best practices.

(6) FACA WAIVER.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the working group.

(b) GAO STUDY.—

(1) IN GENERAL.—Beginning 18 months after the completion of the development of best practices under subsection (a)(3)(A), the Comptroller General of the United States shall conduct a review of the extent to which pharmacies are utilizing such best practices, and the extent to which barriers to accessible information on prescription drug container labels for blind and visually-impaired individuals continue.

(2) REPORT.—Not later than September 30, 2016, the Comptroller General of the United States shall submit to Congress a report on the review conducted under paragraph (1). Such report shall include recommendations about how best to reduce the barriers experienced by blind and visually-impaired individuals to independently accessing information on prescription drug container labels.

(c) DEFINITIONS.—In this section—

(1) the term ''pharmacy'' includes a pharmacy that receives prescriptions and dispenses prescription drugs through an Internet website or by mail;

(2) the term ''prescription drug'' means a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and

(3) the term ''prescription drug container label'' means the label with the directions for use that is affixed to the prescription drug container by the pharmacist and dispensed to the consumer.

SEC. 905. RISK-BENEFIT FRAMEWORK.

Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: ''The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for premarket approval of a drug.''.

SEC. 906. INDEPENDENT STUDY ON MEDICAL INNOVATION INDUCEMENT MODEL.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into an agreement with the National Academies to provide expert consultation and conduct a study that evaluates the feasibility and possible consequences of the use of innovation inducement prizes to reward successful medical innovations. Under the agreement, the National Academies shall submit to the Secretary a report on such study not later than 15 months after the date of enactment of this Act.

(b) REQUIREMENTS.—

(1) IN GENERAL.—The study conducted under subsection (a) shall model at least 3 separate segments on the medical technologies market as candidate targets for the new incentive system and consider different medical innovation inducement prize design issues, including the challenges presented in the implementation of prizes for end products, open source dividend prizes, and prizes for upstream research.

(2) MARKET SEGMENTS.—The segments on the medical technologies market that shall be considered under paragraph (1) include—

(A) all pharmaceutical and biologic drugs and vaccines;

(B) drugs and vaccines used solely for the treatment of HIV/AIDS; and

(C) antibiotics.

(c) ELEMENTS.—The study conducted under subsection (a) shall include consideration of each of the following:

(1) Whether a system of large innovation inducement prizes could work as a replacement for the existing product monopoly/patent-based system, as in effect on the date of enactment of this Act.

(2) How large the innovation prize funds would have to be in order to induce at least as much research and development investment in innovation as is induced under the current system of time-limited market exclusivity, as in effect on the date of enactment of this Act.

(3) Whether a system of large innovation inducement prizes would be more or less expensive than the current system of time-limited market exclusivity, as in effect on the date of enactment of this Act, calculated over different time periods.

(4) Whether a system of large innovation inducement prizes would expand access to new products and improve health outcomes.

(5) The type of information and decision-making skills that would be necessary to manage end product prizes.

(6) Whether there would there be major advantages in rewarding the incremental impact of innovations, as benchmarked against existing products.

(7) How open-source dividend prizes could be managed, and whether such prizes would increase access to knowledge, materials, data and technologies.

(8) Whether a system of competitive intermediaries for interim research prizes would provide an acceptable solution to the valuation challenges for interim prizes.

SEC. 907. ORPHAN PRODUCT GRANTS PROGRAM.

(a) REAUTHORIZATION OF PROGRAM.—Section 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended by striking ''2008 through 2012'' and inserting ''2013 through 2017''.

(b) HUMAN CLINICAL TESTING.—Section 5(b)(1)(A)(ii)) of the Orphan Drug Act (21 U.S.C. 360ee(b)(1)(A)(ii)) is amended by striking ''after the date such drug is designated under section 526 of such Act and''.

SEC. 908. REPORTING OF INCLUSION OF DEMOGRAPHIC SUBGROUPS IN CLINICAL TRIALS AND DATA ANALYSIS IN APPLICATIONS FOR DRUGS, BIOLOGICS, AND DEVICES.

(a) REPORT.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner, shall publish on the Internet website of the Food and Drug Administration a report, consistent with the regulations of the Food and Drug Administration pertaining to the protection of sponsors' confidential commercial information as of the date of enactment of this Act, addressing the extent to which clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups including sex, age, race, and ethnicity, is included in applications submitted to the Food and Drug Administration, and shall provide such publication to Congress.

(2) CONTENTS OF REPORT.—The report described in paragraph (1) shall contain the following:

(A) A description of existing tools to ensure that data to support demographic analyses are submitted in applications for drugs, biological products, and devices, and that these analyses are conducted by applicants consistent with applicable Food and Drug Administration requirements and Guidance for Industry. The report shall address how the Food and Drug Administration makes available information about differences in safety and effectiveness of medical products according to demographic subgroups, such as sex, age, racial, and ethnic subgroups, to healthcare providers, researchers, and patients.

(B) An analysis of the extent to which demographic data subset analyses on sex, age, race, and ethnicity is presented in applications for new drug applications for new molecular entities under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), in biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262), and in premarket approval applications under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) for products approved or licensed by the Food and Drug Administration, consistent with applicable requirements and Guidance for Industry, and consistent with the regulations of the Food and Drug Administration pertaining to the protection of sponsors' confidential commercial information as of the date of enactment of this Act.

(C) An analysis of the extent to which demographic subgroups, including sex, age, racial, and ethnic subgroups, are represented in clinical studies to support applications for approved or licensed new molecular entities, biological products, and devices.

(D) An analysis of the extent to which a summary of product safety and effectiveness data by demographic subgroups including sex, age, race, and ethnicity is readily available to the public in a timely manner by means of the product labeling or the Food and Drug Administration's Internet website.

(b) ACTION PLAN.—

(1) IN GENERAL.—Not later than 1 year after the publication of the report described in subsection (a), the Secretary, acting through the Commissioner, shall publish an action plan on the Internet website of the Food and Drug Administration, and provide such publication to Congress.

(2) CONTENT OF ACTION PLAN.—The plan described in paragraph (1) shall include—

(A) recommendations, as appropriate, to improve the completeness and quality of analyses of data on demographic subgroups in summaries of product safety and effectiveness data and in labeling;

(B) recommendations, as appropriate, on the inclusion of such data, or the lack of availability of such data in labeling;

(C) recommendations, as appropriate, to otherwise improve the public availability of such data to patients, healthcare providers, and researchers; and

(D) a determination with respect to each recommendation identified in subparagraphs (A) through (C) that distinguishes between product types referenced in subsection (a)(2)(B) insofar as the applicability of each such recommendation to each type of product.

(c) DEFINITIONS.—In this section:

(1) The term ''Commissioner'' means the Commissioner of Food and Drugs.

(2) The term ''device'' has the meaning given such term in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(3) The term ''drug'' has the meaning given such term in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)).

(4) The term ''biological product'' has the meaning given such term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(5) The term ''Secretary'' means the Secretary of Health and Human Services.

TITLE X—DRUG SHORTAGES

SEC. 1001. DRUG SHORTAGES.

(a) IN GENERAL.—Section 506C (21 U.S.C. 356c) is amended to read as follows:

''SEC. 506C. DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF LIFE-SAVING DRUGS.

''(a) IN GENERAL.—A manufacturer of a drug—

''(1) that is—

''(A) life-supporting;

''(B) life-sustaining;

''(C) intended for use in the prevention of a debilitating disease or condition;

''(D) a sterile injectable product; or

''(E) used in emergency medical care or during surgery; and

''(2) that is not a radio pharmaceutical drug product, a human tissue replaced by a recombinant product, a product derived from human plasma protein, or any other product as designated by the Secretary,

shall notify the Secretary, in accordance with subsection (b), of a permanent discontinuance in the manufacture of the drug or an interruption of the manufacture of the drug that could lead to a meaningful disruption in the supply of that drug in the United States.

''(b) TIMING.—A notice required under subsection (a) shall be submitted to the Secretary—

''(1) at least 6 months prior to the date of the discontinuance or interruption; or

''(2) if compliance with paragraph (1) is not possible, as soon as practicable.

''(c) EXPEDITED INSPECTIONS AND REVIEWS.—If, based on notifications described in subsection (a) or any other relevant information, the Secretary concludes that there is, or is likely to be, a drug shortage of a drug described in subsection (a), the Secretary may—

''(1) expedite the review of a supplement to a new drug application submitted under section 505(b), an abbreviated new drug application submitted under section 505(j), or a supplement to such an application submitted under section 505(j) that could help mitigate or prevent such shortage; or

''(2) expedite an inspection or reinspection of an establishment that could help mitigate or prevent such drug shortage.

''(d) COORDINATION.—

''(1) TASK FORCE AND STRATEGIC PLAN.—

''(A) IN GENERAL.—

''(i) TASK FORCE.—As soon as practicable after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall establish a Task Force to develop and implement a strategic plan for enhancing the Secretary's response to preventing and mitigating drug shortages.

''(ii) STRATEGIC PLAN.—The strategic plan described in clause (i) shall include—

''(I) plans for enhanced interagency and intraagency coordination, communication, and decisionmaking;

''(II) plans for ensuring that drug shortages are considered when the Secretary initiates a regulatory action that could precipitate a drug shortage or exacerbate an existing drug shortage;

''(III) plans for effective communication with outside stakeholders, including who the Secretary should alert about potential or actual drug shortages, how the communication should occur, and what types of information should be shared; and

''(IV) plans for considering the impact of drug shortages on research and clinical trials.

''(iii) CONSULTATION.—In carrying out this subparagraph, the Task Force shall ensure consultation with the appropriate offices within the Food and Drug Administration, including the Office of the Commissioner, the Center for Drug Evaluation and Research, the Office of Regulatory Affairs, and employees within the Department of Health and Human Services with expertise regarding drug shortages. The Secretary shall engage external stakeholders and experts as appropriate.

''(B) TIMING.—Not later than 1 year after the date of enactment Food and Drug Administration Safety and Innovation Act, the Task Force shall—

''(i) publish the strategic plan described in subparagraph (A); and

''(ii) submit such plan to Congress.

''(2) COMMUNICATION.—The Secretary shall ensure that, prior to any enforcement action or issuance of a warning letter that the Secretary determines could reasonably be anticipated to lead to a meaningful disruption in the supply in the United States of a drug described under subsection (a), there is communication with the appropriate office of the Food and Drug Administration with expertise regarding drug shortages regarding whether the action or letter could cause, or exacerbate, a shortage of the drug.

''(3) ACTION.—If the Secretary determines, after the communication described in paragraph (2), that an enforcement action or a warning letter could reasonably cause or exacerbate a shortage of a drug described under subsection (a), then the Secretary shall evaluate the risks associated with the impact of such shortage upon patients and those risks associated with the violation involved before taking such action or issuing such letter, unless there is imminent risk of serious adverse health consequences or death to humans.

''(4) REPORTING BY OTHER ENTITIES.—The Secretary shall identify or establish a mechanism by which healthcare providers and other third-party organizations may report to the Secretary evidence of a drug shortage.

''(5) REVIEW AND CONSTRUCTION.—No determination, finding, action, or omission of the Secretary under this subsection shall—

''(A) be subject to judicial review; or

''(B) be construed to establish a defense to an enforcement action by the Secretary.

''(e) RECORDKEEPING AND REPORTING.—

''(1) RECORDKEEPING.—The Secretary shall maintain records related to drug shortages, including with respect to each of the following:

''(A) The number of manufacturers that submitted a notification to the Secretary under subsection (a) in each calendar year.

''(B) The number of drug shortages that occurred in each calendar year and a list of drug names, drug types, and classes that were the subject of such shortages.

''(C) A list of the known factors contributing to the drug shortages described in subparagraph (B).

''(D)(i) A list of major actions taken by the Secretary to prevent or mitigate the drug shortages described in subparagraph (B).

''(ii) The Secretary shall include in the list under clause (i) the following:

''(I) The number of applications for which the Secretary expedited review under subsection (c)(1) in each calendar year.

''(II) The number of establishment inspections or reinspections that the Secretary expedited under subsection (c)(2) in each calendar year.

''(E) The number of notifications submitted to the Secretary under subsection (a) in each calendar year.

''(F) The names of manufacturers that the Secretary has learned did not comply with the notification requirement under subsection (a) in each calendar year.

''(G) The number of times in each calendar year that the Secretary determined under subsection (d)(3) that an enforcement action or a warning letter could reasonably cause or exacerbate a shortage of a drug described under subsection (a), but did not evaluate the risks associated with the impact of such shortage upon patients and those risks associated with the violation involved before taking such action or issuing such letter on the grounds that there was imminent risk of serious adverse health consequences or death to humans, and a summary of the determinations.

''(H) A summary of the communications made and actions taken under subsection (d) in each calendar year.

''(I) Any other information the Secretary deems appropriate to better prevent and mitigate drug shortages.

''(2) TREND ANALYSIS.—The Secretary is authorized to retain a third party to conduct a study, if the Secretary believes such a study would help clarify the causes, trends, or solutions related to drug shortages.

''(3) ANNUAL SUMMARY.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, 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 summarizing, with respect to the 1-year period preceding such report, the information described in paragraph (1). Such report shall not include any information that is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section.

''(f) DEFINITIONS.—For purposes of this section—

''(1) the term 'drug'—

''(A) means a drug (as defined in section 201(g)) that is intended for human use; and

''(B) does not include biological products (as defined in section 351 of the Public Health Service Act), unless otherwise provided by the Secretary in the regulations promulgated under subsection (h);

''(2) the term 'drug shortage' or 'shortage', with respect to a drug, means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug; and

''(3) the term 'meaningful disruption'—

''(A) means a change in production that is reasonably likely to lead to a reduction in the supply of a drug by a manufacturer that is more than negligible and impacts the ability of the manufacturer to fill orders or meet expected demand for its product; and

''(B) does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

''(g) DISTRIBUTION.—To the maximum extent practicable, the Secretary may distribute information on drug shortages and on the permanent discontinuation of the drugs described in this section to appropriate provider and patient organizations, except that any such distribution shall not include any information that is exempt from disclosure under section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section.

''(h) REGULATIONS.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt a final regulation implementing this section.

''(2) INCLUSION OF BIOLOGICAL PRODUCTS.—

''(A) IN GENERAL.—The Secretary may by regulation apply this section to biological products (as defined in section 351 of the Public Health Service Act) if the Secretary determines such inclusion would benefit the public health.

''(B) RULE FOR VACCINES.—If the Secretary applies this section to vaccines pursuant to subparagraph (A), the Secretary shall—

''(i) consider whether the notification requirement under subsection (a) may be satisfied by submitting a notification to the Centers for Disease Control and Prevention under the vaccine shortage notification program of such Centers; and

''(ii) explain the determination made by the Secretary under clause (i) in the regulation.

''(3) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the regulation's effective date.

''(4) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing this section, the Secretary shall only promulgate regulations as described in paragraph (3).''.

(b) EFFECT OF NOTIFICATION.—The submission of a notification to the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') for purposes of complying with the requirement in section 506C(a) of the Federal Food, Drug, and

Cosmetic Act (as amended by subsection (a)) shall not be construed—

(1) as an admission that any product that is the subject of such notification violates any provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

(2) as evidence of an intention to promote or market the product for an indication or use for which the product has not been approved by the Secretary.

(c) INTERNAL REVIEW.—Not later than 2 years after the date of enactment of this Act, the Secretary shall—

(1) analyze and review the regulations promulgated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the guidances or policies issued under such Act related to drugs intended for human use, and the practices of the Food and Drug Administration regarding enforcing such Act related to manufacturing of such drugs, to identify any such regulations, guidances, policies, or practices that cause, exacerbate, prevent, or mitigate drug shortages (as defined in section 506C of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)); and

(2) determine how regulations, guidances, policies, or practices identified under paragraph (1) should be modified, streamlined, expanded, or discontinued in order to reduce or prevent such drug shortages, taking into consideration the effect of any changes on the public health.

(d) STUDY ON MARKET FACTORS CONTRIBUTING TO DRUG SHORTAGES AND STOCKPILING.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States, in consultation with the Secretary, the Department of Health and Human Services Office of the Inspector General, the Attorney General, and Chairman of the Federal Trade Commission, shall publish a report reviewing any findings that drug shortages (as so defined) have led market participants to stockpile affected drugs or sell them at significantly increased prices, the impact of such activities on Federal revenue, and any economic factors that have exacerbated or created a market for such actions.

(2) CONTENT.—The report under paragraph (1) shall include—

(A) an analysis of the incidence of any of the activities described in paragraph (1) and the effect of such activities on the public health;

(B) an evaluation of whether in such cases there is a correlation between drugs in shortage and—

(i) the number of manufacturers producing such drugs;

(ii) the pricing structure, including Federal reimbursements, for such drugs before such drugs were in shortage, and to the extent possible, revenue received by each such manufacturer of such drugs;

(iii) pricing structure and revenue, to the extent possible, for the same drugs when sold under the conditions described in paragraph (1); and

(iv) the impact of contracting practices by market participants (including manufacturers, distributors, group purchasing organizations, and providers) on competition, access to drugs, and pricing of drugs;

(C) whether the activities described in paragraph (1) are consistent with applicable law; and

(D) recommendations to Congress on what, if any, additional reporting or enforcement actions are necessary.

(3) TRADE SECRET AND CONFIDENTIAL INFORMATION.—Nothing in this subsection alters or amends section 1905 of title 18, United States Code, or section 552(b)(4) of title 5, United States Code.

(e) GUIDANCE REGARDING REPACKAGING.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue guidance that clarifies the policy of the Food and Drug Administration regarding hospital pharmacies repackaging and safely transferring repackaged drugs among hospitals within a common health system during a drug shortage, as identified by the Secretary.

TITLE XI—OTHER PROVISIONS

Subtitle A—Reauthorizations

SEC. 1101. REAUTHORIZATION OF PROVISION RELATING TO EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

(a) IN GENERAL.—Section 505(u)(4) (21 U.S.C. 355(u)(4)) is amended by striking ''2012'' and inserting ''2017''.

(b) AMENDMENT.—Section 505(u)(1)(A)(ii)(II) (21 U.S.C. 355(u)(1)(A)(ii)(II)) is amended by inserting ''clinical'' after ''any''.

SEC. 1102. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

Section 566(f) (21 U.S.C. 360bbb–5(f)) is amended by striking ''2012'' and inserting ''2017''.

Subtitle B—Medical Gas Product Regulation

SEC. 1111. REGULATION OF MEDICAL GAS PRODUCTS.

(a) REGULATION.—Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter G—Medical Gas Products

"SEC. 575. DEFINITIONS.

''In this subchapter:

''(1) The term 'designated medical gas product' means any of the following:

''(A) Oxygen, that meets the standards set forth in an official compendium.

''(B) Nitrogen, that meets the standards set forth in an official compendium.

''(C) Nitrous oxide, that meets the standards set forth in an official compendium.

''(D) Carbon dioxide, that meets the standards set forth in an official compendium.

''(E) Helium, that meets the standards set forth in an official compendium.

''(F) Carbon monoxide, that meets the standards set forth in an official compendium.

''(G) Medical air, that meets the standards set forth in an official compendium.

''(H) Any other medical gas product deemed appropriate by the Secretary, unless any period of exclusivity under section 505(c)(3)(E)(ii) or 505(j)(5)(F)(ii), or the extension of any such period under section 505A, applicable to such medical gas product has not expired.

''(2) The term 'medical gas product' means a drug that—

''(A) is manufactured or stored in a liquefied, nonliquefied, or cryogenic state; and

''(B) is administered as a gas.

"SEC. 576. REGULATION OF MEDICAL GAS PRODUCTS.

''(a) CERTIFICATION OF DESIGNATED MEDICAL GAS PRODUCTS.—

''(1) SUBMISSION.—

''(A) IN GENERAL.—Beginning on the date of enactment of this section, any person may file with the Secretary a request for a certification of a designated medical gas product.

''(B) CONTENT.—A request under subparagraph (A) shall contain—

''(i) a description of the medical gas product;

''(ii) the name and address of the sponsor;

''(iii) the name and address of the facility or facilities where the gas product is or will be manufactured; and

''(iv) any other information deemed appropriate by the Secretary to determine whether the medical gas product is a designated medical gas product.

''(2) GRANT OF CERTIFICATION.—A certification described under paragraph (1)(A) shall be determined to have been granted unless, not later than 60 days after the filing of a request under paragraph (1), the Secretary finds that—

''(A) the medical gas product subject to the certification is not a designated medical gas product;

''(B) the request does not contain the information required under paragraph (1) or otherwise lacks sufficient information to permit the Secretary to determine that the gas product is a designated medical gas product; or

''(C) granting the request would be contrary to public health.

''(3) EFFECT OF CERTIFICATION.—

''(A) IN GENERAL.—

''(i) APPROVED USES.—A designated medical gas product for which a certification is granted under paragraph (2) is deemed, alone or in combination with another designated gas product or products as medically appropriate, to have in effect an approved application under section 505 or 512, subject to all applicable postapproval requirements, for the following indications for use:

''(I) Oxygen for the treatment or prevention of hypoxemia or hypoxia.

''(II) Nitrogen for use in hypoxic challenge testing.

''(III) Nitrous oxide for analgesia.

''(IV) Carbon dioxide for use in extracorporeal membrane oxygenation therapy or respiratory stimulation.

''(V) Helium for the treatment of upper airway obstruction or increased airway resistance.

''(VI) Medical air to reduce the risk of hyperoxia.

''(VII) Carbon monoxide for use in lung diffusion testing.

''(VIII) Any other indication for use for a designated medical gas product or combination of designated medical gas products deemed appropriate by the Secretary, unless any period of exclusivity under clause (iii) or (iv) of section 505(c)(3)(E), under clause (iii) or (iv) of section 505(j)(5)(F), or under section 527, or the extension of any such period under section 505A, applicable to such indication for use for such gas product or combination of products has not expired.

''(ii) LABELING.—The requirements established in sections 503(b)(4) and 502(f) shall be deemed to have been met for a designated medical gas product if the labeling on final use containers of such gas product bears the information required by section 503(b)(4) and a warning statement concerning the use of the gas product, as determined by the Secretary by regulation, as well as appropriate directions and warnings concerning storage and handling.

''(B) INAPPLICABILITY OF EXCLUSIVITY PROVISIONS.—

''(i) EFFECT ON INELIGIBILITY.—No designated medical gas product deemed under paragraph (3)(A)(i) to have in effect an approved application shall be eligible for any periods of exclusivity under sections 505(c), 505(j), or 527, or the extension of any such period under section 505A, on the basis of such deemed approval.

''(ii) EFFECT ON CERTIFICATION.—No period of exclusivity under sections 505(c), 505(j), or section 527, or the extension of any such period under section 505A, with respect to an application for a drug shall prohibit, limit, or otherwise affect the submission, grant, or effect of a certification under this section, except as provided in paragraph (3)(A)(i)(VIII).

''(4) WITHDRAWAL, SUSPENSION, OR REVOCATION OF APPROVAL.—

''(A) IN GENERAL.—Nothing in this subchapter limits the authority of the Secretary

to withdraw or suspend approval of a drug, including a designated medical gas product deemed under this section to have in effect an approved application, under section 505 or section 512.

''(B) REVOCATION.—The Secretary may revoke the grant of a certification under this section if the Secretary determines that the request for certification contains any material omission or falsification.

''(b) PRESCRIPTION REQUIREMENT.—

''(1) IN GENERAL.—A designated medical gas product shall be subject to section 503(b)(1) unless the Secretary exercises the authority provided in section 503(b)(3) to remove such gas product from the requirements of section 503(b)(1) or the use in question is authorized pursuant to another provision of this Act relating to use of medical products in emergencies.

''(2) EXCEPTION FOR OXYGEN.—

''(A) IN GENERAL.—Notwithstanding paragraph (1), oxygen may be provided without a prescription for the following uses:

''(i) The use in the event of depressurization or other environmental oxygen deficiency.

''(ii) The use in the event of oxygen deficiency or use in emergency resuscitation, when administered by properly trained personnel.

''(B) LABELING.—For oxygen provided pursuant to subparagraph (A), the requirements established in section 503(b)(4) shall be deemed to have been met if the labeling of the oxygen bears a warning that the medical gas product can be used for emergency use only and for all other medical applications a prescription is required.

''(c) INAPPLICABILITY OF DRUGS FEES TO DESIGNATED MEDICAL GAS PRODUCTS.—A designated medical gas product deemed under this section to have in effect an approved application shall not be assessed fees under section 736(a) on the basis of such deemed approval.''.

SEC. 1112. REGULATIONS.

(a) REVIEW OF REGULATIONS.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall, after obtaining input from medical gas product manufacturers, and any other interested members of the public, 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 regarding any changes to the Federal drug regulations in title 21, Code of Federal Regulations that the Secretary determines to be necessary.

(b) AMENDED REGULATIONS.—If the Secretary determines that changes to the Federal drug regulations in title 21, Code of Federal Regulations are necessary under subsection (a), the Secretary shall issue final regulations implementing such changes not later than 4 years after the date of enactment of this Act.

SEC. 1113. APPLICABILITY.

Nothing in this subtitle or the amendments made by this subtitle shall apply to—

(1) a drug that is covered by an application under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360b) approved prior to May 1, 2012; or

(2) any of the gases listed in subparagraphs (A) through (G) of section 575(1) of such Act (as added by section 1111), or any mixture of any such gases, for an indication that—

(A) is not included in, or is different from, those specified in subclauses (I) through (VII) of section 576(a)(3)(i) of such Act (as added by section 1111); and

(B) is approved on or after May 1, 2012, pursuant to an application submitted under section 505 or 512 of such Act.

Subtitle C—Miscellaneous Provisions

SEC. 1121. ADVISORY COMMITTEE CONFLICTS OF INTEREST.

Section 712 (21 U.S.C. 379d–1) is amended—

(1) in subsection (b)—

(A) by striking paragraph (2); and

(B) in paragraph (1)—

(i) by redesignating subparagraph (B) as paragraph (2) and moving such paragraph, as so redesignated, 2 ems to the left;

(ii) in subparagraph (A), by redesignating clauses (i) through (iii) as subparagraphs (A) through (C), respectively, and moving such subparagraphs, as so redesignated, 2 ems to the left;

(iii) in subparagraph (A), as so redesignated, by inserting '', including strategies to increase the number of special Government employees across medical and scientific specialties in areas where the Secretary would benefit from specific scientific, medical, or technical expertise necessary for the performance of its regulatory responsibilities'' before the semicolon at the end;

(iv) by striking ''(1) RECRUITMENT.—'' and inserting ''(1) RECRUITMENT IN GENERAL.—The Secretary shall—'';

(v) by striking ''(A) IN GENERAL.—The Secretary shall—'';

(vi) by redesignating clauses (i) through (iii) of paragraph (2) (as so redesignated) as subparagraphs (A) through (C), respectively, and moving such subparagraphs, as so redesignated, 2 ems to the left;

(vii) in paragraph (2) (as so redesignated), in the matter before subparagraph (A) (as so redesignated), by striking ''subparagraph (A)'' and inserting ''paragraph (1)''; and

(viii) by adding at the end the following:

''(3) RECRUITMENT THROUGH REFERRALS.—In carrying out paragraph (1), the Secretary shall, in order to further the goal of including in advisory committees highly qualified and specialized experts in the specific diseases to be considered by such advisory committees, at least every 180 days, request referrals from a variety of stakeholders, such as the Institute of Medicine, the National Institutes of Health, product developers, patient groups, disease advocacy organizations, professional societies, medical societies, including the American Academy of Medical Colleges, and other governmental organizations.'';

(2) by amending subsection (c)(2)(C) to read as follows:

''(C) CONSIDERATION BY SECRETARY.—The Secretary shall ensure that each determination made under subparagraph (B) considers the type, nature, and magnitude of the financial interests at issue and the public health interest in having the expertise of the member with respect to the particular matter before the advisory committee.'';

(3) in subsection (e), by inserting '', and shall make publicly available,'' after ''House of Representatives''; and

(4) by adding at the end the following:

''(g) GUIDANCE ON REPORTED FINANCIAL INTEREST OR INVOLVEMENT.—The Secretary shall issue guidance that describes how the Secretary reviews the financial interests and involvement of advisory committee members that are reported under subsection (c)(1) but that the Secretary determines not to meet the definition of a disqualifying interest under section 208 of title 18, United States Code for the purposes of participating in a particular matter.''.

SEC. 1122. GUIDANCE DOCUMENT REGARDING PRODUCT PROMOTION USING THE INTERNET.

Not later than 2 years after the date of enactment this Act, the Secretary of Health and Human Services shall issue guidance that describes Food and Drug Administration policy regarding the promotion, using the Internet (including social media), of medical products that are regulated by such Administration.

SEC. 1123. ELECTRONIC SUBMISSION OF APPLICATIONS.

Subchapter D of chapter VII (21 U.S.C. 379k et seq.) is amended by inserting after section 745 the following:

''SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.

''(a) DRUGS AND BIOLOGICS.—

''(1) IN GENERAL.—Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for comment, submissions under subsection (b), (i), or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act shall be submitted in such electronic format as specified by the Secretary in such guidance.

''(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

''(A) provide a timetable for establishment by the Secretary of further standards for electronic submission as required by such paragraph; and

''(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

''(3) EXCEPTION.—This subsection shall not apply to submissions described in section 561.

''(b) DEVICES.—

''(1) IN GENERAL.—Beginning after the issuance of final guidance implementing this paragraph, pre-submissions and submissions for devices under section 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of this Act or section 351 of the Public Health Service Act, and any supplements to such pre-submissions or submissions, shall include an electronic copy of such pre-submissions or submissions.

''(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

''(A) provide standards for the electronic copy required under such paragraph; and

''(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.''.

SEC. 1124. COMBATING PRESCRIPTION DRUG ABUSE.

(a) IN GENERAL.—To combat the significant rise in prescription drug abuse and the consequences of such abuse, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs (referred to in this section as the ''Commissioner'') and in coordination with other Federal agencies, as appropriate, shall review current Federal initiatives and identify gaps and opportunities with respect to ensuring the safe use and disposal of prescription drugs with the potential for abuse.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall post a report on the Internet website of the Food and Drug Administration on the findings of the review under subsection (a). Such report shall include findings and recommendations on—

(1) how best to leverage and build upon existing Federal and federally funded data sources, such as prescription drug monitoring program data and the sentinel initiative of the Food and Drug Administration under section 505(k)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(k)(3)), as it relates to collection of information relevant to adverse events, patient safety, and patient outcomes, to create a centralized data clearinghouse and early warning tool;

(2) how best to develop and disseminate widely best practices models and suggested standard requirements to States for achieving greater interoperability and effectiveness of prescription drug monitoring programs, especially with respect to provider

participation, producing standardized data on adverse events, patient safety, and patient outcomes; and

(3) how best to develop provider, pharmacist, and patient education tools and a strategy to widely disseminate such tools and assess the efficacy of such tools.

(c) GUIDANCE ON ABUSE-DETERRENT PRODUCTS.—Not later than 6 months after the date of enactment of this Act, the Secretary, acting through the Commissioner, shall promulgate guidance on the development of abuse-deterrent drug products.

(d) STUDY AND REPORT ON PRESCRIPTION DRUG ABUSE.—Not later than 1 year after the date of enactment of this Act, the Secretary shall seek to enter into an agreement with the Institute of Medicine to conduct a study and report on prescription drug abuse. Such report shall evaluate trends in prescription drug abuse, assess opportunities to inform and educate the public, patients, and health care providers on issues related to prescription drug abuse and misuse, and identify potential barriers, if any, to prescription drug monitoring program participation and implementation.

SEC. 1125. TANNING BED LABELING.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall determine whether to amend the warning label requirements for sunlamp products to include specific requirements to more clearly and effectively convey the risks that such products pose for the development of irreversible damage to the eyes and skin, including skin cancer.

SEC. 1126. OPTIMIZING GLOBAL CLINICAL TRIALS.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by section 903, is further amended by adding at the end the following:

"SEC. 569A. OPTIMIZING GLOBAL CLINICAL TRIALS.

''(a) IN GENERAL.—The Secretary shall—

''(1) work with other regulatory authorities of similar standing, medical research companies, and international organizations to foster and encourage uniform, scientifically-driven clinical trial standards with respect to medical products around the world; and

''(2) enhance the commitment to provide consistent parallel scientific advice to manufacturers seeking simultaneous global development of new medical products in order to—

''(A) enhance medical product development;

''(B) facilitate the use of foreign data; and

''(C) minimize the need to conduct duplicative clinical studies, preclinical studies, or non-clinical studies.

''(b) MEDICAL PRODUCT.—In this section, the term 'medical product' means a drug, as defined in subsection (g) of section 201, a device, as defined in subsection (h) of such section, or a biological product, as defined in section 351(i) of the Public Health Service Act.

''(c) SAVINGS CLAUSE.—Nothing in this section shall alter the criteria for evaluating the safety or effectiveness of a medical product under this Act.

"SEC. 569B. USE OF CLINICAL INVESTIGATION DATA FROM OUTSIDE THE UNITED STATES.

''(a) IN GENERAL.—In determining whether to approve, license, or clear a drug or device pursuant to an application submitted under this chapter, the Secretary shall accept data from clinical investigations conducted outside of the United States, including the European Union, if the applicant demonstrates that such data are adequate under applicable standards to support approval, licensure, or clearance of the drug or device in the United States.

''(b) NOTICE TO SPONSOR.—If the Secretary finds under subsection (a) that the data from clinical investigations conducted outside the United States, including in the European Union, are inadequate for the purpose of making a determination on approval, clearance, or licensure of a drug or device pursuant to an application submitted under this chapter, the Secretary shall provide written notice to the sponsor of the application of such finding and include the rationale for such finding.''.

SEC. 1127. ADVANCING REGULATORY SCIENCE TO PROMOTE PUBLIC HEALTH INNOVATION.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall develop a strategy and implementation plan for advancing regulatory science for medical products in order to promote the public health and advance innovation in regulatory decisionmaking.

(b) REQUIREMENTS.—The strategy and implementation plan developed under subsection (a) shall be consistent with the user fee performance goals in the Prescription Drug User Fee Agreement commitment letter, the Generic Drug User Fee Agreement commitment letter, and the Biosimilar User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 13, 2012, and the Medical Device User Fee Agreement commitment letter transmitted by the Secretary to Congress on April 20, 2012, and shall—

(1) identify a clear vision of the fundamental role of efficient, consistent, and predictable, science-based decisions throughout regulatory decisionmaking of the Food and Drug Administration with respect to medical products;

(2) identify the regulatory science priorities of the Food and Drug Administration directly related to fulfilling the mission of the agency with respect to decisionmaking concerning medical products and allocation of resources towards such regulatory science priorities;

(3) identify regulatory and scientific gaps that impede the timely development and review of, and regulatory certainty with respect to, the approval, licensure, or clearance of medical products, including with respect to companion products and new technologies, and facilitating the timely introduction and adoption of new technologies and methodologies in a safe and effective manner;

(4) identify clear, measurable metrics by which progress on the priorities identified under paragraph (2) and gaps identified under paragraph (3) will be measured by the Food and Drug Administration, including metrics specific to the integration and adoption of advances in regulatory science described in paragraph (5) and improving medical product decisionmaking, in a predictable and science-based manner; and

(5) set forth how the Food and Drug Administration will ensure that advances in regulatory science for medical products are adopted, as appropriate, on an ongoing basis and in an manner integrated across centers, divisions, and branches of the Food and Drug Administration, including by senior managers and reviewers, including through the—

(A) development, updating, and consistent application of guidance documents that support medical product decisionmaking; and

(B) the adoption of the tools, methods, and processes under section 566 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–5).

(c) ANNUAL PERFORMANCE REPORTS.—As part of the annual performance reports submitted to Congress under sections 736B(a) (as amended by section 104), 738A(a) (as amended by section 204), 744C(a) (as added by section 303), and 744I(a) (as added by section 403) of the Federal Food, Drug, and Cosmetic Act for each of fiscal years 2013 through 2017, the Secretary shall annually report on the progress made with respect to—

(1) advancing the regulatory science priorities identified under paragraph (2) of subsection (b) and resolving the gaps identified under paragraph (3) of such subsection, including reporting on specific metrics identified under paragraph (4) of such subsection;

(2) the integration and adoption of advances in regulatory science as set forth in paragraph (5) of such subsection; and

(3) the progress made in advancing the regulatory science goals outlined in the Prescription Drug User Fee Agreement commitment letter, the Generic Drug User Fee Agreement commitment letter, and the Biosimilar User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 13, 2012, and the Medical Device User Fee Agreement transmitted by the Secretary to Congress on April 20, 2012.

(d) INDEPENDENT ASSESSMENT.—Not later than January 1, 2016, the Comptroller General of the United States shall submit to Congress a report—

(1) detailing the progress made by the Food and Drug Administration in meeting the priorities and addressing the gaps identified in subsection (b), including any outstanding gaps; and

(2) containing recommendations, as appropriate, on how regulatory science initiatives for medical products can be strengthened and improved to promote the public health and advance innovation in regulatory decisionmaking.

(e) MEDICAL PRODUCT.—In this section, the term ''medical product'' means a drug, as defined in subsection (g) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), a device, as defined in subsection (h) of such section, or a biological product, as defined in section 351(i) of the Public Health Service Act.

SEC. 1128. INFORMATION TECHNOLOGY.

(a) HHS REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) report to Congress on—

(A) the milestones and a completion date for developing and implementing a comprehensive information technology strategic plan to align the information technology systems modernization projects with the strategic goals of the Food and Drug Administration, including results-oriented goals, strategies, milestones, performance measures;

(B) efforts to finalize and approve a comprehensive inventory of the information technology systems of the Food and Drug Administration that includes information describing each system, such as costs, system function or purpose, and status information, and incorporate use of the system portfolio into the information investment management process of the Food and Drug Administration;

(C) the ways in which the Food and Drug Administration uses the plan described in subparagraph (A) to guide and coordinate the modernization projects and activities of the Food and Drug Administration, including the interdependencies among projects and activities; and

(D) the extent to which the Food and Drug Administration has fulfilled or is implementing recommendations of the Government Accountability Office with respect to the Food and Drug Administration and information technology; and

(2) develop—

(A) a documented enterprise architecture program management plan that includes the tasks, activities, and timeframes associated with developing and using the architecture and addresses how the enterprise architecture program management will be performed in coordination with other management disciplines, such as organizational strategic planning, capital planning and investment control, and performance management; and

(B) a skills inventory, needs assessment, gap analysis, and initiatives to address skills gaps as part of a strategic approach to information technology human capital planning.

(b) GAO REPORT.—Not later than January 1, 2016, the Comptroller General of the United States shall issue a report regarding the strategic plan described in subsection (a)(1)(A) and related actions carried out by the Food and Drug Administration. Such report shall assess the progress the Food and Drug Administration has made on—

(1) the development and implementation of a comprehensive information technology strategic plan, including the results-oriented goals, strategies, milestones, and performance measures identified in subsection (a)(1)(A);

(2) the effectiveness of the comprehensive information technology strategic plan described in subsection (a)(1)(A), including the results-oriented goals and performance measures; and

(3) the extent to which the Food and Drug Administration has fulfilled recommendations of the Government Accountability Office with respect to such agency and information technology.

SEC. 1129. REPORTING REQUIREMENTS.

Subchapter A of chapter VII (21 U.S.C. 371 et seq.), as amended by section 208, is further amended by adding at the end the following:

"SEC. 715. REPORTING REQUIREMENTS.

''(a) NEW DRUGS.—Beginning with fiscal year 2013 and ending with fiscal year 2017, not later than 120 days after the end of each fiscal year for which fees are collected under part 2 of subchapter C, 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, for all applications for approval of a new drug under section 505(b) of this Act or a new biological product under section 351(a) of the Public Health Service Act filed in the previous fiscal year—

''(1) the number of such applications that met the goals identified for purposes of part 2 of subchapter C in the letters from the Secretary of Health and Human Services 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;

''(2) the percentage of such applications that were approved;

''(3) the percentage of such applications that were issued complete response letters;

''(4) the percentage of such applications that were subject to a refuse-to-file action;

''(5) the percentage of such applications that were withdrawn; and

''(6) the average total time to decision by the Secretary for all applications for approval of a new drug under section 505(b) of this Act or a new biological product under section 351(a) of the Public Health Service Act filed in the previous fiscal year, including the number of calendar days spent during the review by the Food and Drug Administration and the number of calendar days spent by the sponsor responding to a complete response letter.''.

''(b) GENERIC DRUGS.—Beginning with fiscal year 2013 and ending after fiscal year 2017, not later than 120 days after the end of each fiscal year for which fees are collected under part 7 of subchapter C, 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, for all applications for approval of a generic drug under section 505(j), amendments to such applications, and prior approval supplements with respect to such applications filed in the previous fiscal year—

''(1) the number of such applications that met the goals identified for purposes of part 7 of subchapter C, in the letters from the Secretary of Health and Human Services 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;

''(2) the average total time to decision by the Secretary for applications for approval of a generic drug under section 505(j), amendments to such applications, and prior approval supplements with respect to such applications filed in the previous fiscal year, including the number of calendar days spent during the review by the Food and Drug Administration and the number of calendar days spent by the sponsor responding to a complete response letter;

''(3) the total number of applications under section 505(j), amendments to such applications, and prior approval supplements with respect to such applications that were pending with the Secretary for more than 10 months on the date of enactment of the Food and Drug Administration Safety and Innovation Act; and

''(4) the number of applications described in paragraph (3) on which the Food and Drug Administration took final regulatory action in the previous fiscal year.

''(c) BIOSIMILAR BIOLOGICAL PRODUCTS.—

''(1) IN GENERAL.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year for which fees are collected under part 8 of subchapter C, 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—

''(A) the number of applications for approval filed under section 351(k) of the Public Health Service Act; and

''(B) the percentage of applications described in subparagraph (A) that were approved by the Secretary.

''(2) ADDITIONAL INFORMATION.—As part of the performance report described in paragraph (1), the Secretary shall include an explanation of how the Food and Drug Administration is managing the biological product review program to ensure that the user fees collected under part 2 are not used to review an application under section 351(k) of the Public Health Service Act.''.

SEC. 1130. STRATEGIC INTEGRATED MANAGEMENT PLAN.

(a) STRATEGIC INTEGRATED MANAGEMENT PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall submit to Congress a strategic integrated management plan for the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health. Such strategic management plan shall—

(1) identify strategic institutional goals and priorities for the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health;

(2) describe the actions the Secretary will take to recruit, retain, train, and continue to develop the workforce at the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health to fulfill the public health mission of the Food and Drug Administration; and

(3) identify results-oriented, outcome-based measures that the Secretary will use to measure the progress of achieving the strategic goals and priorities identified under paragraph (1) and the effectiveness of the actions identified under paragraph (2), including metrics to ensure that managers and reviewers of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health are familiar with and appropriately and consistently apply the requirements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including new requirements under parts 2, 3, 7, and 8 of subchapter C of title VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.).

(b) REPORT.—Not later than January 1, 2016, the Comptroller General of the United States shall issue a report regarding the strategic management plan described in subsection (a) and related actions carried out by the Food and Drug Administration. Such report shall—

(1) assess the effectiveness of the actions described in subsection (a)(2) in recruiting, retaining, training, and developing the workforce at the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health in fulfilling the public health mission of the Food and Drug Administration;

(2) assess the effectiveness of the measures identified under subsection (a)(3) in gauging progress against the strategic goals and priorities identified under subsection (a)(1);

(3) assess the extent to which the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health are using the identified results-oriented set of performance measures in tracking their workload by strategic goals and the effectiveness of such measures;

(4) assess the extent to which performance information is collected, analyzed, and acted on by managers; and

(5) make recommendations, as appropriate, regarding how the strategic management plan and related actions of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health could be improved to fulfill the public health mission of the Food and Drug Administration in as efficient and effective manner as possible.

SEC. 1131. DRUG DEVELOPMENT AND TESTING.

(a) IN GENERAL.—Section 505–1 (21 U.S.C. 355–1) is amended by adding at the end the following:

''(k) DRUG DEVELOPMENT AND TESTING.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, if a drug is a covered drug, no elements to ensure safe use shall prohibit, or be construed or applied to prohibit, supply of such drug to any eligible drug developer for the purpose of conducting testing necessary to support an application under subsection (b)(2) or (j) of section 505 of this Act or section 351(k) of the Public Health Service Act, if the Secretary has issued a written notice described in paragraph (2), and the eligible drug developer has

agreed to comply with the terms of the notice.

''(2) WRITTEN NOTICE.—For purposes of this subsection, the Secretary shall, within a reasonable period of time, consider and respond to a request by an eligible drug developer for a written notice authorizing the supply of a covered drug for purposes of testing as described in paragraph (1), and the Secretary shall issue a written notice to such eligible drug developer and the holder of an application for a covered drug authorizing the supply of such drug to such eligible drug developer for purposes of testing if—

''(A) the eligible drug developer has agreed to comply with any conditions the Secretary considers necessary;

''(B) in the event the eligible drug developer is conducting bioequivalence or other clinical testing, the eligible drug developer has submitted, and the Secretary has approved, a protocol that includes protections that the Secretary finds will provide assurance of safety comparable to the assurance of safety provided by the elements to ensure safe use in the risk evaluation and mitigation strategy for the covered drug as applicable to such testing; and

''(C) the eligible drug developer is in compliance with applicable laws and regulations related to such testing, including any applicable requirements related to Investigational New Drug Applications or informed consent.

''(3) ADDITIONAL REQUIRED ELEMENT.—The Secretary shall require as an element of each risk evaluation and mitigation strategy with elements to ensure safe use approved by the Secretary that the holder of an application for a covered drug shall not restrict the resale of the covered drug to an eligible drug developer that receives a written notice from the Secretary under paragraph (2) unless, at any time, the Secretary provides written notice to the holder of the application directing otherwise based on a shortage of such drug for patients, national security concerns related to access to such drug, or such other reason as the Secretary may specify.

''(4) VIOLATION AND PENALTIES.—For purposes of subsection (f)(8) and sections 301, 303(f)(4), 502(y), and 505(p), it shall be a violation of the risk evaluation and mitigation strategy for the holder of the application for a covered drug to violate the element described in paragraph (3), or in the case of a holder of an application that is a sole distributor or supplier of a covered drug, to prevent the sale thereof after receipt of a written notice by the Secretary issued under paragraph (2). The Secretary shall provide written notice to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives within 30 days of the Secretary becoming aware that a holder of an application of a covered drug has restricted the sale of such a covered drug to any eligible drug developer after receipt of written notice as provided in paragraph (2).

''(5) LIABILITY.—Unless the holder of the application for a covered drug and the eligible developer are the same entity, the holder of an application for a covered drug shall not be liable for any claim arising out of the eligible drug developer's testing necessary to support an application under subsection (b)(2) or (j) of section 505 of this Act or section 351(k) of the Public Health Service Act for a drug obtained under this subsection. Nothing in this subsection shall be construed to expand or limit the liability of the eligible drug developer or the holder of an application for a covered drug for any other claim.

''(6) CERTIFICATION.—In any request for supply of a covered drug for purposes of testing as described in paragraph (1), an eligible drug developer shall certify to the Secretary that—

''(A) the eligible drug developer will comply with all conditions the Secretary considers necessary, any protocol approved by the Secretary, and all applicable laws and regulations pertaining to such testing; and

''(B) the eligible drug developer intends to submit an application under subsection (b)(2) or (j) of section 505 of this Act or section 351(k) of the Public Health Service Act for the drug for which it is requesting written notice pursuant to paragraph (2), and will use the covered drug only for the purpose of conducting testing to support such an application.

''(7) DEFINITIONS.—

''(A) COVERED DRUG.—Notwithstanding subsection (b)(2), for purposes of this subsection, the term 'covered drug' means a drug, including a biological product licensed under section 351(a) of the Public Health Service Act, that is subject to a risk evaluation and mitigation strategy with elements to ensure safe use under subsection (f), or a drug, including a biological product licensed under section 351(a) of the Public Health Service Act, required to have a risk evaluation and mitigation strategy with elements to ensure safe use under section 909(b) of the Food and Drug Administration Amendments Act of 2007.

''(B) ELIGIBLE DRUG DEVELOPER.—For purposes of this subsection, the term 'eligible drug developer' means a sponsor that has submitted, or intends to submit, an application under subsection (b)(2) or (j) of section 505 of this Act or section 351(k) of the Public Health Service Act to market a version of the covered drug in the United States.

''(8) EFFECT ON OTHER LAW.—Notwithstanding the provisions of this subsection, the antitrust statutes enforced by the Federal Trade Commission, including the Federal Trade Commission Act (15 U.S.C. 41–58), the Sherman Act (15 U.S.C. 1–7), and any other statute properly under such Commission's jurisdiction, shall apply to the conduct described in this subsection to the same extent as such statutes did on the day before the date of enactment of this subsection.''.

(b) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) Section 505–1(c)(2) (21 U.S.C. 355–1(c)(2)) is amended by striking ''(e) and (f)'' and inserting ''(e), (f), and (k)(3)''.

(2) Section 502(y) (21 U.S.C. 352(y)) is amended by striking ''''(d), (e), or (f) of section 505–1'' and inserting ''(d), (e), (f), or (k)(3) of section 505–1''.

SEC. 1132. PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSIONS.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by section 1126, is further amended by adding at the end the following:

''SEC. 569C. PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSION.

''(a) IN GENERAL.—The Secretary shall develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions, including by—

''(1) fostering participation of a patient representative who may serve as a special government employee in appropriate agency meetings with medical product sponsors and investigators; and

''(2) exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.

''(b) FINANCIAL INTEREST.—In this section, the term 'financial interest' means a financial interest under section 208(a) of title 18, United States Code.''.

SEC. 1133. NANOTECHNOLOGY REGULATORY SCIENCE PROGRAM.

(a) IN GENERAL.—Chapter X (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

''SEC. 1013. NANOTECHNOLOGY REGULATORY SCIENCE PROGRAM.

''(a) IN GENERAL.—Not later than 180 days after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary, in consultation as appropriate with the Secretary of Agriculture, shall establish within the Food and Drug Administration a Nanotechnology Regulatory Science Program (referred to in this section as the 'program') to enhance scientific knowledge regarding nanomaterials included or intended for inclusion in products regulated under this Act or other statutes administered by the Food and Drug Administration, to address issues relevant to the regulation of those products, including the potential toxicology of such materials, the effects of such materials on biological systems, and interaction of such materials with biological systems.

''(b) PROGRAM PURPOSES.—The purposes of the program established under subsection (a) may include—

''(1) assessing scientific literature and data on general nanomaterials interactions with biological systems and on specific nanomaterials of concern to the Food and Drug Administration;

''(2) in cooperation with other Federal agencies, developing and organizing information using databases and models that will facilitate the identification of generalized principles and characteristics regarding the behavior of classes of nanomaterials with biological systems;

''(3) promoting Food and Drug Administration programs and participate in collaborative efforts, to further the understanding of the science of novel properties of nanomaterials that might contribute to toxicity;

''(4) promoting and participating in collaborative efforts to further the understanding of measurement and detection methods for nanomaterials;

''(5) collecting, synthesizing, interpreting, and disseminating scientific information and data related to the interactions of nanomaterials with biological systems;

''(6) building scientific expertise on nanomaterials within the Food and Drug Administration, including field and laboratory expertise, for monitoring the production and presence of nanomaterials in domestic and imported products regulated under this Act;

''(7) ensuring ongoing training, as well as dissemination of new information within the centers of the Food and Drug Administration, and more broadly across the Food and Drug Administration, to ensure timely, informed consideration of the most current science pertaining to nanomaterials;

''(8) encouraging the Food and Drug Administration to participate in international and national consensus standards activities pertaining to nanomaterials; and

''(9) carrying out other activities that the Secretary determines are necessary and consistent with the purposes described in paragraphs (1) through (8).

''(c) PROGRAM ADMINISTRATION.—

''(1) DESIGNATED INDIVIDUAL.—In carrying out the program under this section, the Secretary, acting through the Commissioner of Food and Drugs, may designate an appropriately qualified individual who shall supervise the planning, management, and coordination of the program.

''(2) DUTIES.—The duties of the individual designated under paragraph (1) may include—

''(A) developing a detailed strategic plan for achieving specific short- and long-term technical goals for the program;

''(B) coordinating and integrating the strategic plan with activities by the Food and Drug Administration and other departments and agencies participating in the National Nanotechnology Initiative; and

''(C) developing Food and Drug Administration programs, contracts, memoranda of agreement, joint funding agreements, and other cooperative arrangements necessary for meeting the long-term challenges and achieving the specific technical goals of the program.

''(d) REPORT.—Not later than March 15, 2015, the Secretary shall publish on the Internet Web site of the Food and Drug Administration a report on the program carried out under this section. Such report shall include—

''(1) a review of the specific short- and long-term goals of the program;

''(2) an assessment of current and proposed funding levels for the program, including an assessment of the adequacy of such funding levels to support program activities; and

''(3) a review of the coordination of activities under the program with other departments and agencies participating in the National Nanotechnology Initiative.

''(e) EFFECT OF SECTION.—Nothing in this section shall affect the authority of the Secretary under any other provision of this Act or other statutes administered by the Food and Drug Administration.''.

(b) EFFECTIVE DATE; SUNSET.—The Nanotechnology Regulatory Science Program authorized under section 1013 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later. Such Program shall cease to be effective October 1, 2017.

SEC. 1134. ONLINE PHARMACY REPORT TO CONGRESS.

Not later than 1 year after the date of enactment of this Act, 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 that describes any problems posed by pharmacy Internet websites that violate Federal or State law, including—

(1) the methods by which Internet websites are used to sell prescription drugs in violation of Federal or State law or established industry standards;

(2) the harmful health effects that patients experience when they consume prescription drugs purchased through such pharmacy Internet websites;

(3) efforts by the Federal Government and State and local governments to investigate and prosecute the owners or operators of pharmacy Internet websites, to address the threats such websites pose, and to protect patients;

(4) the level of success that Federal, State, and local governments have experienced in investigating and prosecuting such cases;

(5) whether the law, as in effect on the date of the report, provides sufficient authorities to Federal, State, and local governments to investigate and prosecute the owners and operators of pharmacy Internet websites;

(6) additional authorities that could assist Federal, State, and local governments in investigating and prosecuting the owners and operators of pharmacy Internet websites;

(7) laws, policies, and activities that would educate consumers about how to distinguish pharmacy Internet websites that comply with Federal and State laws and established industry standards from those pharmacy Internet websites that do not comply with such laws and standards; and

(8) laws, policies, and activities that would encourage private sector actors to take steps to address the prevalence of illegitimate pharmacy Internet websites.

SEC. 1135. MEDICATION AND DEVICE ERRORS.

The Secretary of Health and Human Services shall continue and further coordinate activities of the Department of Health and Human Services related to the prevention of medication and device errors, including consideration of medication and device errors that affect the pediatric patient population. In developing initiatives to address medication and device errors, the Secretary shall consider the root causes of medication and device errors, including pediatric medication and device errors, in the clinical setting and consult with relevant stakeholders on effective strategies to reduce and prevent medication and device errors in the clinical setting.

SEC. 1136. COMPLIANCE PROVISION.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go-Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this Act, submitted for printing in the Congressional Record by the Chairman of the Senate Budget Committee, provided that such statement has been submitted prior to the vote on passage.

SEC. 1137. ENSURING ADEQUATE INFORMATION REGARDING PHARMACEUTICALS FOR ALL POPULATIONS, PARTICULARLY UNDERREPRESENTED SUBPOPULATIONS, INCLUDING RACIAL SUBGROUPS.

(a) COMMUNICATION PLAN.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall review and modify, as necessary, the Food and Drug Administration's communication plan to inform and educate health care providers, patients, and payors on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

(b) CONTENT.—The communication plan described under subsection (a)—

(1) shall take into account—

(A) the goals and principles set forth in the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities issued by the Department of Health and Human Services;

(B) the nature of the medical product; and

(C) health and disease information available from other agencies within such Department, as well as any new means of communicating health and safety benefits and risks related to medical products;

(2) taking into account the nature of the medical product, shall address the best strategy for communicating safety alerts, labeled indications for the medical products, changes to the label or labeling of medical products (including black box warnings, health advisories, health and safety benefits and risks), particular actions to be taken by healthcare professionals and patients, any information identifying particular subpopulations, and any other relevant information as determined appropriate to enhance communication, including varied means of electronic communication; and

(3) shall include a process for implementation of any improvements or other modifications determined to be necessary.

(c) ISSUANCE AND POSTING OF COMMUNICATION PLAN.—

(1) COMMUNICATION PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall issue the communication plan described under this section.

(2) POSTING OF COMMUNICATION PLAN ON THE OFFICE OF MINORITY HEALTH WEBSITE.—The Secretary, acting through the Commissioner of Food and Drugs, shall publicly post the communication plan on the Internet website of the Office of Minority Health of the Food and Drug Administration, and provide links to any other appropriate webpage, and seek public comment on the communication plan.

SEC. 1138. REPORT ON SMALL BUSINESSES.

Not later than 1 year after the date of enactment of this Act, the Commissioner of Food and Drugs shall submit a report to Congress that includes—

(1) a listing of and staffing levels of all small business offices at the Food and Drug Administration, including the small business liaison program;

(2) the status of partnership efforts between the Food and Drug Administration and the Small Business Administration;

(3) a summary of outreach efforts to small businesses and small business associations, including availability of toll-free telephone help lines;

(4) with respect to the program under the Orphan Drug Act (Public Law 97–414), the number of applications made by small businesses and number of applications approved for research grants, the amount of tax credits issued for clinical research, and the number of companies receiving protocol assistance for the development of drugs for rare diseases and disorders;

(5) with respect to waivers and reductions for small business under the Prescription Drug User Fee Act, the number of small businesses applying for and receiving waivers and reductions from drug user fees under subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.);

(6) the number of small businesses submitting applications and receiving approval for unsolicited grant applications from the Food and Drug Administration;

(7) the number of small businesses submitting applications and receiving approval for solicited grant applications from the Food and Drug Administration;

(8) barriers small businesses encounter in the drug and medical device approval process; and

(9) recommendations for changes in the user fee structure to help alleviate generic drug shortages.

SEC. 1139. PROTECTIONS FOR THE COMMISSIONED CORPS OF THE PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—Section 221(a) of the Public Health Service Act (42 U.S.C. 213a(a)) is amended by adding at the end the following:

''(18) Section 1034, Protected Communications; Prohibition of Retaliatory Personnel Actions.''.

(b) CONFORMING AMENDMENT.—Section 221(b) of the Public Health Service Act (42 U.S.C. 213a(b)) is amended by adding at the end the following: ''For purposes of paragraph (18) of subsection (a), the term 'Inspector General' in section 1034 of such title 10 shall mean the Inspector General of the Department of Health and Human Services.''.

SEC. 1140. REGULATIONS ON CLINICAL TRIAL REGISTRATION; GAO STUDY OF CLINICAL TRIAL REGISTRATION AND REPORTING REQUIREMENTS.

(a) DEFINITIONS.—In this section—

(1) the term ''applicable clinical trial'' has the meaning given such term under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j));

(2) the term ''Director'' means the Director of the National Institutes of Health;

(3) the term ''responsible party'' has the meaning given such term under such section 402(j); and

(4) the term ''Secretary'' means the Secretary of Health and Human Services.

(b) REQUIRED REGULATIONS.—

(1) PROPOSED RULEMAKING.—Not later than 180 days after the date of enactment of this

Act, the Secretary, acting through the Director, shall issue a notice of proposed rulemaking for a proposed rule on the registration of applicable clinical trials by responsible parties under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) (as amended by section 801 of the Food and Drug Administration Amendments Act of 2007).

(2) FINAL RULE.—Not later than 180 days after the issuance of the notice of proposed rulemaking under paragraph (1), the Secretary, acting through the Director, shall issue the final rule on the registration of applicable clinical trials by responsible parties under such section 402(j).

(3) LETTER TO CONGRESS.—If the final rule described in paragraph (2) is not issued by the date required under such paragraph, the Secretary shall submit to Congress a letter that describes the reasons why such final rule has not been issued.

(c) REPORT BY GAO.—

(1) IN GENERAL.—Not later than 2 years after the issuance of the final rule under subsection (b), 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 implementation of the registration and reporting requirements for applicable drug and device clinical trials under section 402(j) the Public Health Service Act (42 U.S.C. 282(j)) (as amended by section 801 of the Food and Drug Administration Amendments Act of 2007).

(2) CONTENT.—The report under paragraph (1) shall include—

(A) information on the rate of compliance and non-compliance (by category of sponsor, category of trial (phase II, III, or IV), whether the applicable clinical trial is conducted domestically, in foreign sites, or a combination of sites, and such other categories as the Comptroller General determines useful) with the requirements of—

(i) registering applicable clinical trials under such section 402(j);

(ii) reporting the results of such trials under such section; and

(iii) the completeness of the reporting of the required data under such section; and

(B) information on the promulgation of regulations for the registration of applicable clinical trials by the responsible parties under such section 402(j).

(3) RECOMMENDATIONS.—If the Comptroller General finds problems with timely compliance or completeness of the data being reported under such section 402(j), or finds that the implementation of registration and reporting requirements under such section 402(j) for applicable drug and device clinical trials could be improved, the Comptroller General shall, after consulting with the Commissioner of Food and Drugs, applicable stakeholders, and experts in the conduct of clinical trials, make recommendations for administrative or legislative actions to increase the compliance with the requirements of such section 402(j).

SEC. 1141. HYDROCODONE AMENDMENT.

The Controlled Substances Act is amended—

(1) in schedule III(d) in section 202(c) (21 U.S.C. 812(c)), by—

(A) striking paragraphs (3) and (4); and

(B) redesignating paragraphs (5), (6), (7), and (8) as paragraphs (3), (4), (5), and (6), respectively; and

(2) in section 401(b)(1) (21 U.S.C. 841(b)(1)), by adding at the end the following:

''(F) In the case of any material, compound, mixture, or preparation containing—

''(i) not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium; or

''(ii) not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts,

subparagraph (C) shall not apply and such case shall be subject to subparagraph (E).''.

SEC. 1142. COMPLIANCE DATE FOR RULE RELATING TO SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE.

In accordance with the final rule issued by the Commissioner of Food and Drug entitled ''Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the- Counter Human Use; Delay of Compliance Dates'' (77 Fed. Reg. 27591 (May 11, 2012)), a product subject to the final rule issued by the Commissioner entitled ''Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use'' (76 Fed. Reg. 35620 (June 17, 2011)), shall comply with such rule not later than—

(1) December 17, 2013, for products subject to such rule with annual sales of less than $25,000 and

(2) December 17, 2012, for all other products subject to such rule.

SEC. 1143. RECOMMENDATIONS ON INTEROPERABILITY STANDARDS.

(a) IN GENERAL.—The Attorney General and the Secretary of Health and Human Services may collaborate to facilitate the development of recommendations on interoperability standards to inform and facilitate the exchange of prescription information across State lines by States receiving grant funds under—

(1) the Harold Rogers Prescription Drug Monitoring Program established under the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2002 (Public Law 107–77; 115 Stat. 748); and

(2) the Controlled Substance Monitoring Program established under section 399O of the Public Health Service Act (42 U.S.C. 280g–3).

(b) REQUIREMENTS.—The Attorney General and the Secretary of Health and Human Services shall consider the following in facilitating the development of recommendations on interoperability of prescription drug monitoring programs under subsection (a)—

(1) open standards that are freely available, without cost and without restriction, in order to promote broad implementation;

(2) the use of exchange intermediaries, or hubs, as necessary to facilitate interstate interoperability by accommodating State-to-hub and direct State-to-State communication;

(3) the support of transmissions that are fully secured as required, using industry standard methods of encryption, to ensure that Protected Health Information and Personally Identifiable Information are not compromised at any point during such transmission; and

(4) access control methodologies to share protected information solely in accordance with State laws and regulations.

(c) REPORT.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Attorney General, in consultation with the Secretary of Health and Human Services, shall submit to the Committee on the Judiciary and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on the Judiciary and the Committee on Energy and Commerce of the House of Representatives a report on enhancing the interoperability of State prescription monitoring programs with other technologies and databases used for detecting and reducing fraud, diversion, and abuse of prescription drugs.

(2) CONTENTS.—The report required under paragraph (1) shall include—

(A) an assessment of legal, technical, fiscal, privacy, or security challenges that have an impact on interoperability;

(B) a discussion of how State prescription monitoring programs could increase the production and distribution of unsolicited reports to prescribers and dispensers of prescription drugs, law enforcement officials, and health professional licensing agencies, including the enhancement of such reporting through interoperability with other States and relevant technology and databases; and

(C) any recommendations for addressing challenges that impact interoperability of State prescription monitoring programs in order to reduce fraud, diversion, and abuse of prescription drugs.

Subtitle D—Synthetic Drugs

SEC. 1151. SHORT TITLE.

This subtitle may be cited as the ''Synthetic Drug Abuse Prevention Act of 2012''.

SEC. 1152. ADDITION OF SYNTHETIC DRUGS TO SCHEDULE I OF THE CONTROLLED SUBSTANCES ACT.

(a) CANNABIMIMETIC AGENTS.—Schedule I, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end the following:

''(d)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

''(2) In paragraph (1):

''(A) The term 'cannabimimetic agents' means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

''(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

''(ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

''(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

''(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

''(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

''(B) Such term includes—

''(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP–47,497);

''(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog);

''(iii) 1-pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678);

''(iv) 1-butyl-3-(1-naphthoyl)indole (JWH–073);

''(v) 1-hexyl-3-(1-naphthoyl)indole (JWH–019);

''(vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200);

''(vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250);

''(viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081);

''(ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122);

''(x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398);

''(xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);

''(xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);

''(xiii) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19 and RCS–4);

''(xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8); and

''(xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH–203).''.

(b) OTHER DRUGS.—Schedule I of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended in subsection (c) by adding at the end the following:

''(18) 4-methylmethcathinone (Mephedrone).

''(19) 3,4-methylenedioxypyrovalerone (MDPV).

''(20) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E).

''(21) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D).

''(22) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C).

''(23) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I).

''(24) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2).

''(25) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4).

''(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C–H).

''(27) 2-(2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C–N).

''(28) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P).''.

SEC. 1153. TEMPORARY SCHEDULING TO AVOID IMMINENT HAZARDS TO PUBLIC SAFETY EXPANSION.

Section 201(h)(2) of the Controlled Substances Act (21 U.S.C. 811(h)(2)) is amended—

(1) by striking ''one year'' and inserting ''2 years''; and

(2) by striking ''six months'' and inserting ''1 year''.

SEC. 1154. PROHIBITION ON IMPOSING MANDATORY MINIMUM SENTENCES.

Section 401(b)(1)(C) of the Controlled Substances Act (21 U.S.C. 841(b)(1)(C)) is amended by adding at the end the following: ''Any mandatory minimum term of imprisonment required to be imposed under this subparagraph shall not apply with respect to any controlled substance added to schedule I by the Synthetic Drug Abuse Prevention Act of 2012.''.

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

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. The majority leader is recognized.

Mr. REID. Madam President, I know people are very anxious to move on. I am, too, but I have to say just a word. I have said in my own caucus how much I appreciate the cooperation of Senator ENZI. He is a fine Senator. He and Senator HARKIN have worked so well together. It is exemplary for what the rest of us should do. I appreciate very much the work they have done. I repeat, it is how we should get other work done.

This is an important piece of legislation, and we made it look simple; it was not. But because of these two fine Senators, we were able to get this done in a very short period of time and get good things done for the American people.

Mr. HARKIN. Madam President, today, with passage of the FDA Safety and Innovation Act and the reauthorization of the FDA user fee agreements, we have helped both the FDA and the biomedical industry ensure that they can get needed medical products to patients quickly and safely.

This legislation will ensure that the FDA can swiftly approve drugs and medical devices, save biomedical industry jobs, protect patient access to new therapies, and preserve America's global leadership in biomedical innovation. It will keep patients safer by modernizing FDA's inspection process for foreign manufacturing facilities, while also improving access to new and innovative medicines and devices. It will reduce drug costs for consumers by speeding the approval of lower cost generic drugs and help prevent and address drug shortages. Finally, by improving the way FDA does business, increasing accountability and transparency, U.S. companies will be better able to innovate and compete in the global marketplace.

By passing the FDA Safety and Innovation Act, we have taken an important step to improve American families' access to lifesaving drugs and medical devices.

As I have said throughout this debate, the bipartisan process that produced this excellent bill has been quite remarkable. I have worked closely with my colleagues on both sides of the aisle, as well as industry stakeholders, patient groups, and consumer groups to solicit ideas and improvements on the critical provisions in this bill. We have a better product thanks to everyone's input.

I extend a special thank-you to my colleague, Ranking Member ENZI. I have been working with Senator ENZI for over a year on this bill. It has been a wonderful and cooperative partnership and a trusting friendship. I can honestly say we would not have gotten this done without his excellent leadership and wise counsel. I thank him for that.

I also thank all of the HELP Committee members, as well as members off the committee, who were thoroughly engaged with this process from the beginning as part of the bipartisan working groups we established. Each of them has contributed significantly to this legislation, and I am sincerely grateful for all their contributions.

Madam President, I will submit for the RECORD a list of all staff members who were part of our bipartisan working groups throughout the past year. We all know we could not have achieved this without the tireless and diligent work of our loyal staffs. I extend my deep appreciation for their hard work and extraordinary efforts.

I ask unanimous consent that the list of staff members be printed in the RECORD.

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

HELP BIPARTISAN WORKING GROUPS

DRUG SHORTAGES

Rachel Pryor—Blumenthal;
Jessica McNiece, Christine Evans—Mikulski;
Deirdre Fruh—Casey;
Andrew Hu—Klobuchar;
Hannah Katch, Whitney Brown—Franken;
Jennifer DeAngelis—Whitehouse;
Sophie Kasimow—Sanders;
Rohini Kosoglu, Sally Mayes—Bennett;
Susan Lexer—Merkley;
Joshua Teitelbaum—Hagan;
Sandra Wilkniss—Bingaman;
Jennifer Boyer—Roberts;
Hayden Rhudy—Hatch;
MarySumpter Lipinski—Alexander;
Christopher Bowlin—McCain;
Anna Abram, Margaret Coulter—Burr;
Anne Oswalt—Corker;
Amanda Makki—Murkowski.

GENERATING ANTIBIOTIC INCENTIVES NOW

Rachel Pryor—Blumenthal;
Hannah Katch, Whitney Brown—Franken;
Sophie Kasimow—Sanders;
Susan Lexer—Merkley;
Rohini Kosoglu—Bennett;
Joshua Teitelbaum—Hagan;
Sandra Wilkniss—Bingaman;
Matt Prowler, Deirdre Fruh—Casey;
Christine Evans, Jessica McNiece—Mikulski;
Margaret Coulter/Anna Abram—Burr;
Amanda Makki—Murkowski;
Ashley Carson Cottingham—Sanders;
Michael Behan—Sanders;
Tyler Thompson, Francie Pastor—Isakson;
MarySumpter Lapinski—Alexander;
Jennifer Boyer—Roberts;
Shauna McCarthy—Kirk;
Hayden Rhudy—Hatch.

PEDIATRICS (BPCA/PREA)

Paula Berg—Murray;
Kate Mevis—Reed;
Rohini Kosoglu, Sally Mayes—Bennett;
Jessica McNiece, Christine Evans—Mikulski;
Deirdre Fruh, Matt Prowler—Casey;
Hannah Katch, Whitney Brown—Franken;
Sophie Kasimow—Sanders;
Anna Abram, Margaret Coulter—Burr;
MarySumpter Lapinski, Nicolas Magallanes—Alexander;
Jennifer Boyer—Roberts;
Tyler Thompson—Isakson;
Amanda Makki—Murkowski;
Hayden Rhudy, Paul Williams—Hatch.

DRUG SUPPLY CHAIN

Rohini Kosoglu—Bennett;
Jennifer DeAngelis, Justin Florence—Whitehouse;
Anna Abram—Burr;
Erika Smith—Grassley.

Mr. HARKIN. On that note, I specifically thank the staff of Ranking Member ENZI's office. I thank Frank Macchiarola, Chuck Clapton, Keith Flanagan, Melissa Pfaff, Grace Stuntz, Katy Spangler, and Riley Swinehart. I

know they have developed a close working relationship with my staff throughout the year, and I am sincerely grateful for their dedicated efforts.

I thank my own staff on the HELP Committee, who have spent many a night, long days, and weekends with Senator ENZI's staff and other Members' offices working to come to consensus on the critical policy issues in this legislation.

I thank our staff director, Dan Smith; his assistant, Pam Smith, who, by the way, will be very shortly taking over as our new staff director. Dan Smith is leaving our staff and going into the private sector. Pam Smith will be taking over as our new staff director. I also thank Jenelle Krishnamoorthy, who heads our health division, for all of the tireless work she has put in. I can't thank her enough for all her hard work. I also thank Elizabeth Jungman, Bill McConagha, Kathleen Laird, Kathleen Wise, Dan Goldberg, Justine Sessions, Kate Frischmann, Elizabeth Donovan, Lory Yudin, Frank Zhang, and Evan Griffis. Each of them has done a remarkable job. I thank them from the bottom of my heart for getting this legislation through.

We would be remiss if we didn't also thank the Congressional Budget Office for their knowledgeable and capable team that was willing to work around the clock to estimate the budgetary effects of this legislation.

Finally, we owe an enormous debt of gratitude to the staff members in the Legislative Counsel's Office. They too worked long hours, nights and weekends, to assist my staff in drafting this critical legislation and working out technical issues.

This bill's passage is a victory for the millions of Americans who need medicines or medical devices—a victory that would not have been possible without the dedicated work of our Senate family. I thank all of you for your extraordinary public service.

STOP THE STUDENT LOAN INTEREST RATE HIKE ACT OF 2012

The PRESIDING OFFICER. Under the previous order, the Senate will proceed to S. 2343, which the clerk will report.

The legislative clerk read as follows:

A bill (S. 2343) to amend the Higher Education Act of 1965 to extend the reduced interest rate for Federal Direct Stafford Loans, and for other purposes.

The PRESIDING OFFICER. Under the previous order, there will be 10 minutes of debate equally divided and controlled between the two leaders or their designees.

The Republican leader.

Mr. MCCONNELL. Madam President, we are in a rather ridiculous staring contest, waiting for our Democratic friends to offer a proposal that can actually pass when we already have one right in front of us. We have wasted actually 2 weeks on this student loan issue for no good reason. Neither I nor the ranking member has heard a word from the Democrats on how they propose to resolve the issue and actually prevent the interest rate from rising.

As we learned earlier this week, the President doesn't seem to even talk to his committee chairmen anymore. All of this suggests that the White House doesn't want to solve the problem; that it would rather allow these rates to double in a few weeks so he can run around all summer pointing the finger at those Republicans in the Senate.

I would still like to believe that is not the case. We had a chance to talk to the President about this and other issues last week down at the White House. I am convinced he would like to get a solution. Yet the fact is, all he would have to do is simply pick up the phone and tell the Democratic leadership that we would like to get this done, and I am pretty confident we could work it out. Unfortunately, we cannot just wait around hoping the President is going to pick up the phone. College students cannot wait either. They want us to resolve the issue now, and I know we can.

To move the ball forward, I would say to my colleague, the majority leader, if he agrees with me—Senator HARKIN and Senator ENZI just did a good job with coming up with a bipartisan solution to the FDA bill. I am confident they could do the same thing on the student loan issue. They are the chairman and the ranking member of the committee that oversees student loan legislation. I have a lot of confidence in their ability to do it.

I am going to proffer a consent agreement that I think would allow us to go forward. My colleague from Tennessee will take the balance of our time after I have concluded.

I ask unanimous consent that following the conclusion of the two scheduled votes on the student loan bill, which we are about to have, the next order of business be a Harkin-Enzi bill dealing with the issue of the current student loan rate; provided further that no motion to proceed to other items be in order unless agreed to by both leaders.

The purpose of this consent agreement I have just proffered is to allow Senator HARKIN and Senator ENZI to negotiate on this important issue, the increase in the student loan rates, and to keep the Senate focused on how to resolve this issue in a timely way before the rate goes up. The bill they would negotiate would be the next order of business, but it would also provide that both leaders could agree to allow the Senate to work on other measures if necessary as those student loan discussions continue.

The PRESIDING OFFICER. Is there objection?

Mr. REID. I am going to use the leader time, not the 5 minutes we were allocated.

Madam President, we have all heard of reverse engineering. What we just heard is reverse reasoning. This is one of the most interesting things I have heard—that makes no sense. We have been trying to get on this bill for weeks. The Republicans have refused to allow us to get on the bill.

The student loan issue is important. We should have already completed this—had we been allowed to get on the bill—but we were not allowed to get on the bill. We were faced with one of our many filibusters—scores of them. Not one, two, three or four, scores of them. This is another example of them stopping us from legislating on a bill. Now to come here and say we could have been doing something—my friend knows the rules of this Senate as well as I do. He knows his suggestion is absurd.

I object.

The PRESIDING OFFICER. Objection is heard.

AMENDMENT NO. 2153

Mr. MCCONNELL. On behalf of Senator ALEXANDER I call up amendment No. 2153.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Kentucky [Mr. MCCONNELL], for Mr. ALEXANDER, for himself, Mr. MCCONNELL, Mr. ENZI, Mr. BARRASSO, Mr. BLUNT, Mr. COATS, Mr. COCHRAN, Mr. CORNYN, Mr. HELLER, Mr. INHOFE, Mr. ISAKSON, Mr. JOHANNS, Mr. ROBERTS, Mrs. HUTCHISON, Mr. RUBIO, and Ms. AYOTTE, proposes an amendment numbered 2153.

The amendment is as follows:

(Purpose: In the nature of a substitute)

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Interest Rate Reduction Act''.

SEC. 2. INTEREST RATE EXTENSION.

Subparagraph (D) of section 455(b)(7) of the Higher Education Act of 1965 (20 U.S.C. 1087e(b)(7)(D)) is amended—

(1) in the matter preceding clause (i), by striking ''2012'' and inserting ''2013''; and

(2) in clause (v), by striking ''2012'' and inserting ''2013''.

SEC. 3. REPEALING PREVENTION AND PUBLIC HEALTH FUND.

(a) IN GENERAL.—Section 4002 of the Patient Protection and Affordable Care Act (42 U.S.C. 300u–11) is repealed.

(b) RESCISSION OF UNOBLIGATED FUNDS.—Of the funds made available by such section 4002, the unobligated balance is rescinded.

SEC. 4. COMPLIANCE WITH STATUTORY PAY-AS-YOU-GO ACT OF 2010.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this Act, submitted for printing in the Congressional Record by the Chairman of the Senate Budget Committee, provided that such statement has been submitted prior to the vote on passage.

The PRESIDING OFFICER. The Senator from Tennessee.

Mr. ALEXANDER. Madam President, on July 1, 7 million students getting new loans to go to college, the rate for interest will go from 3.4 to 6.8. This is an amendment to get a result. This is the House-passed bill. President Obama

says he wants to freeze the rate for a year. Governor Romney says he wants to freeze the rate for a year. The House of Representatives has voted to freeze the rate for a year. A vote yes on the House-passed bill will permit us to send it to them and quickly send it to the President, he will sign it, and we solve the problem.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Mr. President, while I appreciate the confidence the Republican leader has in the ability of Mr. ENZI and me to get things done, frankly, we are confronted now with two votes. Which way do we want to go? What they are proposing is that we totally end, totally eliminate all of the prevention and wellness money that we have out there in the wellness fund.

What would this do? We have vaccinations for children, immunizations, smoking cessation programs, colorectal screenings, diabetes prevention, breast cancer screening, obesity prevention—all funded by this Prevention and Wellness Fund. Not one of those would be funded from that fund if that amendment passes.

The choice is very clear on the two amendments we have coming up. We can either vote to close a tax loophole that allows wealthy tax dodgers not to pay their fair share of taxes—we can close that loophole and keep the interest rates at 3.4 percent—or, as the Republicans want to do, totally eliminate the Wellness and Prevention Fund and end the money that we are putting into diabetes prevention and breast cancer and colorectal screening and all the things I mentioned.

I do not think the choice could be more clear to the American people about the direction we ought to go. Close the tax loophole. Keep the prevention fund in there. Keep our people healthy.

The PRESIDING OFFICER. The Senator from Tennessee.

Mr. ALEXANDER. Mr. President, we have 2 minutes left. I will use one of them.

Our friends on the other side have their usual solution to almost any problem: Let's put some more taxes on small business men and women in America during a time of the greatest recession we have had.

We have a better idea for how to pay for this bill. We will take some of the savings the Congressional Budget Office said they found when they took over the student health program in the health care bill—instead of giving the students the benefit of those savings, they spent it on government. They spent $8.3 billion on the health care bill. We will give back to the students enough money to pay for this freezing of the rate.

We will not tax the small businesspeople. We will have a little left over, and we will reduce the debt. Then we can send our bill to the House, they will pass it like that, send it to the President, and the problem is solved.

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. REED. Madam President, as Senator HARKIN pointed out, the Republican proposal goes right to the heart of prevention, and that will have two effects. It will deny critical services to families all across this country, and it will do something else—it will deny us the chance to bend that proverbial cost curve. If we do not control those costs, we will be in a fiscal disaster. The proposal they are making does not make sense. We have proposed to close a tax loophole that has been described by the Treasury inspector general for tax administration as a multibillion-dollar employment tax shelter.

We have restricted it to the people who are receiving over $200,000 a year. This is not small business men and women. This is not the corner hardware store. These are lobbyists. These are lawyers who have craftily used subchapter S corporations to avoid paying payroll taxes.

This loophole has been criticized on the editorial pages of the Wall Street Journal. This is no ''just raise taxes.'' This is trying to find a loophole which has been criticized by the right as well as the left to pay for and ensure that we do not double the interest rate on students. I cannot think of a clearer choice: Reject the Republican proposal; accept our proposal; do not allow the subsidized student loan interest rate to rise on July 1.

The PRESIDING OFFICER. The Senate will be in order. The Senator from Tennessee.

Mr. ALEXANDER. How much time is remaining?

The PRESIDING OFFICER. There is 1 minute 20 seconds.

Mr. ALEXANDER. It is reassuring to me my friend on the other side of the aisle is reading the editorial pages of the Wall Street Journal. I am sure that will have some constructive benefit over the next several months. But here is the bottom line, a result. This is the same as the House-passed bill which freezes interest at 3.4 percent for a year. We send it to the House, down to the President, he signs it, the problem is solved. Instead of raising taxes on small businesspeople, we give back to students the money they should have had the benefit of when the other side took over the whole student loan program before.

If you want a result, please vote yes. If you want more debate and delay, vote no.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. The President has already said if the Republican measure were to pass and sent to him, he would veto it. That is a nonstarter. Surely my friend from Tennessee does not want to cut out all of this funding that we do for hepatitis screening and colorectal screening, diabetes prevention, vaccination for our kids, all of which are funded. All of that would be ended by their amendment.

I do not know what my friend is talking about in terms of student money and this and that. Their provision takes all of this money out of the Prevention and Wellness Fund. That is not what we want. We do not want to keep our kids from getting vaccinations or hepatitis screening or diabetes prevention in order to keep the interest rates low. Let's close the tax loophole that has been talked about, that both Senator REID from Nevada and Senator REED from Rhode Island talked about. Close that tax loophole and send it to the President. He will sign it. That way we will keep the interest rates down at 3.4 percent and not allow them to double on July 1.

The PRESIDING OFFICER. Who seeks recognition?

Mr. REID. Has all time expired?

The PRESIDING OFFICER. The minority has 35 seconds and the majority 38 seconds.

Mr. ALEXANDER. Our case is so compelling, Mr. President. We yield back the rest of our time.

The PRESIDING OFFICER. The majority leader.

Mr. REID. Time has been yielded back. We think there will be two more votes. I can't say there will be no more votes. We have a few more items to be worked out, such as flood insurance. I can't give everyone that assurance at this time.

I ask for the yeas and nays.

The PRESIDING OFFICER. The question is on agreeing to the amendment offered by the Senator from Kentucky.

Mr. CONRAD. 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.

Ms. SNOWE (when her name was called). Present.

Mr. DURBIN. I announce that the Senator from Connecticut (Mr. BLUMENTHAL) is necessarily absent.

Mr. KYL. The following Senators are necessarily absent: the Senator from Texas (Mrs. HUTCHISON) and the Senator from Illinois (Mr. KIRK).

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

The result was announced—yeas 34, nays 62, as follows:

[Rollcall Vote No. 112 Leg.]

YEAS—34

Alexander	Enzi	Murkowski
Ayotte	Graham	Portman
Barrasso	Grassley	Risch
Blunt	Hatch	Roberts
Boozman	Heller	Rubio
Brown (MA)	Hoeven	Sessions
Chambliss	Isakson	Shelby
Coats	Johanns	Thune
Cochran	Kyl	Vitter
Collins	Lugar	Wicker
Cornyn	McCain	
Crapo	McConnell	

NAYS—62

Akaka	Begich	Bingaman
Baucus	Bennet	Boxer

Brown (OH)	Johnson (SD)	Nelson (FL)
Burr	Johnson (WI)	Paul
Cantwell	Kerry	Pryor
Cardin	Klobuchar	Reed
Carper	Kohl	Reid
Casey	Landrieu	Rockefeller
Coburn	Lautenberg	Sanders
Conrad	Leahy	Schumer
Coons	Lee	Shaheen
Corker	Levin	Stabenow
DeMint	Lieberman	Tester
Durbin	Manchin	Toomey
Feinstein	McCaskill	Udall (CO)
Franken	Menendez	Udall (NM)
Gillibrand	Merkley	Warner
Hagan	Mikulski	Webb
Harkin	Moran	Whitehouse
Inhofe	Murray	Wyden
Inouye	Nelson (NE)	

ANSWERED ''PRESENT''—1

Snowe

NOT VOTING—3

Blumenthal	Hutchison	Kirk

The amendment was rejected.

Mr. INHOFE. Mr. President, while the Republican alternative was definitely better than the Democrat-endorsed proposal, at the end of the day, neither option presented a long term answer to the impending rise in student loan interest rates.

In 2007, Congress passed the College Cost Reduction and Access Act, which I opposed. This legislation used a stepped reduction of interest rates for subsidized Stafford loans, from 6.8 percent to the current 3.4 percent. Also as a part of this law, these rates are scheduled to reset to the original 6.8 percent on July 1. So for five years, we have known this day was coming. A one-year extension of the current interest rate is merely a six billion dollar temporary fix. It would simply postpone finding an actual solution to the problem of college affordability. Congress has gotten too comfortable with band aid fixes: payments to physicians, the Highway bill, and flood insurance being recent examples. It is because of increased government intervention that we continually find ourselves in this predicament. With every government takeover, whether it is education, health care, or the EPA, the result is less competition, less consumer choice, and less innovation.

Mr. President, I understand the importance and value of a good education. My wife was a teacher, and my two daughters became teachers as well, one even at a university. I also commend the efforts of all students who strive to achieve a higher education and improve their lives, especially those struggling through financial burdens. However, we owe it to these students to address the problem, not just put a band aid on it.

The PRESIDING OFFICER. The majority leader is recognized.

EXTENSION OF THE NATIONAL FLOOD INSURANCE PROGRAM

Mr. REID. Mr. President, as we have noted on the floor many times in the last few days, the Flood Insurance Program covers almost 6 million people. It was set to expire next week. If it were to expire, new housing construction would stall—in fact, it may come to a halt—real estate transactions would come to a screaming halt, and taxpayers would be on the hook for future disasters. We have no choice. We have to get this done.

I appreciate the work of Chairman JOHNSON, Ranking Member SHELBY, the chairman of the subcommittee, Senator TESTER, and Ranking Member VITTER. I also appreciate the work that was put into this effort by Senator COBURN, who worked closely with Senator SCHUMER, and we were able to get this extension done. I am grateful for everyone's help. It was team work that got us where we are.

Mr. President, I ask unanimous consent that the Senate proceed to Calendar No. 407, H.R. 5740, flood insurance extension; that a Johnson of South Dakota substitute amendment, which is at the desk, be agreed to; that the bill, as amended, be read a third time and passed; and that motions to reconsider be laid upon the table, with no intervening action or debate. And if anyone has anything to say about this, they can put it in the RECORD.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

The amendment (No. 2154) was agreed to, as follows:

(Purpose: In the nature of a substitute)

Strike all after the enacting clause and insert the following:

SECTION 1. EXTENSION OF THE NATIONAL FLOOD INSURANCE PROGRAM.

(a) PROGRAM EXTENSION.—Section 1319 of the National Flood Insurance Act of 1968 (42 U.S.C. 4026) is amended by striking ''the earlier of the date of the enactment into law of an Act that specifically amends the date specified in this section or May 31, 2012'' and inserting ''July 31, 2012''.

(b) FINANCING.—Section 1309(a) of the National Flood Insurance Act of 1968 (42 U.S.C. 4016(a)) is amended by striking ''the earlier of the date of the enactment into law of an Act that specifically amends the date specified in this section or May 31, 2012'' and inserting ''July 31, 2012''.

SEC. 2. EXCLUSION OF VACATION HOMES AND SECOND HOMES FROM RECEIVING SUBSIDIZED PREMIUM RATES.

(a) IN GENERAL.—Section 1307(a)(2) of the National Flood Insurance Act of 1968 (42 U.S.C. 4014(a)(2)) is amended by inserting before ''; and'' the following: '', except that the Administrator shall not estimate rates under this paragraph for any residential property which is not the primary residence of an individual''.

(b) PHASE-OUT OF SUBSIDIZED PREMIUM RATES.—Section 1308(e) of the National Flood Insurance Act of 1968 (42 U.S.C. 4015(e)) is amended—

(1) by striking ''under this title for any properties within any single'' and inserting the following: ''under this title for—

''(1) any properties within any single''; and

(2) by striking the period at the end and inserting the following: ''; and

''(2) any residential properties which are not the primary residence of an individual, as described in section 1307(a)(2), shall be increased by 25 percent each year, until the average risk premium rate for such properties is equal to the average of the risk premium rates for properties described under paragraph (1).''.

(c) EFFECTIVE DATE.—The first increase in chargeable risk premium rates for residential properties which are not the primary residence of an individual under section 1308(e)(2) of the National Flood Insurance Act of 1968, as added by this Act, shall take effect on July 1, 2012, and the chargeable risk premium rates for such properties shall be increased by 25 percent each year thereafter, as provided in such section 1308(e)(2).

SEC. 3. COMPLIANCE WITH PAYGO.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this Act, submitted for printing in the Congressional Record by the Chairman of the Senate Budget Committee, provided that such statement has been submitted prior to the vote on passage.

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

The bill (H.R. 5740), as amended, was read the third time was passed.

STOP THE STUDENT LOAN INTEREST RATE HIKE ACT OF 2012—Continued

Mr. REID. Mr. President, this will be the last vote coming up. No speeches. We will start voting.

The PRESIDING OFFICER. 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.

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

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The bill having been read the third time, the question is, Shall the bill pass?

The clerk will call the roll.

The legislative clerk called the roll.

Ms. SNOWE (when her name was called). Present.

Mr. DURBIN. I announce that the Senator from Connecticut (Mr. BLUMENTHAL) is necessarily absent.

Mr. THUNE. The following Senators are necessarily absent: the Senator from Wyoming (Mr. ENZI), the Senator from Texas (Mrs. HUTCHISON), the Senator from Illinois (Mr. KIRK), and the Senator from Arizona (Mr. KYL).

The result was announced—yeas 51, nays 43, as follows:

[Rollcall Vote No. 113 Leg.]

YEAS—51

Akaka	Hagan	Murray
Baucus	Harkin	Nelson (NE)
Begich	Inouye	Nelson (FL)
Bennet	Johnson (SD)	Pryor
Bingaman	Kerry	Reed
Boxer	Klobuchar	Reid
Brown (OH)	Kohl	Rockefeller
Cantwell	Landrieu	Sanders
Cardin	Lautenberg	Schumer
Carper	Leahy	Shaheen
Casey	Levin	Stabenow
Conrad	Lieberman	Tester
Coons	Manchin	Udall (CO)
Durbin	McCaskill	Udall (NM)
Feinstein	Menendez	Warner
Franken	Merkley	Whitehouse
Gillibrand	Mikulski	Wyden

NAYS—43

Alexander	DeMint	Murkowski
Ayotte	Graham	Paul
Barrasso	Grassley	Portman
Blunt	Hatch	Risch
Boozman	Heller	Roberts
Brown (MA)	Hoeven	Rubio
Burr	Inhofe	Sessions
Chambliss	Isakson	Shelby
Coats	Johanns	Thune
Coburn	Johnson (WI)	Toomey
Cochran	Lee	Vitter
Collins	Lugar	Webb
Corker	McCain	Wicker
Cornyn	McConnell	
Crapo	Moran	

ANSWERED ''PRESENT''—1

Snowe

NOT VOTING—5

Blumenthal	Hutchison	Kyl
Enzi	Kirk	

The PRESIDING OFFICER (Mr. MANCHIN). Under the previous order requiring 60 votes for passage of the bill, the bill is rejected.

Mr. REID. 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.

PAYCHECK FAIRNESS ACT—MOTION TO PROCEED

Mr. REID. Mr. President, I now move to proceed to calendar No. 410, S. 3220.

The PRESIDING OFFICER. The clerk will report the motion.

The legislative clerk read as follows:

Motion to proceed to Calendar No. 410, S. 3220, a bill to amend the Fair Labor Standards Act of 1938 to provide more effective remedies to victims of discrimination in the payment of wages on the basis of sex, and for other purposes.

CLOTURE MOTION

Mr. REID. Mr. President, I have a cloture motion at the desk.

The PRESIDING OFFICER. The cloture motion having been presented under rule XXII, the Chair directs the clerk to read the motion.

The legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, hereby move to bring to a close debate on the motion to proceed to Calendar No. 410, S. 3220, a bill to amend the Fair Labor Standards Act of 1938 to provide more effective remedies to victims of discrimination in the payment of wages on the basis of sex, and for other purposes.

Barbara A. Mikulski, Harry Reid, Maria Cantwell, Patty Murray, Frank R. Lautenberg, Jeff Bingaman, Sheldon Whitehouse, John F. Kerry, Kent Conrad, Jeanne Shaheen, Bernard Sanders, Tom Udall, Amy Klobuchar, Carl Levin, Mark R. Warner, Mark L. Pryor, Jack Reed, Kirsten E. Gillibrand.

Mr. REID. Mr. President, I ask unanimous consent that the mandatory quorum under rule XXII be waived, and the vote on the motion to invoke cloture on the motion to proceed to S. 3220 occur at 2:15 p.m., on Tuesday, June 5.

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

Mr. REID. Mr. President, we are going to arrange a vote Monday night on one of the nominees who is trying to become a judge.

The PRESIDING OFFICER. The Senator from Rhode Island.

CLIMATE CHANGE

Mr. WHITEHOUSE. Mr. President, I want to take a few moments this afternoon to do something that has become a bit of a ritual with me; that is, to try to take some time each week to speak about the damage we are doing to our atmosphere, to our oceans, and to our climate with the relentless carbon pollution we are discharging.

As each week goes by, the information continues to pile up about the harms we are causing.

A recent story says rising temperatures could eliminate two-thirds of California's snowpack by the end of this century.

The snowpack that helps provide water for California cities and farms could shrink by two-thirds because of climate change, according to new research submitted to the state's Energy Commission.

Higher temperatures appear likely to wipe out a third of the Golden State's snowpack by 2050 and two-thirds by the end of the century, the Scripps Institution of Oceanography found.

Science Daily reports:

Black carbon aerosols and tropospheric ozone, both humanmade pollutants emitted predominantly in the Northern Hemisphere's low- to mid-latitudes—

That is basically us—

are most likely pushing the boundary of the tropics further poleward—

North and south—

in that hemisphere, new research by a team of scientists shows. . . .

The lead climatologist, Robert J. Allen, says:

If the tropics are moving poleward, then the subtropics will become even drier. If a poleward displacement of the mid-latitude storm tracks also occurs, this will shift mid-latitude precipitation poleward, impacting regional agriculture, economy, and society.

The American people have not been taken in by the campaign of propaganda that primarily the polluting industries have put out. There have been significant reports in the past on ExxonMobil's funding of essentially phony research agencies so they can offer their opinions on this issue without having it be ExxonMobil's opinion. They either create or take over or subsidize organizations that then put out the message, and they sound legit—Heartland Institute, Annapolis Center.

But the American people are not fooled, it turns out. Seventy-one percent of visitors who have come to the Nation's wildlife refuges say they were personally concerned about climate change's effects on fish, wildlife, and habitat. Seventy-four percent said that working to limit climate's effects on fish, wildlife, and habitat would benefit future generations. And 69 percent said doing so would improve the quality of life today.

One of the original researchers on climate change—I quoted an article earlier, describing how over time the facts have proven his initial predictions accurate—is James Hansen. He wrote an article a few weeks ago in the New York Times headlined ''Game Over for the Climate.'' It begins with these two sentences:

Global warming isn't a prediction. It is happening.

Clearly we see that in measurements and observations around the planet. But what happens if it keeps going? He is talking about the tar sands up in Canada, and he says this:

If we were to fully exploit this new oil source, and continue to burn our conventional oil, gas, and coal supplies, concentrations of carbon dioxide in the atmosphere would eventually reach levels higher than in the Pliocene era, more than 2.5 million years ago, when sea level was at least 50 feet higher than it is now. That level of heat-trapping gases would assure that the disintegration of the ice sheets would accelerate out of control. Sea levels would rise and destroy coastal cities. Global temperatures would become intolerable. Twenty to 50 percent of the planet's species would be driven to extinction. Civilization would be at risk.

That is clearly, as he admits, a long-term outlook, but it is an outlook that deserves our attention, because when he has given us long-term outlooks in the past, as time has marched forward they have been proven over and over to be true.

It is convenient around here to pretend that none of this is happening. And it would be nice if we could wait until the disaster, the wolf was at the door and then do something about it, but there is a strong likelihood that by the time we take action, it will be too late.

In September of 1940, there was an American living in the Philippines with his wife and son. He looked at what was happening over in Europe. He looked at the threat to Britain. He cabled back to the United States his recommendation. He said:

The history of failure in war can almost be summed up in two words—''too late.'' Too late in comprehending the deadly purpose of a potential enemy. Too late in realizing the mortal danger. Too late in preparedness. Too late in uniting all possible forces for resistance. Too late in standing by one's friends.

The author of that cable was GEN George MacArthur. He continued later on in the cable:

The greatest strategic mistake in all history will be made if America fails to recognize the vital moment, if she permits again the writing of that fatal epitaph ''too late.''

Of course, General MacArthur was talking about what was becoming World War II, he was not talking about climate change. Yet his warning rings very true against this threat as well. ''Too late'' will be the epitaph if we do not prepare now. And I very much regret that we are in a situation in which we do not seem able as a body to take this threat seriously. The House shows no indication whatsoever of taking this threat seriously. Even the White House has dialed back its expressions of interest and concern on this issue, probably for the practical reason that the Republican-controlled House does not

want to deal with this issue at all. Period. End of story. But it is happening out there. It is happening out there.

People see the dying forests of the West as the pine bark beetle works its way more and more north because winters are no longer cold enough to kill off the larvae. People see the habitat of quail, of trout, of pheasant, of game animals, change in their lifetimes.

They see the places where they used to be able to go to fish with their grandchildren no longer available. Farmers see changes. Gardeners see changes. Plants that could not grow in certain zones now can. Tropical plants can grow in northern areas because of changes. In Rhode Island we have had winter blooms of some of our fruit trees because it has gotten so warm.

My wife did her dissertation on the species called the winter flounder, which was a very significant cash crop for the Rhode Island fishing industry. It was not very long ago. She wrote her dissertation about it because it was such an important part of the Rhode Island fishing industry, and because it had an interesting connection with a shrimp, Crangon septemspinosa, in which one fed on the other until it got big enough, and then the predatory cycle reversed itself and the winter flounder began to eat the shrimp instead of vice versa.

Well, landings of winter flounder in Rhode Island have crashed catastrophically. The reason? The mean winter water temperature of Narragansett Bay is up about 4 degrees. That is enough of an ecosystem shift that the winter flounder is gone. Fishermen now catch scup instead, which is a far less remunerative crop and frankly not as good a fish to eat, in my opinion anyway.

So these changes are happening. It is regrettable that we are unable to address them. The science has been discredited by propaganda campaigns that are deliberately and strategically designed to create doubt in the minds of the public where no doubt should exist. The fact is this science is rock solid.

The notion that when you put lots of carbon dioxide up into the atmosphere it warms the atmosphere has been around since the Civil War. The scientist who discovered it was an English-Irish scientist named John Tyndall. He first reported this phenomenon in 1863. For 150 years we have known this. This is nothing new. We can measure the gigatons of carbon that we are discharging into the atmosphere. Of course, it is going to make a difference. The notion that it does not has been a public relations and propaganda campaign by well-heeled special interests to protect pollution, because it makes money for those companies. But with the damage it is doing to our future, it is very hard to honestly look my children in the eye and say I am doing my job for them here in Washington while we do nothing on carbon pollution.

In fact, we continue to subsidize the biggest polluters. ExxonMobil makes more money than any corporation has in the history of the world and they still claim a subsidy from the American taxpayer. It is a ridiculous subsidy. And yet we subsidize them. I see the distinguished chairman of the Health, Education, Labor, and Pensions Committee is here on the floor. I want to conclude my remarks and thank him for the amazing work he and the ranking member, Michael Enzi, did on the FDA bill we just passed with such a strong vote, virtually a unanimous vote. There was a lot of very good work that was done there, so that proves there are areas where we can do good work.

I hope the day comes when we can begin to do good work on the damage we are doing to our atmosphere and to our oceans with our relentless discharge of carbon dioxide into the atmosphere, with our relentless subsidy of the polluters. One day we will be called into account for our inaction, and we will have earned the condemnation of history.

I yield the floor.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. Mr. President, I want to thank my friend from Rhode Island for a very eloquent speech—elegant speech too—eloquent and elegant—in portraying what is so frustrating. And that is science knows what is happening. The scientists know what is happening. We have good data points about what is happening to our climate, our atmosphere, our oceans, and yet it seems we cannot do anything about it.

I say to my friend from Rhode Island, I think I was reading recently in a Scientific American magazine, which I love to read every month, that in terms of this whole global climate change, what is happening is that by the time we recognize it is happening—that is broadly, not just the scientists and others who do know what is happening—by the time it is broadly accepted, it will be too late, that we will have reached that tipping point. But the evidence is there for all to see. It is a shame that we cannot do something about it.

The Senator mentioned the fish catch in Rhode Island. I think also in the recent issue of Scientific American was a story about the fisheries and oceans at large, and there were three pictures. One was a picture taken on a pier in Key West in the 1950s showing the size of the fish that were caught. Big. I think the average weight was like 30-some pounds. Then there was a picture taken in the 1970s—late 1970s, early 1980s—now it is down to maybe 15 pounds. Same pictures, same pier, same dock and everything, and now the catch is down to teeny little fish. Same place, same ocean, same waters.

The article went on to point out how, if you look at the first picture, people are very happy. They are happy with this big fish. Then the second page, people are happy with what they caught. And now you have got this little teeny fish and people are still happy, because we kind of tend to accept what it is right now and be happy with what we have got without realizing what we have lost in the past.

Again, I thank the Senator for his speech. We need to do more of that around here. We need to focus on this. We seem to be drifting. You are right, our grandkids are going to wonder why we did not do something.

Mr. WHITEHOUSE. I would suggest that it is more than just that we are drifting. I would suggest we are being drifted by politics and by the money in politics, particularly the big money the big polluters can throw into politics, not only directly by giving campaign contributions to people but by flooding money into phony so-called scientific organizations that then parrot their message, but without people being able to say: Wait a minute, this is ExxonMobil telling me; maybe I should be a little more guarded about it. So they launder it through a legitimate-sounding organization—not one, dozens—and we get bombarded with false propaganda. Scientists are not good at propaganda. It is not why they went to graduate school. It is not why they got their Ph.D. It is not what they do when they are out in the field taking measurements. So you put them up against a company such as ExxonMobil with all of its money and its propaganda skills and it is not an even contest.

As the Chairman points out, by the time we are looking around and seeing, oh, my gosh, what have we allowed to happen—now we are awake—we reject the propaganda. We have to do something about this, and it will probably be, as General MacArthur said, too late. That is the great danger.

I thank the chairman for his recognition.

The PRESIDING OFFICER. The Senator from South Dakota.

Mr. THUNE. Mr. President, I ask unanimous consent that I be allowed to speak as in morning business.

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

HONORING SENATOR JAMES ABDNOR

Mr. THUNE. Mr. President, I rise today to recognize a former Member of this body and my long-time friend and mentor, Senator Jim Abdnor of South Dakota. Senator Abdnor passed away last Wednesday, May 16, 2012, in South Dakota in the company of friends and family.

We are both products of the dusty short-grass country just west of the Missouri River on the plains of central South Dakota. Jim was a product of the active and civically-minded political culture of Lyman County and I was from next door Jones County. Despite these counties' sports rivalries over the years, Jim took me under his wing and introduced me to the American political process. If not for Jim Abdnor, I would not be standing here today.

After a basketball game when I was a freshman in high school, Jim struck up a conversation with me that would change the course of my life. I went to work for Jim as a legislative assistant when he was a Senator and later at the Small Business Administration. When I first ran for office, Jim's guidance and support were invaluable to me.

This past weekend, hundreds of South Dakotans came out to honor Jim Abdnor and remember his great love for them and his state. His funeral was held in a Lutheran church in the shadow of the State capital in Pierre, where Jim first served in statewide office as Lieutenant Governor. Jim was buried just outside of his small hometown of Kennebec near where his immigrant father first homesteaded.

Mr. President, Jim leaves us with many legacies and I want to mention a few of them here today.

First and foremost, Jim's was an American story. It started as the tale of an immigrant who boarded a ship for the United States not even knowing the English language but knowing he was heading for the land of opportunity. That immigrant, Jim's father Sam Abdelnour, wanted to escape the growing authoritarianism of his native Lebanon, for American freedom.

Jim's story is also a frontier story. His father Sam settled in Lyman County, South Dakota. Sam Abdnor became a homesteader and planted corn and wheat. He also peddled his wares to the other farmers in the area and when Kennebec was organized as a town, Sam was one of the first people to establish a business on main street. Jim grew up learning how to balance the books in a small town store and knowing how to work the family farm. He learned financial responsibility and hard work and how one can climb the ladder of success in America.

Jim's story is also a story of the land and farming. Some of us who knew Jim through politics may forget that before he was elected to Congress Jim had owned and run the family farm for three decades. Jim was very proud of the fact that he was good at representing South Dakota agriculture because he was an active farmer who did the planting and hauled his grain to the elevator in the fall. When he was in Congress, South Dakota was ranked as the most agricultural state in the Nation and Jim was the first farmer elected to Congress from South Dakota. Jim was proud of that correlation and he never forgot his farming roots.

During the 1970s, when people were organizing sit-ins and teach-ins and other protests, Jim helped organize a ''beef-in.'' He brought 100 West River ranchers to Washington, DC, to talk about farm issues. They set up pens of cattle on the Washington mall and met with agriculture officials. Jim didn't rest until these ranchers had their voices heard.

Jim's story is also about water. We all live comfortably now with running water and hot showers, but that's not how Jim grew up. He grew up on his family's windy, dry-land farm in Lyman County. He lived through the droughts of the 1930s. He understood the importance of water. He never stopped working on the issues of water access—including being a champion of the WEB water project in Walworth, Edmunds, and Brown counties in north central South Dakota that began in 1983.

The question of water was never far from Jim's mind and I think it had something to do with his heritage. That's certainly true of his Lyman County roots, which is where the humid Midwest begins to turn into the arid High Plains, but also of his roots in Lebanon, where water is also scarce. His family's home village of Ain Arab was founded because it was a watering hole. Ain Arab literally means ''spring'' or ''well.'' More specifically, it means ''spring of the Arab.'' When they had enough water in Ain Arab they would grow wheat, just like the Abdnors would do out in Lyman County.

Jim's is also a story about organizing. As soon as he came home from college, he started organizing Republicans in Lyman County and became head of the Lyman County Young Republicans. He helped organize and found the Elks lodge in Pierre in 1953. He joined every organization he could and he brought as many people into community affairs and politics and civic organizations as he could.

Jim also pushed other people to organize. He liked to tell the story of the people in Faith, SD, who wanted a new grandstand at their rodeo grounds. They took one look at the Federal regulations involved with some grant program and promptly did everything themselves, raising all the money they needed from local sources and fundraisers and did it at 10 percent of the cost. They put in 4,000 hours of their own time and made it happen themselves and Jim appreciated that. He liked communities working together to solve their own problems.

During the 1970s, when tensions in the Middle East worsened, Jim called for his fellow Arab-Americans to become more involved in the political process. He opposed what he saw as their tendency toward isolation and self-segregation. He said his ethnic compatriots should ''get out and mix.'' ''They should become more involved,'' he said, ''become part of the community.'' Jim never stopped believing in the importance of being involved and working with others to make life better.

This is why Jim had so many friends. He never stopped working to meet people and bring them together around issues and simply to socialize. A friend of mine says that he doesn't think anyone in the State of South Dakota has ever attended more weddings, graduations, ceremonial dinners, or basketball, baseball, and football games than Jim.

As someone from the wide open plains who wanted groups of people to come together to solve problems on their own, Jim was always resisting Federal encroachment on local control. As the son of a small businessman, Jim was sensitive to the growing encroachment of Federal regulations and how much this encroachment cost small businesses. For many years, Jim was especially incensed about OSHA mandating rules for small stores on South Dakota main streets. In the 1970s, Jim also had a big fight with OSHA because it was trying to mandate that South Dakota wheat farmers maintain portapotties in the fields, which a practicing wheat farmer from Lyman County, South Dakota knew was the definition of absurd.

As a small businessman and farmer, Jim was always worried about the bottom line and he constantly tried to apply these concerns in the area of the Federal budget. Jim was sounding the alarm bell in the 1970s when the Federal Government spent less than $400 billion a year, which today seems laughably small given our current state of affairs. Back then, he was attacking deficits of $70 billion. He was also adamantly opposed to the Federal Government bailing out New York City in the 1970s because he said it would set a bad precedent. He attacked a Federal debt ceiling limit of $500 billion as being highly irresponsible. He criticized the fact that each American owed $2,000 because of the Federal Government's debt. Jim liked to quote the editor of the Freeman Courier, who asked ''how can it be that a government which is unable to balance its own budget and lives far beyond its means, has the authority to tell a businessman'' how to run his business.

Jim wasn't afraid to make hard votes to fix our problems, votes that probably cost him his Senate seat. But Jim Abdnor had the moral courage to make the tough decisions.

Mr. President, Jim Abdnor leaves us with a critical reminder. He embodied the American dream. He was the son of a poor Lebanese peddler who built a successful business and raised a great family, including a son who ascended the heights of American politics and became a U.S. Senator. Jim Abdnor shows how hard work and diligence can pay off.

On this occasion of remembrance and during this time of honoring my good friend Jim Abdnor, I hope we can remember our solemn duty to protect the American dream that the Abdnor family represented.

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

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

UNANIMOUS CONSENT REQUEST—H.R. 5652

Mr. REID. Mr. President, last month, the Senate passed the Violence Against Women Act Reauthorization on a strong bipartisan vote of 68 to 31. Fifteen Republican Senators—including all the women on the other side of the aisle—joined Senate Democrats to support this important legislation. Senate Democrats strongly stand behind the bill we passed. It makes clear that all victims of domestic violence and sexual assault should enjoy the protections of the Violence Against Women Act. We don't believe we should be in the business of picking and choosing which victims deserve protection.

In contrast, the bill passed by House Republicans fails to include crucial protections for Native American women—I have 22 tribal organizations in my State, for example—gay and lesbian victims, battered immigrant women, and victims on college campuses and in subsidized housing. The House bill would roll back many important and longstanding protections in current law for abused immigrant victims—protections that have never been controversial and previously have enjoyed widespread bipartisan support.

So there are many differences to be worked out between the House and the Senate in this crucial piece of legislation. The right place to work out these differences is in conference. That is why we seek today to go to conference with the House on this important legislation, and that is why we object to simply passing the House bill that has been sent to us.

The House has raised, I think unfortunately, the so-called blue slip problem, which seems to be an issue they raise all the time when there is a bill they do not like.

Having said that, I now ask unanimous consent that the Senate proceed to the consideration of H.R. 5652, Calendar No. 398; that all after the enacting clause be stricken and the language of S. 1925, the Violence Against Women Act Reauthorization, as passed by the Senate on April 26 by a vote of 68 to 31, be inserted in lieu thereof; that the Senate insist on its amendment, request a conference with the House on the disagreeing votes of the two Houses; and the Chair be authorized to appoint conferees on the part of the Senate, with all the above occurring with no intervening action or debate.

The PRESIDING OFFICER. Is there objection?

Mr. McCONNELL. Mr. President, I object.

The PRESIDING OFFICER. Objection is heard.

UNANIMOUS CONSENT REQUEST—H.R. 4970

Mr. McCONNELL. Mr. President, let me make a few observations and then I intend to offer a consent request myself.

This is a problem that has been created by the majority, and I am sorry they will not accept our offer to fix their problem so we can move forward on this legislation. We have all known for literally years when the Violence Against Women Act was going to expire. We have known that for years. During this time, Democrats controlled the Senate. Yet our friends on the other side waited until February of this year—nearly 6 months after the current authorization expired—before they even reported a bill out of committee, and they chose to wait almost 3 months more to bring a bill to the floor.

I don't know why that decision was made. Press reports indicate that members of the Democratic leadership thought they could use VAWA as a campaign issue. When they finally chose to bring this bill to the Senate floor, Republicans consented to going to the bill, Republicans consented to bringing the debate to a close, and Republicans consented to limiting ourselves to just two amendments—just two. Our Democratic colleagues also added an amendment. It was a complete substitute. They offered it at the last minute.

This substitute was a couple hundred pages long and it added new sections to the bill. One of those sections would generate revenue by assessing new fees on immigration visas. I gather our Democratic colleagues did this because their bill, unlike the Hutchison-Grassley bill, would add over $100 million to the debt.

Including this provision is obviously a problem, in that adding a revenue provision in a Senate bill violates the Origination Clause of the U.S. Constitution. If we sent the Senate bill to the House in its current form, it would trigger a blue slip point of order, as it always does.

It is not our fault Senate Democrats waited until well after VAWA expired to start moving a bill. It is not our fault their bill would add to the debt. It is not our fault our friends waited until the last minute to try to fix the problem, and, in the course of doing so, they created yet another problem. We have offered to help them fix their problem. They do not have to accept our help, but they should stop demagoguing the issue and blaming others.

Therefore, I would offer another consent: I ask unanimous consent that the Senate proceed to the consideration of Calendar No. 406, H.R. 4970, the House-passed Violence Against Women Reauthorization Act; provided further that all after the enacting clause be stricken, the text of the Senate-passed Violence Against Women bill, S. 1925, with a modification that strikes sections 805 and 810 related to the immigration provisions; that the bill be read three times and passed, the Senate insist on its amendment, request a conference with the House, and the Chair be authorized to appoint conferees on the part of the Senate with a ratio agreed to by both leaders.

The PRESIDING OFFICER. Is there objection?

Mr. REID. Mr. President, reserving the right to object, the Republican leader is now proposing an amendment to the Senate-passed bill—a Senate-passed bill that we are very proud of. It has been engineered and advocated by all Democratic Senators but mainly by the 12 women who are part of our caucus. This is an important piece of legislation. We all feel very strongly about this.

I haven't looked at all the details of this amendment, but I understand it. My first response is that the amendment is something the conferees should be working on. We can't do that without the proper input from all the interested parties, and we have 52, other than myself, on my side of the Capitol. That is why I have sought to go to conference with the product the Senate passed.

It may be that sometime in the future, after we evaluate all these pieces that have been suggested by my friend, the Republican leader, we may be able to proceed along this route, if, in fact, we get to conference. But we have to get to conference, and we have to have wider discussions airing the proposed amendment we have had just a little time to look at, at this stage.

I understand my friend's proposal, and I object to it.

The PRESIDING OFFICER. Objection is heard.

MORNING BUSINESS

Mr. REID. Mr. President, I ask unanimous consent that we proceed to 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.

REMEMBERING BILL STEWART

Mr. MANCHIN. Mr. President, before I speak today about the bill before us, I want to commemorate the life of a dear friend and a true West Virginian, Bill Stewart.

Bill was taken from us 2 days ago at the age of 59, but he left behind a lifetime of memories and love for our State.

Bill Stewart was a proud West Virginian in every sense of the word, and he was the best cheerleader this State ever had. Whether it was playing ball at Fairmont State—where I first met him—or coaching West Virginia University to a Fiesta Bowl win—where he took an underdog team to a thrilling victory—you never had to worry about Bill's enthusiasm; he had enough for all of us. In fact, you were either a friend of Bill Stewart's or he hadn't met you yet.

Bill was raised in New Martinsville and was a West Virginian through-and-through. Countless young men thrived under his coaching, but he was also truly dedicated to his family—his wife Karen and his son Blaine. I hope Karen and Blaine know just how much Bill meant to the people of our State, how much we loved him and how much we all will miss him.

My wife Gayle and I will keep Bill's entire family in our thoughts and prayers.

RECOGNIZING GARY BATES

Mr. REID. Mr. President, I rise today to recognize the exemplary citizenship of Gary Bates. This is recognition for a life that has been lived and is continuing to be lived well—the kind of honorable life that too often goes unrecognized.

Gary's life has been defined by fighting. He began life in Henderson, NV fighting to avoid the challenges of a difficult home. He took this fighting spirit into the Marine Corps, where he served honorably until 1966 when he began an impressive career as a professional heavyweight boxer. As a regular name on the Las Vegas strip, he faced off with big names like Ken Norton, Ron Lyle and Gerry Cooney. There is nothing to idealize about many of the choices he made and paths he took in this phase of his life, but what is admirable is how he fought to turn his life around. He learned from the mistakes he made, and turned potential stumbling blocks into effective stepping stones to a productive life.

Recognizing a better way of living, Gary settled down by marrying his wife Carmen and raising two daughters. But Gary did not stop fighting. Finding inspiration in his Catholic faith, he picked up the fight for the less fortunate and endangered. Some of Gary's feats border on the incredible. He once saved the life of a complete stranger, Charles H. Case. While visiting Las Vegas, Charles crashed into an off-ramp rail and his car exploded into flames. Luckily for Charles, Gary witnessed the crash, broke the front left window and freed his pinned body from the enflamed car. Another time, while working in a downtown casino, Gary chased a fleeing thief through an alley into another casino and, as the police reported, decked him with a single punch to the right cheekbone. Gary was never motivated by or sought praise for these actions, a fact that is evidenced by many other low-profile acts of service. He has donated more than 25 gallons of his blood. Additionally, Gary has uniquely compatible blood marrow that he has amazingly matched with five non-relatives. He will tell you that of all his feats he is most proud of his marrow donation that saved the life of a 1-year-old boy.

I am pleased to recognize my friend Gary Bates and to give him some of the praise he has never asked, but certainly deserves. He has said he would take a bullet for me, but I think he would take one for anyone in need. Even at 67 he exercises daily so that he can be physically, not just mentally, ready to meet the call of anyone in distress. He continues to be an example to Nevadans and Americans that anyone can turn in their boxing gloves or brass knuckles for the work gloves of a citizen making our society a better place.

TRIBUTE TO DR. LARRY D. SHINN

Mr. MCCONNELL. Mr. President, I rise today to pay tribute to a great educator who has impacted the lives of thousands of Kentuckians over the course of his career. My good friend, Dr. Larry D. Shinn, will retire in a little more than a month's time after serving 18 years as president of Berea College in Berea, KY, and I know I speak for many when I say I am very sorry to see him go.

Dr. Shinn has served as president since 1994 and is the eighth president of Berea College, a proud liberal-arts college which is dedicated to serving students of great promise and limited economic means. Its primary focus is on serving students from the Appalachian region. Berea College generously offers a full-tuition scholarship to each of its 1,500 students and requires all of them to work in positions on campus. Berea College is proud of its heritage as the first interracial and coeducational college in the South and proud of its focus on a Christian ethic of service and its historic mission to promote the cause of Christ.

Dr. Shinn is a magna cum laude graduate of Baldwin-Wallace College and a summa cum laude graduate of Drew University Theological School. He received his Ph.D. in history of religions from Princeton University. Before coming aboard as Berea's president, he taught at Oberlin College for 14 years and served as dean and vice president at Bucknell University for 10 years. He has authored several books and numerous articles and book reviews.

Then there is the remarkable progress Berea College has made under Dr. Shinn's leadership. During his presidency, Dr. Shinn has led the school's strategic-planning process and the creation of its strategic plan for Berea College to thrive in the 21st century. He has instituted a decisionmaking process that has enhanced virtually every area of academic life, from student retention and graduation rates to residential life, academic planning, development, and facilities renovation. He has led Berea's sustainability initiative, which is responsible for the creation of the Sustainability and Environmental Studies Program; the ecological renovations of several campus buildings, including the first LEED, Leadership in Energy and Environmental Design, building in Kentucky; and the establishment of a residential ''eco-village'' for student families.

Dr. Shinn also led the ''Extending Berea's Legacy'' campaign that raised $162 million for endowments to fund student scholarships, undergraduate research, a new technology program for students, a study abroad program, an entrepreneurship program, and other key initiatives.

I know that Larry and his wife Nancy are looking forward to having a little more time to themselves and to spend with their family, but their gain will certainly be Berea College's and Kentucky's loss. In his 18 years at the helm, Dr. Shinn has proven himself to be one of the finest college presidents in Kentucky and the Nation. I salute him for his incredible legacy of service towards improving the lives of the thousands of Kentuckians and other students who have passed through Berea College's doors. He is a great Kentuckian whom I have been honored to represent and to work with over his nearly two decades as Berea College's president. He will be missed.

Mr. President, the Berea Spotlight, a publication of Berea College, published an article highlighting the many accomplishments of Dr. Larry Shinn around the time he announced his retirement. I ask unanimous consent that said article be printed in the RECORD.

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

[From the Berea Spotlight, Apr. 4, 2011]

LARRY SHINN, BEREA COLLEGE PRESIDENT, PLANS RETIREMENT

(By Tim Jordan)

Berea College President Dr. Larry D. Shinn announced today that he will be retiring from the College, effective June 30, 2012. Berea's 8th president, Dr. Shinn has served in this capacity since 1994. In a letter to trustees, faculty, staff and students, Shinn stated that, with the College emerging strongly from the challenges of the Great Recession, it is a good time for Berea to begin the process of a leadership transition.

The combined efforts of Berea's faculty, staff, administrators, trustees, and other stakeholders have, over the span of the past 17 years, resulted in dramatic progress at the College. Enrollment of African-American students has increased from 6 percent to 18 percent, while service to the Appalachian region has been expanded. Retention and graduation rates have improved more than 30 percent while new program initiatives have enhanced educational quality. The College has successfully completed over $140 million in sustainable building renovations, and in 2005 a $150-million sesquicentennial campaign exceeded its goal. In response to the financial crisis of 2008–09, the College has embraced a bold and creative vision for carrying out its historic mission in a rapidly changing world. Dr. Shinn noted that Berea is a stronger and more resilient institution today that has greater capacity to address future opportunities and challenges.

President Shinn indicated that while he and his wife, Nancy, are looking forward to extended time with their children and grandchildren during their pending retirement, he cited a number of challenging initiatives that Berea must engage over the next 15 months, including the transition from academic departments to divisions, development of the College's new Center for Transformative Learning, and ''deep green'' science and residence hall projects.

Dr. David E. Shelton, chair of the Berea College Board of Trustees, commented: ''President Shinn's unique blend of academic and leadership skills passionately applied to Berea's mission, in partnership with the entire College community, has produced outstanding results. Berea is well-positioned for the future, and we look forward to the unfolding of a number of new developments and opportunities during Larry's remaining tenure as president. Dr. Shinn's extraordinary abilities, personal commitment, and strong work ethic have set the example for the next generation of presidential leadership at

Berea. The Board of Trustees is grateful to Larry and Nancy for their extraordinary service to the College.''

MEMORIAL DAY

Mr. MCCONNELL. Mr. President, this Monday, May 28, is Memorial Day. It is a day for all Americans to honor the brave men and women in uniform who have served and defended our Nation—especially those who sacrificed their very lives for this sacred duty.

It is only right that we set aside this day to remember those who have given us so much. Freedom as we know it in America could not exist without their heroism.

On Memorial Day, we honor servicemembers who laid down their lives fighting under the command of GEN George Washington, to those who have perished in Afghanistan and Iraq. What a proud legacy of fighting for freedom our country has. I am honored to live in a nation that boasts the bravest warriors in the world.

I am also honored to serve my fellow Kentuckians, who understand the importance of this day more, I think, than most. Kentucky has a proud tradition of military service that is upheld today by the many Armed Forces members at our State's military bases, the members of the Kentucky National Guard, our reservists, and Kentuckians fighting around the world. Since September 11, 2001, 107 Kentucky servicemembers have fallen while fighting for their country.

I have been honored to meet many of the family members of these soldiers, sailors, airmen, and Marines who did not return home. I have let them know that their loved ones will not be forgotten. Memorial Day is a chance to make sure that message is heard loud and clear across America.

I want to share with my colleagues a special story about one soldier in particular from Kentucky. SGT Felipe Pereira of the 101st Airborne Division, based out of Fort Campbell, KY, recently was awarded the Nation's second highest military honor, the Distinguished Service Cross, for his acts of bravery in battle.

Sergeant Pereira is the first soldier from the 101st Airborne to be awarded the Distinguished Service Cross since the Vietnam war. At a ceremony this April at Fort Campbell, Chief of Staff of the Army GEN Ray Odierno presented Sergeant Pereira with the venerated military decoration.

According to the award citation, on November 1, 2010, in Kandahar province, Afghanistan, a squad of soldiers that included Sergeant Pereira was on dismounted patrol when an improvised explosive device went off, killing two of Sergeant Pereira's comrades and wounding Sergeant Pereira with shrapnel that caused his lung to begin to collapse. As an enemy ambush began to unfold, ''with little regard for his own safety or care'' Sergeant Pereira drove an all-terrain vehicle into enemy fire to help evacuate wounded soldiers.

After moving the first set of casualties, the sergeant went back into the line of fire once more to help others. Sergeant Pereira is credited with ''saving the lives of two of his fellow soldiers while risking his own [on] multiple occasions. Only after all the wounded soldiers had been evacuated and were receiving medical care did he accept treatment himself.''

Mr. President, Sergeant Pereira's selfless actions demand our admiration and respect. What is more, so does his selfless attitude about his bravery on that fateful day.

''Every time I have the opportunity, I always say remember those that gave the ultimate sacrifice,'' said Sergeant Pereira in an article published by the Fort Campbell Courier. ''I still get to come back and enjoy barbecues with my family and their love and everything. Those guys, they really gave it all. Those are truly the heroes. Just remember those guys. I think even on a happy occasion like this, I think we need to celebrate their life and their sacrifice.''

I can't improve on those words. Sergeant Pereira has captured the meaning of Memorial Day right there, in those words of wisdom.

So I hope this Memorial Day, people will heed the advice of SGT Felipe Pereira. The men and women who ''really gave it all'' are truly the heroes, and this Monday is their day to receive our admiration and our respect. I know my friends in Kentucky and people across America will not forget that.

Mr. CARDIN. Mr. President, Memorial Day is a time to pay tribute to those who have given ''the last full measure of devotion'' in the service of our great country. I believe this Memorial Day is especially significant as we pause to reflect on some of the events of the past year and acknowledge the passing of the last surviving veteran of World War I, the end the Iraq War, and a renewed commitment to wind down our engagement in Afghanistan by 2014.

Since the first colonial troops took up arms in the fight for our independence in 1775, more than 1.1 million American soldiers, sailors, and airmen have died in the wars and conflicts fought to defend our Nation, our freedom, and our ideals. In the past 10 years, we have lost over 6,400 brave Americans in Iraq and Afghanistan. The death of each one of these servicemen and women represents not only a tragic loss to their loved ones, but to their community, and to our Nation.

The American tradition of Memorial Day—originally known as Decoration Day—has its roots in local springtime tributes that were held in the North and the South during and immediately after the Civil War and following the assassination of President Abraham Lincoln on April 14, 1865. On May 1, 1865, nearly 10,000 freedmen, teachers, preachers, missionaries, and Union troops properly landscaped and covered with flowers the unmarked graves of some 250 or more Union prisoners of war who had died in captivity at the Charleston Race Course, a site now known as Hampton Park. On April 26, 1866, grieving mothers, sisters, wives, and daughters in Columbus, MS placed flowers on the graves of Confederate soldiers who had died in the Battle of Shiloh. While they grieved for their own lost loved ones, they saw that nearby graves of the Union soldiers were neglected, so they placed flowers on these graves as well. On May 5, 1866, an official commemoration was held in Waterloo, NY to honor local veterans of the Civil War. Businesses were closed and flags were flown at half-mast to honor the dead. On May 5, 1868, MG John A. Logan, who headed the Grand Army of the Republic, GAR, which was an organization of Union veterans, declared that May 30 of each year should be Decoration Day, a time for the Nation to festoon the graves of Union and Confederate war dead with flowers. Logan said, ''We should guard their graves with sacred vigilance. . . . Let pleasant paths invite the coming and going of reverent visitors and fond mourners. Let no neglect, no ravages of time, testify to the present or to the coming generations that we have forgotten as a people the cost of a free and undivided republic.'' The first large observance was held that same year at Arlington National Cemetery. In 1966, Congress and President Lyndon Johnson declared that Waterloo is the official birthplace of Memorial Day but it is apparent that many communities and people across America can claim some of the credit.

Shortly after World War I, Decoration Day ceremonies were no longer limited to honoring those who had died in the Civil War. Rather, the commemoration was altered to embrace the men and women who have died in all American wars. In 1971, Congress passed legislation to make Memorial Day a national holiday and to fix its date as the last Monday in May. In December 2000, Congress passed ''The National Moment of Remembrance Act'' (Public Law 106–579, which encourages all Americans to pause wherever they are at 3:00 PM local time on Memorial Day for 1 minute of silence to remember and honor those who have died in service to our Nation.

While the Memorial Day we will celebrate this Monday is approaching the sesquicentennial of its birth, the tradition of honoring those who have fallen in war is probably as old—or nearly as old—as human history itself. Over 2,400 years ago—in 431 B.C.E.—Pericles paid tribute to the Athenian soldiers who had fallen in battle at the beginning of the Peloponnesian War, saying

For this offering of their lives made in common by them all they each of them individually received that renown which never grows old, and for a sepulchre, not so much that in which their bones have been deposited, but that noblest of shrines wherein their glory is laid up to be eternally remembered upon every occasion on which deed or story shall call for its commemoration. For heroes have the whole earth for their tomb;

and in lands far from their own, where the column with its epitaph declares it, there is enshrined in every breast a record unwritten with no tablet to preserve it, except that of the heart.

This Memorial Day, in the spirit of compassion and empathy shown by the Confederate widows who placed flowers on the graves of Union soldiers in Columbus, MS nearly 150 years ago, I would like to mention some facts about those fallen servicemen and women we too often neglect to consider. According to a recent study by the Army, suicides among U.S. servicemembers increased 80 percent from 2004 to 2008. The study confirmed that there is an increased risk of suicide among those who experience mental health disorder diagnosis associated with the stress of combat. Protracted military operations requiring multiple deployments over the past decade have made mental health disorders the signature wounds for our military members returning from the conflicts in Iraq and Afghanistan. A comprehensive study by RAND found that approximately 18.5 percent of those servicemen and women returning from deployment reported symptoms consistent with a diagnosis of post-traumatic stress disorder, PTSD, or depression. Up to 30 percent of troops returning home from combat develop serious mental health problems within 3 to 4 months. And since mental health issues often are not immediately addressed while our servicemen and women are on active duty, or because of the lasting traumas of war, we see even higher numbers of mental illness diagnosis among our veterans. According to a Government Accountability Office report, U.S. Department of Veterans Affairs, VA, data ''show that from fiscal year 2004 through fiscal year 2008, the number of unique veterans receiving treatment for PTSD increased by 60 percent from over 274,000 to over 442,000.''

I believe that the best way we can truly honor those who have sacrificed themselves upon the altar of freedom is not just to fulfill our solemn obligation to care for their widows and orphans. More than that, we must care for their brothers and sisters in arms who have also borne the battle, and who have returned to us wounded, ill and injured, and for the family members and other individuals who selflessly care for them. These soldiers and sailors and airmen and their caregivers also deserve our gratitude, our accolades, our compassion—and our support. Therefore, I commend the VA Secretary Shinseki's recent decision to hire an additional 1,900 mental health staff at VA facilities to ensure greater care for our servicemembers suffering from the wounds of war, both physical and emotional.

It is not just about providing adequate resources, however. Having an adequate number of mental health professionals is just one component of ensuring access to care. Former Secretary of Defense Robert Gates correctly acknowledged that the greatest obstacle to servicemembers receiving necessary mental health treatment is the stigma too often associated with seeking help for their psychological injuries. I frequently hear from servicemembers who believe that seeking mental health services will hurt their military and post-military careers. We must overcome these real and perceived barriers to care by changing the policies that govern how we provide mental health care to our active duty military members, reservists, and veterans. Those who suffer in silence will seek treatment only when they are assured they can truly seek such treatment and speak about their problems freely and off-the-record. Meanwhile, as more and more go untreated, we will continue to see a rise in suicides and other tragic incidents among our military members and veterans—a preventable epidemic, which is heaping tragedy upon tragedy.

During this holiday weekend and on Monday in particular we will see many American flags and flowers adorning the graves of those who have made the ultimate sacrifice for our Nation. I will remember in particular the 114 Marylanders who have been killed in our most recent conflicts as I remind myself that our freedom is not free. And I will remind myself that the best way to honor their ultimate sacrifice is to ensure that we are unwavering in our resolve not only to care for their widows and orphans, but also for those who do return to us wounded, ill, and injured—including those whose injuries are emotional. Let us reaffirm our commitment to support all of these individuals and their families and other caregivers this Memorial Day, and every Memorial Day hereafter.

Ms. MURKOWSKI. Mr. President, I rise to recognize the importance of Memorial Day, a day that means so much to me and those I represent in Alaska. For so many of us, it means sunlight nearly all day, the unofficial beginning of summer, and enjoying the great outdoors.

But let us never forget the deep, true meaning of Memorial Day. It means the payment of respect, memories, time and energy to the sacrifices of men and women who have defended the rights and privileges we enjoy today.

Memorial Day first began nearly 100 years before Alaskan statehood, but even in our territorial days we had Alaskans fighting on our own soil against foreign enemies—one of the few States that can say such a thing. It is because of those early successes—and the success of Alaskans from then to those deployed today—that we salute our flag, speak our mind and continue to be a global leader.

As many Alaskans know first-hand, those successes often came at the ultimate price. On Memorial Day we make a small attempt to repay them with our support, prayers and appreciation. I ask that all Alaskans and Americans join me in devoting a few minutes of our time in reflection as a small tribute to those who have given their lives for the cause of freedom.

Although we may not be able to fully measure the cost of our heroes' sacrifice, we can commit ourselves to preserving their memory. So on Memorial Day 2012, I ask that we honor our fallen heroes, comfort the loved ones of those we lost, and carry on our lives in a manner that is worthy of their sacrifice. May God continue to bless our great Nation.

Mr. President, I yield the floor.

Mr. HELLER. Mr. President, today I wish to pay tribute to the men and women of our Nation who have given their lives for the cause of freedom and to honor those who are still with us today. On this Memorial Day weekend, let us stand together as Americans to pay our respects and mourn the loss of those brave soldiers who fought in defense of our liberty. As we gather across the Nation, we need to remember the invaluable sacrifices of our troops and their families are debts that can never fully be repaid.

Every soldier whose life is taken in the line of duty is a great loss to our Nation. Lives have been sadly shortened, and we all feel an absence. We may never be able to measure the loss, but we can take solace in knowing that their lives served to inspire, defend freedom, and preserve life. Today, we commemorate the brave men and women in uniform who gave their lives while serving our country.

We must also remember the members of our Armed Forces who are currently in harm's way. In this trying time in America's history, our soldiers have accepted the call of duty, knowing that the road ahead is dangerous and full of hardship. Their courage and resiliency are what make our military the best in the world. Our servicemembers face perilous situations in order to protect Americans from harm, and I am so grateful for all they do. Their commitment of service and self-sacrifice is what we admire, appreciate, and respect. As we continue withdrawing some of our combat forces, we pray for their safe return.

As someone whose father is a disabled veteran and whose brother served overseas, I understand firsthand the struggles of our servicemembers and the significant sacrifices made by their families. The families of our military men and women also make tremendous sacrifices for our country and for the safety of our Nation. Each and every deployment causes great stress and a burden of separation that every member of these families experience. They have loved ones far away from home and are sacrificing their own well-being for the protection of our country. We must remember that these families serve as the backbone for the men and women who wear the uniform of our armed services, and our Nation owes them a debt of great gratitude.

Today, we honor those who have given their life in service to their country. We will never forget our soldiers

who fought for a better America and served our country with honor. I ask my colleagues to join me today in honoring our Nation's heroes who have given the ultimate sacrifice to make sure that our country remains safe and free.

RECOGNIZING THE S.S. ''BADGER''

Mr. DURBIN. Mr. President, recently Chicagoans were asked in a poll what asset of their great city they valued most. By a large margin, they chose Lake Michigan.

Lake Michigan is the primary source of drinking water for more than 10 million people—not just in my home State of Illinois but also in Wisconsin, Indiana, and Michigan.

The lake is also part of the $7 billion per year Great Lakes fishing industry. Millions of people visit Lake Michigan for its recreational opportunities like swimming, kayaking, boating, or just taking a walk along the beach. It is a beautiful lake.

Unfortunately, we are faced with a threat to the health of our Great Lake.

This week, on Thursday, May 24, the coal-fired car-ferry S.S. *Badger* will begin its 60th year sailing on Lake Michigan.

Many people have fond memories of the *Badger*, steaming from its homeport of Ludington, MI, to Manitowoc, WI, every summer. But they need to be reminded of this: It is the last coal-fired ferry in the United States, and every year it dumps another 500 tons of coal ash into Lake Michigan. Think about that for a moment—500 tons of coal ash every year since the 1950s. What must the bottom of the lake look like?

The owner of the *Badger* insists that the coal ash is basically just sand, but we know better. Scientists are concerned about coal ash because it contains chemicals like arsenic, lead, and mercury.

Once in the lake, these chemicals enter the food chain through the water we drink and the fish we eat. Then they accumulate in our bodies and can cause cancer and neurological damage. In fact, we already are facing problems from mercury contamination of the fish that are part of our food supply. How can we continue to accept behavior that will just make this problem worse?

If the *Badger*'s owners had only recently found that dumping coal was a problem, it might be OK to cut them some slack. But the *Badger*'s owners have a long history of avoiding the steps needed to clean up their act.

Most other vessels on the Great Lakes converted from coal to diesel fuel long ago but not the *Badger*.

In 2008, conversion to a new fuel was way overdue. But a waiver was placed into EPA's vessel general permit to allow the *Badger* to continue dumping coal ash through 2012. I think that was 5 years too many of toxic dumping. But to make matters worse, the *Badger*'s owners still have not made a reasonable effort to stop dumping coal ash into the lake. Instead, they are doing everything they can to avoid switching to a new fuel.

Last fall, the *Badger* was nominated to be a national historic landmark, and an amendment was added to House Coast Guard and Maritime Transportation Act to exempt all vessels of historic significance from environmental regulation.

The national historic landmark designation was created to commemorate properties that have special significance in American history. The designation has been appropriately used to protect sites including the home of President Abraham Lincoln in Springfield, IL, and the S.S. *Milwaukee Clipper*, a retired steamship in Muskegon, MI. The national historic landmark designation was never intended to allow polluters to avoid complying with Federal regulations that protect our health and the environment.

I have urged Interior Secretary Salazar to oppose the designation of the *Badger* as a national historic landmark. I also ask my fellow Senators to join me in opposing language in the House Coast Guard and Maritime Transportation Act that would exempt ''vessels of historic significance'' from EPA regulation.

After I came out in opposition to this strategy, the *Badger*'s owner came to Washington to talk to me.

He mentioned that he was applying for an EPA permit to continue dumping coal ash while he pursues conversion of the *Badger* to run on liquefied natural gas. He would like to make the *Badger* the greenest vessel on the Great Lakes. That would be terrific, but it just isn't a realistic option right now. Today, there are few suppliers of liquefied natural gas. There are no shipyards in the United States qualified to convert passenger vessels to run on liquefied natural gas. And it would take close to $50 million just to develop the infrastructure needed to fuel the *Badger* at the dock.

One day, all the boats on the Great Lakes might be powered by natural gas. But it isn't a realistic plan for the *Badger* to stop dumping coal ash. It is just another delaying tactic, when the *Badger*'s owners were given a deadline 5 years ago.

The *Badger* has blatantly avoided complying with current EPA regulations. We cannot reward the owners for their negligence with permanent statutory protection from EPA regulation.

This is more than a car ferry with a venerable tradition. This is a vessel that generates and dumps 4 tons of coal ash laced with mercury, lead, and arsenic into Lake Michigan every day. This Great Lake cannot take any more toxic dumping, no matter how historic or quaint the source may be.

HONORING OUR ARMED FORCES

Mr. COCHRAN. Mr. President, I rise today to offer a Memorial Day tribute to the brave men and women who have lost their lives protecting the safety and security of our citizens and American interests around the world.

Today, there are media reports about the American people becoming ''war weary'' after more than a decade of combat activities in Afghanistan, Iraq and elsewhere. Many lives and great expense have been marshaled since the 9/11 attacks, but I would submit that Americans are unfaltering in their appreciation for the honor, courage and dedication shown by our servicemen and women. This is especially the case for those who have made the ultimate sacrifice by giving their lives for their country.

This Memorial Day, I will take time to honor our brave fallen warriors, including the more than 70 military personnel from Mississippi who have died in the service of our Nation in Iraq, Afghanistan and around the world over the past decade.

For the RECORD, I offer the names of these brave Mississippians who have fallen since the Nation commemorated Memorial Day last year. They are:

Sgt. Christopher R. Bell, 21, of Golden, who died June 4, 2011.

Petty Officer Stacy O. Johnson, 35, of Rolling Fork, who died July 18, 2011.

LCpl. Edward J. Dycus, 22, of Greenville, who died Feb. 1, 2012.

SFC Billy E. Sutton, 42, of Tupelo, who died Feb. 7, 2012.

MSG Scott E. Pruitt, 38, of Gautier, who died April 28, 2012.

SSG Carlous Perry, 30, of West Point, who died April 30, 2012.

I am confident that the people of my State will join the national commemoration to remember these men and the thousands of Mississippians, who over the course of this great nation's history, have courageously served and sacrificed their lives in that service. We will also recall their families and their profound loss. On this day of remembrance, we salute those sacrifices and express our gratitude for their brave service.

In these challenging times, we should also reaffirm our commitment to the servicemen and women who today put themselves in danger on our behalf. We must remain resolved to ensure that those who join our Armed Forces are the best equipped and best trained in the world, and that we meet our obligations to those who have served and sacrificed in the defense of our nation.

Let me close by expressing my personal gratitude to all our fallen heroes, and communicating my sincere appreciation to those Mississippians and Americans who answer the call to arms and find themselves in harm's way.

VOTE EXPLANATION

Mr. BLUMENTHAL. Mr. President, I was unavoidably absent during today's votes on the Food and Drug Administration Safety and Innovation Act due to my daughter's high school graduation. I supported this bipartisan legislation earlier this year when it was before the Senate Health, Education,

Labor, and Pensions Committee, and had I been able to attend today's votes, I would have voted in support of final passage of this important legislation.

Additionally, I would have voted to support the Bingaman amendment No. 2111, the Murkowski amendment No. 2108, the Sanders amendment No. 2109 and the McCain amendment No. 2107. I would have voted against tabling the Durbin amendment No. 2127 and voted to table the Paul amendment No. 2143.

During the Senate's debate on S. 2343, the Stop the Student Loan Interest Rate Hike Act of 2012, I would have opposed the Alexander amendment No. 2153 and supported passage of S. 2343.

OFFICER SAFETY ACT

Mr. DURBIN. Mr. President, I would like to make clear for the record a matter relating to the Officer Safety Act of 2012. I thank my colleague from Iowa for working with me on this legislation. I cosponsored this bill after changes were made, in the nature of a substitute amendment, to clarify the limited scope of the legislation. The Officer Safety Act clarifies when an officer is ''acting under the color of his office'' for removal purposes only. As my colleague has stated previously, the bill provides no liability protection. Whether a law enforcement officer is deemed to have been ''acting under the color of his office'' for removal purposes under 28 U.S.C. §1442(c), as amended, is a separate question from whether that officer should subsequently be held liable for his conduct, whether the officer should be considered immune from suit, or whether the officer's defense in a criminal trial has merit.

The clarification of ''color of . . . office'' and the expansion of removal eligibility granted by this legislation is not meant to affect those latter determinations of liability and immunity. The bill is simply meant to give these law enforcement officers the ability to make arguments pertaining to liability, immunity, and potential criminal defenses in Federal rather than in State court. Does my colleague agree?

Mr. GRASSLEY. My colleague from Illinois is correct.

STRUGGLING AGAINST BUREAUCRACY

Ms. SNOWE. Mr. President, this week is National Small Business Week, which is a time to celebrate the entrepreneurial spirit behind American enterprise. But, as I was reminded by a piece that was published recently in the Wall Street Journal, it is also a time to remember how government can better serve the small businesses in America. In today's economy, the Nation needs an effective regulatory environment that allows small business to grow and create jobs while keeping our families and environment safe. I ask unanimous consent to have this article printed in the RECORD.

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

[From the Wall Street Journal, May 22, 2012]

THE RED TAPE DIARIES—ONE SMALL BUSINESS OWNER'S STRUGGLE AGAINST BUREAUCRACY

(By Nicholas N. Owens)

This week is National Small Business Week, a time to celebrate the ingenuity of entrepreneurs—and to consider how government can provide better service to the small enterprises that form the backbone of American industry.

Consider the Environmental Protection Agency official who described his agency's work as akin to crucifixion. In a Web video from 2010 that recently came to light, Al Armendariz likened regulatory enforcement to the Roman imperial practice of crucifying people to serve as an example to others: soldiers would go to ''a town somewhere, they'd find the first five guys they saw, and they'd crucify them,'' he explained. ''And then, you know, that town was really easy to manage for the next few years.''

Mr. Armendariz's point was that making examples of certain businesses or industries would serve as a deterrent to ensure compliance. But the way he illustrated his point provoked outrage, and within days he had resigned from the agency—proving again that the journalist Michael Kinsley was right to say that a ''gaffe'' in Washington is when someone accidentally tells the truth.

I know first-hand that Mr. Armendariz's view is a truthful representation of how many regulators view their function. While serving as the Small Business Administration's (SBA) national ombudsman from 2006 to 2009, I worked with small business owners who believed they were falling victim to unfair or excessive regulatory enforcement. All too often, I saw federal regulators take a stridently adversarial stance toward the industries they oversee.

In 2007, for example, I was contacted by Rob Latham, who runs a small Internet sales company in Greenville, S.C. Mr. Latham started his business in 2005 and was prepared to work hard to make it succeed.

He wasn't prepared for how easily a run-in with federal regulators could bring him to the brink of ruin. That's what happened in 2007 after he found himself embroiled in a months-long dispute with the EPA over a shipment of engines he had imported.

The issue came down to labeling. Although the product Mr. Latham was importing met the EPA's environmental standards, regulators ordered the shipment seized because it contained labels that could be removed with a razor blade. (In other words, they were somewhat vulnerable to damage or tampering.) Mr. Latham thought the dispute could be easily resolved but was surprised by the EPA's intransigence—its dedication to junking his entire shipment—when he tried to work with them.

Mr. Latham wasn't ignorant of the regulations that governed his business—quite the opposite. He had carefully studied the rules that governed the products he was importing, and he thought he had taken all appropriate steps to ensure compliance. But as a small business owner with no in-house legal team, he had little idea how complicated the bureaucratic process would be.

He met with regulators in Washington to resolve the issue but found that they doubled down on their position, becoming hostile and aggressive.

That's when he reached out to my office. Hearing of his plight, I contacted the EPA on his behalf and started working with regulators to resolve the case. Soon thereafter, the regulators relented and allowed Mr. Latham's imports to move forward—but only after he paid a substantial penalty of $10,000, an apparent tribute to the regulators to allow them to save face.

The story ends happily: Once the EPA dispute was resolved, Mr. Latham's business grew swiftly. Today his company boasts three warehouses and more than 20 employees.

But had Mr. Latham not connected with my office, he might have lost his business. It's frightening to think what other small business owners encounter in similar situations. What about those who don't know where to turn, or who aren't lucky enough to stumble across the right advice or the right advocate?

As of 2008, small businesses faced an annual regulatory cost of $10,585 per employee, according to an SBA regulatory impact study published two years ago.

So was Rob Latham crucified? That's too strong a word, because it's likely he wasn't specifically targeted—he was simply caught up in a web of red tape and bureaucracy, and the regulators had little interest in helping him get through the impasse. His struggle is a case study in why we need a regulatory regime that's fair, accountable and allows our economy to grow again.

RECOGNIZING NATIONAL SMALL BUSINESS WEEK

Mr. BOOZMAN. Mr. President, this week marks the 49th annual National Small Business Week, a time to celebrate the innovations, ideas, and hard work of our entrepreneurs. Small businesses are the backbone of our economy, accounting for 65 percent of new jobs over the last 17 years. This vital economic component also employs about half of all private sector employees.

As a former small business owner I recognize the difficulty these owners have to plan for future growth and investment. It is our job to make sure we provide an environment that helps these engines of economic growth. We need to make sure our small businesses have the resources they need to continue providing good, well-paying jobs for hard-working Americans. I was pleased to support the American Jobs Act in March. This legislation seeks to increase capital formation, spur the growth of startups and small businesses, and enable more small-scale businesses to enter public markets.

Arkansans are familiar with what it takes to build a business from the ground up. As home to Fortune 500 companies—including the world's largest retailer, Wal-Mart, and the world's largest processor of chicken, Tyson's—that both started as a small business, residents of the Natural State understand the risks and rewards associated with small businesses.

This week the U.S. Small Business Administration recognized the work of Americans who excel in their work to help small businesses. I am proud to say that Kelly Massey of the Henderson State University Small Business and Technology Development Center in Arkadelphia, AR was recognized as the SBA's Small Business Development Center Counselor of the Year winner.

As director of the State's premier business assistance program, Massey dedicates himself to helping the area's small businesses achieve success and promoting the mission and goals of the SBDC program to help spur economic development.

We are also proud of Arkansas Power Electronics International, Inc., for its recognition as the 2012 Arkansas State Small Business Person of the Year. The company continues to strive for success as it develops the next generation of high energy-efficiency power electronics systems. APEI is a great small business model, growing from one person to more than 35 in 15 years, with plans for expansion in the coming years.

These Arkansas business leaders will help move America into the future and construct the groundwork for economic recovery. We need to continue pursuing policies that support the entrepreneurial spirit of these economic building blocks.

TAIWAN'S PRESIDENTIAL ELECTION

Mr. LIEBERMAN. Mr. President, on Sunday, the 20th of May, Taiwan marked the second inauguration of President Ma Ying-jeou. Since its first direct presidential elections in 1996, Taiwan's democracy has emerged as model for the rest of the Asia Pacific region. Over these 16 years, power has changed hands twice between Taiwan's two largest political parties, demonstrating for the world the rapid maturation of its democracy and the commitment of its people to exercising their democratic freedoms. I rise today to congratulate President Ma on his inauguration, and note Taiwan's remarkable history as a kindred democracy, key partner in security and trade, and great friend of the United States.

I take deep pride in the partnership between the United States and the people of Taiwan, which is rooted in shared values, shared interests, and a shared vision for a peaceful and prosperous future. For more than 6 decades, the United States has stood with Taiwan as it has transformed into a prosperous free market democracy.

Just as the United States has supported Taiwan, so too has Taiwan been a great friend to America. Taiwan is among America's top trading partners. Moreover, time and time again from the Korean War, to the Vietnam War, to our continued security cooperation today Taiwan has stood shoulder to shoulder with the United States. I am deeply grateful to the people of Taiwan for their contributions to our shared security and prosperity.

Looking to the future, I hope and believe that President Ma's second inauguration will mark another milestone in the deepening relationship between the United States and Taiwan. For all of our progress, we still have a big agenda ahead.

It is past time for us to remove the barriers to trade between the U.S. and Taiwan and negotiate a Free Trade Agreement with Taiwan. We must also ensure that the people of Taiwan are secure, so they can continue to decide their future for themselves. That, in turn, means the United States should take common-sense steps to deepen our security ties with Taiwan and support Taiwan in acquiring the weapons it needs and has requested. As the United States focuses increasingly on the Asia-Pacific region, the Obama Administration must do more to make Taiwan an integral part of our broader strategy to uphold the balance of power in this critical part of the world as a way to maintain peace.

In closing, I again congratulate President Ma on his inauguration and thank Taiwan's people for their decades of friendship.

TRIBUTE TO RICHARD F. WALSH

Mr. MCCAIN. Mr. President, I would be remiss if I did not recognize that today's meeting of the Senate Committee on Armed Services to vote out its annual Defense authorization bill was the last for Richard F. Walsh of my staff. I know Dick's Winnebago is packed and idling outside and is probably out of gas because he delayed his retirement to see us through mark up, but I want to say a few words before we adjourn.

I believe in the nobility of public service, and I think Dick exemplifies that, not just through his tenure here but throughout his entire career. Many may not know that Dick came to the Armed Services Committee after a distinguished 30-year career in the Navy, much of it as a judge advocate. He served in a number of challenging assignments, including counsel to the Chief of Naval Personnel; commander of the Naval Legal Service Office, National Capital Region; director of legislation in the Navy's Office of Legislative Affairs; and executive director for Senate affairs under the Assistant Secretary of Defense for Legislative Affairs.

In 2001, my good friend Senator John Warner hired Dick to handle personnel issues. From the halls of the service academies to the bones of Tripoli, Dick has seen it all. He has worked on issues of military pay, benefits, and education. Some were high profile, others not. Some were for the dogs, literally and figuratively. During his tenure, he strived to ensure fairness in the military justice system and remained vigilant so that military standards continue to reflect the honor of military service. I am proud of the work we did together on the GI bill to ensure the transferability of military benefits to family members. Through it all, he showed himself a consummate professional.

Our committee works on issues vital to our national security and the men and women who protect it. Dick's work in particular over the last decade touches our soldiers, sailors, airmen, marines, and their families, daily, in very real, very meaningful ways. I know Dick will have mixed emotions when he leaves us, but he can take comfort in the knowledge that he has made a difference.

So from one retired Navy officer to another, I wish Dick Walsh and his wife Gail fair winds and following seas as they board their Winnebago and push off for a well-earned retirement together.

REMEMBERING DENISE ADDISON

Mr. NELSON of Nebraska. Mr. President, I rise today to honor the life of one of my long-time aides, Denise Addison, who was a devoted public servant and cherished friend. Sadly, Denise lost her long battle with cancer on May 12, 2012.

Denise first came to my office back in 2001. While I was just starting my Senate career that year, she was already an experienced veteran, having worked in Congress for 25 years.

Although Denise was not a native of Nebraska, having grown up right here in our Nation's capital, she found something special in our great State and adopted it as her own. In 1998, she began working with former Nebraska Senator Chuck Hagel, later transitioning to the office of then-Senator Bob Kerrey, whose staff members were so impressed by Denise's performance that they strongly recommended she be one of my first hires.

Denise's work with my constituent services team was impeccable. She was well aware of how important my constituents are to me and, as such, took great pride in her work. Her amazing memory and attention to detail made her a valuable staff member, and her complete satisfaction with her daily work made her irreplaceable. In this town, it is rare to find someone who possesses all of the qualities Denise brought to my staff, including loyalty, dedication, and genuine fulfillment.

Yet that was the kind of person Denise was—both at work and in her personal life. Even more remarkable than her tenure in the Senate was her commitment to her family—her husband Carl, whom she affectionately called ''Mr. A;'' her three children, Al, Dominique, and Jasmine; her parents; her five brothers; and her cousins, who were always more like sisters to her.

When Denise and I first started working together, her youngest daughter, Jasmine, was just starting kindergarten. Today, she is almost through high school. Denise was incredibly proud of her children and always put the needs of her family before all else.

Although the last 2 years of Denise's life were definitely a struggle for her, she never complained. Instead, she remained, as always, more concerned for those around her than for herself. I do not think she ever fully recognized what an immense impact she had on all those who knew her.

While Denise was taken from us far too soon, there is solace in knowing

she confronted her illness by continuing to be the same kind, caring person she had always been, living life to the fullest right up to the end. Denise Addison was truly one of a kind, beloved and missed by everyone who had the pleasure of being her friend.

Thank you, Denise, for who you were and for all you did for me, for my staff, and, most important, for the State of Nebraska. The ''good life'' will not be quite the same without you.

TRIBUTE TO COMMANDER BRYAN E. HELLER

Mr. HELLER. Mr. President, I am so proud to rise today to honor a Nevadan whom I have known for my entire life and who has my utmost admiration and respect. It is with great pleasure to recognize my brother, Bryan Heller, as he retires from the U.S. Navy after 20 years of service to his State and country. On June 1, 2012, he will enter the next chapter of his life, and I am thrilled to see what he will accomplish next. On behalf of a grateful nation, I thank Bryan for his many years of faithful, selfless service and extend heartfelt congratulations on the occasion of his retirement.

Bryan began his naval career while studying civil engineering at Brigham Young University. In 1992, he entered the Navy in the Nuclear Propulsion Officer Candidate Program and was later commissioned at Officer Candidate School in Newport, RI. Bryan successfully completed the rigorous nuclear pipeline and submarine school and subsequently reported to the USS Georgia, where he earned his gold dolphins and qualified as nuclear engineer officer.

Over the course of his career, Bryan and his family moved across the country to respond to his next call of duty. Returning to his civil engineering roots, he transferred to the Civil Engineering Corps, CEC, where he experienced his first CEC tour aboard the NAS Oceana and became registered as a professional engineer. He also earned his master of science in civil engineering from the University of Texas. In 2007, Bryan reported to Commander, U.S. Naval forces Central Command, where he headed the Navy's construction program in Bahrain, United Arab Emirates, Oman, Kuwait, Jordan, and Lebanon.

Currently serving as the desert operation officer, Bryan leads the Desert Integrated Product Team, which supports Navy bases outside of San Diego and Ventura County. Bryan continues to be an incredible asset to the naval community, and I know it will be difficult to replace him. Throughout his career, Bryan has been extensively decorated, exemplifying his strong work ethic and commitment to serve. He has been awarded three Meritorious Service Medals, three Navy and Marine Corps Commendation Medals, and two Navy and Marine Corps Achievement Medals.

Today, it is also my distinct honor to recognize and express my gratitude to Bryan's family—his wife, Kristi, and children, Natascha, Heidi, Josef, and Jakob. Their strength during times when their family was apart embodies the resilience that makes our military communities strong. I constantly find myself in awe of the sacrifices and efforts that have been made by our military families. Each and every deployment causes great stress and a burden of separation that every member of these families experience. We must remember that these families serve as the backbone for the men and women who wear the uniform of our armed services, and they deserve our support. The invaluable sacrifices of our servicemembers and their families are debts that can never fully be repaid.

I am proud to honor my brother today and recognize his accomplished career in the U.S. Navy. On the eve of this Memorial Day holiday weekend, we must recognize all our brave servicemembers and their commitment to our country. It is with great appreciation that I ask my colleagues to stand with me in honoring Bryan's service to our Nation as he moves onto the next phase of his life.

ADDITIONAL STATEMENTS

DENVER GAY MEN'S CHORUS

• Mr. BENNET. Mr. President, today I wish to congratulate the Denver Gay Men's Chorus on its 30th anniversary. For the last 30 years, the group has shown great commitment to educational, cultural, and social enrichment in the community on behalf of the Rocky Mountain Arts Association.

Since the Denver Gay Men's Chorus was formed in 1982, it has performed more than 130 concerts and more than 1,400 compositions, arrangements, and medleys. The group has commissioned 25 works. It performed at the 1996 World Summer Olympics in Atlanta at the opening of the Olympic Diversity Center. It has also received the Denver Mayor's Award for Excellence in the Arts.

Today, the organization has more than 170 volunteer singers who perform at numerous community outreach events every year. They include performances at Manhattan Middle School's Diversity Week to end school bullying and a performance at the World AIDS Day Concert.

I join the State of Colorado in thanking this organization for working to address social issues and spread a message of tolerance and for enriching our community and our State. I look forward to its future work and the effect it will continue to have on our community.•

RECOGNIZING THE WORLD TRADE CENTER UTAH

• Mr. HATCH. Mr. President, today I wish to congratulate the World Trade Center Utah on the naming of one of Utah's finest buildings in their honor. On May 23, 2012, my Utah staff had the pleasure of attending a ceremony whereby the building formerly known as Eagle Gate Tower became the World Trade Center at City Creek. Naming one of Salt Lake's premier business addresses after the World Trade Center Utah is a fitting tribute to the important role the organization plays in guiding Utah's world-leading companies into new markets. This achievement is all the more remarkable when you consider that the organization was only founded in 2006.

We hear time and time again about the fact that 95 percent of our potential consumers live outside the United States. But we all know that reaching those customers can be difficult. Since 2006, the World Trade Center Utah has assisted over 1,000 companies to do just that, through educational classes and seminars, international business development events, and networking opportunities. The World Trade Center Utah rightly prides itself on being the ''first stop'' for Utah businesses seeking to expand their trade opportunities. By assessing their capabilities, providing educational opportunities and connections to the right people and organizations, the World Trade Center Utah provides the businesses of the Beehive State a much needed roadmap to engaging in international trade.

Their hard work has paid off. Thanks in no small part to the World Trade Center Utah and the leadership of its CEO, Lew Cramer, Utah merchandise exports increased 37 percent in 2011 compared to 2010, growing from $13.8 billion to $18.9 billion. In a time of great economic difficulty for our Nation, this was no easy feat and was no doubt welcome news to the nearly 93,000 Utahns whose jobs depend on exports, as well as the companies in Utah which collectively exported to over 190 foreign markets.

I congratulate the World Trade Center Utah, as well as its founding CEO, Lew Cramer, and his dedicated staff for this achievement.•

KEEPING CHILDREN ALCOHOL FREE

• Mr. HOEVEN. Mr. President, I ask unanimous consent to have printed the attached statement in the CONGRESSIONAL RECORD.

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

RECOGNIZING THE LEADERSHIP TO KEEP CHILDREN ALCOHOL FREE FOUNDATION

Mr. HOEVEN. Mr. President, today it is my honor to recognize the accomplishments of a group of dedicated volunteers who have devoted extensive time, resources and energy toward the worthy effort of helping our children avoid the pitfalls of alcohol dependence and binge drinking. The Leadership To Keep Children Alcohol Free Foundation is a unique coalition of current and former Governors' spouses, Federal agencies, and public and private organizations united in their goal to prevent the use of alcohol by children

ages nine to fifteen. It is the only national effort that focuses on alcohol use in this age group. Childhood drinking leads to adolescent alcohol abuse, and in my state of North Dakota, I want to acknowledge that the rate of alcohol abuse among young people is an ongoing challenge that we must address. For this reason especially, I am motivated by a sense of duty and public concern to extend my gratitude to the volunteers of this Foundation and enter into the CONGRESSIONAL RECORD a comprehensive summary of the accomplishments and impact that this Foundation has achieved from 2000 to 2012 for the families of my state and our nation.

I would like to provide some background on how this Foundation came to be. In partnership with The Robert Wood Johnson Foundation (RWJF) and in response to childhood drinking as a national public health threat, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), an institute of the National Institutes of Health charged with research on alcohol abuse and its causes, the many medical and social consequences of heavy drinking, and approaches to new prevention and treatment, established the Leadership Initiative in 2000. The initiative would engage First Spouses in each state, with the underlying assumption that top-level state leadership could serve as a collective and powerful force to bring the scope and dangers of early alcohol use to the public's attention and to mobilize National, State, and local action to prevent it. And thus, it was launched as a national initiative in 2000 and subsequently evolved in 2004 as The Leadership To Keep Children Alcohol Free Foundation with a non-profit, non-partisan membership of over 50 current and former governors' spouses.

The seamless transition from the Initiative into the Foundation enabled the work of the Leadership Initiative to continue without interruption. Its purpose, membership, and accomplishments remained the same. That is, its purpose is to support the efforts of current Governor's spouses or their representatives, both in their states and nationally, to prevent or reduce underage drinking, especially among the 9–15 year old population.

This multiyear, multimillion-dollar initiative provided support to participating Governors' spouses, who conveyed the initiative's messages within their States and nationally through State policy briefings, outreach to and through the media, broad distribution of educational materials and public service announcements, and personal appearances. Both the RWJ and NIAAA funding ended in 2007.

Leadership membership has always been composed of Governors' spouses or their designate that are also prosecutors, judges, educators, business leaders, substance abuse prevention specialists, and parents. They often act as a point of contact in their state conveying news about their state's underage drinking prevention initiatives, and also taking information back to their constituency. The Leadership initiative provides members with a source of information to use as they reach out to these audiences.

At this time, The Leadership Foundation has 26 current spouses as members, 22 emeritus spouses as members, and 20 Partners of like-minded organizations.

I will now offer to you, Mr. President, the major accomplishments of The Leadership Foundation form 2000 through 2011. As originally conceptualized, The Leadership to Keep Children Alcohol Free Foundation has been uniquely qualified to help move the conversation around underage drinking to a higher level and broader audience. Its niche has been its ability to educate and engage policy makers at all levels. Its non-partisan membership of over 50 current and former governors' spouses has allowed it to influence the debate over childhood drinking both nationally and within states.

It has been remarkably successful in a relatively short time. Many organizations and experts in the field of prevention view the Governors' spouses' work on childhood drinking as key in placing childhood and underage drinking front and center on the national agenda. Often in collaboration with national and state partners, The Leadership Foundation has accomplished our purpose by voicing concerns in national conversations on related issues; providing ongoing support of First Spouse underage prevention activity within their respective states; maintaining timely contact and delivery of information on underage drinking; and distributing resources/tools to assist the efforts of First Spouses in their states.

In the first few years of formation (2000–2005), members of the Leadership to Keep Children Alcohol Free initiative worked extensively at the federal level in support of a federal collaborative effort to address underage drinking. During that period, members engaged in the following activities: encouraged Congress to call for the National Academy of Science's Institute of Medicine Report on Underage Drinking; worked with several US Surgeon Generals to produce the Call to Action to Prevent and Reduce Underage Drinking; provided information related to the STOP Act of 2006; testified before several Congressional Committees, served as key partners in April is Alcohol Awareness Month activities with the National Council on Alcoholism and Drug Dependence (NCADD); served on the Advisory Councils of Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP), Center for Substance Abuse Treatment (CSAT), National Institute on Alcoholism and Alcohol Abuse (NIAAA), Safe and Drug Free Schools and Communities Act, Drug Free Communities Act, and NIAAA's Steering Committee for Underage Drinking Research Initiative, and the board of the National Center on Addiction and Substance Abuse at Columbia University (CASA); garnered national media attention in newspapers and magazines; and worked with the National Attorneys Generals Association's Youth Access to Alcohol standing committee to convince the alcohol industry not to advertise to youth.

In addition to the aforementioned national accomplishments and activities, the Leadership Foundation provides ongoing service to its membership through such activities as providing ongoing support of underage drinking prevention activities by First Spouses within their respective states.

Annually, a one-day seminar is held for Leadership membership, usually in conjunction with the winter Community Anti-Drug Coalitions of America (CADCA) conference. SAMHSA/CSAP and NABCA have been strong supporters of the Prevention Days. In 2010, the Center for Substance Abuse Prevention, National Institute on Alcohol, Abuse and Alcoholism, National Alcohol Control Beverage Association, Shinnyo-en Foundation, Wyoming Association of Sheriffs and Chiefs of Police, Paxis Institute, International Survey Associates/Pride Survey, The Christopher D. Smithers Foundation Inc., and State Farm Insurance Company provided financial support for the 10th anniversary education seminar in Washington DC in February. At these annual events, speakers are engaged to provide latest research news on products such as alcohol energy drinks, coalition creation and maintenance, and minimum drinking age laws.

In 2008 and 2009, with financial support from SAMHSA, the Leadership Foundation organized thirteen state visits for the US Surgeon General to promote his Call to Action to Prevent and Reduce Underage Drinking. The Leadership Foundation President, Hope Taft, accompanied the Surgeon General on the visits at the invitation of the First Spouses, and/or their designate. At these state visits, First Spouses convened and encouraged statewide partnerships to address underage drinking within their respective states through such activities as the following:

In Hawaii, the Lieutenant Governor James R. ''Duke'' Aiona, Jr., Co-Chair of Leadership to Keep Children Alcohol Free, hosted the Surgeon General's visit to Hawaii to promote the Call to Action. They provided media interviews; visited an inner-city Honolulu elementary school, where Lt. Governor Aiona conducted a teach-in, engaging students in an interactive, lively discussion and delivering a presentation on Too Smart to Start, a SAMHSA-sponsored underage alcohol use prevention initiative; met with Hawaii Governor Linda Lingle to discuss the Call to Action; met with the Hawaii Partnership to Prevent Underage Drinking (HPPUD); and attended a Town Hall meeting sponsored by HPPUD at which 120 university researchers, health care providers, Department of Health officials, policymakers, law enforcement personnel, educators, business representatives, members of the faith-based community, youth, and parents were in attendance.

In Maine, the First Lady Karen Baldacci and the Surgeon General met with the Governor and Maine legislators in the Senate and House of Representatives, Maine's Attorney General, and community leaders. The Surgeon General also gave a keynote address at the annual New England School of Addiction Studies. As part of Maine's response to the Call to Action, the Department of Health and Human Services Office of Substance Abuse (OSA) announced the second phase of a statewide media campaign, ''Find Out More, Do More,'' targeted to parents.

In Nebraska, the First Lady Sally Ganem and the Surgeon General provided several speaking engagements with teachers, parents, students, and community leaders. Follow-up activities included the following: twenty-one town hall meetings were held in the spring of 2008; the Nebraska Liquor Control Commission requested that Nebraska wholesalers limit pocket-sized liquor containers until an investigative panel evaluates the product's appeal to youth; the First Lady raised funds to make a video of the Acting Surgeon General's Town Hall Meeting for distribution throughout the State; officials and other stakeholders developed a Nebraska ''call to action'' on underage drinking; Nebraska Educational Television (NET) developed a 30-minute documentary on underage drinking featuring First Lady Sally Ganem; and the First Lady and University of Nebraska's Coach Bo Pelini developed PSAs to be shown during every high school sports events covered by NET. The PSAs are expected to reach more than 85,000 people with a message about underage drinking.

In New Mexico, the First Lady Barbara Richardson and the Surgeon General provided a medical round table discussion, a public forum in Santa Fe about underage drinking, and a lecture in Albuquerque as part of Governor Bill Richardson's DWI Research Speaker Series.

In North Carolina, during the Surgeon General's visit, the First Lady Mary Easley announced the states ''Media Ready'' program, a media literacy substance abuse prevention program that is taught in middle schools. They also met with State legislators, policy makers, education leaders, and representatives from the Governor's Office,

the judicial system, law enforcement, and health and substance abuse prevention organizations that work on the State and local levels to address underage drinking in North Carolina. In addition, the Surgeon General spoke about the Call to Action at North Carolina State University's Millennium Seminar.

In North Dakota, the First Lady Mikey Hoeven and the Surgeon General provided an address at the 2007 Alcohol and Substance Abuse Summit in Bismarck and visited a middle school where the Surgeon General spoke to students.

In Ohio, the First Lady Frances Strickland hosted the Surgeon General's visit that included an address to college and university presidents, as well as an address to the prevention and treatment professionals in Ohio.

In Oklahoma, the Surgeon General spoke at several events including a town hall meeting at the Oklahoma History Center in Oklahoma City, and an address at the University of Oklahoma College of Public Health.

In Oregon, the Surgeon General and the Oregon Attorney General spoke at a news conference on underage drinking where the Attorney General announced he was reconstituting a State underage-drinking task force to examine binge drinking on college campuses, energy drinks that contain alcohol, and the possible creation of a driver's license suspension program for minors caught with alcohol.

In Wyoming, the First Lady Nancy Freudenthal hosted the Surgeon General's visit that included a news conference at the annual meeting of the National Prevention Network, a meeting on Wind River Reservation to discuss underage drinking, and participation at a Town Hall Meeting on the Central Wyoming Campus that highlighted not only the Surgeon General's information but also the prevention efforts under way across the State. This event also served as the kick-off meeting for the national Town Halls. In addition, Wyoming Public Television taped a discussion of underage drinking issues including the Surgeon General, Wyoming youth involved in prevention activities, and community members.

In Montana, the First Lady Nancy Schweitzer hosted the Surgeon General's three-day visit to Montana that included several speaking engagements with community groups, teens, and university staff/students; production of a PSA of the Surgeon General and First Lady; and meeting with the Lt Governor and the State Interagency Coordinating Council. Following the Surgeon General's visit, there were twenty-six town hall meetings in Montana on underage drinking.

In Maryland, the First Lady Katie O'Malley and the Surgeon General met with the Lt Governor, Attorney General and several state leaders; gave a press conference; provided remarks to the House and Senate legislators; gave a keynote address and roundtable discussion at the Baltimore Health Department; and attended a meeting with students in a middle school.

In Rhode Island, the First Lady Suzanne Carcieri hosted the Surgeon General's visit that included a meeting with Family Court and Traffic Tribunal Judges with RI Family Court Chief Judge Jeremiah S. Jeremiah who presented information about the Family Court's Alcohol Calendar; a press conference on underage drinking, a meeting with Substance Abuse Task Force Coordinators, State Room, State House; a Lunch with Governor and Mrs. Carcieri in the Governor's Personal Office; a speaking engagement with university presidents, vice presidents, and researchers, hosted by University of Rhode Island President Dr. Robert Carothers; a meeting with Policymakers in Providence, State Room, State House; an address in both the House of Representatives and Senate; and a Town Hall Meeting in Woonsocket, RI, City Hall.

Additionally, in 2008–2009, through the generosity of Motorola, P&G, and Pride Surveys, the Foundation was able to give stipends to support 25 Town Hall Meetings in member states across the country to focus community attention on underage drinking. These Town Hall Meetings were in addition to the ones funded by SAMHSA/CSAP.

The Leadership also worked with Utah 2009 on a meeting of medical examiners with NIAAA and CDC to see how the routine screening for alcohol use in all deaths of persons under the age of 21 could be actualized.

To accomplish its purpose of supporting First Spouse underage drinking prevention initiatives, the Leadership Foundation has produced weekly email updates, an information-packed website, distribution of opinion editorials, and presentations at national conferences.

The Weekly Update was supported with funding from NIAAA, a Scaife Foundation grant in 2009, and their own resources. The Weekly Update was distributed weekly from 2000–2011 to more than 1,900 individuals. The Update contained timely information on latest research, news from states, new partners, grant and conference information. When a Facebook page was developed, the Leadership decided to use the social media network to distribute timely alerts about underage drinking prevention. The website is also used extensively to distribute information with an average of 400 new visitors each week.

As issues pertaining to underage drinking have arisen, The Leadership Foundation provided Draft Opinion Editorials to First Spouses. First Spouses were encouraged to shape a final draft based on their state data and/or opinions for distribution to their media outlets. The Op Eds were intended to raise awareness in the early 2000's on childhood/underage drinking and more recently on specific issues such as the costs of underage drinking to states, the minimum drinking age laws, and alcohol energy drinks.

The Leadership Foundation has also been recognized as a leader in the area of underage drinking prevention. As such, representatives of the Leadership Foundation have been invited to present at a variety of national and state conferences. These included numerous presentations at the Enforcing Underage Drinking Laws (EUDL) Conference, the Mid-Year CADCA Institute, NPN/NASADAD conference, and state conferences such as the Ohio Prevention and Education Conference.

Since 2000, the Leadership Foundation membership, in particular Advisory Board members, have provided significant support at the national level by prompting the development of important documents such as the Surgeon General's Call to Action [SAMHSA, NIAAA, SG], and a state-level analysis of alcohol costs to the state [NM, CDC].

In addition several products were developed and distributed on-line, at conferences, and in print. All materials are free, and downloadable from the Foundation's website at *http://www.alcoholfreechildren.org*. These have included a statistical brochure for lay audiences which distills the most current research findings about early alcohol use and its effects; a brochure describing three basic strategies for preventing alcohol use by children, and bookmarks on ''Stay Smart; Don't Start,'' a video entitled ''Drinking It In,'' a program for Drug Free Workplace, a discussion guide for communities on childhood drinking and a parent ''book club'' discussion guide on the book ''Messengers in Denim.''

Several members of the Leadership Foundation have been recognized for their outstanding efforts through The Racicot Leadership Award, and The Hope Award.

In 2009, the Leadership Foundation Board of Directors created the Racicot Award to be named for Theresa Racicot, first lady emeritus of Montana for her efforts to turn the Leadership Initiative into the Leadership Foundation in 2006–7. The Award would be given annually to a sitting First Spouse who had made significant accomplishments in his/her state on underage drinking prevention and contributed time and energy into the Leadership Foundation's work. Recipients of the Racicot Award have been First Lady Mikey Hoeven who served as co-chair of the Leadership Foundation Board, started the successful ''Let's Keep Our Kids Alcohol Free'' campaign, raised money for her efforts through Applebee's and a MOMS cookbook, created the ''I Choose'' CD and served on the Governor's Prevention Advisory Council on Drugs and Alcohol during her tenure as First Spouse; Wyoming First Lady Nancy Freudenthal who worked collaboratively with the Wyoming Liquor Division, the Mental Health & Substance Abuse Division of the Wyoming Department of Health, the Wyoming Association of Sheriffs and Chiefs of Police and parents to develop new partnerships and programs on underage drinking prevention; and First Lady Sally Ganem of Nebraska who worked to create several videos that are still widely used in Nebraska and available to other states that serve as discussion openers.

In 2011, the Leadership Board of Directors voted at their 10th Anniversary Annual Meeting to create a recognition program for Emeritus spouses to be named for Hope Taft, first lady emeritus of Ohio and current president of the Foundation. Patterned after the annual Racicot Leadership Award, the Hope Award recipient is selected from nominations of Leadership members and given to a former governor's spouse who has stayed involved and committed to the vision of the Leadership Foundation after leaving the Governor's Residence. Recipients of the Hope Award have been Hope Taft, First Lady Emeritus of Ohio who was a leader in underage drinking prevention in Ohio during her tenure as First Spouse, and who has represented the Leadership Foundation at the national level; and Karen Baldacci, First Lady Emeritus of Maine who has led the recruiting effort, and stayed on as chair of the Leadership Foundation beyond the normal term.

In 2010, the Leadership Foundation developed a Promise Partnership Program where agencies with a like-minded mission were invited to submit an application for becoming a Leadership partner Promise Partners include the Hepatitis Foundation; Marin Institute (AlcoholJustice.org); Drug Free Action Alliance; Lee County Coalition For a Drug Free Southwest Florida; NABCA; Dr. Parnell Donahue, author of Messengers in Denim; FACE; Prevention Council of Roanoke County; Kansas Family Partnership; Outside the Classroom; The NV Children's Cabinet; 7 Valleys Council on Alcoholism and Substance Abuse, Inc.; Center for Prevention and Counseling; Partnership for a Drug Free Community of S. Florida; Coalition for a Healthy Middletown; Operation Snowball, Inc.; Hope Council on Alcohol and Other Drug Abuse; Hope Whispers Community Organization; Southwest Counseling Services; Parent Resource Center at Families in Action/

In closing, the Leadership Foundation, through its strong advocacy by First Spouses, have prompted significant state-level advancements in underage drinking prevention. Many states have passed laws focused on environmental issues such as keg registration, server training, social hosting and graduated licensing. Many members

have worked in their states to bring awareness to the issue, changes in policy and coordination in efforts to prevent childhood drinking. As an example of extensive grassroots activity in underage drinking, more than 2,000 grassroots events were held in 2010 to focus on underage drinking.

The combined national initiatives, state focus, and grassroots activities have contributed to a significant decline in underage drinking in the United States as discussed on page 1–2 of this document. In 1991 when the first Youth Risk Behavior Surveillance System, Centers for Disease Control and Prevention (YRBS) survey was administered, 50.8% of youth in grades 9–12 reported current alcohol use, or use with 30 days prior to the survey. The latest survey results in 2009 showed that number had dropped to 41.8%, a statistically significant drop with a p-value of 0.00. That statistical difference means that youth in 1991 were more likely than youth in 2009 to be current drinkers. The number of states and territories participating in YRBS survey data collection was fifty-three (53) in 2009; thirty-six (36) were states in which there was a First Spouse member of the Leadership Foundation. When looking at the data from those specific states, all states showed a marked decline in current alcohol with an average decline of 9.4%. Ten out of the 36 showed a statistically significant decline in current youth alcohol users. The front-runners in decline were New Mexico, Rhode Island and North Dakota, and Utah showed the lowest rate of current alcohol use among all states in 1991 and 2009 (26.6 to 18.2).

Despite significant headway in the prevention of underage drinking, current levels are still too high. Researchers continue to document the importance of protecting the development of the adolescent brain from the toxic effect of alcohol. Adolescent alcohol use contributes to a host of social, emotional, legal, academic, and physical consequences. Children who begin using alcohol before age 15 are more likely to develop a full-blown addiction and a lifetime of lost productivity from it. The country's attention to it must be continued and expanded.

Therefore, the Leadership Foundation has launched a 2012 initiative to create ''virtual statewide coalitions'' with support from NABCA (National Alcohol Beverage Control Board Association). The website, with the First Spouse as the convener, provides a place for all the coalitions in a state to register along with vital, relevant state departments, and agencies as well as relevant alcohol reduction and youth serving agencies. The purpose of this initiative is to facilitate more effective conversations between state and local efforts to prevent underage drinking, and to distribute timely alerts from national agencies to state and local groups.

Mr. President, I hereby offer these aforementioned accomplishments of The Leadership To Keep Children Alcohol Free Foundation, and in so doing, seek to commemorate for posterity their important work and highlight the value of protecting our nation's children from the dangers of underage drinking.●

TRIBUTE TO LOUIE A. WRIGHT

● Mrs. MCCASKILL Mr. President, today I Wish to honor the work of Louie A. Wright. In our great Nation, there are labor leaders and then there are exceptional labor leaders. Louie Wright is one of those exceptional labor leaders.

Louie recently retired as the head of the International Association of Firefighters Local 42 in Kansas City, but Louie will never stop working and fighting for working men and women of Missouri and, for that matter, the Nation.

Louie is exceptional for many reasons, not the least of which are his intellect, his professionalism, and his ability to work with, not against, management to the benefit of his membership.

I have known Louie for over 30 years. I have watched him under pressure. I have watched him succeed. I have watched him stumble from time to time. But through it all he remained steadfast and loyal to his friends and willing to do anything for his fellow firefighters.

Louie grew up in Kansas City and, as a young man, became a firefighter for the city of Kansas City, MO, Fire Department. It was a full-time job, but for Louie full-time is 24 hours-a-day, so in 1988 he entered law school at the University of Missouri in Kansas City.

He received a law degree and was admitted to the Missouri, Kansas, Colorado and Federal bar. Louie also clerked in the U.S. District Court in the Western District of Missouri, and he accomplished all of this while serving the people of Kansas City as one of their most dedicated firefighters.

Having a labor leader with a law degree is a powerful force when negotiating labor contracts, and the men and women of the city's fire department recognized that, electing Louie president of IAFF Local 42 in 1995.

What also set Louie apart was his understanding that for firefighters to expect decent wages and benefits, the department had to demand that it become a first-rate firefighting and fire prevention force. And today Kansas City has one of the best and most well-respected fire departments in the Nation.

Louie did not just care about his firefighters, but he cared for all the working men and women of Kansas City and was and remains a member of the executive committee of the Greater Kansas City AFL–CIO. In addition, one of his true passions is health care and its delivery to all Kansas Citians. Louie spent untold volunteer hours on the board of the Truman Medical Center and the Mid-America Health Coalition.

In conclusion, we honor him today as an exceptional labor leader. Upon Louie's retirement, IAFF Local 42 lost an amazing president. However, Kansas City has not lost one of its finest advocates for the working men and women. Thankfully, his work will continue. I treasure his friendship and am proud to recognize his immense contributions.●

RURAL HEALTH EDUCATION NETWORK

● Mr. NELSON of Nebraska. Mr. President, today I wish to recognize the 20th anniversary of a successful program in my home State of Nebraska called the Rural Health Education Network, or RHEN which focuses on increasing the health workforce.

The RHEN program was established at the University of Nebraska Medical Center, UNMC, as an effort to develop a network of volunteer faculty in communities across the State who would serve as mentors for students entering into various health care professions to perform rural rotations as part of their training. This partnership between UNMC and these Nebraska communities provides hands-on training for these health profession students.

Working with volunteer faculty across rural Nebraska communities, almost all UNMC students are able to complete a rural rotation during their education. Students spend up to 2 months living and working in a rural community under the guidance of a local health professional. In 2010, more than 530 students from UNMC participated in 854 rural rotations in 74 Nebraska communities. The program allows these UNMC students to experience the good life in Nebraska communities, inspiring many students to launch a health career in a smaller community.

The RHEN program has since expanded to promote career opportunities in health care to students in rural areas and smaller communities. In fact, RHEN has become the umbrella under which most of UNMC's rural outreach education activities are accomplished.

One goal of RHEN has been to create innovative programs at the undergraduate level and establish a career pipeline for students from rural areas to become health care professionals in rural Nebraska. A key component in attaining this goal was the establishment of the Rural Health Opportunities Program, or RHOP.

Built on the logic that persons raised in rural areas are more likely to return to rural areas after school, RHOP gives youth from rural areas a head start in pursuing a health care career. Under RHOP, qualified high school graduates receive tentative acceptance into one of nine UNMC health profession programs when they begin undergraduate studies at either Chadron State or Wayne State College in Nebraska. The undergraduate tuition is waived for these students, provided they meet all applicable academic standards.

The RHOP program provides students a career path to nearly every health care field, including medicine, nursing, pharmacy, dentistry, dental hygiene, physical therapy, physician assistant, radiography, and clinical laboratory science. Since its inception,

Seventy-five percent of all practicing UNMC RHOP graduates have worked in a rural community for at least part of their careers;

Currently, 183 out of 359 practicing RHOP graduates are health care providers in rural Nebraska;

Two hundred fifty-three RHOP alumni are practicing in 57 Nebraska counties; and

Seventy percent of RHOP graduates stay in Nebraska.

Based on RHOP's initial success, UNMC has since developed three additional early admission programs:

The Kearney Health Opportunities Program grants students at the University of Nebraska-Kearney, UNK, pre-admission to UNMC in five programs including medicine, nursing, pharmacy, radiography, and clinical laboratory science.

A collaboration between Peru State College and the UNMC College of Pharmacy reserves three slots each year in the College of Pharmacy for Peru State graduates.

The Public Health Early Admission Student Track allows Chadron State, Wayne State, Peru State, and UNK to each annually select three students for direct enrollment into a UNMC Public Health graduate program to help relieve the critical shortage of public health workers in rural Nebraska.

Additionally, since 1993, UNMC has sponsored annual science meets for eighth graders in Nebraska communities to get students interested in science-based careers. More than 1,000 students have participated in these meets. Further, RHEN hosts a career day each year for more than 250 students to visit and experience UNMC.

Now recognized as one of the most effective health workforce development programs in my state, RHEN's anniversary provides the perfect opportunity to recognize the accomplishments of this amazing program and how it is making a difference across Nebraska. To illustrate, RHEN's focus is one of the reasons why U.S. News & World Report ranks UNMC's primary care medicine program among the top 10 in the country.

In closing, the Rural Health Education Network program has made a significant difference in helping students become health care professionals for rural Nebraska, and I extend my congratulations to this program on 20 years of making a positive impact and increasing the health care workforce across Nebraska.●

JEWISH HERITAGE MONTH

● Mr. BROWN of Ohio. Mr. President, throughout the month of May, we celebrate Jewish Heritage Month, a time to reflect upon and celebrate those who have helped shape Jewish culture and the shared American experience. Since arriving on the shores of New Amsterdam in 1654, the men and women of the Jewish faith have worked to promote opportunity, justice, and equality for all.

In communities across the United States, public service, social action, and charity are rooted in both the religious and cultural components of Judaism.

Every day, members of Ohio's Jewish community make contributions that better the lives of their families, friends, and cities. While so many of these men and women deserve our praise and gratitude, I would like to highlight a few leaders within the Ohio Jewish community both past and present.

Dr. Albert Sabin, a pioneer in the field of medicine, called Cincinnati, OH home. While a professor at the University of Cincinnati College of Medicine, Dr. Sabin developed and perfected the oral polio vaccine. In 1960, after extensive preliminary trials, Dr. Sabin's oral polio vaccine was first used in Europe.

Between the years of 1962 and 1964, nearly 100 million people—children and adults—benefited from this vaccine in the United States. Dr. Sabin's contributions to the field of medical research saved countless lives from the ravages of polio and in the process, shaped modern vaccine study. It is no exaggeration to say that his efforts bettered and saved the lives of millions worldwide.

The success of Dr. Sabin clearly reflects Jewish values a commitment to social justice and a desire to work towards bettering society.

Such values are also extremely evident in the work of Rabbi Abraham Joshua Heschel. Born in Poland in 1907 and deported by the Nazi's in 1938, he was rescued and brought to the United States by Cincinnati's Hebrew Union College. Both an activist and religious leader, Rabbi Heschel played a powerful role in forging the bonds of faith, social action, and civil rights. In 1965, Rabbi Heschel marched arm-in-arm with Rev. Martin Luther King, Jr., in Selma in support of the civil rights movement. Following this experience, he spoke the iconic words: ''I felt my feet were praying.''

Just 3 years later, on March 25, 1968—10 days before that fateful day in Memphis, TN—Rabbi Heschel introduced Dr. King to the 68th Annual Convention of the Rabbinical Assembly. Rabbi Heschel closed his introduction by saying, ''The situation of the poor in America is our plight, our sickness. To be deaf to their cry is to condemn ourselves.''

Dr. King began his opening statement by saying, ''I have heard 'We Shall Overcome' probably more than I have heard any other song over the last few years. It is something of the theme song for our struggle. But tonight was the first time that I ever heard it in Hebrew, what a beautiful experience for me.''

Rabbi Heschel's legacy is carried on by his daughter, Dr. Susannah Heschel, a professor of Jewish studies at Dartmouth College. I was proud to join Dr. Heschel at a series of events we conducted in Ohio to celebrate her father's legacy and to discuss the future of social action and civil rights.

Another resident of Ohio who had a tremendous impact on Jewish heritage is Samuel Melton. Born in Austria-Hungary in 1900, Melton was just 4 years old when he and his mother joined his father in Toledo, OH.

As a student at the Ohio State University, Mr. Melton first became interested in reforming how Judaism was studied. While his career path led him away from Judaism and into the production of stainless steel fittings, his passion for Jewish education remained.

After Mr. Melton's retirement from Capitol Manufacturing and Supply of Columbus in 1959, he devoted his time and financial resources to modernizing and reforming Jewish education. He established the Melton Fellowship to encourage talented men and women to pursue work in Jewish education and financed the Samuel M. Melton Center for Jewish Studies at the Ohio State University, the first center for Jewish Studies at an American public university. Additionally, Mr. Melton's impact on Jewish heritage spans the globe through his entrepreneurial and philanthropic involvement in Israel.

Some have said that Mr. Melton spent the first half of his life earning his fortune and the second half giving it away. I commend Mr. Melton for this generosity. His passion for Judaism has impacted thousands of young Jewish men and women in Ohio and across the world.

Finally, I would like to highlight Alfred Tibor, a current Columbus resident, who was born in Hungary in 1920. Mr. Tibor has used his experiences as a Holocaust survivor to create sculptures that not only commemorate but also inspire humanity.

In his youth, Mr. Tibor was a talented gymnast and acrobat, but his Jewish heritage kept him from competing in the 1936 Olympics in Berlin. In 1940, he was forced by the Germans to perform slave labor before being sent to a prisoner of war camp in Siberia. After the war, Alfred and his brother returned to Hungary to find that they were the only members of their family to escape the war. Fearing further anti-Semitic activities, he fled Hungary, arriving in the United States and settling in Columbus.

For more than half a century, Alfred Tibor has used his talents to inspire and educate. According to Mr. Tibor, ''Art for art's sake is not enough.'' His sculptures are seen across the world as tributes to those lost and as reminders of hope and faith in times of tragedy and unspeakable horror.

During Jewish Heritage Month, let's honor Dr. Sabin, Rabbi Heschel, Mr. Melton, and Mr. Tibor, as well as all the men and women within the Ohio Jewish community who are seeking to better their neighborhoods while working to advance social justice. Thank you for your service to the Nation.●

MESSAGES FROM THE PRESIDENT

Messages from the President of the United States were communicated to the Senate by Mrs. Neiman, 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 appropriate committees.

(The nominations received today are printed at the end of the Senate proceedings.)

MEASURES READ THE FIRST TIME

The following joint resolution was read the first time:

S.J. Res. 41. Joint resolution expressing the sense of Congress regarding the nuclear program of the Government of the Islamic Republic of Iran.

EXECUTIVE AND OTHER COMMUNICATIONS

The following communications were laid before the Senate, together with accompanying papers, reports, and documents, and were referred as indicated:

EC–6241. A communication from the Regulatory Ombudsman, Federal Motor Carrier Safety Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''National Registry of Certified Medical Examiners'' (RIN2126–AB97) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6242. A communication from the Associate Bureau Chief, Wireless Telecommunications Bureau, Federal Communications Commission, transmitting, pursuant to law, the report of a rule entitled ''Amendment of the Commission's Rules Governing Hearing Aid-Compatible Mobile Handsets'' (WT Docket No. 07–250; DA 12–550) received during adjournment of the Senate in the Office of the President of the Senate on May 11, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6243. A communication from the Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Fisheries Off West Coast States; West Coast Salmon Fisheries; 2012 Management Measures'' (RIN0648–XA921) received in the Office of the President of the Senate on May 10, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6244. A communication from the Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Fisheries of the Northeastern United States; Northeast Multispecies Fishery; 2012 Sector Operations Plans and Contracts, and Allocation of Northeast Multispecies Annual Catch Entitlements'' (RIN0648–XA797) received in the Office of the President of the Senate on May 10, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6245. A communication from the Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Interim Action; Republication'' (RIN0648–BB89) received in the Office of the President of the Senate on May 10, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6246. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Removal of Category IIIa, IIIb, and IIIc Definitions; Delay of Effective Date and Reopening of Comment Period'' ((RIN2120–AK03) (Docket No. FAA–2012–0019)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6247. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Damage Tolerance and Fatigue Evaluation for Composite Rotorcraft Structures, and Damage Tolerance and Fatigue Evaluation for Metallic Structures; Correction'' ((RIN2120–AJ51, 2120–AJ52) (Docket No. FAA–2009–0660)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6248. A communication from the Trial Attorney, Federal Railroad Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Positive Train Control Systems (RRR)'' (RIN2130–AC27) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6249. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Amendment of Restricted Areas R–5801 and R–5803; Chambersburg, PA'' ((RIN2120–AA66) (Docket No. FAA–2012–0174)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6250. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Amendment of Class E Airspace; Lamar, CO'' ((RIN2120–AA66) (Docket No. FAA–2011–1262)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6251. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Amendment of Class E Airspace; Hastings, NE'' ((RIN2120–AA66) (Docket No. FAA–2011–0499)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6252. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Amendment of Class E Airspace; Tobe, CO'' ((RIN2120–AA66) (Docket No. FAA–2011–1338)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6253. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Amendment of Class E Airspace; Springfield, CO'' ((RIN2120–AA66) (Docket No. FAA–2011–1247)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6254. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Amendment of Class E Airspace; Willcox, AZ, and Revocation of Class E Airspace; Cochise, AZ'' ((RIN2120–AA66) (Docket No. FAA–2011–1314)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6255. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Establishment of Class E Airspace; Boyne City, MI'' ((RIN2120–AA66) (Docket No. FAA–2011–0828)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6256. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Establishment of Class E Airspace; Marion, AL'' ((RIN2120–AA66) (Docket No. FAA–2011–0590)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6257. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Revocation of Class E Airspace; Southport, NC, and Establishment of Class E Airspace; Oak Island, NC'' ((RIN2120–AA66) (Docket No. FAA–2011–1148)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6258. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Standard Instrument Approach Procedures; Miscellaneous Amendments (12); Amdt. No. 3475'' (RIN2120–AA65) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6259. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Standard Instrument Approach Procedures; Miscellaneous Amendments (144); Amdt. No. 3474'' (RIN2120–AA65) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6260. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Standard Instrument Approach Procedures; Miscellaneous Amendments (39); Amdt. No. 3473'' (RIN2120–AA65) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6261. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Standard Instrument Approach Procedures; Miscellaneous Amendments (53); Amdt. No. 3472'' (RIN2120–AA65) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6262. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Establishment of Class E Airspace; Piseco, NY'' ((RIN2120–AA66) (Docket No. FAA–2011–0726)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6263. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation,

transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Pratt and Whitney Turbofan Engines'' ((RIN2120–AA64) (Docket No. FAA–2007–27023)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6264. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; The Boeing Company Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2011–0566)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6265. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Airbus Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2012–0297)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6266. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; DASSAULT AVIATION Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2011–1164)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6267. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Airbus Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2012–0295)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6268. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Airbus Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2094)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6269. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Pilatus Aircraft Ltd. Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2012–0018) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6270. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; DG Flugzeugbau GmbH Gliders'' ((RIN2120–AA64) (Docket No. FAA–2012–0017)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6271. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Rolls-Royce plc Turbofan Engines'' ((RIN2120–AA64) (Docket No. FAA–2010–0821)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6272. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Fokker Services B.V. Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2011–1226)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6273. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Bombardier, Inc. Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2011–1088)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6274. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; The Boeing Company Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2012–0110)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6275. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Airbus Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2012–0033)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6276. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Turbomeca S.A. Turboshaft Engines'' ((RIN2120–AA64) (Docket No. FAA–2012–0010)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6277. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Airplanes'' ((RIN2120–AA64) (Docket No. FAA–20)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6278. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Learjet Inc.'' ((RIN2120–AA64) (Docket No. FAA–2011–1069)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6279. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Bombardier, Inc. Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2011–1223)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6280. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Learjet Inc. Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2011–1258)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6281. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; The Boeing Company Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2011–0644)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6282. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Turbomeca S.A. Turboshaft Engines'' ((RIN2120–AA64) (Docket No. FAA–2009–0330)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6283. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters'' ((RIN2120–AA64) (Docket No. FAA–2011–1115)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6284. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Agusta S.p.A. Helicopters'' ((RIN2120–AA64) (Docket No. FAA–2012–0409)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6285. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; 328 Support Services GmbH Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2011–1318)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6286. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Airworthiness Directives; Goodrich Evacuation Systems Approved Under Technical Standard Order (TSO) TSO-C69b and Installed on Airbus Airplanes'' ((RIN2120–AA64) (Docket No. FAA–2011–0223)) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6287. A communication from the Acting Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration, Department of Commerce, transmitting, pursuant to law, a report entitled, ''2011 Status of U.S. Fisheries''; to the Committee on Commerce, Science, and Transportation.

EC–6288. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Acibenzolar-S-methyl; Time-Limited Pesticide Tolerances'' (FRL No. 9349–3) received in the Office of the President of the Senate on May 22, 2012; to the Committee on Agriculture, Nutrition, and Forestry.

EC–6289. A communication from the Secretary of the Commission, Office of the General Counsel, Commodity Futures Trading Commission, transmitting, pursuant to law, the report of a rule entitled ''Further Definition of 'Swap Dealer,' 'Security-Based Swap Dealer,' 'Major Swap Participant,' 'Major

Security-Based Swap Participant' and 'Eligible Contract Participant'" (RIN3235–AK65) received in the Office of the President of the Senate on May 23, 2012; to the Committee on Agriculture, Nutrition, and Forestry.

EC–6290. A communication from the Acting Under Secretary of Defense (Acquisition, Technology, and Logistics), transmitting, pursuant to law, a report entitled ''Annual Corrosion Budget Materials Report''; to the Committee on Armed Services.

EC–6291. A communication from the Acting Under Secretary of Defense (Acquisition, Technology, and Logistics), transmitting, pursuant to law, a report entitled ''Defense Production Act Annual Fund Report for Fiscal Year 2011''; to the Committee on Armed Services.

EC–6292. A communication from the Acting Under Secretary of Defense (Acquisition, Technology and Logistics), transmitting, pursuant to law, a report relative to Department of Defense purchases from foreign entities for fiscal year 2011; to the Committee on Armed Services.

EC–6293. A communication from the Director of Defense Procurement and Acquisition Policy, Department of Defense, transmitting, pursuant to law, the report of a rule entitled ''Defense Federal Acquisition Regulation Supplement; Contracting with the Canadian Commercial Corporation'' ((RIN0750–AH42) (DFARS Case 2011–D049)) received in the Office of the President of the Senate on May 21, 2012; to the Committee on Armed Services.

EC–6294. A communication from the Secretary of the Treasury, transmitting, pursuant to law, a six-month report on the national emergency that was originally declared in Executive Order 13159 relative to the risk of nuclear proliferation created by the accumulation of weapons-usable fissile material in the territory of the Russian Federation; to the Committee on Banking, Housing, and Urban Affairs.

EC–6295. A communication from the Assistant General Counsel, General Law, Ethics, and Regulation, Department of the Treasury, transmitting, pursuant to law, (6) reports relative to vacancies within the Department, received in the Office of the President of the Senate on May 23, 2012; to the Committee on Banking, Housing, and Urban Affairs.

EC–6296. A communication from the Chief Counsel, Federal Emergency Management Agency, Department of Homeland Security, transmitting, pursuant to law, the report of a rule entitled ''Final Flood Elevation Determinations'' ((44 CFR Part 67) (Docket No. FEMA–2012–0003)) received in the Office of the President of the Senate on May 23, 2012; to the Committee on Banking, Housing, and Urban Affairs.

EC–6297. A communication from the Chief Counsel, Federal Emergency Management Agency, Department of Homeland Security, transmitting, pursuant to law, the report of a rule entitled ''Changes in Flood Elevation Determinations'' ((44 CFR Part 65) (Docket No. FEMA–2012–0003)) received in the Office of the President of the Senate on May 23, 2012; to the Committee on Banking, Housing, and Urban Affairs.

EC–6298. A communication from the Chief Counsel, Federal Emergency Management Agency, Department of Homeland Security, transmitting, pursuant to law, the report of a rule entitled ''Suspension of Community Eligibility'' ((44 CFR Part 64) (Docket No. FEMA–2012–0003)) received in the Office of the President of the Senate on May 23, 2012; to the Committee on Banking, Housing, and Urban Affairs.

EC–6299. A communication from the First Vice President, Controller and Chief Accounting Officer, Federal Home Loan Bank of Boston, transmitting, pursuant to law, the Bank's 2011 Management Report and statement on the system of internal control; to the Committee on Banking, Housing, and Urban Affairs.

EC–6300. A communication from the Assistant Secretary, Office of Fossil Energy, Department of Energy, transmitting, pursuant to law, a report entitled ''Liquefied Natural Gas Safety Research Report''; to the Committee on Energy and Natural Resources.

EC–6301. A communication from the Secretary of Energy, transmitting, pursuant to law, a report relative to the status of construction of the mixed oxide fuel fabrication facility (MOX facility) at the Department of Energy's Savannah River Site in South Carolina; to the Committee on Energy and Natural Resources.

EC–6302. A communication from the Assistant General Counsel for Legislation, Regulation and Energy Efficiency, Department of Energy, transmitting, pursuant to law, the report of a rule entitled ''Loan Guarantees for Projects That Employ Innovative Technologies'' (RIN1901–AB32) received in the Office of the President of the Senate on May 22, 2012; to the Committee on Energy and Natural Resources.

EC–6303. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Partial Approval and Promulgation of Implementation Plans; Washington: Infrastructure Requirements for the 1997 8-Hour Ozone National Ambient Air Quality Standard'' (FRL No. 9674–2) received in the Office of the President of the Senate on May 22, 2012; to the Committee on Environment and Public Works.

EC–6304. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of Air Quality Implementation Plans; Massachusetts and New Hampshire; Determination of Attainment of the One-hour and 1997 Eight-hour Ozone Standards for Eastern Massachusetts'' (FRL No. 9675–9) received in the Office of the President of the Senate on May 22, 2012; to the Committee on Environment and Public Works.

EC–6305. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of Implementation Plans; New Mexico; Albuquerque/Bernalillo County; Fees for Permits and Administrative Actions'' (FRL No. 9672–7) received in the Office of the President of the Senate on May 22, 2012; to the Committee on Environment and Public Works.

EC–6306. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Approval and Promulgation of Air Quality Implementation Plans; Illinois; Small Container Exemption from VOC Coating Rules'' (FRL No. 9677–3) received in the Office of the President of the Senate on May 22, 2012; to the Committee on Environment and Public Works.

EC–6307. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''Revision to the South Coast Air Quality Management District Portion of the California State Implementation Plan, South Coast Rule 1315'' (FRL No. 9669–8) received in the Office of the President of the Senate on May 22, 2012; to the Committee on Environment and Public Works.

EC–6308. A communication from the Director of Congressional Affairs, Office of International Programs, Nuclear Regulatory Commission, transmitting, pursuant to law, the report of a rule entitled ''Export and Import of Nuclear Equipment and Material; Export of International Atomic Energy Agency Safeguards Samples'' (RIN3150–AJ04) received in the Office of the President of the Senate on May 21, 2012; to the Committee on Environment and Public Works.

EC–6309. A communication from the Chief of the Publications and Regulations Branch, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled ''Applicable Federal Rates—June 2012'' (Rev. Rul. 2012–15) received in the Office of the President of the Senate on May 22, 2012; to the Committee on Finance.

EC–6310. A communication from the Chief of the Publications and Regulations Branch, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled ''Health Insurance Premium Tax Credit'' (TD 9590) received in the Office of the President of the Senate on May 22, 2012; to the Committee on Finance.

EC–6311. A communication from the Assistant Attorney General, Civil Rights Division, Department of Justice, transmitting, pursuant to law, the report of a rule entitled ''Amendment of Americans with Disabilities Act Title II and Title III Regulations to Extend Compliance Date for Certain Requirements Related to Existing Pools and Spas Provided by State and Local Governments and by Public Accommodations'' (RIN1190–AA69) received in the Office of the President of the Senate on May 21, 2012; to the Committee on Health, Education, Labor, and Pensions.

EC–6312. A communication from the Chairman of the Federal Energy Regulatory Commission, transmitting, pursuant to law, the Commission's fiscal year 2012 annual report relative to the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002; to the Committee on Homeland Security and Governmental Affairs.

EC–6313. A communication from the Equal Employment Opportunity Director, Farm Credit Administration, transmitting, pursuant to law, the Farm Credit Administration's fiscal year 2012 annual report relative to the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002; to the Committee on Homeland Security and Governmental Affairs.

EC–6314. A communication from the Equal Employment Opportunity and Inclusion Director, Farm Credit System Insurance Corporation, transmitting, pursuant to law, the Farm Credit System Insurance Corporation's fiscal year 2011 annual report relative to the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002; to the Committee on Homeland Security and Governmental Affairs.

EC–6315. A communication from the Chairman of the National Credit Union Administration, transmitting, pursuant to law, the Semi-Annual Report of the Inspector General for the period from October 1, 2011 through March 31, 2012; to the Committee on Homeland Security and Governmental Affairs.

EC–6316. A communication from the Executive Director, Interstate Commission on the Potomac River Basin, transmitting, pursuant to law, the Commission's Seventy-First Financial Statement for the period of October 1, 2010 through September 30, 2011; to the Committee on Homeland Security and Governmental Affairs.

EC–6317. A communication from the Assistant Attorney General, Office of Legislative Affairs, Department of Justice, transmitting, pursuant to law, a report on the activities of the Community Relations Service for

Fiscal Year 2011; to the Committee on the Judiciary.

EC–6318. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–354, ''Fiscal Year 2012 Revised Budget Request Adjustment Temporary Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6319. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–355, ''Vendor Sales Tax Collection and Remittance Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6320. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–356, ''Combined Condominium Real Property Tax Amendment Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6321. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–357, ''Carver 2000 Low-Income and Senior Housing Project Amendment Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6322. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–358, ''Senior HIV/AIDS Education and Outreach Program Establishment Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6323. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–359, ''King Towers Residential Housing Real Property Tax Exemption Clarification Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6324. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–360, ''Adolf Cluss Court Alley Designation Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6325. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–361, ''People First Respectful Language Modernization Amendment Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6326. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–362, ''Real Property Tax Appeals Commission Establishment Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6327. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–363, ''HIV/AIDS Continuing Education Requirements Amendment Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6328. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–364, ''Advisory Neighborhood Commissions Boundaries Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6329. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–365, ''Jubilee Housing Residential Rental Project Real Property Tax Exemption Clarification Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6330. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–366, ''Firearms Amendment Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6331. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–367, ''Elizabeth P. Thomas Way Designation Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6332. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–368, ''Where Lincoln's Legacy Lives Designation Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6333. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–369, ''Capitol Riverfront BID Amendment Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6334. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–372, ''Foster Care Youth Employment Amendment Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6335. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–373, ''Hilda H.M. Mason Way Designation Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6336. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–374, ''Child Abuse Prevention and Treatment Amendment Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6337. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–375, ''Age-in-Place and Equitable Senior Citizen Real Property Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6338. A communication from the Chairman of the Council of the District of Columbia, transmitting, pursuant to law, a report on D.C. Act 19–376, ''Technical Amendments Act of 2012''; to the Committee on Homeland Security and Governmental Affairs.

EC–6339. A communication from the Chairman of the National Endowment for the Arts, transmitting, pursuant to law, the Semiannual Report of the Inspector General, the Chairman's Semiannual Report on Final Action Resulting from Audit Reports, Inspection Reports, and Evaluation Reports for the period from October 1, 2011 through March 31, 2012; to the Committee on Homeland Security and Governmental Affairs.

EC–6340. A communication from the Deputy Chief, Consumer and Governmental Affairs Bureau, Federal Communications Commission, transmitting, pursuant to law, the report of a rule entitled ''Empowering Consumers to Prevent and Detect Billing for Unauthorized Charges (''Cramming''); Consumer Information and Disclosure; Truth-in-Billing and Billing Format'' (FCC 12–42) received in the Office of the President of the Senate on May 24, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6341. A communication from the General Counsel, Federal Energy Regulatory Commission, transmitting, pursuant to law, the report of a rule entitled ''Automatic Underfrequency Load Shedding and Load Shedding Plans Reliability Standards'' (Docket No. RM11–20–000) received in the Office of the President of the Senate on May 24, 2012; to the Committee on Energy and Natural Resources.

REPORTS OF COMMITTEES

The following reports of committees were submitted:

By Mr. LIEBERMAN, from the Committee on Homeland Security and Governmental Affairs, with amendments:

S. 2061. A bill to provide for an exchange of land between the Department of Homeland Security and the South Carolina State Ports Authority (Rept. No. 112–171).

By Mr. LEAHY, from the Committee on Appropriations, without amendment:

S. 3241. An original bill making appropriations for the Department of State, foreign operations, and related programs for the fiscal year ending September 30, 2013, and for other purposes (Rept. No. 112–172).

By Mr. LEAHY, from the Committee on the Judiciary, without amendment:

S. 2370. A bill to amend title 11, United States Code, to make bankruptcy organization more efficient for small business debtors, and for other purposes.

By Ms. STABENOW, from the Committee on Agriculture, Nutrition, and Forestry, without amendment:

S. 3240. An original bill to reauthorize agricultural programs through 2017, and for other purposes.

EXECUTIVE REPORT OF COMMITTEE

The following executive report of a nomination was submitted:

By Mr. LEAHY for the Committee on the Judiciary.

Charles Thomas Massarone, of Kentucky, to be a Commissioner of the United States Parole Commission for a term of six years.

(Nominations without an asterisk were reported with the recommendation that they be confirmed.)

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 Mr. BLUMENTHAL (for himself, Ms. SNOWE, Ms. MIKULSKI, Mrs. MURRAY, and Mr. TESTER):

S. 3234. A bill to amend the Internal Revenue Code of 1986 to extend the time period for contributing military death gratuities to Roth IRAs and Coverdell education savings accounts; to the Committee on Finance.

By Mr. PRYOR (for himself and Mr. JOHANNS):

S. 3235. A bill to amend title 38, United States Code, to require, as a condition on the receipt by a State of certain funds for veterans employment and training, that the State ensures that training received by a veteran while on active duty is taken into consideration in granting certain State certifications or licenses, and for other purposes; to the Committee on Veterans' Affairs.

By Mr. PRYOR:

S. 3236. A bill to amend title 38, United States Code, to improve the protection and enforcement of employment and reemployment rights of members of the uniformed services, and for other purposes; to the Committee on Veterans' Affairs.

By Mr. WHITEHOUSE (for himself, Ms. COLLINS, Mr. BROWN of Ohio, Ms. MURKOWSKI, Mrs. SHAHEEN, Mr. HELLER, Mr. WARNER, and Mr. GRASSLEY):

S. 3237. A bill to provide for the establishment of a Commission to Accelerate the End of Breast Cancer; to the Committee on Health, Education, Labor, and Pensions.

By Mr. BROWN of Ohio (for himself and Mr. PORTMAN):

S. 3238. A bill to designate the Department of Veterans Affairs community based outpatient clinic in Mansfield, Ohio, as the David F. Winder Department of Veterans Affairs Community Based Outpatient Clinic, and for other purposes; to the Committee on Veterans' Affairs.

By Mrs. FEINSTEIN:

S. 3239. A bill to provide for a uniform national standard for the housing and treatment of egg-laying hens, and for other purposes; to the Committee on Agriculture, Nutrition, and Forestry.

By Ms. STABENOW:

S. 3240. An original bill to reauthorize agricultural programs through 2017, and for other purposes; from the Committee on Agriculture, Nutrition, and Forestry; placed on the calendar.

By Mr. LEAHY:

S. 3241. An original bill making appropriations for the Department of State, foreign operations, and related programs for the fiscal year ending September 30, 2013, and for other purposes; from the Committee on Appropriations; placed on the calendar.

By Mr. MENENDEZ:

S. 3242. A bill to amend title XVIII of the Social Security Act to provide Medicare beneficiaries coordinated care and greater choice with regard to accessing hearing health services and benefits; to the Committee on Finance.

By Mrs. GILLIBRAND (for herself, Mr. LEAHY, and Mr. SANDERS):

S. 3243. A bill to amend the Internal Revenue Code of 1986 to increase the amount of the low-income housing credit that may be allocated in States damaged in 2011 by Hurricane Irene or Tropical Storm Lee; to the Committee on Finance.

By Mr. FRANKEN (for himself, Mr. HARKIN, Mr. GRASSLEY, Mr. BLUMENTHAL, Mr. SCHUMER, Ms. MIKULSKI, Mr. JOHNSON of South Dakota, Mr. WYDEN, and Mr. CARDIN):

S. 3244. A bill to amend the Higher Education Opportunity Act to add disclosure requirements to the institution financial aid offer form and to amend the Higher Education Act of 1965 to make such form mandatory; to the Committee on Health, Education, Labor, and Pensions.

By Mr. LEAHY (for himself and Mr. GRASSLEY):

S. 3245. A bill to permanently reauthorize the EB–5 Regional Center Program, the E-Verify Program, the Special Immigrant Nonminister Religious Worker Program, and the Conrad State 30 J–1 Visa Waiver Program; to the Committee on the Judiciary.

By Ms. SNOWE:

S. 3246. A bill to improve the Service Corps of Retired Executives, and for other purposes; to the Committee on Small Business and Entrepreneurship.

By Mr. ISAKSON:

S. 3247. A bill to direct the Secretary of the Interior to conduct a special resource study of the West Hunter Street Baptist Church in Atlanta, Georgia, and for other purposes; to the Committee on Energy and Natural Resources.

By Mr. ENZI (for himself, Mr. JOHNSON of South Dakota, Mr. CONRAD, Mr. HOEVEN, Mr. THUNE, Mr. BENNET, Mr. UDALL of Colorado, Mr. MORAN, Mr. UDALL of New Mexico, Mr. JOHANNS, and Mr. WHITEHOUSE):

S. 3248. A bill to designate the North American bison as the national mammal of the United States; to the Committee on the Judiciary.

By Mr. BROWN of Massachusetts (for himself, Mr. CHAMBLISS, and Mr. RISCH):

S. 3249. A bill to require a report on the designation of Boko Haram as a foreign terrorist organization, and for other purposes; to the Committee on Foreign Relations.

By Mr. CORNYN (for himself, Mr. BENNET, Mr. KIRK, Ms. KLOBUCHAR, Mr. FRANKEN, and Ms. COLLINS):

S. 3250. A bill to amend the DNA Analysis Backlog Elimination Act of 2000 to provide for Debbie Smith grants for auditing sexual assault evidence backlogs and to establish a Sexual Assault Forensic Evidence Registry, and for other purposes; to the Committee on the Judiciary.

By Ms. KLOBUCHAR (for herself and Mr. FRANKEN):

S. 3251. A bill to amend title 46, United States Code, with respect to Mille Lacs Lake, Minnesota, and for other purposes; to the Committee on Commerce, Science, and Transportation.

By Mr. PORTMAN (for himself, Mr. BROWN of Ohio, Mr. HOEVEN, Ms. AYOTTE, Mr. BEGICH, Mr. VITTER, Mr. BLUNT, Mr. BARRASSO, Mr. BLUMENTHAL, Mr. CORNYN, Mr. RISCH, Mr. COCHRAN, Mr. UDALL of Colorado, Mr. COBURN, Mr. RUBIO, Mr. JOHNSON of Wisconsin, Mr. NELSON of Florida, Mr. TOOMEY, Mr. WICKER, Mr. LEE, Mr. COONS, Mr. GRAHAM, Ms. LANDRIEU, and Mr. CARPER):

S. 3252. A bill to provide for the award of a gold medal on behalf of Congress to Jack Nicklaus, in recognition of his service to the Nation in promoting excellence, good sportsmanship, and philanthropy; to the Committee on Banking, Housing, and Urban Affairs.

By Ms. LANDRIEU (for herself and Ms. SNOWE):

S. 3253. A bill to amend the Small Business Investment Act of 1958 to enhance the Small Business Investment Company Program, and for other purposes; to the Committee on Small Business and Entrepreneurship.

By Mr. GRAHAM (for himself, Mr. CASEY, Mr. LIEBERMAN, Ms. AYOTTE, Mr. BLUMENTHAL, Mr. BOOZMAN, Mr. BROWN of Massachusetts, Mr. BROWN of Ohio, Mr. CARDIN, Mr. CHAMBLISS, Mr. COATS, Ms. COLLINS, Mr. COONS, Mr. CORNYN, Mrs. GILLIBRAND, Mr. HATCH, Mr. HELLER, Mr. HOEVEN, Mrs. HUTCHISON, Mr. INHOFE, Mr. MCCAIN, Mrs. MCCASKILL, Mr. MENENDEZ, Ms. MIKULSKI, Mr. NELSON of Florida, Mr. NELSON of Nebraska, Mr. PORTMAN, Mr. PRYOR, Mr. RISCH, Mr. SCHUMER, Mr. UDALL of Colorado, Mr. WYDEN, Ms. SNOWE, Mr. VITTER, Mr. ISAKSON, Mr. SESSIONS, Mr. WICKER, Mr. MANCHIN, Mr. WHITEHOUSE, Mr. BURR, Mr. MORAN, Mr. CRAPO, Mr. KIRK, Mrs. HAGAN, Mr. GRASSLEY, Mr. LAUTENBERG, Mr. TOOMEY, Mr. BENNET, Mr. RUBIO, Ms. STABENOW, Mr. LUGAR, Mr. WARNER, Mr. CARPER, Mr. LEE, Mr. DEMINT, Mr. MCCONNELL, Mr. COCHRAN, Mr. JOHANNS, Mr. BLUNT, Mr. BARRASSO, Ms. LANDRIEU, Mr. TESTER, Mr. ROBERTS, Mr. BEGICH, Ms. KLOBUCHAR, Mr. INOUYE, Mr. AKAKA, Mr. COBURN, Mr. ROCKEFELLER, Mrs. MURRAY, Mr. JOHNSON of Wisconsin, Mr. KOHL, Ms. CANTWELL, Mr. THUNE, Ms. MURKOWSKI, Mr. SHELBY, Mr. MERKLEY, and Mr. DURBIN):

S.J. Res. 41. A joint resolution expressing the sense of Congress regarding the nuclear program of the Government of the Islamic Republic of Iran; read the first time.

SUBMISSION OF CONCURRENT AND SENATE RESOLUTIONS

The following concurrent resolutions and Senate resolutions were read, and referred (or acted upon), as indicated:

By Mr. ENZI (for himself, Ms. AYOTTE, Mr. BLUMENTHAL, and Mr. BEGICH):

S. Res. 472. A resolution designating October 7, 2012, as ''Operation Enduring Freedom Veterans Day''; to the Committee on the Judiciary.

By Mr. DURBIN (for himself, Mr. KIRK, Mr. BROWN of Ohio, Mr. MENENDEZ, Mr. LUGAR, and Mr. LAUTENBERG):

S. Res. 473. A resolution commending Rotary International and others for their efforts to prevent and eradicate polio; to the Committee on Foreign Relations.

By Mr. AKAKA (for himself, Mr. INOUYE, Mr. REID, Mr. BEGICH, Mrs. MURRAY, and Mr. MENENDEZ):

S. Res. 474. A resolution recognizing the significance of May 2012 as Asian-Pacific American Heritage Month and the importance of celebrating the significant contributions of Asian-Americans and Pacific Islanders to the history of the United States; to the Committee on the Judiciary.

By Mr. THUNE (for himself, Mr. JOHNSON of South Dakota, Mr. REID, Mr. MCCONNELL, Mr. AKAKA, Mr. ALEXANDER, Ms. AYOTTE, Mr. BARRASSO, Mr. BAUCUS, Mr. BEGICH, Mr. BENNET, Mr. BINGAMAN, Mr. BLUMENTHAL, Mr. BLUNT, Mr. BOOZMAN, Mrs. BOXER, Mr. BROWN of Massachusetts, Mr. BROWN of Ohio, Mr. BURR, Ms. CANTWELL, Mr. CARDIN, Mr. CARPER, Mr. CASEY, Mr. CHAMBLISS, Mr. COATS, Mr. COBURN, Mr. COCHRAN, Ms. COLLINS, Mr. CONRAD, Mr. COONS, Mr. CORKER, Mr. CORNYN, Mr. CRAPO, Mr. DEMINT, Mr. DURBIN, Mr. ENZI, Mrs. FEINSTEIN, Mr. FRANKEN, Mrs. GILLIBRAND, Mr. GRAHAM, Mr. GRASSLEY, Mrs. HAGAN, Mr. HARKIN, Mr. HATCH, Mr. HELLER, Mr. HOEVEN, Mrs. HUTCHISON, Mr. INHOFE, Mr. INOUYE, Mr. ISAKSON, Mr. JOHANNS, Mr. JOHNSON of Wisconsin, Mr. KERRY, Mr. KIRK, Ms. KLOBUCHAR, Mr. KOHL, Mr. KYL, Ms. LANDRIEU, Mr. LAUTENBERG, Mr. LEAHY, Mr. LEE, Mr. LEVIN, Mr. LIEBERMAN, Mr. LUGAR, Mr. MANCHIN, Mr. MCCAIN, Mrs. MCCASKILL, Mr. MENENDEZ, Mr. MERKLEY, Ms. MIKULSKI, Mr. MORAN, Ms. MURKOWSKI, Mrs. MURRAY, Mr. NELSON of Nebraska, Mr. NELSON of Florida, Mr. PAUL, Mr. PORTMAN, Mr. PRYOR, Mr. REED, Mr. RISCH, Mr. ROBERTS, Mr. ROCKEFELLER, Mr. RUBIO, Mr. SANDERS, Mr. SCHUMER, Mr. SESSIONS, Mrs. SHAHEEN, Mr. SHELBY, Ms. SNOWE, Ms. STABENOW, Mr. TESTER, Mr. TOOMEY, Mr. UDALL of Colorado, Mr. UDALL of New Mexico, Mr. VITTER, Mr. WARNER, Mr. WEBB, Mr. WHITEHOUSE, Mr. WICKER, and Mr. WYDEN):

S. Res. 475. A resolution relating to the death of the Honorable E. James Abdnor, former United States Senator and Congressman from the State of South Dakota; considered and agreed to.

ADDITIONAL COSPONSORS

S. 52

At the request of Mr. INOUYE, the name of the Senator from Oregon (Mr. WYDEN) was added as a cosponsor of S.

52, a bill to establish uniform administrative and enforcement procedures and penalties for the enforcement of the High Seas Driftnet Fishing Moratorium Protection Act and similar statutes, and for other purposes.

S. 362

At the request of Mr. WHITEHOUSE, the name of the Senator from Georgia (Mr. ISAKSON) was added as a cosponsor of S. 362, a bill to amend the Public Health Service Act to provide for a Pancreatic Cancer Initiative, and for other purposes.

S. 847

At the request of Mr. LAUTENBERG, the names of the Senator from Iowa (Mr. HARKIN) and the Senator from Washington (Ms. CANTWELL) were added as cosponsors of S. 847, a bill to amend the Toxic Substances Control Act to ensure that risks from chemicals are adequately understood and managed, and for other purposes.

S. 881

At the request of Mr. JOHANNS, his name was added as a cosponsor of S. 881, a bill to amend the Consumer Credit Protection Act to assure meaningful disclosures of the terms of rental-purchase agreements, including disclosures of all costs to consumers under such agreements, to provide substantive rights to consumers under such agreements, and for other purposes.

S. 1005

At the request of Mr. BOOZMAN, the name of the Senator from Oklahoma (Mr. COBURN) was added as a cosponsor of S. 1005, a bill to provide for parental notification and intervention in the case of a minor seeking an abortion.

S. 1039

At the request of Mr. CARDIN, the name of the Senator from Wisconsin (Mr. JOHNSON) was added as a cosponsor of S. 1039, a bill to impose sanctions on persons responsible for the detention, abuse, or death of Sergei Magnitsky, for the conspiracy to defraud the Russian Federation of taxes on corporate profits through fraudulent transactions and lawsuits against Hermitage, and for other gross violations of human rights in the Russian Federation, and for other purposes.

S. 1224

At the request of Mr. BINGAMAN, the name of the Senator from New Mexico (Mr. UDALL) was added as a cosponsor of S. 1224, a bill to amend Public Law 106–392 to maintain annual base funding for the Upper Colorado and San Juan fish recovery program through fiscal year 2023.

S. 1460

At the request of Mr. BAUCUS, the name of the Senator from Illinois (Mr. DURBIN) was added as a cosponsor of S. 1460, a bill to grant the congressional gold medal, collectively, to the First Special Service Force, in recognition of its superior service during World War II.

S. 1461

At the request of Mr. NELSON of Florida, the name of the Senator from Nebraska (Mr. NELSON) was added as a cosponsor of S. 1461, a bill to amend the Federal Food, Drug, and Cosmetic Act to clarify the Food and Drug Administration's jurisdiction over certain tobacco products, and to protect jobs and small businesses involved in the sale, manufacturing and distribution of traditional and premium cigars.

S. 1796

At the request of Mr. JOHANNS, his name was added as a cosponsor of S. 1796, a bill to make permanent the Internal Revenue Service Free File program.

S. 1935

At the request of Mrs. HAGAN, the name of the Senator from North Carolina (Mr. BURR) was added as a cosponsor of S. 1935, a bill to require the Secretary of the Treasury to mint coins in recognition and celebration of the 75th anniversary of the establishment of the March of Dimes Foundation.

S. 1947

At the request of Mr. BLUMENTHAL, the name of the Senator from Oregon (Mr. WYDEN) was added as a cosponsor of S. 1947, a bill to prohibit attendance of an animal fighting venture, and for other purposes.

S. 1989

At the request of Ms. CANTWELL, the name of the Senator from Iowa (Mr. HARKIN) was added as a cosponsor of S. 1989, a bill to amend the Internal Revenue Code of 1986 to make permanent the minimum low-income housing tax credit rate for unsubsidized buildings and to provide a minimum 4 percent credit rate for existing buildings.

S. 1993

At the request of Mr. NELSON of Florida, the name of the Senator from New Jersey (Mr. MENENDEZ) was added as a cosponsor of S. 1993, a bill to posthumously award a Congressional Gold Medal to Lena Horne in recognition of her achievements and contributions to American culture and the civil rights movement.

S. 2078

At the request of Mr. MENENDEZ, the name of the Senator from Georgia (Mr. ISAKSON) was added as a cosponsor of S. 2078, a bill to enable Federal and State chartered banks and thrifts to meet the credit needs of the Nation's home builders, and to provide liquidity and ensure stable credit for meeting the Nation's need for new homes.

S. 2165

At the request of Mrs. BOXER, the name of the Senator from Mississippi (Mr. COCHRAN) was added as a cosponsor of S. 2165, a bill to enhance strategic cooperation between the United States and Israel, and for other purposes.

S. 2205

At the request of Mr. MORAN, the name of the Senator from Pennsylvania (Mr. TOOMEY) was added as a cosponsor of S. 2205, a bill to prohibit funding to negotiate a United Nations Arms Trade Treaty that restricts the Second Amendment rights of United States citizens.

S. 2283

At the request of Mr. TESTER, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of S. 2283, a bill to amend the Robert T. Stafford Disaster Relief and Emergency Assistance Act to include procedures for requests from Indian tribes for a major disaster or emergency declaration, and for other purposes.

S. 3083

At the request of Mr. RUBIO, the name of the Senator from Idaho (Mr. CRAPO) was added as a cosponsor of S. 3083, a bill to amend the Internal Revenue Code of 1986 to require certain nonresident aliens to provide valid immigration documents to claim the refundable portion of the child tax credit.

S. 3203

At the request of Mr. LAUTENBERG, the name of the Senator from New Jersey (Mr. MENENDEZ) was added as a cosponsor of S. 3203, 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. 3204

At the request of Mr. JOHANNS, the names of the Senator from Georgia (Mr. ISAKSON) and the Senator from Georgia (Mr. CHAMBLISS) were added as cosponsors of S. 3204, a bill to address fee disclosure requirements under the Electronic Fund Transfer Act, and for other purposes.

S. 3217

At the request of Mr. MORAN, the name of the Senator from Massachusetts (Mr. BROWN) was added as a cosponsor of S. 3217, a bill to jump-start the economic recovery through the formation and growth of new businesses, and for other purposes.

S. 3228

At the request of Mr. THUNE, the names of the Senator from Ohio (Mr. PORTMAN) and the Senator from Florida (Mr. RUBIO) were added as cosponsors of S. 3228, a bill to require the President to provide a report detailing the sequester required by the Budget Control Act of 2011 on January 2, 2013.

S.J. RES. 40

At the request of Mr. RUBIO, the name of the Senator from Idaho (Mr. RISCH) was added as a cosponsor of S.J. Res. 40, a joint resolution providing for congressional disapproval under chapter 8 of title 5, United States Code, of the rules submitted by the Department of the Treasury and the Internal Revenue Service relating to the reporting requirements for interest that relates to the deposits maintained at United States offices of certain financial institutions and is paid to certain nonresident alien individuals.

S. RES. 401

At the request of Mr. WHITEHOUSE, the name of the Senator from Ohio

(Mr. BROWN) was added as a cosponsor of S. Res. 401, a resolution expressing appreciation for Foreign Service and Civil Service professionals who represent the United States around the globe.

S. RES. 435

At the request of Mr. CASEY, the name of the Senator from New York (Mrs. GILLIBRAND) was added as a cosponsor of S. Res. 435, a resolution calling for democratic change in Syria, and for other purposes.

S. RES. 439

At the request of Mr. BLUMENTHAL, the name of the Senator from Maine (Ms. COLLINS) was added as a cosponsor of S. Res. 439, a resolution expressing the sense of the Senate that Village Voice Media Holdings, LLC should eliminate the ''adult entertainment'' section of the classified advertising website Backpage.com.

S. RES. 449

At the request of Mr. BROWN of Massachusetts, his name was added as a cosponsor of S. Res. 449, a resolution calling on all governments to assist in the safe return of children abducted from or wrongfully retained outside the country of their habitual residence.

S. RES. 462

At the request of Ms. LANDRIEU, the names of the Senator from Alaska (Mr. BEGICH), the Senator from Maine (Ms. COLLINS), the Senator from Michigan (Mr. LEVIN), the Senator from South Dakota (Mr. JOHNSON), the Senator from Washington (Mrs. MURRAY), the Senator from Oregon (Mr. WYDEN), the Senator from Connecticut (Mr. BLUMENTHAL), the Senator from Missouri (Mr. BLUNT), the Senator from Oklahoma (Mr. INHOFE), the Senator from Maryland (Mr. CARDIN) and the Senator from Nebraska (Mr. NELSON) were added as cosponsors of S. Res. 462, a resolution recognizing National Foster Care Month as an opportunity to raise awareness about the challenges faced by children in the foster care system, acknowledging the dedication of foster care parents, advocates, and workers, and encouraging Congress to implement policy to improve the lives of children in the foster care system.

AMENDMENT NO. 2145

At the request of Mr. WHITEHOUSE, his name was added as a cosponsor of amendment No. 2145 proposed to S. 3187, a bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

AMENDMENT NO. 2146

At the request of Mr. PORTMAN, the names of the Senator from Minnesota (Ms. KLOBUCHAR) and the Senator from Rhode Island (Mr. REED) were added as cosponsors of amendment No. 2146 proposed to S. 3187, a bill to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mrs. FEINSTEIN:

S. 3239. A bill to provide for a uniform national standard for the housing and treatment of egg-laying hens, and for other purposes; to the Committee on Agriculture, Nutrition, and Forestry.

Mrs. FEINSTEIN. Mr. President, I rise today to introduce legislation, with Senators BLUMENTHAL, BROWN, CANTWELL, MERKLEY, VITTER, and WYDEN, that will codify an agreement reached by the nation's largest egg producer organization, the United Egg Producers, and the largest animal welfare organization, the Humane Society of the United States.

In its most simple terms, the legislation sets a national standard for the treatment of egg-laying hens and the labeling of eggs.

As of today, 6 States, including California, have set their own standards about how egg-laying hens should be raised, and 18 other States allow citizen ballot initiatives could initiate similar laws in the future.

These State standards will make it difficult for egg producers to freely ship across State lines.

Starting in 2015, eggs produced in Iowa, Indiana and other egg-exporting states can no longer be shipped to California because the hens will have been raised in cages that do not meet California's standards.

Different standards in Michigan and Ohio will take effect later, further adding to the patchwork of regulations.

As States with disparate standards continue to protect their own egg producers by banning the sale of eggs from States with lower or no standards, a complicated web of State laws will impair interstate commerce.

I have met with a number of egg producers and their concerns vary.

For some producers, different regulations increase costs because new cages must be designed for each State in which they operate.

Other producers fear that egg prices in states without regulations will plummet as imports flood their market.

Some egg producers selling to national grocery stores will have to produce eggs that meet different standards in different States.

Concerns don't end with producers.

Consumers can expect to see higher prices at grocery stores and restaurants will have to pay more for every egg they prepare.

Millions of individuals, including myself, are concerned about the living conditions of these animals.

That is why I am pleased to introduce this legislation today. The United Egg Producers and the Humane Society of the United States worked for over a year to reach this compromise, and I believe it is one that strikes a very fair balance.

Producers must enlarge cages for egg-laying hens and allow space for the birds to engage in natural behaviors such as nesting and perching.

Producers will have up to 18 years to meet this standard and make the required investments.

The legislation will officially outlaw the practice of starving chickens to increase egg-production, a cruel practice that is rarely used today, and one with consensus to end.

The bill will also lead to improved air quality in hen-houses by prohibiting excessive ammonia levels and it requires humane euthanasia of spent hens. This is also already common practice in the industry.

At its heart, this legislation is about protecting the future of the egg industry.

The egg industry brought this legislation to Congress and has asked us to help them implement the uniform regulations needed to survive and grow.

With this legislation, egg producers will have the market certainty they need and a reasonable timetables to make the required changes.

Producers need these uniform national standards so they can invest in new cages without facing the risk of more stringent state laws rendering their investments moot.

The egg industry is prepared to make these investments, many of which can be accomplished during the normal course of replacing aged equipment.

In addition to promoting industry stability, this bill will save jobs and strengthen the economy.

Furthermore, consumers are already embracing these reforms. Polls indicate broad support for the provisions in this bill and for humane treatment of egg-laying hens in general.

A recent survey found that 64 percent of Americans say that these newer facilities should be required through Federal legislation.

A majority, 58 percent, of American consumers also support a national standard.

The survey found 92 percent of consumers support the industry transitioning to these new enriched cages.

Candidly, it is not often that we see this sort of compromise in Washington.

Two groups that have been in fundamental conflict for years sat down and reached a deal.

The egg industry and the Humane Society are lock-step in their support for this bill. They are joined in endorsing the bill by the American Veterinary Medical Association and the Consumer Federation of America.

Even though the egg industry supports this bill, some still target this legislation as anti-agriculture they suggest the legislation will somehow be applied to, or set a precedent for Federal regulation of other industries.

That is simply not the case.

I want to be clear: requirements in the Egg Products Inspection Act Amendments of 2012 only apply to the production of eggs. The bill will not affect any other agricultural product including beef, pork, poultry and milk.

This legislation is a responsible compromise between those who advocate for more humane treatment for egg-laying hens and those who put breakfast on our tables.

I hope that even in this partisan climate we can enact this commonsense and widely endorsed legislation.

This legislation protects restaurants, bakers, food processors and American consumers from unnecessarily high egg prices. It protects egg producers from having eggs they can't sell.

This legislation is a reasonable, widely-supported solution to a real, costly and growing problem. The bill has the support of the United Egg Producers, which represents nearly 90 percent of the Nation's egg industry, as well as nine state and regional egg producer groups, more than 100 individual egg farms and more than 880 other family farms.

I urge you to join me in supporting this important legislation.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 3239

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 ''Egg Products Inspection Act Amendments of 2012''.

SEC. 2. HEN HOUSING AND TREATMENT STANDARDS.

(a) DEFINITIONS.—Section 4 of the Egg Products Inspection Act (21 U.S.C. 1033) is amended—

(1) by redesignating subsection (a) as subsection (c);

(2) by redesignating subsections (b), (c), (d), (e), (f), and (g) as subsections (f), (g), (h), (i), (j), and (k), respectively;

(3) by redesignating subsections (h) and (i) as subsections (n) and (o), respectively;

(4) by redesignating subsections (j), (k), and (l) as subsections (r), (s), and (t), respectively;

(5) by redesignating subsections (m), (n), (o), (p), (q), (r), (s), (t), (u), (v), (w), (x), (y), and (z) as subsections (v), (w), (x), (y), (z), (aa), (bb), (cc), (dd), (ee), (ff), (gg), (hh), and (ii), respectively;

(6) by inserting before subsection (c), as redesignated by paragraph (1), the following new subsections:

''(a) The term 'adequate environmental enrichments' means adequate perch space, dust bathing or scratching areas, and nest space, as defined by the Secretary of Agriculture, based on the best available science, including the most recent studies available at the time that the Secretary defines the term. The Secretary shall issue regulations defining this term not later than January 1, 2017, and the final regulations shall go into effect on December 31, 2018.

''(b) The term 'adequate housing-related labeling' means a conspicuous, legible marking on the front or top of a package of eggs accurately indicating the type of housing that the egg-laying hens were provided during egg production, in one of the following formats:

''(1) 'Eggs from free-range hens' to indicate that the egg-laying hens from which the eggs or egg products were derived were, during egg production—

''(A) not housed in caging devices; and

''(B) provided with outdoor access.

''(2) 'Eggs from cage-free hens' to indicate that the egg-laying hens from which the eggs or egg products were derived were, during egg production, not housed in caging devices.

''(3) 'Eggs from enriched cages' to indicate that the egg-laying hens from which the eggs or egg products were derived were, during egg production, housed in caging devices that—

''(A) contain adequate environmental enrichments; and

''(B) provide the hens a minimum of 116 square inches of individual floor space per brown hen and 101 square inches of individual floor space per white hen.

''(4) 'Eggs from caged hens' to indicate that the egg-laying hens from which the eggs or egg products were derived were, during egg production, housed in caging devices that either—

''(A) do not contain adequate environmental enrichments; or

''(B) do not provide the hens a minimum of 116 square inches of individual floor space per brown hen and 101 square inches of individual floor space per white hen.'';

(7) by inserting after subsection (c), as redesignated by paragraph (1), the following new subsections:

''(d) The term 'brown hen' means a brown egg-laying hen used for commercial egg production.

''(e) The term 'caging device' means any cage, enclosure, or other device used for the housing of egg-laying hens for the production of eggs in commerce, but does not include an open barn or other fixed structure without internal caging devices.'';

(8) by inserting after subsection (k), as redesignated by paragraph (2), the following new subsections:

''(l) The term 'egg-laying hen' means any female domesticated chicken, including white hens and brown hens, used for the commercial production of eggs for human consumption.

''(m) The term 'existing caging device' means any caging device that was continuously in use for the production of eggs in commerce up through and including December 31, 2011.'';

(9) by inserting after subsection (o), as redesignated by paragraph (3), the following new subsections:

''(p) The term 'feed-withdrawal molting' means the practice of preventing food intake for the purpose of inducing egg-laying hens to molt.

''(q) The term 'individual floor space' means the amount of total floor space in a caging device available to each egg-laying hen in the device, which is calculated by measuring the total floor space of the caging device and dividing by the total number of egg-laying hens in the device.'';

(10) by inserting after subsection (t), as redesignated by paragraph (4), the following new subsection:

''(u) The term 'new caging device' means any caging device that was not continuously in use for the production of eggs in commerce on or before December 31, 2011.''; and

(11) by inserting at the end the following new subsections:

''(jj) The term 'water-withdrawal molting' means the practice of preventing water intake for the purpose of inducing egg-laying hens to molt.

''(kk) The term 'white hen' means a white egg-laying hen used for commercial egg production.''.

(b) HOUSING AND TREATMENT OF EGG-LAYING HENS.—The Egg Products Inspection Act (21 U.S.C. 1031 et seq.) is amended by inserting after section 7 the following new sections:

''§ 7A. Housing and treatment of egg-laying hens

''(a) ENVIRONMENTAL ENRICHMENTS.—

''(1) EXISTING CAGING DEVICES.—All existing caging devices must provide egg-laying hens housed therein, beginning 15 years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, adequate environmental enrichments.

''(2) NEW CAGING DEVICES.—All new caging devices must provide egg-laying hens housed therein, beginning nine years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, adequate environmental enrichments.

''(3) CAGING DEVICES IN CALIFORNIA.—All caging devices in California must provide egg-laying hens housed therein, beginning December 31, 2018, adequate environmental enrichments.

''(b) FLOOR SPACE.—

''(1) EXISTING CAGING DEVICES.—All existing cages devices must provide egg-laying hens housed therein—

''(A) beginning four years after the date of enactment of the Egg Products Inspection Act Amendments of 2012 and until the date that is 15 years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, a minimum of 76 square inches of individual floor space per brown hen and 67 square inches of individual floor space per white hen; and

''(B) beginning 15 years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, a minimum of 144 square inches of individual floor space per brown hen and 124 square inches of individual floor space per white hen.

''(2) NEW CAGING DEVICES.—Except as provided in paragraph (3), all new caging devices must provide egg-laying hens housed therein—

''(A) beginning three years after the date of enactment of the Egg Products Inspection Act Amendments of 2012 and until the date that is six years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, a minimum of 90 square inches of individual floor space per brown hen and 78 square inches of individual floor space per white hen;

''(B) beginning six years after the date of enactment of the Egg Products Inspection Act Amendments of 2012 and until the date that is nine years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, a minimum of 102 square inches of individual floor space per brown hen and 90 square inches of individual floor space per white hen;

''(C) beginning nine years after the date of enactment of the Egg Products Inspection Act Amendments of 2012 and until the date that is 12 years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, a minimum of 116 square inches of individual floor space per brown hen and 101 square inches of individual floor space per white hen;

''(D) beginning 12 years after the date of enactment of the Egg Products Inspection Act Amendments of 2012 and until the date that is 15 years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, a minimum of 130 square inches of individual floor space per brown hen and 113 square inches of individual floor space per white hen; and

''(E) beginning 15 years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, a minimum of 144 square inches of individual floor space per brown hen and 124 square inches of individual floor space per white hen.

''(3) CALIFORNIA CAGING DEVICES.—All caging devices in California must provide egg-laying hens housed therein—

''(A) beginning January 1, 2015, and through December 31, 2020, a minimum of 134 square inches of individual floor space per brown hen and 116 square inches of individual floor space per white hen; and

''(B) beginning January 1, 2021, a minimum of 144 square inches of individual floor space per brown hen and 124 square inches of individual floor space per white hen.

''(c) AIR QUALITY.—Beginning two years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, an egg handler shall provide all egg-laying hens under his ownership or control with acceptable air quality, which does not exceed more than 25 parts per million of ammonia during normal operations.

''(d) FORCED MOLTING.—Beginning two years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, no egg handler may subject any egg-laying hen under his ownership or control to feed-withdrawal or water-withdrawal molting.

''(e) EUTHANASIA.—Beginning two years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, an egg handler shall provide, when necessary, all egg-laying hens under his ownership or control with euthanasia that is humane and uses a method deemed 'Acceptable' by the American Veterinary Medical Association.

''(f) PROHIBITION ON NEW UNENRICHABLE CAGES.—No person shall build, construct, implement, or place into operation any new caging device for the production of eggs to be sold in commerce unless the device—

''(1) provides the egg-laying hens to be contained therein a minimum of 76 square inches of individual floor space per brown hen or 67 square inches of individual floor space per white hen; and

''(2) is capable of being adapted to accommodate adequate environmental enrichments.

''(g) EXEMPTIONS.—

''(1) RECENTLY-INSTALLED EXISTING CAGING DEVICES.—The requirements contained in subsections (a)(1) and (b)(1)(B) shall not apply to any existing caging device that was first placed into operation between January 1, 2008, and December 31, 2011. This exemption shall expire 18 years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, at which time the requirements contained in subsections (a)(1) and (b)(1)(B) shall apply to all existing caging devices.

''(2) HENS ALREADY IN PRODUCTION.—The requirements contained in subsections (a)(1), (a)(2), (b)(1)(B), and (b)(2) shall not apply to any caging device containing egg-laying hens who are already in egg production on the date that such requirement takes effect. This exemption shall expire on the date that such egg-laying hens are removed from egg production.

''(3) SMALL PRODUCERS.—Nothing contained in this section shall apply to an egg handler who buys, sells, handles, or processes eggs or egg products solely from one flock of not more than 3,000 egg-laying hens.

''§ 7B. Phase-in conversion requirements

''(a) FIRST CONVERSION PHASE.—As of six years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, at least 25 percent of the egg-laying hens in commercial egg production shall be housed either in new caging devices or in existing caging devices that provide the hens contained therein with a minimum of 102 square inches of individual floor space per brown hen and 90 square inches of individual floor space per white hen.

''(b) SECOND CONVERSION PHASE.—As of 12 years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, at least 55 percent of the egg-laying hens in commercial egg production shall be housed either in new caging devices or in existing caging devices that provide the hens contained therein with a minimum of 130 square inches of individual floor space per brown hen and 113 square inches of individual floor space per white hen.

''(c) FINAL CONVERSION PHASE.—As of December 31, 2029, all egg-laying hens confined in caging devices shall be provided adequate environmental enrichments and a minimum of 144 square inches of individual floor space per brown hen and 124 square inches of individual floor space per white hen.

''(d) COMPLIANCE.—

''(1) At the end of six years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, the Secretary shall determine, after having reviewed and analyzed the results of an independent, national survey of caging devices conducted in 2018, whether the requirements of subsection (a) have been met. If the Secretary finds that the requirements of subsection (a) have not been met, then beginning January 1, 2020, the floor space requirements (irrespective of the date such requirements expire) related to new caging devices contained in subsection (b)(2)(B) of section 7A shall apply to existing caging devices placed into operation prior to January 1, 1995.

''(2) At the end of 12 years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, and again after December 31, 2029, the Secretary shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report on compliance with subsections (b) and (c).

''(3) Notwithstanding section 12, the remedies provided in this subsection shall be the exclusive remedies for violations of this section.''.

(c) INSPECTIONS.—Section 5 of the Egg Products Inspection Act (21 U.S.C. 1034) is amended—

(1) in subsection (d), by inserting ''(other than requirements with respect to housing, treatment, and house-related labeling)'' after ''as he deems appropriate to assure compliance with such requirements''; and

(2) in subsection (e)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking ''and'';

(ii) by redesignating subparagraph (B) as subparagraph (C);

(iii) by inserting after subparagraph (A) the following new subparagraph:

''(B) are derived from egg-laying hens housed and treated in compliance with section 7A; and''; and

(iv) in subparagraph (C), as redesignated by clause (ii), by inserting ''adequate housing-related labeling and'' after ''contain'';

(B) in paragraph (2), by striking ''In the case of a shell egg packer'' and inserting ''In the cases of an egg handler with a flock of more than 3,000 egg-laying hens and a shell egg packer'';

(C) in paragraph (3), by inserting ''(other than requirements with respect to housing, treatment, and housing-related labeling)'' after ''to ensure compliance with the requirements of paragraph (1)''; and

(D) in paragraph (4), by striking ''with a flock of not more than 3,000 layers.'' and inserting ''who buys, sells, handles, or processes eggs or egg products solely from one flock of not more than 3,000 egg-laying hens.''.

(d) LABELING.—Section 7 of the Egg Products Inspection Act of 1970 (21 U.S.C. 1036) is amended in subsection (a) by inserting ''adequate housing-related labeling,'' after ''plant where the products were processed,''.

(e) LIMITATION ON EXEMPTIONS BY SECRETARY.—Section 15 of the Egg Products Inspection Act of 1970 (21 U.S.C. 1044) is amended in subsection (a) by inserting '', not including subsection (c) of section 8,'' after ''exempt from specific provisions''.

(f) IMPORTS.—Section 17 of the Egg Products Inspection Act of 1970 (21 U.S.C. 1046) is amended in paragraph (2) of subsection (a) by striking ''subdivision thereof and are labeled and packaged'' and inserting ''subdivision thereof; and no eggs or egg products capable of use as human food shall be imported into the United States unless they are produced, labeled, and packaged''.

SEC. 3. ENFORCEMENT OF HEN HOUSING AND TREATMENT STANDARDS.

(a) IN GENERAL.—Section 8 of the Egg Products Inspection Act (21 U.S.C. 1037) is amended—

(1) by redesignating subsections (c), (d), (e), and (f) as subsections (d), (e), (f), and (g), respectively;

(2) by inserting after subsection (b) the following new subsection:

''(c)(1) No person shall buy, sell, or transport, or offer to buy or sell, or offer or receive for transportation, in any business or commerce any eggs or egg products derived from egg-laying hens housed or treated in violation of any provision of section 7A.

''(2) No person shall buy, sell, or transport, or offer to buy or sell, or offer or receive for transportation, in any business or commerce any eggs or egg products derived from egg-laying hens unless the container or package, including any immediate container, of the eggs or egg products, beginning one year after the date of enactment of the Egg Products Inspection Act Amendments of 2012, contains adequate housing-related labeling.

''(3) No person shall buy, sell, or transport, or offer to buy or sell, or offer or receive for transportation, in any business or commerce, in California, any eggs or egg products derived from egg-laying hens unless the egg-laying hens are—

''(A) provided—

''(i) beginning January 1, 2015, and through December 31, 2020, a minimum of 134 square inches of individual floor space per brown hen and 116 square inches of individual floor space per white hen; and

''(ii) beginning January 1, 2021, a minimum of 144 square inches of individual floor space per brown hen and 124 square inches of individual floor space per white hen; and

''(B) provided, beginning December 31, 2018, adequate environmental enrichments.''; and

(3) in subsection (e), as redesignated by paragraph (1), by inserting ''7A,'' after ''section''.

(b) LIMITATION ON AUTHORITY OF SECRETARY OF HEALTH AND HUMAN SERVICES.—Section 13 of the Egg Products Inspection Act of 1970 (21 U.S.C. 1042) is amended by inserting ''(with respect to violations other than those related to requirements with respect to housing, treatment, and housing-related labeling) the'' after ''Before any violation of this chapter is reported by the Secretary of Agriculture or''.

SEC. 4. STATE AND LOCAL AUTHORITY.

Section 23 of the Egg Products Inspection Act (21 U.S.C. 1052) is amended—

(a) by redesignating subsections (c) and (d) as subsections (d) and (e), respectively;

(b) by inserting after subsection (b) the following new subsection:

''(c) PROHIBITION AGAINST ADDITIONAL OR DIFFERENT REQUIREMENTS THAN FEDERAL REQUIREMENTS RELATED TO MINIMUM SPACE ALLOTMENTS FOR HOUSING EGG-LAYING HENS IN COMMERCIAL EGG PRODUCTION.—Requirements within the scope of this chapter with respect to minimum floor space allotments or enrichments for egg-laying hens housed in commercial egg production which are in addition to or different than those made under this chapter may not be imposed by any State or local jurisdiction. Otherwise the provisions of this chapter shall not invalidate any law or other provisions of any State or other jurisdiction in the absence of a conflict with this chapter.''; and

(c) by inserting after subsection (e), as redesignated by subsection (a), the following new subsection:

''(f) ROLE OF CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE.—With respect to eggs produced, shipped, handled, transported or received in California prior to the date that is 18 years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, the Secretary shall delegate to the California Department of Food and Agriculture the authority to enforce sections 7A(a)(3), 7A(b)(3), 8(c)(3), and 11.''.

SEC. 5. EFFECTIVE DATE.

This Act shall take effect upon enactment.

By Mr. LEAHY (for himself and Mr. GRASSLEY):

S. 3245. A bill to permanently reauthorize the EB–5 Regional Center Program, the E-Verify Program, the Special Immigrant Nonminister Religious Worker Program, and the Conrad State 30 J–1 Visa Waiver Program; to the Committee on the Judiciary.

Mr. LEAHY. Mr. President, today I am pleased to be joined by Senator GRASSLEY, in introducing legislation that will permanently authorize four expiring immigration programs. I thank Senator GRASSLEY for working with me on this needed legislation.

The bill we introduce will permanently authorize the EB–5 Regional Center Program, the voluntary E-Verify electronic work authorization program, the State 30 J–1 Visa program that Senator CONRAD champions and the Special Immigrant Nonminister Religious Worker Program that is so important to Senator HATCH. All of these programs have been in temporary status for many years, and the time has come for Congress to make them permanent so that the proponents of these programs can get to work building upon the benefits these programs bring to communities across the country. Permanency for these programs will strengthen our economy, create jobs, and enhance the security of American workers. Permanency will help medically underserved areas obtain talented physicians and religious institutions welcome individuals from around the world to participate in good works. These programs serve diverse and important interests in America, and should become permanent fixtures in our immigration law.

I am particularly pleased that the EB–5 Regional Center Program is a part of this package. With permanency, I believe this program can become an even greater economic driver than it has been in communities across the United States. Making the program permanent will also create a solid foundation for me and others interested in its success to begin in earnest to make improvements and reforms that will make it more business friendly, more predictable and stable for investors, and will provide U.S. Citizenship and Immigration Services with the tools it needs to ensure that the program meets the highest standards of quality and integrity. There is little reason that this program should not continue to improve as a deficit-neutral source of capital investment and job creation across America.

I hope our introduction of this legislation today is the beginning of a strong bipartisan effort to make these programs permanent. I look forward to working with Senator GRASSLEY and others to accomplish this goal.

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. 3245

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. PERMANENT REAUTHORIZATION OF EB–5 REGIONAL CENTER PROGRAM.

Section 610 of the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 1993 (8 U.S.C. 1153 note) is amended—

(1) by striking ''pilot'' each place such term appears; and

(2) in subsection (b), by striking ''until September 30, 2012''.

SEC. 2. PERMANENT REAUTHORIZATION OF E–VERIFY.

(a) IN GENERAL.—Section 401 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (8 U.S.C. 1324a note) is amended—

(1) in subsection (a), by striking ''pilot'';

(2) in subsection (b)—

(A) by striking ''the pilot programs'' and inserting ''the programs required under this subtitle''; and

(B) by striking ''Unless the Congress otherwise provides, the Secretary of Homeland Security shall terminate a pilot program on September 30, 2012.''; and

(3) in subsection (d)—

(A) by redesignating paragraphs (1), (2), (3), (4), (5), (6), and (7) as paragraphs (4), (1), (5), (2), (3), (7), and (6), respectively; and

(B) by amending paragraph (4), as redesignated, to read as follows:

''(4) PROGRAM.—The term 'program' means any of the 3 programs provided for under this subtitle.''.

(b) CONFORMING AMENDMENTS.—Subtitle A of title IV of division C of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (8 U.S.C. 1324a note) is amended—

(1) in section 402, by striking ''pilot'' each place such term appears; and

(2) in section 403(a)(2)—

(A) in subparagraph (A), by amending clause (i) to read as follows:

''(i) A document referred to in section 274A(b)(1)(B)(ii) of the Immigration and Nationality Act (8 U.S.C. 1324a(b)(1)(B)(ii)) shall be designated by the Secretary of Homeland Security as suitable for the purpose of identification in a program provided for under this subtitle.''; and

(B) in subparagraph (B), by striking ''pilot''.

SEC. 3. PERMANENT REAUTHORIZATION OF SPECIAL IMMIGRANT NONMINISTER RELIGIOUS WORKER PROGRAM.

Section 101(a)(27)(C)(ii) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(27)(C)(ii)) is amended—

(1) in subclause (II), by striking ''before September 30, 2012,''; and

(2) in subclause (III), by striking ''before September 30, 2012,''.

SEC. 4. PERMANENT REAUTHORIZATION OF CONRAD STATE 30 J–1 VISA WAIVER PROGRAM.

Section 220(c) of the Immigration and Nationality Technical Corrections Act of 1994 (8 U.S.C. 1182 note) is amended by striking ''and before September 30, 2012''.

By Ms. SNOWE:

S. 3246. A bill to improve the Service Corps of Retired Executives, and for other purposes; to the Committee on Small Business and Entrepreneurship.

Ms. SNOWE. Mr. President, I rise today to introduce legislation to strengthen the resources and support that we provide to entrepreneurs, and to strengthen oversight of the SCORE program.

In 1964, the Small Business Administration recognized that retired business executives who volunteered to share their knowledge and expertise could be invaluable to entrepreneurs. From this, SCORE was established and has since grown to over 360 chapters across America. As with any type of growth, there comes an essential need for increased organization and oversight. This bill seeks to assist the SBA and SCORE with just that.

The key to getting our nation on the road to economic recovery lies in the hands of small business, which is why I am always looking for ways to improve the SBA's entrepreneurial assistance programs. By creating a SCORE Advisory Board which functions to monitor and develop initiatives for programs affecting SCORE chapters, we can ensure that entrepreneurs in all areas of our economy are served by high-quality mentoring services. Specifically, this board is compromised of six members coming from the owners and employees of small businesses themselves, in addition to current members of SCORE chapters.

While some may argue that funding for SCORE should be increased, in this budget environment, where Federal revenues and spending are misaligned to the tune of $1.1 trillion this year alone, we must find ways to be more efficient with existing resources. I am hopeful that with administrative reforms and increased transparency, we can make the SCORE program more cost effective, while maintaining its vital assistance to small businesses.

For example, there is currently no oversight for funding allocations to individual SCORE chapters. In the past three fiscal years, only $2.5 million of the $7 million appropriated to SCORE has been distributed to the SCORE districts and chapters. The bulk of their funding, $4.5 million, has been spent on

staffing, administrative expenses, technology, and overhead. As a non-profit organization, SCORE seeks to support small businesses across the country with thousands of volunteers but only very limited resources. It is imperative that there are transparent and fair practices in place for allocation of SBA funding to best provide for these small businesses. Therefore, my bill requires the creation of an Allocation Committee, comprised of Advisory Board members who will ensure that not less than 50 percent of SCORE's total allocation goes to the districts and chapters that directly serve small business clients.

To safeguard funds appropriated to SCORE, my bill also places a limit on the taxpayer funded salary of SCORE's CEO, which according to the latest Internal Revenue Service filing, is 43 percent higher than that of the SBA's Administrator, who oversees the entire agency, including SCORE. This bill establishes in statute that the SCORE CEO follow the salary cap of a Senior Executive Service level Federal employee, ensuring that more money is available for the small businesses driving our economy. Additionally, this bill proposes to limit the Federal share of this salary even further when that CEO serves in a leadership capacity on a foundation affiliated with SCORE.

Through the Advisory Board and its Allocation Committee, we will add much needed improvements to an already successful program. By enhancing integration between SCORE chapters and the SBA, small businesses will have even more support to sustain their contributions to our recovering economy.

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. 3246

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 ''SCORE Program Improvement Act of 2012''.

SEC. 2. DEFINITIONS.

In this Act—

(1) the terms ''Administration'' and ''Administrator'' mean the Small Business Administration and the Administrator thereof, respectively;

(2) the term ''SCORE'' means the Service Corps of Retired Executives established under section 8(b)(1) of the Small Business Act (15 U.S.C. 637(b)(1));

(3) the term ''SCORE Advisory Board'' means the SCORE Advisory Board established under section 101 of this Act;

(4) the term ''SCORE chapter'' means a chapter of the Service Corps of Retired Executives; and

(5) the term ''small business concern'' has the meaning given that term under section 3 of the Small Business Act (15 U.S.C. 632).

TITLE I—SCORE ADVISORY BOARD

SEC. 101. ESTABLISHMENT OF ADVISORY BOARD.

(a) ESTABLISHMENT.—There is established the SCORE Advisory Board.

(b) MEMBERSHIP.—

(1) COMPOSITION.—The SCORE Advisory Board shall be composed of 6 members, who shall be appointed from among individuals having outstanding qualifications and known to be familiar with and sympathetic to the needs and problems of small business concerns.

(2) LIMITATIONS.—Of the individuals appointed under paragraph (1)—

(A) not more than 3 may be members of a SCORE chapter; and

(B) 3 shall be owners or employees of small business concerns or members of an association that represents small business concerns.

(3) PROHIBITION.—The members of the SCORE Advisory Board may not be employees of the Federal Government.

(4) DATE.—The appointments of the members of the SCORE Advisory Board shall be made not later than 90 days after the date of enactment of this Act.

(c) TERMS.—

(1) IN GENERAL.—Except as provided in paragraph (2), a member of the SCORE Advisory Board shall be appointed for a term of 3 years.

(2) FIRST MEMBERS.—Of the members first appointed to the SCORE Advisory Board—

(A) 2 shall be appointed for a term of 4 years, of whom 1 shall be a member described in subsection (b)(2)(A) and 1 shall be a member described in subsection (b)(2)(B);

(B) 2 shall be appointed for a term of 3 years, of whom 1 shall be a member described in subsection (b)(2)(A) and 1 shall be a member described in subsection (b)(2)(B); and

(C) 2 shall be appointed for a term of 2 years, of whom 1 shall be a member described in subsection (b)(2)(A) and 1 shall be a member described in subsection (b)(2)(B).

(d) VACANCIES.—

(1) IN GENERAL.—A vacancy on the SCORE Advisory Board shall be filled in the manner in which the original appointment was made and shall be subject to any conditions which applied with respect to the original appointment.

(2) FILLING UNEXPIRED TERM.—An individual chosen to fill a vacancy shall be appointed for the unexpired term of the member replaced.

(e) INITIAL MEETING.—Not later than 60 days after the date on which all members of the SCORE Advisory Board have been appointed, the SCORE Advisory Board shall hold its first meeting.

(f) MEETINGS.—The SCORE Advisory Board shall meet—

(1) not less frequently than semiannually; and

(2) at the call of the Chairman.

(g) QUORUM.—A majority of the members of the SCORE Advisory Board shall constitute a quorum, but a lesser number of members may hold hearings.

(h) CHAIRMAN.—The SCORE Advisory Board shall select a Chairman from among its members.

SEC. 102. DUTIES OF THE SCORE ADVISORY BOARD.

(a) DUTIES.—The SCORE Advisory Board shall—

(1) review and monitor plans and programs developed in the public and private sector which affect SCORE chapters;

(2) provide advice on improving coordination between plans and programs described in paragraph (1);

(3) advise SCORE chapters on the use of Federal funds allocated to SCORE;

(4) develop and promote initiatives, policies, programs, and plans designed to assist with the mentoring services offered by SCORE chapters throughout the United States; and

(5) advise the Administrator on the development and implementation of an annual comprehensive plan under subsection (b).

(b) DEVELOPMENT OF PLAN.—The Administrator shall develop and implement an annual comprehensive plan for joint efforts by the public and private sectors to facilitate the formation and development of mentoring by SCORE volunteers.

(c) ANNUAL REPORT.—Not later than 30 days after the end of each fiscal year, the SCORE Advisory Board shall submit to the President, the Committee on Small Business and Entrepreneurship of the Senate, and the Committee on Small Business of the House of Representatives a report that contains—

(1) the minutes of each meeting of the SCORE Advisory Board during the fiscal year to which the report relates;

(2) a detailed description of the activities of the SCORE Advisory Board during the fiscal year to which the report relates, including how the SCORE Advisory Board carried out the duties described in subsection (a);

(3) recommendations for promoting SCORE chapters and mentoring services; and

(4) any concurring or dissenting views of the Administrator.

SEC. 103. POWERS OF THE SCORE ADVISORY BOARD.

(a) HEARINGS.—The SCORE Advisory Board may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the SCORE Advisory Board considers advisable to carry out this Act.

(b) TASK GROUPS.—The SCORE Advisory Board may establish a temporary task group to carry out any duty of the SCORE Advisory Board described in section 4.

(c) INFORMATION FROM FEDERAL AGENCIES.—The SCORE Advisory Board may secure directly from any Federal department or agency such information as the SCORE Advisory Board considers necessary to carry out this Act. Upon request of the Chairman of the SCORE Advisory Board, the head of such department or agency shall furnish such information to the SCORE Advisory Board.

(d) POSTAL SERVICES.—The SCORE Advisory Board may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

(e) GIFTS.—The SCORE Advisory Board may accept, use, and dispose of gifts or donations of services or property.

SEC. 104. SCORE ADVISORY BOARD PERSONNEL MATTERS.

(a) COMPENSATION.—Members of the SCORE Advisory Board shall not be compensated for services performed on behalf of the SCORE Advisory Board.

(b) TRAVEL EXPENSES.—The members of the SCORE Advisory Board shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the SCORE Advisory Board.

(c) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the SCORE Advisory Board without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

SEC. 105. INAPPLICABILITY OF THE FEDERAL ADVISORY COMMITTEE ACT TO THE SCORE ADVISORY BOARD.

Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply with respect to the SCORE Advisory Board.

SEC. 106. FUNDING.

The expenses of the SCORE Advisory Board, including expenses relating to personnel, as described in section 104, shall be paid by SCORE, from amounts made available to SCORE to carry out section 8(b)(1)(B)

of the Small Business Act (15 U.S.C. 637(b)(1)(B)).

TITLE II—FINANCIAL REFORMS

SEC. 201. REAUTHORIZATION.

Section 20 of the Small Business Act (15 U.S.C. 631 note) is amended—

(1) by redesignating subsection (j) as subsection (f); and

(2) by adding at the end the following:

''(g) SCORE PROGRAM.—The Administrator may make grants and enter into cooperative agreements to carry out the SCORE program authorized by section 8(b)(1) in a total amount that does not exceed $7,000,000 for each of fiscal years 2013, 2014, and 2015.''.

SEC. 202. CHIEF EXECUTIVE OFFICER OF SCORE.

(a) LIMITATION ON AMOUNT OF SALARY.—The rate of basic pay of the chief executive officer of SCORE may not exceed the maximum rate of basic pay established under section 5382 of title 5, United States Code, for a position in the Senior Executive Service.

(b) FEDERAL SHARE OF SALARY.—For any year during which the chief executive officer of SCORE serves in a leadership capacity on a foundation affiliated with SCORE, the Federal share of the basic pay of the chief executive officer of SCORE may not exceed 80 percent.

SEC. 203. ALLOCATION COMMITTEE.

(a) ESTABLISHMENT.—SCORE shall establish a committee to determine the amount allocated each year to each SCORE chapter.

(b) MEMBERS.—The members of the committee established under subsection (a) shall include—

(1) 1 member of the staff of SCORE who is not the chief executive officer of SCORE; and

(2) not fewer than 4 members of the SCORE Advisory Board.

SEC. 204. ALLOCATION OF AMOUNTS.

SCORE shall establish a method for allocating amounts received by SCORE from the Federal Government, which shall—

(1) ensure that not less than 50 percent of the amounts are allocated to SCORE chapters; and

(2) be subject to the approval of the Administrator and the committee established under section 203.

SEC. 205. GAO STUDY AND REPORT.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of the technology activities of SCORE that includes an examination of each expenditure by SCORE for technology activities and the result of each such expenditure.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General shall submit to Congress and the Administrator a report that contains—

(1) a detailed description of the amounts SCORE has expended for technology activities, including how SCORE expended Federal funds to carry out and sustain technology initiatives during the 4-year period ending on the date of enactment of this Act;

(2) a determination of whether SCORE has expended Federal funds efficiently and effectively to carry out technology activities;

(3) an evaluation of—

(A) how well SCORE has met objectives relating to technology spending; and

(B) the policy that resulted in the establishment of objectives relating to technology spending; and

(4) recommendations for actions by SCORE to achieve objectives relating to technology spending while safeguarding Federal funds.

By Mr. ENZI (for himself, Mr. JOHNSON of South Dakota, Mr. CONRAD, Mr. HOEVEN, Mr. THUNE, Mr. BENNET, Mr. UDALL of Colorado, Mr. MORAN, Mr. UDALL of New Mexico, Mr. JOHANNS, and Mr. WHITEHOUSE):

S. 3248. A bill to designate the North American bison as the national mammal of the United States; to the Committee on the Judiciary.

Mr. ENZI. Mr. President, I wish to provide a few comments regarding the introduction of the Bison Legacy Act. Senator TIM JOHNSON of South Dakota and I are introducing this legislation today because of the significant role the North American Bison has played in the history of our Nation. This bill honors that legacy by designating the bison as the national mammal of the United States.

The bison has been integrally linked to the economic and spiritual lives of many Native American tribes over the centuries. Since our frontier days, the bison has become a symbol of American strength and determination. The Department of Interior has depicted the bison on its official seal for 94 years and the buffalo nickel played an important role in modernizing our currency in the early 20th century. At one point in American history, bison were brought in to graze outside the original Smithsonian building here in Washington, DC.

I must also add that my home State of Wyoming is one of three states that recognize the bison as its official state mammal and has honored an image of a bison on the Wyoming state flag since it was first adopted in 1917. Today, thousands of American bison freely roam Yellowstone and Grand Teton National Park in Wyoming. The bison is also important to our state's economic well-being with a growing number of ranchers raising bison for consumers all over the world.

This bill is supported by a wide variety of stakeholders. I want to recognize the National Bison Association who represents the interests of the bison ranchers in nearly every single State. Also behind this bill is the Intertribal Bison Council supporting the cultural role the bison has played in Native American history. Finally, there is the Wildlife Conservation Society who wishes to honor the restoration of bison in North America since the 19th century.

I ask my colleagues to help me support and pass this legislation honoring the bison and designating it as our national mammal. The bison has and will continue to be a symbol of America, its people and a way of life.

By Ms. LANDRIEU (for herself and Ms. SNOWE):

S. 3253. A bill to amend the Small Business Investment Act of 1958 to enhance the Small Business Investment Company Program, and for other purposes; to the Committee on Small Business and Entrepreneurship.

Ms. LANDRIEU. Mr. President, as National Small Business Week is coming to a close, I come to the floor today to make a strong commitment that the Senate Committee on Small Business and Entrepreneurship will not lose momentum on our relentless push to help America's small businesses grow, thrive, and excel. So today, along with the senior senator from Maine, I am introducing the Expanding Access to Capital for Entrepreneurial Leaders Act, or the EXCEL Act. This legislation will enhance the already successful Small Business Investment Company, SBIC, program at the Small Business Administration, SBA, that has helped over 100,000 small businesses. The best part of our bill is that the EXCEL Act should not cost the taxpayer anything.

The SBA runs a venture capital program by guaranteeing money borrowed by qualified investment funds who invest in small businesses. The qualified funds, or Small Business Investment Companies, SBICs, are privately owned and operated, but licensed and regulated by the SBA. Using a combination of private investments and the loans guaranteed by the SBA, typically at a ratio of $2 in guaranteed funds for every $1 of private capital, SBICs make long-term investments in American small businesses. In order to participate in the program, funds pay licensing fees which serve to cover all SBIC program costs. As a result, the core SBIC program, Debenture SBICs, not only boasts a strong success rate, but also incurs no cost to the U.S. government. Since the program's inception, over $50 billion has been invested in over 100,000 small businesses.

The Ranking Member of the Small Business Committee and I conducted a roundtable with 14 participants from the SBA, SBICs, investors in SBICs, and small businesses to elicit suggestions on enhancing the program. Out of that was born the EXCEL Act.

The EXCEL Act is a bipartisan effort encompassing much-needed changes that will allow the SBIC program to meet growing demand and will make improvements so that more small businesses can access capital.

The first thing the EXCEL Act does is raises the SBIC program authorization level from $3 billion to $4 billion and pegs it to inflation. This change is long overdue—the ceiling has been at $3 for some time, despite inflation and the impressive growth in the SBIC program. To illustrate: the program grew 50 percent in FY2011 alone. In order to meet demand, we need to give the program room to grow.

Secondly, the EXCEL Act will encourage successful investors by raising the limit on ''families of funds.'' Family of funds refers to a team of SBIC fund managers who operate several funds. These are currently limited to $225 million of SBA-guaranteed debt. However, SBIC fund managers who manage more than one fund generally see better investment results. The EXCEL Act will encourage that kind of success by giving families of funds a higher limit of $350 million, which will be indexed to inflation.

Next, the EXCEL Act improves transparency and accountability in the program. The legislation requires that

the SBA make public how effective individual SBICs are in their small business investments, guaranteeing that SBA-backed money is being used responsibly.

Finally, the EXCEL Act promotes outreach, thereby ensuring that the maximum possible number of small businesses can benefit from the SBIC program. The legislation encourages outreach to community banks and other lenders, states and municipalities, and asks the SBA to make their SBIC website more user-friendly.

The EXCEL Act contains a number of common sense provisions supported across the aisle, and is sponsored by the Chair and Ranking Member of the Small Business Committee. It enhances a program with proven success in providing capital to small businesses, and does so with the expectation that it will not add a dime to the deficit. Let us get this bill passed. Let us help small businesses excel.

SUBMITTED RESOLUTIONS

SENATE RESOLUTION 472—DESIGNATING OCTOBER 7, 2012, AS ''OPERATION ENDURING FREEDOM VETERANS DAY''

Mr. ENZI (for himself, Ms. AYOTTE, Mr. BLUMENTHAL, and Mr. BEGICH) submitted the following resolution; which was referred to the Committee on the Judiciary:

S. RES. 472

Whereas the initial volley of Operation Enduring Freedom took place in Afghanistan on October 7, 2001, and October 7, 2012, marks the eleventh anniversary of the war;

Whereas Operation Enduring Freedom, launched in response to the terrorist attacks committed against the United States on September 11, 2001, targeted al-Qaida and the Taliban protectors of al-Qaida in Afghanistan;

Whereas Operation Enduring Freedom is the longest ongoing war in which the United States is involved;

Whereas the wounded warriors who have served in Operation Enduring Freedom carry the scars of war, both seen and unseen;

Whereas nearly 1,800 patriots in the United States Armed Forces have made the ultimate sacrifice while serving in Afghanistan;

Whereas the war in Afghanistan should not fade from the hearts and minds of the people of the United States; and

Whereas the ongoing sacrifices made by the men and women of the Armed Forces should be recognized and honored: Now, therefore, be it

Resolved, That the Senate—

(1) designates October 7, 2012, as ''Operation Enduring Freedom Veterans Day'';

(2) honors the brave men and women who gave their lives while serving the United States in Operation Enduring Freedom; and

(3) encourages the people of the United States to salute the more than half a million men and women who have served bravely in Afghanistan to preserve our shared security and freedom.

SENATE RESOLUTION 473—COMMENDING ROTARY INTERNATIONAL AND OTHERS FOR THEIR EFFORTS TO PREVENT AND ERADICATE POLIO

Mr. DURBIN (for himself, Mr. KIRK, Mr. BROWN of Ohio, Mr. MENENDEZ, Mr. LUGAR, and Mr. LAUTENBERG) submitted the following resolution; which was referred to the Committee on Foreign Relations:

S. RES. 473

Whereas polio is a highly infectious disease that primarily affects children and for which there is no known cure;

Whereas polio can leave survivors permanently disabled from muscle paralysis of the limbs and occasionally leads to a particularly difficult death through the paralysis of respiratory muscles;

Whereas polio was once one of the most dreaded diseases in the United States, killing thousands annually in the late 19th and early 20th centuries and leaving thousands more with permanent disability, including the 32nd President of the United States, Franklin Delano Roosevelt;

Whereas severe polio outbreaks in the 1940s and 1950s caused panic in the United States, as parents kept children indoors, public health officials quarantined infected individuals, and the Federal Government restricted commerce and travel;

Whereas 1952 was the peak of the polio epidemic in the United States, with more than 57,000 people affected, 21,000 of whom were paralyzed and 3,000 of whom died;

Whereas safe and effective polio vaccines, including the Inactivated Polio Vaccine (commonly known as ''IPV''), developed in 1952 by Jonas Salk, and the Oral Polio Vaccine (commonly known as ''OPV''), developed in 1957 by Albert Sabin, rendered polio preventable and contributed to the rapid decline of polio incidence in the United States;

Whereas polio, a preventable disease that the United States has been free from since 1979, still needlessly lays victim to children and adults in several countries where challenges such as active conflict and lack of infrastructure hamper access to vaccines;

Whereas the eradication of polio is the highest priority of Rotary International, a global association that was founded in 1905 in Chicago, Illinois, is currently headquartered in Evanston, Illinois, and has 1,200,000 members in more than 170 countries;

Whereas Rotary International and its members (commonly known as ''Rotarians'') have contributed more than $1,000,000,000 and volunteered countless hours in the global fight against polio;

Whereas the Federal Government is the leading public sector donor to the Global Polio Eradication Initiative and provides technical and operational leadership to this global effort through the work of the Centers for Disease Control and the United States Agency for International Development;

Whereas Rotary International, the World Health Organization, the United States Government, the United Nations Children's Fund (commonly known as ''UNICEF''), and the Bill and Melinda Gates Foundation have joined together with national governments to successfully reduce cases of polio by more than 99 percent since 1988, from 350,000 reported cases in 1988 to fewer than 700 reported cases in 2011;

Whereas polio was recently eliminated in India and is now endemic only in Nigeria, Pakistan, and Afghanistan; and

Whereas the eradication of polio is imminently achievable and will be a victory shared by all of humanity: Now, therefore, be it

Resolved, That the Senate—

(1) commends Rotary International and others for their efforts in vaccinating children around the world against polio and for the tremendous strides made toward eradicating the disease once and for all;

(2) encourages the international community of governments and non-governmental organizations to remain committed to the elimination of polio; and

(3) encourages continued commitment and funding by the United States Government to the global effort to rid the world of polio.

SENATE RESOLUTION 474—RECOGNIZING THE SIGNIFICANCE OF MAY 2012 AS ASIAN-PACIFIC AMERICAN HERITAGE MONTH AND THE IMPORTANCE OF CELEBRATING THE SIGNIFICANT CONTRIBUTIONS OF ASIAN-AMERICANS AND PACIFIC ISLANDERS TO THE HISTORY OF THE UNITED STATES

Mr. AKAKA (for himself, Mr. INOUYE, Mr. REID of Nevada, Mr. BEGICH, Mrs. MURRAY, and Mr. MENENDEZ) submitted the following resolution; which was referred to the Committee on the Judiciary:

S. RES. 474

Whereas the United States joins together each May to pay tribute to the contributions of generations of Asian-Americans and Pacific Islanders who have enriched the history of the United States;

Whereas the history of Asian-Americans and Pacific Islanders in the United States is inextricably tied to the story of the United States;

Whereas the Asian-American and Pacific Islander community is an inherently diverse population, comprised of over 45 distinct ethnicities and over 100 language dialects;

Whereas according to the United States Census Bureau, the Asian-American population grew faster than any other racial or ethnic group over the last decade, surging nearly 46 percent between 2000 and 2010, which is a growth rate 4 times faster than the total United States population;

Whereas the 2010 decennial census estimated that there are 17,300,000 United States residents who identify as Asian and 1,200,000 United States residents who identify as Native Hawaiian and Other Pacific Islander, making up nearly 6 percent of the total United States population;

Whereas the month of May was selected for Asian-Pacific American Heritage Month because the first Japanese immigrants arrived in the United States on May 7, 1843, and the first transcontinental railroad was completed on May 10, 1869, with substantial contributions from Chinese immigrants;

Whereas the year 2012 marks several important historic milestones for the Asian American and Pacific Islander community, including the—

(1) 20th anniversary of the formal establishment of Asian-Pacific American Heritage Month;

(2) 30th anniversary of the unpunished murder of Vincent Chin;

(3) 70th anniversary of the signing of Executive Order 9066, which authorized the internment of Japanese-Americans;

(4) 100th anniversary of the planting of the first cherry tree in Washington, D.C. from Japan;

(5) 130th anniversary of the enactment of the Act entitled ''An Act to execute certain treaty stipulations relating to Chinese'', approved May 6, 1882 (22 Stat. 58, chapter 126); and

(6) 150th anniversary of the enactment of the Act of July 1, 1862 (12 Stat. 489, chapter 120), which promoted the construction of the transcontinental railroad;

Whereas section 102 of title 36, United States Code, officially designates May as Asian-Pacific American Heritage Month and requests the President to issue each year a proclamation calling on the people of the United States to observe the month with appropriate programs, ceremonies, and activities;

Whereas the Congressional Asian Pacific American Caucus, a bicameral caucus of Members of Congress advocating on behalf of Asian-Americans and Pacific Islanders, is composed of a record high 41 Members in 2012;

Whereas today, Asian-Americans and Pacific Islanders are serving in State legislatures across the United States, in States as diverse as Alaska, Arizona, California, Connecticut, Georgia, Hawaii, Idaho, Maryland, New Jersey, New York, Ohio, Pennsylvania, Texas, Virginia, Utah, and Washington;

Whereas the commitment of the United States to diversity in the judiciary has been demonstrated by the nominations of high-caliber Asian-American and other minority jurists at all levels of the Federal bench;

Whereas there still remains much to be done to ensure that Asian-Americans and Pacific Islanders have access to resources, a voice in the Federal Government, and continue to advance in the political landscape of the United States; and

Whereas celebrating May 2012 as Asian-Pacific American Heritage Month provides the people of the United States with an opportunity to recognize the achievements, contributions, and history of, and address the challenges faced by, Asian-Americans and Pacific Islanders: Now, therefore, be it

Resolved, That the Senate recognizes—

(1) the significance of May 2012 as Asian-Pacific American Heritage Month as an important time to celebrate the significant contributions of Asian-Americans and Pacific Islanders to the history of the United States; and

(2) that the Asian-American and Pacific Islander community enhances the rich diversity of, and strengthens, the United States.

SENATE RESOLUTION 475—RELATING TO THE DEATH OF THE HONORABLE E. JAMES ABDNOR, FORMER UNITED STATES SENATOR AND CONGRESSMAN FROM THE STATE OF SOUTH DAKOTA

Mr. THUNE (for himself, Mr. JOHNSON of South Dakota, Mr. REID of Nevada, Mr. MCCONNELL, Mr. AKAKA, Mr. ALEXANDER, Ms. AYOTTE, Mr. BARRASSO, Mr. BAUCUS, Mr. BEGICH, Mr. BENNET, Mr. BINGAMAN, Mr. BLUMENTHAL, Mr. BLUNT, Mr. BOOZMAN, Mrs. BOXER, Mr. BROWN of Massachusetts, Mr. BROWN of Ohio, Mr. BURR, Ms. CANTWELL, Mr. CARDIN, Mr. CARPER, Mr. CASEY, Mr. CHAMBLISS, Mr. COATS, Mr. COBURN, Mr. COCHRAN, Ms. COLLINS, Mr. CONRAD, Mr. COONS, Mr. CORKER, Mr. CORNYN, Mr. CRAPO, Mr. DEMINT, Mr. DURBIN, Mr. ENZI, Mrs. FEINSTEIN, Mr. FRANKEN, Mrs. GILLIBRAND, Mr. GRAHAM, Mr. GRASSLEY, Mrs. HAGAN, Mr. HARKIN, Mr. HATCH, Mr. HELLER, Mr. HOEVEN, Mrs. HUTCHISON, Mr. INHOFE, Mr. INOUYE, Mr. ISAKSON, Mr. JOHANNS, Mr. JOHNSON of Wisconsin, Mr. KERRY, Mr. KIRK, Ms. KLOBUCHAR, Mr. KOHL, Mr. KYL, Ms. LANDRIEU, Mr. LAUTENBERG, Mr. LEAHY, Mr. LEE, Mr. LEVIN, Mr. LIEBERMAN, Mr. LUGAR, Mr. MANCHIN, Mr. MCCAIN, Mrs. MCCASKILL, Mr. MENENDEZ, Mr. MERKLEY, Ms. MIKULSKI, Mr. MORAN, Ms. MURKOWSKI, Mrs. MURRAY, Mr. NELSON of Nebraska, Mr. NELSON of Florida, Mr. PAUL, Mr. PORTMAN, Mr. PRYOR, Mr. REED of Rhode Island, Mr. RISCH, Mr. ROBERTS, Mr. ROCKEFELLER, Mr. RUBIO, Mr. SANDERS, Mr. SCHUMER, Mr. SESSIONS, Mrs. SHAHEEN, Mr. SHELBY, Ms. SNOWE, Ms. STABENOW, Mr. TESTER, Mr. TOOMEY, Mr. UDALL of Colorado, Mr. UDALL of New Mexico, Mr. VITTER, Mr. WARNER, Mr. WEBB, Mr. WHITEHOUSE, Mr. WICKER, and Mr. WYDEN) submitted the following resolution; which was considered and agreed to:

S. RES. 475

Whereas James Abdnor was born in Kennebec, South Dakota, on February 13, 1923, and was the son of an immigrant from Lebanon who peddled and homesteaded in Lyman County, South Dakota;

Whereas James Abdnor enlisted in the United States Army during World War II, farmed in Kennebec after graduating from the University of Nebraska in 1945, and later taught and coached in neighboring Presho;

Whereas James Abdnor served as Chairman of the Lyman County Young Republicans in 1950, Chairman of the State Young Republicans from 1950 to 1952, and Farm Chairman of the Young Republican National Federation from 1953 to 1955;

Whereas James Abdnor served as the First Assistant Chief Clerk of the South Dakota House of Representatives during the legislative sessions of 1951, 1953, and 1955;

Whereas James Abdnor was elected to the South Dakota Senate in 1956, where he served until his election as the 30th Lieutenant Governor of the State of South Dakota, a position he served in from 1969 through 1971;

Whereas James Abdnor was elected to the United States House of Representatives for the 93rd United States Congress in 1972 and served a total of 4 consecutive terms, representing the Second Congressional District of South Dakota;

Whereas James Abdnor served on the Committee on Public Works of the House of Representatives, the Committee on Veterans' Affairs of the House of Representatives, and the Select Committee on Aging of the House of Representatives;

Whereas James Abdnor was elected to the United States Senate for the 97th United States Congress in 1980 and was appointed Chairman of 3 subcommittees on his first day, including the Subcommittee on Treasury, Postal Service, and General Government of the Committee on Appropriations of the Senate, the Subcommittee on Water Resources of the Committee on Environment and Public Works of the Senate, and the Subcommittee on Agriculture and Transportation of the Joint Economic Committee;

Whereas James Abdnor was appointed Vice Chairman of the Joint Economic Committee and served on the Committee on Indian Affairs of the Senate;

Whereas James Abdnor was a voice for the rural United States in Congress, where he advocated for family farms and small business, rural water systems and electrification, a balanced budget, and small-town values;

Whereas James Abdnor was appointed by President Ronald Reagan to serve as the Administrator of the United States Small Business Administration from 1987 to 1989 following his service in the United States Congress;

Whereas James Abdnor will be remembered for his humble service to his constituents, dedication to the youth of South Dakota, and defining influence on South Dakota politics; and

Whereas the hallmarks of James Abdnor's public service were his integrity, kindness, respect for the common man, and love for South Dakota: Now, therefore, be it

Resolved, That—

(1) the Senate expresses profound sorrow and deep regret regarding the death of the Honorable James Abdnor, former member of the United States Senate and House of Representatives for the State of South Dakota, on May 16, 2012;

(2) the Senate respectfully requests that the Secretary of the Senate communicate this resolution to the House of Representatives and transmit an enrolled copy of this resolution to the family of the deceased; and

(3) when the Senate adjourns today, the Senate stand adjourned as a further mark of respect to the memory of the Honorable James Abdnor.

AMENDMENTS SUBMITTED AND PROPOSED

SA 2153. Mr. ALEXANDER (for himself, Mr. MCCONNELL, Mr. ENZI, Mr. BARRASSO, Mr. BLUNT, Mr. COATS, Mr. COCHRAN, Mr. CORNYN, Mr. HELLER, Mr. INHOFE, Mr. ISAKSON, Mr. JOHANNS, Mr. ROBERTS, Mrs. HUTCHISON, Mr. RUBIO, Ms. AYOTTE, and Mr. HOEVEN) submitted an amendment intended to be proposed by him to the bill S. 2343, to amend the Higher Education Act of 1965 to extend the reduced interest rate for Federal Direct Stafford Loans, and for other purposes.

SA 2154. Mr. REID (for Mr. JOHNSON of South Dakota) proposed an amendment to the bill H.R. 5740, to extend the National Flood Insurance Program, and for other purposes.

SA 2155. Mr. REID (for Mr. LEVIN) proposed an amendment to the bill S. 739, to authorize the Architect of the Capitol to establish battery recharging stations for privately owned vehicles in parking areas under the jurisdiction of the Senate at no net cost to the Federal Government.

TEXT OF AMENDMENTS

SA 2153. Mr. ALEXANDER (for himself, Mr. MCCONNELL, Mr. ENZI, Mr. BARRASSO, Mr. BLUNT, Mr. COATS, Mr. COCHRAN, Mr. CORNYN, Mr. HELLER, Mr. INHOFE, Mr. ISAKSON, Mr. JOHANNS, Mr. ROBERTS, Mrs. HUTCHISON, Mr. RUBIO, Ms. AYOTTE, and Mr. HOEVEN) submitted an amendment intended to be proposed by him to the bill S. 2343, to amend the Higher Education Act of 1965 to extend the reduced interest rate for Federal Direct Stafford Loans, and for other purposes; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Interest Rate Reduction Act''.

SEC. 2. INTEREST RATE EXTENSION.

Subparagraph (D) of section 455(b)(7) of the Higher Education Act of 1965 (20 U.S.C. 1087e(b)(7)(D)) is amended—

(1) in the matter preceding clause (i), by striking ''2012'' and inserting ''2013''; and

(2) in clause (v), by striking ''2012'' and inserting ''2013''.

SEC. 3. REPEALING PREVENTION AND PUBLIC HEALTH FUND.

(a) IN GENERAL.—Section 4002 of the Patient Protection and Affordable Care Act (42 U.S.C. 300u–11) is repealed.

(b) RESCISSION OF UNOBLIGATED FUNDS.—Of the funds made available by such section 4002, the unobligated balance is rescinded.

SEC. 4. COMPLIANCE WITH STATUTORY PAY-AS-YOU-GO ACT OF 2010.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this Act, submitted for printing in the Congressional Record by the Chairman of the Senate Budget Committee, provided that such statement has been submitted prior to the vote on passage.

SA 2154. Mr. REID (for Mr. JOHNSON of South Dakota) proposed an amendment to the bill H.R. 5740, to extend the National Flood Insurance Program, and for other purposes; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. EXTENSION OF THE NATIONAL FLOOD INSURANCE PROGRAM.

(a) PROGRAM EXTENSION.—Section 1319 of the National Flood Insurance Act of 1968 (42 U.S.C. 4026) is amended by striking ''the earlier of the date of the enactment into law of an Act that specifically amends the date specified in this section or May 31, 2012'' and inserting ''July 31, 2012''.

(b) FINANCING.—Section 1309(a) of the National Flood Insurance Act of 1968 (42 U.S.C. 4016(a)) is amended by striking ''the earlier of the date of the enactment into law of an Act that specifically amends the date specified in this section or May 31, 2012'' and inserting ''July 31, 2012''.

SEC. 2. EXCLUSION OF VACATION HOMES AND SECOND HOMES FROM RECEIVING SUBSIDIZED PREMIUM RATES.

(a) IN GENERAL.—Section 1307(a)(2) of the National Flood Insurance Act of 1968 (42 U.S.C. 4014(a)(2)) is amended by inserting before ''; and'' the following: '', except that the Administrator shall not estimate rates under this paragraph for any residential property which is not the primary residence of an individual''.

(b) PHASE-OUT OF SUBSIDIZED PREMIUM RATES.—Section 1308(e) of the National Flood Insurance Act of 1968 (42 U.S.C. 4015(e)) is amended—

(1) by striking ''under this title for any properties within any single'' and inserting the following: ''under this title for—

''(1) any properties within any single''; and

(2) by striking the period at the end and inserting the following: ''; and

''(2) any residential properties which are not the primary residence of an individual, as described in section 1307(a)(2), shall be increased by 25 percent each year, until the average risk premium rate for such properties is equal to the average of the risk premium rates for properties described under paragraph (1).''.

(c) EFFECTIVE DATE.—The first increase in chargeable risk premium rates for residential properties which are not the primary residence of an individual under section 1308(e)(2) of the National Flood Insurance Act of 1968, as added by this Act, shall take effect on July 1, 2012, and the chargeable risk premium rates for such properties shall be increased by 25 percent each year thereafter, as provided in such section 1308(e)(2).

SEC. 3. COMPLIANCE WITH PAYGO.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this Act, submitted for printing in the Congressional Record by the Chairman of the Senate Budget Committee, provided that such statement has been submitted prior to the vote on passage.

SA 2155. Mr. REID (for Mr. LEVIN) proposed an amendment to the bill S. 739, to authorize the Architect of the Capitol to establish battery recharging stations for privately owned vehicles in parking areas under the jurisdiction of the Senate at no net cost to the Federal Government; as follows:

On page 4, strike lines 14 through 19, and insert the following:

(e) REPORTS.—

(1) IN GENERAL.—Not later than 30 days after the end of each fiscal year, the Architect of the Capitol shall submit a report on the financial administration and cost recovery of activities under this section with respect to that fiscal year to the Committee on Rules and Administration of the Senate.

(2) AVOIDING SUBSIDY.—

(A) DETERMINATION.—Not later than 3 years after the date of enactment of this Act and every 3 years thereafter, the Architect of the Capitol shall submit a report to the Committee on Rules and Administration of the Senate determining whether Senators and covered employees using battery charging stations as authorized by this Act are receiving a subsidy from the taxpayers.

(B) MODIFICATION OF RATES AND FEES.—If a determination is made under subparagraph (A) that a subsidy is being received, the Architect of the Capital shall submit a plan to the Committee on Rules and Administration of the Senate on how to update the program to ensure no subsidy is being received. If the committee does not act on the plan within 60 days, the Architect of the Capitol shall take appropriate steps to increase rates or fees to ensure reimbursement for the cost of the program consistent with an appropriate schedule for amortization, to be charged to those using the charging stations.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

Mr. HARKIN. Mr. President, I ask unanimous consent that the Committee on Agriculture, Nutrition, and Forestry be authorized to meet during the session of the Senate on May 24, 2012, at 2 p.m.

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

COMMITTEE ON ARMED SERVICES

Mr. HARKIN. Mr. President, I ask unanimous consent that the Committee on Armed Services be authorized to meet during the session of the Senate on May 24, 2012, at 9:30 a.m.

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

COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS

Mr. HARKIN. Mr. President, I ask unanimous consent that the Committee on Banking, Housing, and Urban Affairs be authorized to meet during the session of the Senate on May 24, 2012, at 10 a.m., to conduct a committee hearing entitled ''The Responsible Homeowner Refinancing Act of 2012.''

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

COMMITTEE ON FOREIGN RELATIONS

Mr. HARKIN. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on May 24, 2012, at 10:30 a.m., to hold a hearing entitled, ''Ivory and Insecurity: The Global Implications of Poaching in Africa.''

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

COMMITTEE ON INDIAN RELATIONS

Mr. HARKIN. Mr. President, I ask unanimous consent that the Committee on Indian Relations be authorized to meet during the session of the Senate on May 24, 2012, in room SD–628 of the Dirksen Senate Office Building, at 2:15 p.m., to conduct a hearing entitled ''Programs and Services for Native Veterans.''

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

COMMITTEE ON THE JUDICIARY

Mr. HARKIN. Mr. President, I ask unanimous consent that the Committee on the Judiciary be authorized to meet during the session of the Senate on May 24, 2012, at 10 a.m., in SD–226 of the Dirksen Senate Office Building, to conduct an executive business meeting.

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

SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT INFORMATION, FEDERAL SERVICES, AND INTERNATIONAL SECURITY

Mr. HARKIN. Mr. President, I ask unanimous consent that the Committee on Homeland Security and Governmental Affairs' Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security be authorized to meet during the session of the Senate on May 24, 2012, at 10 a.m., to conduct a hearing entitled, ''Innovating with Less: Examining Efforts to Reform Information Technology Spending.''

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

IRAN THREAT REDUCTION ACT OF 2011

On Monday, May 21, 2012, the Senate passed H.R. 1905, as amended as follows:

H.R. 1905

Resolved, That the bill from the House of Representatives (H.R. 1905) entitled ''An Act to strengthen Iran sanctions laws for the purpose of compelling Iran to abandon its pursuit of nuclear weapons and other threatening activities, and for other purposes.'', do pass with the following amendment:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Iran Sanctions, Accountability, and Human Rights Act of 2012''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

Sec. 3. Definitions.

TITLE I—EXPANSION OF MULTILATERAL SANCTIONS REGIME WITH RESPECT TO IRAN

Sec. 101. Policy of the United States with respect to development of nuclear weapons capabilities by Iran.

Sec. 102. Sense of Congress on enforcement of multilateral sanctions regime and expansion and implementation of sanctions laws.

Sec. 103. Diplomatic efforts to expand multilateral sanctions regime.

Sec. 104. Sense of Congress regarding the imposition of sanctions with respect to Iran.

TITLE II—EXPANSION OF SANCTIONS RELATING TO THE ENERGY SECTOR OF IRAN AND PROLIFERATION OF WEAPONS OF MASS DESTRUCTION BY IRAN

Subtitle A—Expansion of Iran Sanctions Act of 1996

Sec. 201. Imposition of sanctions with respect to joint ventures with the Government of Iran relating to developing petroleum resources.

Sec. 202. Imposition of sanctions with respect to the provision of goods, services, technology, or support for the energy or petrochemical sectors of Iran.

Sec. 203. Imposition of sanctions with respect to joint ventures with the Government of Iran relating to mining, production, or transportation of uranium.

Sec. 204. Expansion of sanctions available under the Iran Sanctions Act of 1996.

Sec. 205. Expansion of definitions under the Iran Sanctions Act of 1996.

Subtitle B—Additional Measures Relating to Sanctions Against Iran

Sec. 211. Imposition of sanctions with respect to the provision of vessels or shipping services to transport certain goods related to proliferation or terrorism activities to Iran.

Sec. 212. Imposition of sanctions with respect to subsidiaries and agents of persons sanctioned by United Nations Security Council resolutions.

Sec. 213. Liability of parent companies for violations of sanctions by foreign subsidiaries.

Sec. 214. Disclosures to the Securities and Exchange Commission relating to sanctionable activities.

Sec. 215. Identification of, and immigration restrictions on, senior officials of the Government of Iran and their family members.

Sec. 216. Reports on, and authorization of imposition of sanctions with respect to, the provision of specialized financial messaging services to the Central Bank of Iran and other sanctioned Iranian financial institutions.

Sec. 217. Government Accountability Office report on foreign entities that invest in the energy sector of Iran or export refined petroleum products to Iran.

Sec. 218. Reporting on the importation to and exportation from Iran of crude oil and refined petroleum products.

TITLE III—SANCTIONS WITH RESPECT TO IRAN'S REVOLUTIONARY GUARD CORPS

Subtitle A—Identification of, and Sanctions With Respect to, Officials, Agents, Affiliates, and Supporters of Iran's Revolutionary Guard Corps and Other Sanctioned Persons

Sec. 301. Identification of, and imposition of sanctions with respect to, officials, agents, and affiliates of Iran's Revolutionary Guard Corps.

Sec. 302. Identification of, and imposition of sanctions with respect to, persons that support or conduct certain transactions with Iran's Revolutionary Guard Corps or other sanctioned persons.

Sec. 303. Rule of construction.

Subtitle B—Additional Measures Relating to Iran's Revolutionary Guard Corps

Sec. 311. Expansion of procurement prohibition to foreign persons that engage in certain transactions with Iran's Revolutionary Guard Corps.

Sec. 312. Determinations of whether the National Iranian Oil Company and the National Iranian Tanker Company are agents or affiliates of Iran's Revolutionary Guard Corps.

TITLE IV—MEASURES RELATING TO HUMAN RIGHTS ABUSES IN IRAN

Subtitle A—Expansion of Sanctions Relating to Human Rights Abuses in Iran

Sec. 401. Findings.

Sec. 402. Sense of Congress.

Sec. 403. Imposition of sanctions with respect to the transfer of goods or technologies to Iran that are likely to be used to commit human rights abuses.

Sec. 404. Imposition of Sanctions with respect to persons who engage in censorship or other related activities against citizens of Iran.

Subtitle B—Additional Measures to Promote Human Rights in Iran

Sec. 411. Expedited consideration of requests for authorization of certain human rights-, humanitarian-, and democracy-related activities with respect to Iran.

Sec. 412. Comprehensive strategy to promote Internet freedom and access to information in Iran.

Sec. 413. Sense of Congress on political prisoners.

TITLE V—MISCELLANEOUS

Sec. 501. Exclusion of citizens of Iran seeking education relating to the nuclear and energy sectors of Iran.

Sec. 502. Technical correction.

Sec. 503. Interests in certain financial assets of Iran.

Sec. 504. Report on membership of Iran in international organizations.

Sec. 505. Increased capacity for efforts to combat unlawful or terrorist financing.

TITLE VI—GENERAL PROVISIONS

Sec. 601. Technical implementation; penalties.

Sec. 602. Applicability to certain intelligence activities.

Sec. 603. Rule of Construction with respect to use of force against Iran and Syria.

Sec. 604. Termination.

TITLE VII—SANCTIONS WITH RESPECT TO HUMAN RIGHTS ABUSES IN SYRIA

Sec. 701. Short title.

Sec. 702. Imposition of sanctions with respect to certain persons who are responsible for or complicit in human rights abuses committed against citizens of Syria or their family members.

Sec. 703. Imposition of sanctions with respect to the transfer of goods or technologies to Syria that are likely to be used to commit human rights abuses.

Sec. 704. Imposition of sanctions with respect to persons who engage in censorship or other forms of repression in Syria.

Sec. 705. Waiver.

Sec. 706. Termination.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Successive Presidents of the United States have determined that the pursuit of nuclear weapons capabilities by the Government of Iran presents a danger to the United States, its friends and allies, and to global security.

(2) Successive Congresses have recognized the threat that the Government of Iran and its policies present to the United States, its friends and allies, and to global security, and responded with successive bipartisan legislative initiatives, including most recently the enactment of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8501 et seq.) on July 1, 2010.

(3) If the Government of Iran achieves a nuclear weapons capability, it would pose a threat to the United States and allies and friends of the United States, particularly Israel, destabilize the Middle East, increase the threat of nuclear terrorism, and significantly undermine global nonproliferation efforts.

(4) The United States and its allies in the international community recognize the threat posed by the pursuit of nuclear weapons capabilities by the Government of Iran and have imposed significant sanctions against the Government of Iran, including through the enactment of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 in the United States and the adoption of a series of successive, increasingly stringent United Nations Security Council resolutions. While such efforts, together with others, have served to slow the development of Iran's nuclear program, they have not yet deterred Iran from its nuclear ambitions, and international efforts to do so must be intensified.

SEC. 3. DEFINITIONS.

In this Act:

(1) APPROPRIATE CONGRESSIONAL COMMITTEES.—The term ''appropriate congressional committees'' has the meaning given that term in section 14 of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note).

(2) CREDIBLE INFORMATION.—The term ''credible information'' has the meaning given that term in section 14 of the Iran Sanctions Act of 1996, as amended by section 205 of this Act.

(3) KNOWINGLY.—The term ''knowingly'' has the meaning given that term in section 14 of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note).

(4) UNITED STATES PERSON.—The term ''United States person'' has the meaning given that term in section 101 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8511).

TITLE I—EXPANSION OF MULTILATERAL SANCTIONS REGIME WITH RESPECT TO IRAN

SEC. 101. POLICY OF THE UNITED STATES WITH RESPECT TO DEVELOPMENT OF NUCLEAR WEAPONS CAPABILITIES BY IRAN.

It shall be the policy of the United States—

(1) to prevent the Government of Iran from—

(A) acquiring or developing nuclear weapons;

(B) developing its advanced conventional weapons and ballistic missile capabilities; and

(C) continuing its support for terrorist organizations and other activities aimed at undermining and destabilizing its neighbors and other countries; and

(2) to fully implement all multilateral and bilateral sanctions against Iran, as part of larger

multilateral and bilateral diplomatic efforts, in order to compel the Government of Iran—

(A) to abandon efforts to acquire a nuclear weapons capability;

(B) to abandon and dismantle its ballistic missile and unconventional weapons programs; and

(C) to cease all support for terrorist organizations and other terrorist activities aimed at undermining and destabilizing its neighbors and other countries.

SEC. 102. SENSE OF CONGRESS ON ENFORCEMENT OF MULTILATERAL SANCTIONS REGIME AND EXPANSION AND IMPLEMENTATION OF SANCTIONS LAWS.

It is the sense of Congress that the goal of compelling Iran to abandon efforts to acquire a nuclear weapons capability and other threatening activities can be effectively achieved through a comprehensive policy that includes economic sanctions, diplomacy, and military planning, capabilities and options, and that this objective is consistent with the one stated by President Barack Obama in the 2012 State of the Union Address: ''Let there be no doubt: America is determined to prevent Iran from getting a nuclear weapon, and I will take no options off the table to achieve that goal''. Among these economic sanctions are—

(1) prompt enforcement of the current multilateral sanctions regime with respect to Iran;

(2) full, timely, and vigorous implementation of all sanctions enacted into law, including sanctions imposed or expanded by this Act or amendments made by this Act, through—

(A) intensified monitoring by the President and his designees, including the Secretary of the Treasury and the Secretary of State, along with senior officials in the intelligence community, as appropriate;

(B) more extensive use of extraordinary authorities provided for under the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) and other sanctions laws;

(C) reallocation of resources to provide the personnel necessary, within the Department of the Treasury, the Department of State, and the Department of Defense, and, where appropriate, the intelligence community, to apply and enforce sanctions; and

(D) expanded cooperation with international sanctions enforcement efforts;

(3) urgent consideration of the expansion of existing sanctions with respect to such areas as—

(A) the provision of energy-related services to Iran;

(B) the provision of insurance and reinsurance services to Iran;

(C) the provision of shipping services to Iran;

(D) those Iranian financial institutions not currently designated for the imposition of sanctions that may be acting as intermediaries for Iranian financial institutions that are designated for the imposition of sanctions; and

(4) a focus on countering Iran's efforts to evade sanctions, including—

(A) the activities of telecommunications, Internet, and satellite service providers, within and outside of Iran, to ensure that such providers are not participating in or facilitating, directly or indirectly, the evasion of the sanctions regime with respect to Iran or violations of the human rights of the people of Iran;

(B) the activities of financial institutions or other businesses or government agencies, within or outside of Iran, not yet designated for the imposition of sanctions; and

(C) urgent and ongoing evaluation of Iran's energy, national security, financial, and telecommunications sectors, to gauge the effects of, and possible defects in, particular sanctions, with prompt efforts to correct any gaps in the existing sanctions regime with respect to Iran.

SEC. 103. DIPLOMATIC EFFORTS TO EXPAND MULTILATERAL SANCTIONS REGIME.

(a) MULTILATERAL NEGOTIATIONS.—In order to further the policy set forth in section 101, Congress urges the President to intensify diplomatic efforts, both in appropriate international fora such as the United Nations and bilaterally with allies of the United States, to expand the multilateral sanctions regime with respect to Iran, including—

(1) expanding the United Nations Security Council sanctions regime to include—

(A) a prohibition on the issuance of visas to any official of the Government of Iran who is involved in—

(i) human rights violations in or outside of Iran;

(ii) the development of a nuclear weapons program and a ballistic missile capability in Iran; or

(iii) support by the Government of Iran for terrorist organizations, including Hamas and Hezbollah; and

(B) a requirement that each member country of the United Nations prohibit the Islamic Republic of Iran Shipping Lines from landing at seaports, and cargo flights of Iran Air from landing at airports, in that country because of the role of those organizations in proliferation and illegal arms sales;

(2) expanding the range of sanctions imposed with respect to Iran by allies of the United States;

(3) expanding efforts to limit the development of petroleum resources and the importation of refined petroleum products by Iran;

(4) developing additional initiatives to—

(A) increase the production of crude oil in countries other than Iran; and

(B) assist countries that purchase or otherwise obtain crude oil or petroleum products from Iran to reduce their dependence on crude oil and petroleum products from Iran; and

(5) eliminating the revenue generated by the Government of Iran from the sale of petrochemical products produced in Iran to other countries.

(b) REPORTS TO CONGRESS.—Not later than 180 days after the date of the enactment of this Act, and every 180 days thereafter, the President shall submit to the appropriate congressional committees a report on the extent to which diplomatic efforts described in subsection (a) have been successful that includes—

(1) an identification of the countries that have agreed to impose additional sanctions or take other measures to further the policy set forth in section 101 and a description of those measures;

(2) an identification of the countries that have not agreed to impose such sanctions or measures;

(3) recommendations for additional measures that the United States could take to further the policy set forth in section 101; and

(4) a description of any decision by the World Trade Organization with respect to whether the imposition by any country of any sanction with respect to Iran is inconsistent with the obligations of that country as a member of the World Trade Organization or under the General Agreement on Tariffs and Trade, done at Geneva October 30, 1947.

SEC. 104. SENSE OF CONGRESS REGARDING THE IMPOSITION OF SANCTIONS WITH RESPECT TO IRAN.

It is the sense of Congress that all efforts should be made by the President to maximize the effects of existing sanctions with respect to Iran and the United States should take all necessary measures to preserve robust information-sharing activities.

TITLE II—EXPANSION OF SANCTIONS RELATING TO THE ENERGY SECTOR OF IRAN AND PROLIFERATION OF WEAPONS OF MASS DESTRUCTION BY IRAN

Subtitle A—Expansion of Iran Sanctions Act of 1996

SEC. 201. IMPOSITION OF SANCTIONS WITH RESPECT TO JOINT VENTURES WITH THE GOVERNMENT OF IRAN RELATING TO DEVELOPING PETROLEUM RESOURCES.

Section 5(a) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) is amended—

(1) in the subsection heading, by striking ''WITH RESPECT TO'' and all that follows through ''TO IRAN'' and inserting ''RELATING TO THE ENERGY SECTOR OF IRAN''; and

(2) by adding at the end the following:

''(4) JOINT VENTURES WITH IRAN RELATING TO DEVELOPING PETROLEUM RESOURCES.—

''(A) IN GENERAL.—Except as provided in subparagraph (B) and subsection (f), the President shall impose 3 or more of the sanctions described in section 6(a) with respect to a person if the President determines that the person knowingly participates, on or after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, in a joint venture with respect to the development of petroleum resources outside of Iran if—

''(i) the joint venture is established on or after January 1, 2002; and

''(ii)(I) the Government of Iran is a substantial partner or investor in the joint venture; or

''(II) Iran could, through a direct operational role in the joint venture or by other means, receive technological knowledge or equipment not previously available to Iran that could directly and significantly contribute to the enhancement of Iran's ability to develop petroleum resources in Iran.

''(B) APPLICABILITY.—Subparagraph (A) shall not apply with respect to participation in a joint venture established on or after January 1, 2002, and before the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012 if the person participating in the joint venture terminates that participation not later than the date that is 180 days after such date of enactment.''.

SEC. 202. IMPOSITION OF SANCTIONS WITH RESPECT TO THE PROVISION OF GOODS, SERVICES, TECHNOLOGY, OR SUPPORT FOR THE ENERGY OR PETROCHEMICAL SECTORS OF IRAN.

Section 5(a) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note), as amended by section 201, is further amended by adding at the end the following:

''(5) SUPPORT FOR THE DEVELOPMENT OF PETROLEUM RESOURCES AND REFINED PETROLEUM PRODUCTS IN IRAN.—

''(A) IN GENERAL.—Except as provided in subsection (f), the President shall impose 3 or more of the sanctions described in section 6(a) with respect to a person if the President determines that the person knowingly, on or after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, sells, leases, or provides to Iran goods, services, technology, or support described in subparagraph (B)—

''(i) any of which has a fair market value of $1,000,000 or more; or

''(ii) that, during a 12-month period, have an aggregate fair market value of $5,000,000 or more.

''(B) GOODS, SERVICES, TECHNOLOGY, OR SUPPORT DESCRIBED.—Goods, services, technology, or support described in this subparagraph are goods, services, technology, or support that could directly and significantly contribute to the maintenance or enhancement of Iran's—

''(i) ability to develop petroleum resources located in Iran; or

''(ii) domestic production of refined petroleum products, including any direct and significant

assistance with respect to the construction, modernization, or repair of petroleum refineries or directly associated infrastructure, including port facilities, railroads, or roads, if the predominant use of those facilities, railroads, or roads is for the transportation of refined petroleum products.

''(6) DEVELOPMENT AND PURCHASE OF PETROCHEMICAL PRODUCTS FROM IRAN.—

''(A) IN GENERAL.—Except as provided in subsection (f), the President shall impose 3 or more of the sanctions described in section 6(a) with respect to a person if the President determines that the person knowingly, on or after the date of the enactment of Iran Sanctions, Accountability, and Human Rights Act of 2012, sells, leases, or provides to Iran goods, services, technology, or support described in subparagraph (B)—

''(i) any of which has a fair market value of $250,000 or more; or

''(ii) that, during a 12-month period, have an aggregate fair market value of $1,000,000 or more.

''(B) GOODS, SERVICES, TECHNOLOGY, OR SUPPORT DESCRIBED.—Goods, services, technology, or support described in this subparagraph are goods, services, technology, or support that could directly and significantly contribute to the maintenance or expansion of Iran's domestic production of petrochemical products.''.

SEC. 203. IMPOSITION OF SANCTIONS WITH RESPECT TO JOINT VENTURES WITH THE GOVERNMENT OF IRAN RELATING TO MINING, PRODUCTION, OR TRANSPORTATION OF URANIUM.

Section 5(b) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) is amended—

(1) in paragraph (1)—

(A) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and moving such clauses, as so redesignated, 2 ems to the right;

(B) by striking ''a person has, on or after'' and inserting the following: ''a person has—

''(A) on or after'';

(C) in subparagraph (A)(ii), as redesignated, by striking the period and inserting ''; or''; and

(D) by adding at the end the following:

''(B) except as provided in paragraph (3), knowingly participated, on or after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, in a joint venture—

''(i) with—

''(I) the Government of Iran;

''(II) an entity incorporated in Iran or subject to the jurisdiction of the Government of Iran; or

''(III) a person acting on behalf of or at the direction of, or owned or controlled by, the Government of Iran or an entity described in subclause (II); and

''(ii) that involves any activity relating to the mining, production, or transportation of uranium.''; and

(2) by adding at the end the following:

''(3) APPLICABILITY OF SANCTIONS WITH RESPECT TO JOINT VENTURES RELATING TO THE MINING, PRODUCTION, OR TRANSPORTATION OF URANIUM.—

''(A) IN GENERAL.—Paragraph (1)(B) shall apply with respect to participation, on or after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, in—

''(i) a joint venture established on or after such date of enactment; and

''(ii) except as provided in subparagraph (B), a joint venture established before such date of enactment.

''(B) EXCEPTION.—Paragraph (1)(B) shall not apply with respect to participation in a joint venture described in subparagraph (A)(ii) if the person participating in the joint venture terminates that participation not later than the date that is 180 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012.''.

SEC. 204. EXPANSION OF SANCTIONS AVAILABLE UNDER THE IRAN SANCTIONS ACT OF 1996.

(a) IN GENERAL.—Section 6(a) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) is amended—

(1) by redesignating paragraph (9) as paragraph (11); and

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

''(9) EXCLUSION OF CORPORATE OFFICERS.—The President may direct the Secretary of State to deny a visa to, and the Secretary of Homeland Security to exclude from the United States, any alien that the President determines is a corporate officer or principal of, or a shareholder with a controlling interest in, a sanctioned person.

''(10) SANCTIONS ON PRINCIPAL EXECUTIVE OFFICERS.—The President may impose on the principal executive officer or officers of any sanctioned person, or on persons performing similar functions and with similar authorities as such officer or officers, any of the sanctions under this subsection.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on the date of the enactment of this Act and apply with respect to activities described in section 5 of the Iran Sanctions Act of 1996, as amended by this Act, commenced on or after such date of enactment.

SEC. 205. EXPANSION OF DEFINITIONS UNDER THE IRAN SANCTIONS ACT OF 1996.

(a) IN GENERAL.—Section 14 of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) is amended by adding at the end the following:

''(19) CREDIBLE INFORMATION.—The term 'credible information', with respect to a person—

''(A) includes—

''(i) a public announcement by the person that the person has engaged in an activity described in section 5; and

''(ii) information set forth in a report to stockholders of the person indicating that the person has engaged in such an activity; and

''(B) may include, in the discretion of the President—

''(i) an announcement by the Government of Iran that the person has engaged in such an activity; or

''(ii) information indicating that the person has engaged in such an activity that is set forth in—

''(I) a report of the Government Accountability Office, the Energy Information Administration, or the Congressional Research Service; or

''(II) a report or publication of a similarly reputable governmental organization.

''(20) PETROCHEMICAL PRODUCT.—The term 'petrochemical product' includes any aromatic, olefin, or synthesis gas, and any derivative of such a gas, including ethylene, propylene, butadiene, benzene, toluene, xylene, ammonia, methanol, and urea.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act and apply with respect to activities described in section 5 of the Iran Sanctions Act of 1996, as amended by this Act, commenced on or after such date of enactment.

Subtitle B—Additional Measures Relating to Sanctions Against Iran

SEC. 211. IMPOSITION OF SANCTIONS WITH RESPECT TO THE PROVISION OF VESSELS OR SHIPPING SERVICES TO TRANSPORT CERTAIN GOODS RELATED TO PROLIFERATION OR TERRORISM ACTIVITIES TO IRAN.

(a) IN GENERAL.—Except as provided in subsection (c), if the President determines that a person, on or after the date of the enactment of this Act, knowingly provides a vessel, insurance or reinsurance, or any other shipping service for the transportation to or from Iran of goods that could materially contribute to the activities of the Government of Iran with respect to the proliferation of weapons of mass destruction or support for acts of international terrorism, the President shall, pursuant to Executive Order 13382 (70 Fed. Reg. 38567; relating to blocking of property of weapons of mass destruction proliferators and their supporters) or Executive Order 13224 (66 Fed. Reg. 49079; relating to blocking property and prohibiting transactions with persons who commit, threaten to commit, or support terrorism), or otherwise pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.), block and prohibit all transactions in all property and interests in property of the persons specified in subsection (b) if such property and interests in property are in the United States, come within the United States, or are or come within the possession or control of a United States person.

(b) PERSONS SPECIFIED.—The persons specified in this subsection are—

(1) the person that provided a vessel, insurance or reinsurance, or other shipping service described in subsection (a); and

(2) any person that—

(A) is a successor entity to the person referred to in paragraph (1);

(B) owns or controls the person referred to in paragraph (1), if the person that owns or controls the person referred to in paragraph (1) had actual knowledge or should have known that the person referred to in paragraph (1) provided the vessel, insurance or reinsurance, or other shipping service; or

(C) is owned or controlled by, or under common ownership or control with, the person referred to in paragraph (1), if the person owned or controlled by, or under common ownership or control with (as the case may be), the person referred to in paragraph (1) knowingly engaged in the provision of the vessel, insurance or reinsurance, or other shipping service.

(c) WAIVER.—The President may waive the requirement to impose sanctions with respect to a person under subsection (a) on or after the date that is 30 days after the President—

(1) determines that such a waiver is in the national security interests of the United States; and

(2) submits to the appropriate congressional committees a report that contains the reasons for that determination.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the President to designate persons for the imposition of sanctions pursuant to Executive Order 13382 (70 Fed. Reg. 38567; relating to the blocking of property of weapons of mass destruction proliferators and their supporters) or Executive Order 13224 (66 Fed. Reg. 49079; relating to blocking property and prohibiting transactions with persons who commit, threaten to commit, or support terrorism), or otherwise pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).

SEC. 212. IMPOSITION OF SANCTIONS WITH RESPECT TO SUBSIDIARIES AND AGENTS OF PERSONS SANCTIONED BY UNITED NATIONS SECURITY COUNCIL RESOLUTIONS.

(a) IN GENERAL.—Section 104(c)(2)(B) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(B)) is amended—

(1) by striking ''of a person subject'' and inserting the following: ''of—

''(i) a person subject'';

(2) in clause (i), as redesignated, by striking the semicolon and inserting ''; or''; and

(3) by adding at the end the following:

''(ii) a person acting on behalf of or at the direction of, or owned or controlled by, a person described in clause (i);''.

(b) REGULATIONS.—Not later than 90 days after the date of the enactment of this Act, the Secretary of the Treasury shall make such revisions to the regulations prescribed under section

104 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513) as are necessary to carry out the amendments made by subsection (a).

SEC. 213. LIABILITY OF PARENT COMPANIES FOR VIOLATIONS OF SANCTIONS BY FOREIGN SUBSIDIARIES.

(a) DEFINITIONS.—In this section:

(1) ENTITY.—The term ''entity'' means a partnership, association, trust, joint venture, corporation, or other organization.

(2) OWN OR CONTROL.—The term ''own or control'' means, with respect to an entity—

(A) to hold more than 50 percent of the equity interest by vote or value in the entity;

(B) to hold a majority of seats on the board of directors of the entity; or

(C) to otherwise control the actions, policies, or personnel decisions of the entity.

(b) PROHIBITION.—Not later than 60 days after the date of the enactment of this Act, the President shall prohibit an entity owned or controlled by a United States person and established or maintained outside the United States from engaging in any transaction directly or indirectly with the Government of Iran or any person subject to the jurisdiction of that Government that would be prohibited by an order or regulation issued pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) if the transaction were engaged in by a United States person or in the United States.

(c) CIVIL PENALTY.—The civil penalties provided for in section 206(b) of the International Emergency Economic Powers Act (50 U.S.C. 1705(b)) shall apply to a United States person to the same extent that such penalties apply to a person that commits an unlawful act described in section 206(a) of that Act if an entity owned or controlled by the United States person and established or maintained outside the United States violates, attempts to violate, conspires to violate, or causes a violation of any order or regulation issued to implement subsection (b).

(d) APPLICABILITY.—Subsection (c) shall not apply with respect to a transaction described in subsection (b) by an entity owned or controlled by a United States person and established or maintained outside the United States if the United States person divests or terminates its business with the entity not later than the date that is 180 days after the date of the enactment of this Act.

SEC. 214. DISCLOSURES TO THE SECURITIES AND EXCHANGE COMMISSION RELATING TO SANCTIONABLE ACTIVITIES.

(a) IN GENERAL.—Section 13 of the Securities Exchange Act of 1934 (15 U.S.C. 78m) is amended by adding at the end the following new subsection:

''(r) DISCLOSURE OF CERTAIN ACTIVITIES RELATING TO IRAN.—

''(1) IN GENERAL.—Each issuer required to file an annual or quarterly report under subsection (a) shall disclose in that report the information required by paragraph (2) if, during the period covered by the report, the issuer or any affiliate of the issuer—

''(A) knowingly engaged in an activity described in section 5 of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note);

''(B) knowingly engaged in an activity described in subsection (c)(2) of section 104 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513) or a transaction described in subsection (d)(1) of that section;

''(C) knowingly engaged in an activity described in section 105A(b)(2) of that Act; or

''(D) knowingly conducted any transaction or dealing with—

''(i) any person the property and interests in property of which are blocked pursuant to Executive Order 13224 (66 Fed. Reg. 49079; relating to blocking property and prohibiting transactions with persons who commit, threaten to commit, or support terrorism);

''(ii) any person the property and interests in property of which are blocked pursuant to Executive Order 13382 (70 Fed. Reg. 38567; relating to blocking of property of weapons of mass destruction proliferators and their supporters); or

''(iii) any person identified under section 560.304 of title 31, Code of Federal Regulations (relating to the definition of the Government of Iran).

''(2) INFORMATION REQUIRED.—If an issuer or an affiliate of the issuer has engaged in any activity described in paragraph (1), the issuer shall disclose a detailed description of each such activity, including—

''(A) the nature and extent of the activity;

''(B) the gross revenues and net profits, if any, attributable to the activity; and

''(C) whether the issuer or the affiliate of the issuer (as the case may be) intends to continue the activity.

''(3) NOTICE OF DISCLOSURES.—If an issuer reports under paragraph (1) that the issuer or an affiliate of the issuer has knowingly engaged in any activity described in that paragraph, the issuer shall separately file with the Commission, concurrently with the annual or quarterly report under subsection (a), a notice that the disclosure of that activity has been included in that annual or quarterly report that identifies the issuer and contains the information required by paragraph (2).

''(4) PUBLIC DISCLOSURE OF INFORMATION.—Upon receiving a notice under paragraph (3) that an annual or quarterly report includes a disclosure of an activity described in paragraph (1), the Commission shall promptly—

''(A) transmit the report to—

''(i) the President;

''(ii) the Committee on Foreign Affairs and the Committee on Financial Services of the House of Representatives; and

''(iii) the Committee on Foreign Relations and the Committee on Banking, Housing, and Urban Affairs of the Senate; and

''(B) make the information provided in the disclosure and the notice available to the public by posting the information on the Internet website of the Commission.

''(5) INVESTIGATIONS.—Upon receiving a report under paragraph (4) that includes a disclosure of an activity described in paragraph (1) (other than an activity described in subparagraph (D)(iii) of that paragraph), the President shall—

''(A) initiate an investigation into the possible imposition of sanctions under the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note), section 104 or 105A of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, an Executive Order specified in clause (i) or (ii) of paragraph (1)(D), or any other provision of law relating to the imposition of sanctions with respect to Iran, as applicable; and

''(B) not later than 180 days after initiating such an investigation, make a determination with respect to whether sanctions should be imposed with respect to the issuer or the affiliate of the issuer (as the case may be).

''(6) SUNSET.—The provisions of this subsection shall terminate on the date that is 30 days after the date on which the President makes the certification described in section 401(a) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8551(a)).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect with respect to reports required to be filed with the Securities and Exchange Commission after the date that is 180 days after the date of the enactment of this Act.

SEC. 215. IDENTIFICATION OF, AND IMMIGRATION RESTRICTIONS ON, SENIOR OFFICIALS OF THE GOVERNMENT OF IRAN AND THEIR FAMILY MEMBERS.

(a) IDENTIFICATION.—Not later than 180 days after the date of the enactment of this Act, and annually thereafter, the President shall publish a list of each individual the President determines is—

(1) a senior official of the Government of Iran described in subsection (b) that is involved in Iran's—

(A) illicit nuclear activities or proliferation of weapons of mass destruction or delivery systems for weapons of mass destruction;

(B) support for international terrorism; or

(C) commission of serious human rights abuses against citizens of Iran or their family members; or

(2) a family member of such an official.

(b) SENIOR OFFICIALS OF THE GOVERNMENT OF IRAN DESCRIBED.—A senior official of the Government of Iran described in this subsection is any senior official of that Government, including—

(1) the Supreme Leader of Iran, Ali Khamenei;

(2) the President of Iran, Mahmoud Ahmadinejad;

(3) a member of the Cabinet of the Government of Iran;

(4) a member of the Assembly of Experts;

(5) a senior member of the Intelligence Ministry of Iran; or

(6) a member of Iran's Revolutionary Guard Corps with the rank of brigadier general or higher, including a member of a paramilitary organization such as Ansar-e-Hezbollah or Basij-e Motaz'afin.

(c) RESTRICTIONS ON VISAS AND ADJUSTMENTS IN IMMIGRATION STATUS.—Except as provided in subsection (d), the Secretary of State and the Secretary of Homeland Security may not grant an individual on the list required by subsection (a) immigration status in, or admit the individual to, the United States.

(d) EXCEPTION TO COMPLY WITH UNITED NATIONS HEADQUARTERS AGREEMENT.—Subsection (c) shall not apply to an individual if admitting the individual to the United States is necessary to permit the United States to comply with the Agreement between the United Nations and the United States of America regarding the Headquarters of the United Nations, signed June 26, 1947, and entered into force November 21, 1947.

(e) WAIVER.—The President may waive the application of subsection (a) or (c) with respect to an individual if the President—

(1) determines that such a waiver is in the national interest of the United States; and

(2) not less than 7 days before the waiver takes effect, notifies Congress of the waiver and the reason for the waiver.

SEC. 216. REPORTS ON, AND AUTHORIZATION OF IMPOSITION OF SANCTIONS WITH RESPECT TO, THE PROVISION OF SPECIALIZED FINANCIAL MESSAGING SERVICES TO THE CENTRAL BANK OF IRAN AND OTHER SANCTIONED IRANIAN FINANCIAL INSTITUTIONS.

(a) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) providers of specialized financial messaging services are a critical link to the international financial system;

(2) the European Union is to be commended for strengthening the multilateral sanctions regime against Iran by deciding that specialized financial messaging services may not be provided to the Central Bank of Iran and other sanctioned Iranian financial institutions by persons subject to the jurisdiction of the European Union; and

(3) the loss of access by sanctioned Iranian financial institutions to specialized financial messaging services must be maintained.

(b) REPORTS REQUIRED.—

(1) IN GENERAL.—Not later than 60 days after the date of the enactment of this Act, and every 90 days thereafter, the Secretary of the Treasury shall submit to the appropriate congressional committees a report that contains—

(A) a list of all persons that the Secretary has identified that directly provide specialized financial messaging services to, or enable or facilitate direct or indirect access to such messaging services for, the Central Bank of Iran or

a financial institution described in section 104(c)(2)(E)(ii) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(E)(ii)); and

(B) a detailed assessment of the status of efforts by the Secretary to end the direct provision of such messaging services to, and the enabling or facilitation of direct or indirect access to such messaging services for, the Central Bank of Iran or a financial institution described in section 104(c)(2)(E)(ii) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(E)(ii)).

(2) ENABLING OR FACILITATION OF ACCESS TO SPECIALIZED FINANCIAL MESSAGING SERVICES THROUGH INTERMEDIARY FINANCIAL INSTITUTIONS.—For purposes of paragraph (1) and subsection (c), enabling or facilitating direct or indirect access to specialized financial messaging services for the Central Bank of Iran or a financial institution described in section 104(c)(2)(E)(ii) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(E)(ii)) includes doing so by serving as an intermediary financial institution with access to such messaging services.

(3) FORM OF REPORT.—A report submitted under paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

(c) AUTHORIZATION OF THE IMPOSITION OF SANCTIONS.—

(1) IN GENERAL.—Except as provided in paragraph (2), if, on or after the date that is 90 days after the date of the enactment of this Act, a person continues to knowingly and directly provide specialized financial messaging services to, or knowingly enable or facilitate direct or indirect access to such messaging services for, the Central Bank of Iran or a financial institution described in paragraph (2)(E)(ii) of section 104(c) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)), the President may impose sanctions pursuant to that section or the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) with respect to the person.

(2) EXCEPTION.—The President may not impose sanctions pursuant to paragraph (1) with respect to a person for directly providing specialized financial messaging services to, or enabling or facilitating direct or indirect access to such messaging services for, the Central Bank of Iran or a financial institution described in section 104(c)(2)(E)(ii) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(E)(ii)) if—

(A) the person is subject to a sanctions regime under its governing foreign law that requires it to eliminate the knowing provision of such messaging services to, and the knowing enabling and facilitation of direct or indirect access to such messaging services for—

(i) the Central Bank of Iran; and

(ii) a group of Iranian financial institutions identified under such governing foreign law for purposes of that sanctions regime if the President determines that—

(I) the group is substantially similar to the group of financial institutions described in section 104(c)(2)(E)(ii) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(E)(ii)); and

(II) the differences between those groups of financial institutions do not adversely affect the national interest of the United States; and

(B) the person has, pursuant to that sanctions regime, terminated the knowing provision of such messaging services to, and the knowing enabling and facilitation of direct or indirect access to such messaging services for, the Central Bank of Iran and each Iranian financial institution identified under such governing foreign law for purposes of that sanctions regime.

SEC. 217. GOVERNMENT ACCOUNTABILITY OFFICE REPORT ON FOREIGN ENTITIES THAT INVEST IN THE ENERGY SECTOR OF IRAN OR EXPORT REFINED PETROLEUM PRODUCTS TO IRAN.

(a) INITIAL REPORT.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the appropriate congressional committees a report—

(A) listing all foreign investors in the energy sector of Iran during the period specified in paragraph (2), including—

(i) all entities that exported gasoline and other refined petroleum products to Iran;

(ii) all entities involved in providing refined petroleum products to Iran, including—

(I) entities that provided ships to transport refined petroleum products to Iran; and

(II) entities that provided insurance or reinsurance for shipments of refined petroleum products to Iran; and

(iii) all entities involved in commercial transactions of any kind, including joint ventures anywhere in the world, with Iranian energy companies; and

(B) identifying the countries in which gasoline and other refined petroleum products exported to Iran during the period specified in paragraph (2) were produced or refined.

(2) PERIOD SPECIFIED.—The period specified in this paragraph is the period beginning on January 1, 2006, and ending on the date that is 150 days after the date of the enactment of this Act.

(b) UPDATED REPORTS.—Not later than one year after submitting the report required by subsection (a), and annually thereafter, the Comptroller General of the United States shall submit to the appropriate congressional committees a report containing the matters required in the report under subsection (a)(1) for the one-year period beginning on the date that is 30 days before the date on which the preceding report was required to be submitted by this section.

SEC. 218. REPORTING ON THE IMPORTATION TO AND EXPORTATION FROM IRAN OF CRUDE OIL AND REFINED PETROLEUM PRODUCTS.

Section 110(b) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8518(b)) is amended by striking ''a report containing the matters'' and all that follows through the period at the end and inserting the following: ''a report, covering the 180-day period beginning on the date that is 30 days before the date on which the preceding report was required to be submitted by this section, that—

''(1) contains the matters required in the report under subsection (a)(1); and

''(2) identifies—

''(A) the volume of crude oil and refined petroleum products imported to and exported from Iran (including through swaps and similar arrangements);

''(B) the persons selling and transporting crude oil and refined petroleum products described in subparagraph (A), the countries with primary jurisdiction over those persons, and the countries in which those products were refined;

''(C) the sources of financing for imports to Iran of crude oil and refined petroleum products described in subparagraph (A); and

''(D) the involvement of foreign persons in efforts to assist Iran in—

''(i) developing upstream oil and gas production capacity;

''(ii) importing advanced technology to upgrade existing Iranian refineries;

''(iii) converting existing chemical plants to petroleum refineries; or

''(iv) maintaining, upgrading, or expanding refineries or constructing new refineries.''.

TITLE III—SANCTIONS WITH RESPECT TO IRAN'S REVOLUTIONARY GUARD CORPS

Subtitle A—Identification of, and Sanctions With Respect to, Officials, Agents, Affiliates, and Supporters of Iran's Revolutionary Guard Corps and Other Sanctioned Persons

SEC. 301. IDENTIFICATION OF, AND IMPOSITION OF SANCTIONS WITH RESPECT TO, OFFICIALS, AGENTS, AND AFFILIATES OF IRAN'S REVOLUTIONARY GUARD CORPS.

(a) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, and as appropriate thereafter, the President shall—

(1) identify foreign persons that are officials, agents, or affiliates of Iran's Revolutionary Guard Corps; and

(2) for each foreign person identified under paragraph (1) that is not already designated for the imposition of sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.)—

(A) designate that foreign person for the imposition of sanctions pursuant to that Act; and

(B) block and prohibit all transactions in all property and interests in property of that foreign person if such property and interests in property are in the United States, come within the United States, or are or come within the possession or control of a United States person.

(b) PRIORITY FOR INVESTIGATION.—In identifying foreign persons pursuant to subsection (a)(1) as officials, agents, or affiliates of Iran's Revolutionary Guard Corps, the President shall give priority to investigating—

(1) foreign persons identified under section 560.304 of title 31, Code of Federal Regulations (relating to the definition of the Government of Iran); and

(2) foreign persons for which there is a reasonable basis to find that the person has conducted or attempted to conduct one or more sensitive transactions or activities described in subsection (c).

(c) SENSITIVE TRANSACTIONS AND ACTIVITIES DESCRIBED.—A sensitive transaction or activity described in this subsection is—

(1) a financial transaction or series of transactions valued at more than $1,000,000 in the aggregate in any 12-month period involving a non-Iranian financial institution;

(2) a transaction to facilitate the manufacture, importation, exportation, or transfer of items needed for the development by Iran of nuclear, chemical, biological, or advanced conventional weapons, including ballistic missiles;

(3) a transaction relating to the manufacture, procurement, or sale of goods, services, and technology relating to Iran's energy sector, including a transaction relating to the development of the energy resources of Iran, the exportation of petroleum products from Iran, the importation of refined petroleum to Iran, or the development of refining capacity available to Iran;

(4) a transaction relating to the manufacture, procurement, or sale of goods, services, and technology relating to Iran's petrochemical sector; or

(5) a transaction relating to the procurement of sensitive technologies (as defined in section 106(c) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8515(c))).

(d) EXCLUSION FROM UNITED STATES.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary of State shall deny a visa to, and the Secretary of Homeland Security shall exclude from the United States, any alien who, on or after the date of the enactment of this Act, is a foreign person designated pursuant to subsection (a) for the imposition of sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).

(2) REGULATORY EXCEPTIONS TO COMPLY WITH INTERNATIONAL OBLIGATIONS.—The requirement to deny visas to and exclude aliens from the United States pursuant to paragraph (1) shall

be subject to such regulations as the President may prescribe, including regulatory exceptions to permit the United States to comply with the Agreement between the United Nations and the United States of America regarding the Headquarters of the United Nations, signed June 26, 1947, and entered into force November 21, 1947, and other applicable international obligations.

(e) WAIVER OF IMPOSITION OF SANCTIONS.—

(1) IN GENERAL.—The President may waive the application of subsection (a)(2) or (d) with respect to a foreign person if the President—

(A) determines that it is in the national security interests of the United States to do so; and

(B) submits to the appropriate congressional committees a report that—

(i) identifies the foreign person with respect to which the waiver applies; and

(ii) sets forth the reasons for the determination.

(2) FORM OF REPORT.—A report submitted under paragraph (1)(B) shall be submitted in unclassified form but may contain a classified annex.

(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to remove any sanction of the United States in force with respect to Iran's Revolutionary Guard Corps as of the date of the enactment of this Act.

SEC. 302. IDENTIFICATION OF, AND IMPOSITION OF SANCTIONS WITH RESPECT TO, PERSONS THAT SUPPORT OR CONDUCT CERTAIN TRANSACTIONS WITH IRAN'S REVOLUTIONARY GUARD CORPS OR OTHER SANCTIONED PERSONS.

(a) IDENTIFICATION.—

(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, and every 180 days thereafter, the President shall submit to the appropriate congressional committees a report identifying foreign persons that the President determines, on or after the date of the enactment of this Act, knowingly—

(A) materially assist, sponsor, or provide financial, material, or technological support for, or goods or services in support of, Iran's Revolutionary Guard Corps or any of its officials, agents, or affiliates the property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.);

(B) engage in a significant transaction or transactions with Iran's Revolutionary Guard Corps or any such official, agent, or affiliate; or

(C) engage in a significant transaction or transactions with—

(i) a person subject to financial sanctions pursuant to United Nations Security Council Resolution 1737 (2006), 1747 (2007), 1803 (2008), or 1929 (2010), or any other resolution that is adopted by the Security Council and imposes sanctions with respect to Iran or modifies such sanctions; or

(ii) a person acting on behalf of or at the direction of, or owned or controlled by, a person described in clause (i).

(2) FORM OF REPORT.—A report submitted under paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

(3) BARTER TRANSACTIONS.—For purposes of paragraph (1), the term ''transaction'' includes a barter transaction.

(b) IMPOSITION OF SANCTIONS.—If the President determines under subsection (a)(1) that a foreign person has knowingly engaged in an activity described in that subsection, the President—

(1) shall impose 3 or more of the sanctions described in section 6(a) of the Iran Sanctions Act of 1996, as amended by section 204 of this Act; and

(2) may impose additional sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) with respect to the person.

(c) TERMINATION.—The President may terminate a sanction imposed with respect to a foreign person pursuant to subsection (b) if the President determines that the person—

(1) no longer engages in the activity for which the sanction was imposed; and

(2) has provided assurances to the President that the person will not engage in any activity described in subsection (a)(1) in the future.

(d) WAIVER OF IMPOSITION OF SANCTIONS.—

(1) IN GENERAL.—The President may waive the imposition of sanctions under subsection (b) with respect to a foreign person if the President—

(A)(i) determines that the person has ceased the activity for which sanctions would otherwise be imposed and has taken measures to prevent a recurrence of the activity; or

(ii) determines that it is in the national security interests of the United States to do so; and

(B) submits to the appropriate congressional committees a report that—

(i) identifies the foreign person with respect to which the waiver applies;

(ii) describes the activity that would otherwise subject the foreign person to the imposition of sanctions under subsection (b); and

(iii) sets forth the reasons for the determination.

(2) FORM OF REPORT.—A report submitted under paragraph (1)(B) shall be submitted in unclassified form but may contain a classified annex.

(e) WAIVER OF IDENTIFICATIONS AND DESIGNATIONS.—Notwithstanding any other provision of this subtitle and subject to paragraph (2), the President shall not be required to make any identification of a foreign person under subsection (a) or any identification or designation of a foreign person under section 301(a) if the President—

(1) determines that doing so would cause damage to the national security of the United States, including through the divulgence of sources or methods of obtaining intelligence or other critical classified information; and

(2) notifies the appropriate congressional committees of the exercise of the authority provided under this subsection.

(f) APPLICATION OF PROVISIONS OF IRAN SANCTIONS ACT OF 1996.—The following provisions of the Iran Sanctions Act of 1996, as amended by this Act, apply with respect to the imposition under subsection (b)(1) of sanctions relating to activities described in subsection (a)(1) to the same extent that such provisions apply with respect to the imposition of sanctions under section 5(a) of the Iran Sanctions Act of 1996:

(1) Subsections (c) and (e) of section 4.

(2) Subsections (c), (d), and (f) of section 5.

(3) Section 8.

(4) Section 9.

(5) Section 11.

(6) Section 12.

(7) Subsection (b) of section 13.

(8) Section 14.

SEC. 303. RULE OF CONSTRUCTION.

Nothing in this subtitle shall be construed to limit the authority of the President to designate foreign persons for the imposition of sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).

Subtitle B—Additional Measures Relating to Iran's Revolutionary Guard Corps

SEC. 311. EXPANSION OF PROCUREMENT PROHIBITION TO FOREIGN PERSONS THAT ENGAGE IN CERTAIN TRANSACTIONS WITH IRAN'S REVOLUTIONARY GUARD CORPS.

(a) IN GENERAL.—Section 6(b)(1) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) is amended—

(1) by striking ''Not later than 90 days'' and inserting the following:

''(A) CERTIFICATIONS RELATING TO ACTIVITIES DESCRIBED IN SECTION 5.—Not later than 90 days''; and

(2) by adding at the end the following:

''(B) CERTIFICATIONS RELATING TO TRANSACTIONS WITH IRAN'S REVOLUTIONARY GUARD CORPS.—Not later than 90 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, the Federal Acquisition Regulation shall be revised to require a certification from each person that is a prospective contractor that the person, and any person owned or controlled by the person, does not knowingly engage in a significant transaction or transactions with Iran's Revolutionary Guard Corps or any of its officials, agents, or affiliates the property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).''.

(b) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) Section 6(b) of the Iran Sanctions Act of 1996, as amended by subsection (a), is further amended—

(A) in paragraph (1)(A), as redesignated, by striking ''issued pursuant to section 25 of the Office of Federal Procurement Policy Act (41 U.S.C. 421)'';

(B) in paragraph (2)—

(i) in subparagraph (A), by striking ''the revision'' and inserting ''the applicable revision''; and

(ii) in subparagraph (B), by striking ''issued pursuant to section 25 of the Office of Federal Procurement Policy Act (41 U.S.C. 421)'';

(C) by striking paragraph (6) and inserting the following:

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

''(A) EXECUTIVE AGENCY.—The term 'executive agency' has the meaning given that term in section 133 of title 41, United States Code.

''(B) FEDERAL ACQUISITION REGULATION.—The term 'Federal Acquisition Regulation' means the regulation issued pursuant to section 1303(a)(1) of title 41, United States Code.''; and

(D) in paragraph (7)—

(i) by striking ''The revisions to the Federal Acquisition Regulation required under paragraph (1)'' and inserting the following:

''(A) CERTIFICATIONS RELATING TO ACTIVITIES DESCRIBED IN SECTION 5.—The revisions to the Federal Acquisition Regulation required under paragraph (1)(A)''; and

(ii) by adding at the end the following:

''(B) CERTIFICATIONS RELATING TO TRANSACTIONS WITH IRAN'S REVOLUTIONARY GUARD CORPS.—The revisions to the Federal Acquisition Regulation required under paragraph (1)(B) shall apply with respect to contracts for which solicitations are issued on or after the date that is 90 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012.''.

(2) Section 101(3) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8511(3)) is amended by striking ''section 4 of the Office of Federal Procurement Policy Act (41 U.S.C. 403)'' and inserting ''section 133 of title 41, United States Code''.

SEC. 312. DETERMINATIONS OF WHETHER THE NATIONAL IRANIAN OIL COMPANY AND THE NATIONAL IRANIAN TANKER COMPANY ARE AGENTS OR AFFILIATES OF IRAN'S REVOLUTIONARY GUARD CORPS.

(a) IN GENERAL.—Section 104(c) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)) is amended by adding at the end the following:

''(4) DETERMINATIONS REGARDING NIOC AND NITC.—

''(A) DETERMINATIONS.—For purposes of paragraph (2)(E)(i), the Secretary of the Treasury shall, not later than 60 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012—

''(i) determine whether the NIOC or the NITC is an agent or affiliate of Iran's Revolutionary Guard Corps; and

''(ii) submit to the appropriate congressional committees a report on the determinations made under clause (i), together with the reasons for those determinations.

''(B) FORM OF REPORT.—A report submitted under subparagraph (A)(ii) shall be submitted in unclassified form but may contain a classified annex.

''(C) APPLICABILITY WITH RESPECT TO PETROLEUM TRANSACTIONS.—

''(i) APPLICATION OF SANCTIONS.—Except as provided in clause (ii), the regulations prescribed under paragraph (1) shall apply to a transaction for the purchase of petroleum or petroleum products from, or to financial services relating to such a transaction for, the NIOC or the NITC on or after the date that is 180 days after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2012 (Public Law 112–81) only if the President has determined, pursuant to section 1245(d)(4)(B) of that Act, that there is a sufficient supply of petroleum and petroleum products produced in countries other than Iran to permit purchasers of petroleum and petroleum products from Iran to reduce significantly in volume their purchases from Iran.

''(ii) EXCEPTION FOR CERTAIN COUNTRIES.—The regulations prescribed under paragraph (1) shall not apply to a foreign financial institution that facilitates a significant transaction or transactions for the purchase of petroleum or petroleum products from, or that provides significant financial services relating to such a transaction for, the NIOC or the NITC if the President determines and reports to Congress, not later than 90 days after the date on which the President makes the determination required by section 1245(d)(4)(B) of the National Defense Authorization Act for Fiscal Year 2012, and every 180 days thereafter, that the country with primary jurisdiction over the foreign financial institution has significantly reduced its volume of crude oil purchases from Iran during the period beginning on the date on which the President submitted the last report with respect to the country under this clause.

''(D) DEFINITIONS.—In this paragraph:

''(i) NIOC.—The term 'NIOC' means the National Iranian Oil Company.

''(ii) NITC.—The term 'NITC' means the National Iranian Tanker Company.''.

(b) CONFORMING AMENDMENTS.—Section 104(g) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(g)) is amended by striking ''subsection (c)(1)'' each place it appears and inserting ''paragraph (1) or (4) of subsection (c)''.

TITLE IV—MEASURES RELATING TO HUMAN RIGHTS ABUSES IN IRAN

Subtitle A—Expansion of Sanctions Relating to Human Rights Abuses in Iran

SEC. 401. FINDINGS.

Congress makes the following findings:

(1) The Government of Iran continues to violate systematically the basic human rights of citizens of Iran, including by cutting off their access to information and technology, suppressing their freedom of expression, and punishing severely, and sometimes brutally, their attempts to exercise political rights.

(2) In a March 20, 2012, speech celebrating Nowruz, the Iranian New Year, President Barack Obama described censorship of the Internet and monitoring of computers and cell phones by the Government of Iran as depriving the people of Iran of ''the information they want [and] stopping the free flow of information and ideas into the country''. The President concluded that ''in recent weeks, Internet restrictions have become so severe that Iranians cannot communicate freely with their loved ones within Iran, or beyond its borders, [so that] an electronic curtain has fallen around Iran.''.

(3) At a time when growing numbers of Iranians turn to the Internet as a source for news and political debate, the response of the Government of Iran has combined increasingly pervasive jamming and filtering of the Internet, blocking of email, social networking and other websites, and interception of Internet, telephonic, and mail communications.

(4) The March 2012 Report of the United Nations Human Rights Council Special Rapporteur on Iran details the Government of Iran's widespread human rights abuses and censorship, its chronic disregard of due process, and its equally chronic harassment, abuse, and intimidation of the people of Iran.

(5) There has been no independent investigation into the months of violence that followed Iran's fraudulent 2009 presidential election, violence that included the beatings of scores of Tehran University students by security forces using weapons, such as chains, metal rods, and electrified batons, and the subsequent imprisonment of many students, some of whom died in captivity.

(6) The Government of Iran has failed to cooperate with human rights investigations by the Special Rapporteur, and its failure to cooperate in those and similar investigations has been criticized in reports of the United Nations Secretary-General, General Assembly, and Human Rights Council, even as human rights abuses continue.

SEC. 402. SENSE OF CONGRESS.

It is the sense of Congress that—

(1) the Government of Iran, especially Iran's Revolutionary Guard Corps, continues to engage in serious, systematic, and ongoing violations of human rights and the rise in the level of such violations after the 2009 presidential elections has not abated;

(2) the Government of Iran is engaging in a systematic campaign to prevent news, entertainment, and opinions from reaching media that are not subject to government control and to eliminate any free Internet or other electronic media discussion among the people of Iran; and

(3) the Government of Iran has refused to cooperate with international organizations, including the United Nations, seeking to investigate or to alleviate those conditions.

SEC. 403. IMPOSITION OF SANCTIONS WITH RESPECT TO THE TRANSFER OF GOODS OR TECHNOLOGIES TO IRAN THAT ARE LIKELY TO BE USED TO COMMIT HUMAN RIGHTS ABUSES.

(a) IN GENERAL.—The Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8501 et seq.) is amended by inserting after section 105 the following:

''SEC. 105A. IMPOSITION OF SANCTIONS WITH RESPECT TO THE TRANSFER OF GOODS OR TECHNOLOGIES TO IRAN THAT ARE LIKELY TO BE USED TO COMMIT HUMAN RIGHTS ABUSES.

''(a) IN GENERAL.—The President shall impose sanctions in accordance with subsection (c) with respect to each person on the list required by subsection (b).

''(b) LIST.—

''(1) IN GENERAL.—Not later than 90 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, the President shall submit to the appropriate congressional committees a list of persons that the President determines have knowingly engaged in an activity described in paragraph (2) on or after such date of enactment.

''(2) ACTIVITY DESCRIBED.—

''(A) IN GENERAL.—A person engages in an activity described in this paragraph if the person—

''(i) transfers, or facilitates the transfer of, goods or technologies described in subparagraph (C) to Iran, any entity organized under the laws of Iran or otherwise subject to the jurisdiction of the Government of Iran, or any national of Iran, for use in or with respect to Iran; or

''(ii) provides services (including services relating to hardware, software, and specialized information, and professional consulting, engineering, and support services) with respect to goods or technologies described in subparagraph (C) after such goods or technologies are transferred to Iran.

''(B) APPLICABILITY TO CONTRACTS AND OTHER AGREEMENTS.—A person engages in an activity described in subparagraph (A) without regard to whether the activity is carried out pursuant to a contract or other agreement entered into before, on, or after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012.

''(C) GOODS OR TECHNOLOGIES DESCRIBED.—Goods or technologies described in this subparagraph are goods or technologies that the President determines are likely to be used by the Government of Iran or any of its agencies or instrumentalities (or by any other person on behalf of the Government of Iran or any of such agencies or instrumentalities) to commit serious human rights abuses against the people of Iran, including—

''(i) firearms or ammunition (as those terms are defined in section 921 of title 18, United States Code), rubber bullets, police batons, pepper or chemical sprays, stun grenades, electroshock weapons, tear gas, water cannons, or surveillance technology; or

''(ii) sensitive technology (as defined in section 106(c)).

''(3) SPECIAL RULE TO ALLOW FOR TERMINATION OF SANCTIONABLE ACTIVITY.—The President shall not be required to include a person on the list required by paragraph (1) if the President certifies in writing to the appropriate congressional committees that—

''(A) the person is no longer engaging in, or has taken significant verifiable steps toward stopping, the activity described in paragraph (2) for which the President would otherwise have included the person on the list; and

''(B) the President has received reliable assurances that the person will not knowingly engage in any activity described in paragraph (2) in the future.

''(4) UPDATES OF LIST.—The President shall submit to the appropriate congressional committees an updated list under paragraph (1)—

''(A) each time the President is required to submit an updated list to those committees under section 105(b)(2)(A); and

''(B) as new information becomes available.

''(5) FORM OF REPORT; PUBLIC AVAILABILITY.—

''(A) FORM.—The list required by paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

''(B) PUBLIC AVAILABILITY.—The unclassified portion of the list required by paragraph (1) shall be made available to the public and posted on the websites of the Department of the Treasury and the Department of State.

''(c) APPLICATION OF SANCTIONS.—

''(1) IN GENERAL.—Subject to paragraph (2), the President shall impose sanctions described in section 105(c) with respect to a person on the list required by subsection (b).

''(2) TRANSFERS TO IRAN'S REVOLUTIONARY GUARD CORPS.—In the case of a person on the list required by subsection (b) for transferring, or facilitating the transfer of, goods or technologies described in subsection (b)(2)(C) to Iran's Revolutionary Guard Corps, or providing services with respect to such goods or technologies after such goods or technologies are transferred to Iran's Revolutionary Guard Corps, the President shall—

''(A) impose sanctions described in section 105(c) with respect to the person; and

''(B) impose such other sanctions from among the sanctions described in section 6(a) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) as the President determines appropriate.''.

(b) CLERICAL AMENDMENT.—The table of contents for the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 is amended by inserting after the item relating to section 105 the following:

''Sec. 105A. Imposition of sanctions with respect to the transfer of goods or technologies to Iran that are likely to be used to commit human rights abuses.''.

SEC. 404. IMPOSITION OF SANCTIONS WITH RESPECT TO PERSONS WHO ENGAGE IN CENSORSHIP OR OTHER RELATED ACTIVITIES AGAINST CITIZENS OF IRAN.

(a) IN GENERAL.—The Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8501 et seq.), as amended by section 401, is further amended by inserting after section 105A the following:

"SEC. 105B. IMPOSITION OF SANCTIONS WITH RESPECT TO PERSONS WHO ENGAGE IN CENSORSHIP OR OTHER RELATED ACTIVITIES AGAINST CITIZENS OF IRAN.

''(a) IN GENERAL.—The President shall impose sanctions described in section 105(c) with respect to each person on the list required by subsection (b).

''(b) LIST OF PERSONS WHO ENGAGE IN CENSORSHIP.—

''(1) IN GENERAL.—Not later than 90 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, the President shall submit to the appropriate congressional committees a list of persons that the President determines have, on or after June 12, 2009, engaged in censorship or other activities that—

''(A) prohibit, limit, or penalize the exercise of freedom of expression or assembly by citizens of Iran; or

''(B) limit access to print or broadcast media, including the facilitation or support of intentional frequency manipulation by the Government of Iran that would jam or restrict an international signal or the failure to prohibit intentional frequency manipulation by the Government of Iran that would jam or restrict an international signal by satellite service providers that provide satellite services to the Government of Iran or an entity owned or controlled by the Government of Iran.

''(2) UPDATES OF LIST.—The President shall submit to the appropriate congressional committees an updated list under paragraph (1)—

''(A) each time the President is required to submit an updated list to those committees under section 105(b)(2)(A); and

''(B) as new information becomes available.

''(3) FORM OF REPORT; PUBLIC AVAILABILITY.—

''(A) FORM.—The list required by paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

''(B) PUBLIC AVAILABILITY.—The unclassified portion of the list required by paragraph (1) shall be made available to the public and posted on the websites of the Department of the Treasury and the Department of State.''.

(b) CLERICAL AMENDMENT.—The table of contents for the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, as amended by section 401, is further amended by inserting after the item relating to section 105A the following:

''Sec. 105B. Imposition of sanctions with respect to persons who engage in censorship or other related activities against citizens of Iran.''.

(c) CONFORMING AMENDMENTS.—Section 401(b)(1) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8551(b)(1)) is amended—

(1) by inserting '', 105A(a), or 105B(a)'' after ''105(a)''; and

(2) by inserting '', 105A(b), or 105B(b)'' after ''105(b)''.

Subtitle B—Additional Measures to Promote Human Rights in Iran

SEC. 411. EXPEDITED CONSIDERATION OF REQUESTS FOR AUTHORIZATION OF CERTAIN HUMAN RIGHTS-, HUMANITARIAN-, AND DEMOCRACY-RELATED ACTIVITIES WITH RESPECT TO IRAN.

(a) REQUIREMENT.—The Office of Foreign Assets Control, in consultation with the Department of State, shall establish an expedited process for the consideration of complete requests for authorization to engage in human rights-, humanitarian-, or democracy-related activities relating to Iran that are submitted by—

(1) entities receiving funds from the Department of State to engage in the proposed activity;

(2) the Broadcasting Board of Governors; and

(3) other appropriate agencies of the United States Government.

(b) PROCEDURES.—Requests for authorization under subsection (a) shall be submitted to the Office of Foreign Assets Control in conformance with the agency's regulations, including section 501.801 of title 31, Code of Federal Regulations (commonly known as the Reporting, Procedures and Penalties Regulations). Applicants must fully disclose the parties to the transactions as well as describe the activities to be undertaken. License applications involving the exportation or reexportation of goods, technology, or software to Iran must provide a copy of an official Commodity Classification issued by the Department of Commerce, Bureau of Industry and Security, as part of the license application.

(c) FOREIGN POLICY REVIEW.—The Department of State shall complete a foreign policy review of a request for authorization under subsection (a) not later than 30 days after the request is referred to the Department by the Office of Foreign Assets Control.

(d) LICENSE DETERMINATIONS.—License determinations for complete requests for authorization under subsection (a) shall be made not later than 90 days after receipt by the Office of Foreign Assets Control, with the following exceptions:

(1) Any requests involving the exportation or reexportation to Iran of goods, technology, or software listed on the Commerce Control List maintained pursuant to part 774 of the Export Administration Regulations shall be processed in a manner consistent with the Iran-Iraq Arms Non-Proliferation Act of 1992 (title XVI of Public Law 102–484) and other applicable provisions of law.

(2) Any other requests presenting novel or extraordinary circumstances.

(e) REGULATIONS.—The Secretary of the Treasury may prescribe such regulations as are appropriate to carry out this section.

SEC. 412. COMPREHENSIVE STRATEGY TO PROMOTE INTERNET FREEDOM AND ACCESS TO INFORMATION IN IRAN.

Not later than 90 days after the date of the enactment of this Act, the President shall submit to the appropriate congressional committees a comprehensive strategy developed in consultation with the Department of State, the Department of the Treasury, and other Federal agencies, as appropriate, to—

(1) assist the people of Iran to produce, access, and share information freely and safely via the Internet, including in Farsi and regional languages;

(2) support the development of counter-censorship technologies that enable the citizens of Iran to undertake Internet activities without interference from the Government of Iran;

(3) increase the capabilities and availability of secure communications through connective technology among human rights and democracy activists in Iran;

(4) provide resources for digital safety training for media and academic and civil society organizations in Iran;

(5) provide accurate and substantive Internet content in local languages in Iran;

(6) increase emergency resources for the most vulnerable human rights advocates seeking to organize, share information, and support human rights in Iran;

(7) expand surrogate radio, television, live stream, and social network communications inside Iran, including Voice of America's Persian News Network and Radio Free Europe/Radio Liberty's Radio Farda, to provide hourly live news update programming and breaking news coverage capability 24 hours a day and 7 days a week;

(8) expand activities to safely assist and train human rights, civil society, and democracy activists in Iran to operate effectively and securely;

(9) identify and utilize all available resources to overcome attempts by the Government of Iran to jam or otherwise deny international satellite broadcasting signals; and

(10) expand worldwide United States embassy and consulate programming for and outreach to Iranian dissident communities.

SEC. 413. SENSE OF CONGRESS ON POLITICAL PRISONERS.

It is the sense of Congress that—

(1) the Secretary of State should support efforts to research and identify prisoners of conscience and cases of human rights abuses in Iran;

(2) the United States Government should—

(A) offer refugee status or political asylum in the United States to political dissidents in Iran if requested and consistent with the laws and national security interests of the United States; and

(B) offer to assist, through the United Nations High Commissioner for Refugees, with the relocation of such political prisoners to other countries if requested, as appropriate and with appropriate consideration for United States national security interests; and

(3) the Secretary of State should publicly call for the release of Iranian dissidents by name and raise awareness with respect to individual cases of Iranian dissidents and prisoners of conscience, as appropriate and if requested by the dissidents or prisoners themselves or their families.

TITLE V—MISCELLANEOUS

SEC. 501. EXCLUSION OF CITIZENS OF IRAN SEEKING EDUCATION RELATING TO THE NUCLEAR AND ENERGY SECTORS OF IRAN.

(a) IN GENERAL.—The Secretary of State shall deny a visa to, and the Secretary of Homeland Security shall exclude from the United States, any alien who is a citizen of Iran that the Secretary of State determines seeks to enter the United States to participate in coursework at an institution of higher education (as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a))) to prepare the alien for a career in the energy sector of Iran or in nuclear science or nuclear engineering or a related field in Iran.

(b) APPLICABILITY.—Subsection (a) applies with respect to visa applications filed on or after the date of the enactment of this Act.

SEC. 502. TECHNICAL CORRECTION.

(a) IN GENERAL.—Section 1245(d)(2) of the National Defense Authorization Act for Fiscal Year 2012 (Public Law 112–81) is amended—

(1) in the paragraph heading, by inserting ''AGRICULTURAL COMMODITIES,'' after ''SALES OF''; and

(2) in the text, by inserting ''agricultural commodities,'' after ''sale of''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect as if included in the National Defense Authorization Act for Fiscal Year 2012 (Public Law 112–81).

SEC. 503. INTERESTS IN CERTAIN FINANCIAL ASSETS OF IRAN.

(a) INTERESTS IN BLOCKED ASSETS.—Notwithstanding any other provision of law, including any provision of law relating to sovereign immunity, and preempting any inconsistent provision of State law, a financial asset that is—

(1) property in the United States of a foreign securities intermediary doing business in the United States,

(2) a blocked asset (whether or not subsequently unblocked) that is property described in subsection (b), and

(3) equal in value to a financial asset of Iran, including an asset of the central bank or monetary authority of the Government of Iran or any agency or instrumentality of that Government,

that such foreign securities intermediary or a related intermediary holds abroad,

shall be available for all attachments and other proceedings in aid of execution, with respect to judgments entered against Iran for damages for personal injury or death caused by an act of torture, extrajudicial killing, aircraft sabotage, or hostage-taking, or the provision of material support or resources for such an act.

(b) PROPERTY DESCRIBED.—Property described in this subsection is property that is identified in and the subject of proceedings in the United States District Court for the Southern District of New York in Peterson et al. v. Islamic Republic of Iran et al., Case No. 10 Civ. 4518 (BSJ) (GWG).

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the availability, or lack thereof, of a right to satisfy a judgment in any other action against a terrorist party in any proceedings other than proceedings referred to in subsection (b).

(d) DEFINITIONS.—In this section:

(1) BLOCKED ASSET.—The term ''blocked asset''—

(A) means any asset seized or frozen by the United States under section 5(b) of the Trading With the Enemy Act (50 U.S.C. App. 5(b)) or under section 202 or 203 of the International Emergency Economic Powers Act (50 U.S.C. 1701 and 1702); and

(B) does not include property that—

(i) is subject to a license issued by the United States Government for final payment, transfer, or disposition by or to a person subject to the jurisdiction of the United States in connection with a transaction for which the issuance of the license has been specifically required by a provision of law other than the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) or the United Nations Participation Act of 1945 (22 U.S.C. 287 et seq.); or

(ii) is property subject to the Vienna Convention on Diplomatic Relations or the Vienna Convention on Consular Relations, or that enjoys equivalent privileges and immunities under the laws of the United States, and is being used exclusively for diplomatic or consular purposes.

(2) FINANCIAL ASSET; SECURITIES INTERMEDIARY.—The terms ''financial asset'' and ''securities intermediary'' have the meanings given those terms in the Uniform Commercial Code, but the former includes cash.

(3) IRAN.—The term ''Iran'' means the Government of Iran, including the central bank or monetary authority of that Government and any agency or instrumentality of that Government.

(4) PERSON.—

(A) IN GENERAL.—The term ''person'' means an individual or entity.

(B) ENTITY.—The term ''entity'' means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization.

(5) TERRORIST PARTY.—The term ''terrorist party'' has the meaning given that term in section 201(d) of the Terrorism Risk Insurance Act of 2002 (28 U.S.C. 1610 note).

(6) UNITED STATES.—The term ''United States'' includes all territory and waters, continental, or insular, subject to the jurisdiction of the United States.

SEC. 504. REPORT ON MEMBERSHIP OF IRAN IN INTERNATIONAL ORGANIZATIONS.

Not later than 180 days after the date of the enactment of this Act, and annually thereafter not later than September 1, the Secretary of State shall submit to Congress a report listing the international organizations of which Iran is a member and detailing the amount that the United States contributes to each such organization on an annual basis.

SEC. 505. INCREASED CAPACITY FOR EFFORTS TO COMBAT UNLAWFUL OR TERRORIST FINANCING.

(a) AUTHORIZATION OF APPROPRIATIONS FOR OFFICE OF TERRORISM AND FINANCIAL INTELLIGENCE AND BUREAU OF INDUSTRY AND SECURITY.—Section 109 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8517) is amended—

(1) in subsection (b)(2), by striking ''and 2013'' and inserting ''through 2016''; and

(2) in subsection (d)(2), by striking ''and 2013'' and inserting ''through 2016''.

(b) AUTHORIZATION OF APPROPRIATIONS FOR FINANCIAL CRIMES ENFORCEMENT NETWORK.—Section 310(d)(1) of title 31, United States Code, is amended by striking ''and 2013'' and inserting ''through 2016''.

TITLE VI—GENERAL PROVISIONS

SEC. 601. TECHNICAL IMPLEMENTATION; PENALTIES.

(a) IMPLEMENTATION.—The President may exercise all authorities provided under sections 203 and 205 of the International Emergency Economic Powers Act (50 U.S.C. 1702 and 1704) to carry out—

(1) sections 211, 213, and 216, subtitle A of title III, and title VII of this Act; and

(2) sections 105A and 105B of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, as added by subtitle A of title IV of this Act.

(b) PENALTIES.—

(1) IN GENERAL.—The penalties provided for in subsections (b) and (c) of section 206 of the International Emergency Economic Powers Act (50 U.S.C. 1705) shall apply to a person that violates, attempts to violate, conspires to violate, or causes a violation of a provision specified in paragraph (2) of this subsection, or an order or regulation prescribed under such a provision, to the same extent that such penalties apply to a person that commits an unlawful act described in section 206(a) of that Act.

(2) PROVISIONS SPECIFIED.—The provisions specified in this paragraph are the following:

(A) Sections 211 and 216, subtitle A of title III, and title VII of this Act.

(B) Sections 105A and 105B of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, as added by subtitle A of title IV of this Act.

SEC. 602. APPLICABILITY TO CERTAIN INTELLIGENCE ACTIVITIES.

Nothing in this Act or the amendments made by this Act shall apply to the authorized intelligence activities of the United States.

SEC. 603. RULE OF CONSTRUCTION WITH RESPECT TO USE OF FORCE AGAINST IRAN AND SYRIA.

Nothing in this Act or the amendments made by this Act shall be construed as a declaration of war or an authorization of the use of force against Iran or Syria.

SEC. 604. TERMINATION.

The provisions of sections 211, 213, 215, 216, 217, and 501, title I, and subtitle A of title III shall terminate on the date that is 30 days after the date on which the President makes the certification described in section 401(a) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8551(a)).

TITLE VII—SANCTIONS WITH RESPECT TO HUMAN RIGHTS ABUSES IN SYRIA

SEC. 701. SHORT TITLE.

This title may be cited as the ''Syria Human Rights Accountability Act of 2012''.

SEC. 702. IMPOSITION OF SANCTIONS WITH RESPECT TO CERTAIN PERSONS WHO ARE RESPONSIBLE FOR OR COMPLICIT IN HUMAN RIGHTS ABUSES COMMITTED AGAINST CITIZENS OF SYRIA OR THEIR FAMILY MEMBERS.

(a) IN GENERAL.—The President shall impose sanctions described in subsection (c) with respect to each person on the list required by subsection (b).

(b) LIST OF PERSONS WHO ARE RESPONSIBLE FOR OR COMPLICIT IN CERTAIN HUMAN RIGHTS ABUSES.—

(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the President shall submit to the appropriate congressional committees a list of persons who are officials of the Government of Syria or persons acting on behalf of that Government that the President determines, based on credible evidence, are responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against citizens of Syria or their family members, regardless of whether such abuses occurred in Syria.

(2) UPDATES OF LIST.—The President shall submit to the appropriate congressional committees an updated list under paragraph (1)—

(A) not later than 270 days after the date of the enactment of this Act and every 180 days thereafter; and

(B) as new information becomes available.

(3) FORM OF REPORT; PUBLIC AVAILABILITY.—

(A) FORM.—The list required by paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

(B) PUBLIC AVAILABILITY.—The unclassified portion of the list required by paragraph (1) shall be made available to the public and posted on the websites of the Department of the Treasury and the Department of State.

(4) CONSIDERATION OF DATA FROM OTHER COUNTRIES AND NONGOVERNMENTAL ORGANIZATIONS.—In preparing the list required by paragraph (1), the President shall consider credible data already obtained by other countries and nongovernmental organizations, including organizations in Syria, that monitor the human rights abuses of the Government of Syria.

(c) SANCTIONS DESCRIBED.—The sanctions described in this subsection are sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.), including blocking of property and restrictions or prohibitions on financial transactions and the exportation and importation of property, subject to such regulations as the President may prescribe.

SEC. 703. IMPOSITION OF SANCTIONS WITH RESPECT TO THE TRANSFER OF GOODS OR TECHNOLOGIES TO SYRIA THAT ARE LIKELY TO BE USED TO COMMIT HUMAN RIGHTS ABUSES.

(a) IN GENERAL.—The President shall impose sanctions described in section 702(c) with respect to—

(1) each person on the list required by subsection (b); and

(2) any person that—

(A) is a successor entity to a person on the list;

(B) owns or controls a person on the list, if the person that owns or controls the person on the list had actual knowledge or should have known that the person on the list engaged in the activity described in subsection (b)(2) for which the person was included in the list; or

(C) is owned or controlled by, or under common ownership or control with, the person on the list, if the person owned or controlled by, or under common ownership or control with (as the case may be), the person on the list knowingly engaged in the activity described in subsection (b)(2) for which the person was included in the list.

(b) LIST.—

(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the President shall submit to the appropriate congressional committees a list of persons that the President determines have knowingly engaged in an activity described in paragraph (2) on or after such date of enactment.

(2) ACTIVITY DESCRIBED.—

(A) IN GENERAL.—A person engages in an activity described in this paragraph if the person—

(i) transfers, or facilitates the transfer of, goods or technologies described in subparagraph (C) to Syria; or

(ii) provides services with respect to goods or technologies described in subparagraph (C) after such goods or technologies are transferred to Syria.

(B) APPLICABILITY TO CONTRACTS AND OTHER AGREEMENTS.—A person engages in an activity described in subparagraph (A) without regard to whether the activity is carried out pursuant to a contract or other agreement entered into before, on, or after the date of the enactment of this Act.

(C) GOODS OR TECHNOLOGIES DESCRIBED.—Goods or technologies described in this subparagraph are goods or technologies that the President determines are likely to be used by the Government of Syria or any of its agencies or instrumentalities to commit human rights abuses against the people of Syria, including—

(i) firearms or ammunition (as those terms are defined in section 921 of title 18, United States Code), rubber bullets, police batons, pepper or chemical sprays, stun grenades, electroshock weapons, tear gas, water cannons, or surveillance technology; or

(ii) sensitive technology.

(D) SENSITIVE TECHNOLOGY DEFINED.—

(i) IN GENERAL.—For purposes of subparagraph (C), the term ''sensitive technology'' means hardware, software, telecommunications equipment, or any other technology, that the President determines is to be used specifically—

(I) to restrict the free flow of unbiased information in Syria; or

(II) to disrupt, monitor, or otherwise restrict speech of the people of Syria.

(ii) EXCEPTION.—The term ''sensitive technology'' does not include information or informational materials the exportation of which the President does not have the authority to regulate or prohibit pursuant to section 203(b)(3) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)(3)).

(3) SPECIAL RULE TO ALLOW FOR TERMINATION OF SANCTIONABLE ACTIVITY.—The President shall not be required to include a person on the list required by paragraph (1) if the President certifies in writing to the appropriate congressional committees that—

(A) the person is no longer engaging in, or has taken significant verifiable steps toward stopping, the activity described in paragraph (2) for which the President would otherwise have included the person on the list; and

(B) the President has received reliable assurances that the person will not knowingly engage in any activity described in paragraph (2) in the future.

(4) UPDATES OF LIST.—The President shall submit to the appropriate congressional committees an updated list under paragraph (1)—

(A) not later than 270 days after the date of the enactment of this Act and every 180 days thereafter; and

(B) as new information becomes available.

(5) FORM OF REPORT; PUBLIC AVAILABILITY.—

(A) FORM.—The list required by paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

(B) PUBLIC AVAILABILITY.—The unclassified portion of the list required by paragraph (1) shall be made available to the public and posted on the websites of the Department of the Treasury and the Department of State.

SEC. 704. IMPOSITION OF SANCTIONS WITH RESPECT TO PERSONS WHO ENGAGE IN CENSORSHIP OR OTHER FORMS OF REPRESSION IN SYRIA.

(a) IN GENERAL.—The President shall impose sanctions described in section 702(c) with respect to each person on the list required by subsection (b).

(b) LIST OF PERSONS WHO ENGAGE IN CENSORSHIP.—

(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the President shall submit to the appropriate congressional committees a list of persons that the President determines have engaged in censorship, or activities relating to censorship, in a manner that prohibits, limits, or penalizes the legitimate exercise of freedom of expression by citizens of Syria.

(2) UPDATES OF LIST.—The President shall submit to the appropriate congressional committees an updated list under paragraph (1)—

(A) not later than 270 days after the date of the enactment of this Act and every 180 days thereafter; and

(B) as new information becomes available.

(3) FORM OF REPORT; PUBLIC AVAILABILITY.—

(A) FORM.—The list required by paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

(B) PUBLIC AVAILABILITY.—The unclassified portion of the list required by paragraph (1) shall be made available to the public and posted on the websites of the Department of the Treasury and the Department of State.

SEC. 705. WAIVER.

The President may waive the requirement to include a person on a list required by section 702, 703, or 704 or to impose sanctions pursuant to any such section if the President—

(1) determines that such a waiver is in the national security interests of the United States; and

(2) submits to the appropriate congressional committees a report on the reasons for that determination.

SEC. 706. TERMINATION.

(a) IN GENERAL.—The provisions of this title and any sanctions imposed pursuant to this title shall terminate on the date on which the President submits to the appropriate congressional committees—

(1) the certification described in subsection (b); and

(2) a certification that—

(A) the Government of Syria is democratically elected and representative of the people of Syria; or

(B) a legitimate transitional government of Syria is in place.

(b) CERTIFICATION DESCRIBED.—A certification described in this subsection is a certification by the President that the Government of Syria—

(1) has unconditionally released all political prisoners;

(2) has ceased its practices of violence, unlawful detention, torture, and abuse of citizens of Syria engaged in peaceful political activity;

(3) has ceased its practice of procuring sensitive technology designed to restrict the free flow of unbiased information in Syria, or to disrupt, monitor, or otherwise restrict the right of citizens of Syria to freedom of expression;

(4) has ceased providing support for foreign terrorist organizations and no longer allows such organizations, including Hamas, Hezbollah, and Palestinian Islamic Jihad, to maintain facilities in territory under the control of the Government of Syria; and

(5) has ceased the development and deployment of medium- and long-range surface-to-surface ballistic missiles;

(6) is not pursuing or engaged in the research, development, acquisition, production, transfer, or deployment of biological, chemical, or nuclear weapons, and has provided credible assurances that it will not engage in such activities in the future; and

(7) has agreed to allow the United Nations and other international observers to verify that the Government of Syria is not engaging in such activities and to assess the credibility of the assurances provided by that Government.

(c) SUSPENSION OF SANCTIONS AFTER ELECTION OF DEMOCRATIC GOVERNMENT.—If the President submits to the appropriate congressional committees the certification described in subsection (a)(2), the President may suspend the provisions of this title and any sanctions imposed under this title for not more than one year to allow time for a certification described in subsection (b) to be submitted.

EXECUTIVE SESSION

NOMINATIONS DISCHARGED

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to executive session and the Foreign Relations Committee be discharged from further consideration of Presidential Nomination 1520, David J. Lane of Florida, for the rank of Ambassador during his tenure of service as U.S. Representative to the United Nations Agencies for Food and Agriculture; that the nomination be confirmed; the motion to reconsider be made and laid upon the table with no intervening action or debate; that no further motions be in order to the nomination; that any related statements be printed in the RECORD; and that President Obama be immediately notified of the Senate's action.

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

The nomination considered and confirmed is as follows:

FOREIGN SERVICE

David J. Lane, of Florida, for the rank of Ambassador during his tenure of service as U.S. Representative to the United Nations Agencies for Food and Agriculture.

Mr. REID. Mr. President, I ask unanimous consent that the HELP Committee be discharged from further consideration of PN 1565, 16 Public Health Service nominations received by the Senate on April 26, 2012, beginning with Joseph R. Fontana and ending with Joy A. Mobley; and PN 1679, 114 Public Health Service nominations received by the Senate on May 15, 2012, beginning with Mary J. Choi and ending with Meghan M. Zomorodi; that the nominations be confirmed; the motion to reconsider be considered made and laid upon the table, with no intervening action or debate; that no further motions be in order to the nominations; that any related statements be printed in the RECORD; and that President Obama be immediately notified of the Senate's action.

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

The nominations considered and confirmed are as follows:

PUBLIC HEALTH SERVICE

To be surgeon

Joseph R. Fontana
Rakhee S. Palekar
Christopher L. Perdue

To be senior assistant surgeon

Pamela J. Horn

To be dental officer

Scott W. Brown
Deborah L. Fuller

To be senior assistant dental officer

Alexander D. Gamber

To be assistant dental officer

Erika A. Crawford
Antonio S. Parameswaran

To be assistant nurse officer

Omoronke O. Adegbuji
Mark E. Arena
Michael J. Reed

To be assistant scientist officer

Brandy E. Hellman

To be assistant health services officer

George S. Chow
Sarah M. Lee
Joy A. Mobley

PUBLIC HEALTH SERVICE

To be surgeon

Mary J. Choi
Laura A. Cooley
Patricia H. David
Duke J. Ruktanonchai

To be senior assistant surgeon

Francisca Abanyie
Nina Ahmad
Andrew I. Geller
Leah K. Gilbert
Aaron M. Harris
Fiona Havers
Rachel T. Idowu
Preetha J. Iyengar
Stephen C. Ko
Gayathri S. Kumar
Keren Z. Landman
Philip A. Lederer
Anna-Binney McCague
Erin McNelley
Jolene H. Nakao
Vuong D. Nguyen
Monica Patton
Celia L. Quinn
Kenneth B. Quinto
Alison D. Ridpath
Miriam L. Shiferaw
Neil M. Vora
Joseph V. Woodring
Brian R. Yablon

To be junior assistant nurse officer

Kimberly A. Brinker

To be assistant scientist officer

Shalon M. Irving
Jonetta L. Johnson
Michael T. Lowe
Matthew Lozier
Leigh A. Miller
Elizabeth Russell
Amee M. Schwitters
Alice M. Shumate
Angela M. Thompson-Paul
Tatiana Y. Warren
Jason A. Wilken

To be assistant veterinary officer

Laura Adams
Tara C. Anderson
Abbey Canon
Lizette O. Durand
Laura S. Edison
Ilana J. Schafer
Ryan M. Wallace

To be assistant pharmacy officer

Frank A. Acheampong
Irene Adu-Gyamfi
Mackenzie P. Brown
Jacqueline R. Campbell
Kaleb Chamberlain
Lindsey N. Childress
Whitney A. Conroy
Alejandra G. Cuevas
Lauren Davis
Allan Demuth
Andrea R. Dyer
Alla Y. Fabrikant
Ashley A. Fitch
Jesse Foster
Dewey Foutz
Christopher M. Frazer
RaeAnne G. Fuller
Amy N. Goodpaster
Megan E. Groshner
Jason D. Harris
Kellee T. James
Kendra N. Jenkins
Anna B. Jewula
Russell B. Kern
Anna U. Kit
Randi J. Kuns
Bryan P. Leland
Heather S. Lim
Jennifer N. Lind
Alicia Loh
James O. Lott
Sara H. Low
Michael J. MacMillan
Madalene Mandap
Julia E. Marie
Cullen M. McChristian
Kamilah M. McKinnon
Christopher R. McKnight
Brock E. O'Keefe
Jonathan H. Owen
Kelly S. Pak
Sarah S. Pak
Heena V. Patel
Ronnie L. Rael
Salvador Rivas, Jr.
Matthew K. Sasaki
Marianne V. Schnarr
Alison M. Smith
Kristina M. Snyder
Thanh D. Ta
Patrick R. Tully
Ann P. Upshaw
Jennifer M. Utigard
Keith R. Warshany
Mary K. Wen
Riley J. Williams II
Valerie S. Wilson
Rebecca Wong

To be junior assistant health services officer

Amelia M. Breyre
Daniel V. DiGiacoma
Tiphany D. Jackson
Sarah R. Kaslow
Vinita Puri
Christopher J. Salmon
Leah M. Sitler
Colin M. Smith
Meghan M. Zomorodi

NOMINATION OF SARA MARGALIT AVIEL TO BE UNITED STATES ALTERNATE EXECUTIVE DIRECTOR OF THE INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to consider the following nomination: Calendar No. 640, and that the Senate proceed to vote without intervening action or debate.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report the nomination.

The legislative clerk read the nomination of Sara Margalit Aviel, of California, to be United States Alternate Executive Director of the International Bank for Reconstruction and Development.

The PRESIDING OFFICER. Without objection, the Senate will proceed to consideration of the nomination.

Mr. BARRASSO. Mr. President, I rise to speak on the nomination of Sara Aviel to be the Alternate Executive Director to the International Bank for Reconstruction and Development. Had the Senate conducted a recorded vote, I would have voted against Ms. Aviel's nomination.

In 2011, the World Bank released a new 10-year energy sector lending strategy which includes a proposal to limit lending for new coal generation projects. I strongly disagree with the World Bank blocking any access to coal-powered energy. Their strategy will drive up energy prices around the world, and will make affordable and reliable energy for poor countries difficult to secure.

The World Bank should be focused on poverty reduction and economic growth. Using advanced technologies, coal provides a clean, low cost and reliable energy source which is critical to countries looking for assistance in poverty alleviation and economic development. I believe representatives of the United States at the World Bank should support low cost and dependable energy sources as a means to help countries spur economic growth.

Sara Aviel supports the World Bank providing financing for coal power generation but only to the poorest countries when no other options are available. She reiterated this point when I asked her whether she would support the World Bank's financing of a new coal-fired power plant project in Kosovo. She stated:

> There are a number of compelling reasons in favor of this project. First, Kosovo, one of the poorest countries in Europe, is greatly in need of reliable base load power and there appears to be no other viable alternatives.

Since the majority of lending by the World Bank is for middle-income countries, and not to the poorest of countries, the World Bank strategy supported by Sara Aviel will place significant limits, if not eliminate, lending for coal power generation. I believe she will use the World Bank 10-year energy strategy as a means to restrict World Bank lending for coal power generation projects, even when the proposal represents the most cost effective alternative. Requiring borrowers to accept higher cost projects when affordable and reliable alternatives are readily available is no way to operate a bank, especially when the bank is being funded with taxpayer dollars.

The World Bank has also started a shift from providing financing to help the poorest of countries with economic growth and reducing poverty, to a focus in other areas with a strong emphasis on lending to middle-income countries. Middle-income countries that receive the vast majority of World Bank financing include nations such as China and Brazil.

While Sara Aviel agrees that middle-income countries are able to borrow on international capital markets at commercial rates, she believes the World Bank should continue its lending to these countries. I disagree with her support of this policy.

The World Bank should be aggressively working towards the graduation of middle-income countries from borrowers to donors. The resources of the World Bank should be directed at helping the poorest of countries eradicate poverty and implement successful economic development projects. Their primary focus should be on assisting countries that cannot access international capital markets at commercial rates, not financing middle-income

countries that can tap other financing resources.

The World Bank is at a critical juncture. The Bank needs to pursue serious reforms, especially in the areas of corruption and transparency. It must not be used to push social agendas and political priorities to the detriment of poor nations, or to use donor funds in a manner that is not cost-effective. The United States representative must be a strong advocate for reform and accountability. I do not believe that Sara Aviel is the person to get that job done.

It is for these reasons that I oppose the nomination of Sara Aviel.

The PRESIDING OFFICER. The question is, Will the Senate advise and consent to the nomination of Sara Margalit Aviel to be United States Alternate Executive Director of the International Bank for Reconstruction and Development?

The nomination was confirmed.

EXECUTIVE CALENDAR

Mr. REID. Mr. President, I ask unanimous consent the Senate consider the following nominations: Calendar Nos. 261, 338, 339, 340, 665, 678, 679, 680, 681, 682, 706, 707, 708, 710, 711, 712, 713, 715, 716, 717, 725, 727 through 757, and 758; and all nominations placed on the Secretary's desk in the Air Force, Army, Foreign Service, Marine Corps, and Navy; that the nominations be confirmed en bloc, the motions to reconsider be considered made and laid on the table, there being no intervening action or debate, and no further motions be in order to any of the nominations; that any related statements be printed in the RECORD; that President Obama be immediately notified of the Senate's action and the Senate then resume legislative session.

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

The nominations considered and confirmed are as follows:

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Matthew Francis McCabe, of Pennsylvania, to be a Member of the Board of Directors of the Corporation for National and Community Service for a term expiring October 6, 2013.

SECURITIES INVESTOR PROTECTION CORPORATION

Anthony Frank D'Agostino, of Maryland, to be a Director of the Securities Investor Protection Corporation for a term expiring December 31, 2011.

Anthony Frank D'Agostino, of Maryland, to be a Director of the Securities Investor Protection Corporation for a term expiring December 31, 2014.

Gregory Karawan, of Virginia, to be a Director of the Securities Investor Protection Corporation for a term expiring December 31, 2013.

Roy Wallace McLeese III, of the District of Columbia, to be an Associate Judge of the District of Columbia Court of Appeals for the term of fifteen years.

DEPARTMENT OF ENERGY

Adam E. Sieminski, of Pennsylvania, to be Administrator of the Energy Information Administration.

FEDERAL ENERGY REGULATORY COMMISSION

Anthony T. Clark, of North Dakota, to be a Member of the Federal Energy Regulatory Commission for the term expiring June 30, 2016.

John Robert Norris, of Iowa, to be a Member of the Federal Energy Regulatory Commission for the term expiring June 30, 2017.

THE JUDICIARY

Margaret Bartley, of Maryland, to be a Judge of the United States Court of Appeals for Veterans Claims for the term of fifteen years.

Coral Wong Pietsch, of Hawaii, to be a Judge of the United States Court of Appeals for Veterans Claims for the term of fifteen years.

DEPARTMENT OF STATE

Michael A. Raynor, of Maryland, a Career Member of the Senior Foreign Service, Class of Counselor, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Republic of Benin.

Scott H. DeLisi, of Minnesota, a Career Member of the Senior Foreign Service, Class of Minister-Counselor, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Republic of Uganda.

Makila James, of the District of Columbia, a Career Member of the Senior Foreign Service, Class of Counselor, to be Ambassador Extraordinary and Plenipotentiary of the United States of America to the Kingdom of Swaziland.

DEPARTMENT OF DEFENSE

Jessica Lynn Wright, of Pennsylvania, to be an Assistant Secretary of Defense.

James N. Miller, Jr., of Virginia, to be Under Secretary of Defense for Policy.

Frank Kendall III, of Virginia, to be Under Secretary of Defense for Acquisition, Technology, and Logistics.

Erin C. Conaton, of the District of Columbia, to be Under Secretary of Defense for Personnel and Readiness.

Derek H. Chollet, of Nebraska, to be an Assistant Secretary of Defense.

Kathleen H. Hicks, of Virginia, to be a Principal Deputy Under Secretary of Defense.

EXECUTIVE OFFICE OF THE PRESIDENT

Joseph G. Jordan, of Massachusetts, to be Administrator for Federal Procurement Policy.

DEPARTMENT OF DEFENSE

Katharina G. McFarland, of Virginia, to be an Assistant Secretary of Defense.

AIR FORCE

The following Air National Guard of the United States officer for appointment in the Reserve of the 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. Michael D. Dubie

The following named officer for appointment in the United States Air Force to the grade indicated under title 10, U.S.C., section 624:

To be brigadier general

Col. Bobby V. Page

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 general

Gen. Philip M. Breedlove

The following named officer for appointment as the Vice Chief of Staff, United States Air Force, and appointment to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., sections 8034 and 601:

To be general

Lt. Gen. Larry O. Spencer

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. Noel T. Jones

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., sections 12203 and 12212:

To be brigadier general

Col. Wayne A. Zimmet

IN THE ARMY

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

Maj. Gen. Theodore C. Nicholas

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. Francisco A. Espaillat

The following Army National Guard of the United States officer for appointment in the Reserve of the Army to the grade indicated under title 10, U.S.C., sections 12203 and 12211:

To be major general

Brig. Gen. William R. Phillips, II

The following named officers for appointment in the Reserve of the Army to the grades indicated under title 10, U.S.C., sections 12203 and 12211:

To be major general

Brigadier General Leslie J. Carroll
Brigadier General Bryan R. Kelly
Brigadier General Peter S. Lennon
Brigadier General Gary A. Medvigy
Brigadier General David W. Puster
Brigadier General Megan P. Tatu
Brigadier General Daniel L. York
Brigadier General James V. Young, Jr.

To be brigadier general

Colonel Douglas F. Anderson
Colonel Danny C. Baldwin
Colonel William P. Barriage
Colonel Leanne P. Burch
Colonel Mitchell R. Chitwood
Colonel Stephen K. Curda
Colonel Arlan M. Deblieck
Colonel Chris R. Gentry
Colonel Norman B. Green
Colonel Lewis G. Irwin
Colonel Phillip S. Jolly
Colonel Robert A. Karmazin
Colonel Troy D. Kok
Colonel William S. Lee
Colonel Tammy S. Smith
Colonel Michael S. Toumey

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. Michael T. Flynn

IN THE MARINE CORPS

The following named officer for appointment in the United States Marine Corps 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. Thomas D. Waldhauser

The following named officer for appointment to the grade of lieutenant general in the United States Marine Corps while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be lieutenant general

Maj. Gen. Jon M. Davis

The following named officer for appointment in the United States Marine Corps 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. Robert E. Schmidle, Jr.

The following named officer for appointment in the United States Marine Corps 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. Terry G. Robling

The following named officer for appointment in the United States Marine Corps Reserve to the grade indicated under title 10, U.S.C., section 12203:

To be brigadier general

Col. Burke W. Whitman

The following named officer for appointment in the United States Marine Corps Reserve to the grade indicated under title 10, U.S.C., section 12203:

To be major general

Brig. Gen. James M. Lariviere

The following named officer for appointment to the grade of lieutenant general in the United States Marine Corps while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be lieutenant general

Lt. Gen. John M. Paxton, Jr.

The following named officer for appointment in the United States Marine Corps 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. John A. Toolan, Jr.

The following named officer for appointment in the United States Marine Corps Reserve to the grade indicated under title 10, U.S.C., section 12203:

To be brigadier general

Col. Paul K. Lebidine

The following named officer for appointment in the United States Marine Corps 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. Robert B. Neller

IN THE NAVY

The following named officer for appointment in the United States Navy to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be admiral

Vice Adm. William E. Gortney

The following named officer for appointment in the United States Navy to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be vice admiral

Rear Adm. Kurt W. Tidd

The following named officer for appointment in the United States Navy to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be vice admiral

Vice Adm. David H. Buss

The following named officer for appointment in the United States Navy to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be vice admiral

Rear Adm. Michelle J. Howard

The following named officer for appointment in the United States Navy to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be vice admiral

Rear Adm. Thomas H. Copeman, III

The following named officer for appointment in the United States Navy to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be vice admiral

Vice Adm. Richard W. Hunt

The following named officer for appointment in the United States Navy to the grade indicated under title 10, U.S.C., section 624:

To be rear admiral (lower half)

Capt. John F. Kirby

The following named officer for appointment in the United States Navy to the grade indicated under title 10, U.S.C., section 624:

To be rear admiral (lower half)

Capt. Brian B. Brown

JAMES MADISON MEMORIAL FELLOWSHIP FOUNDATION

Drew R. McCoy, of Massachusetts, to be a Member of the Board of Trustees of the James Madison Memorial Fellowship Foundation for a term expiring January 27, 2016.

Pauline R. Maier, of Massachusetts, to be a Member of the Board of Trustees of the James Madison Memorial Fellowship Foundation for a term expiring November 17, 2017.

U.S. PAROLE COMMISSION

Charles Thomas Massarone, of Kentucky, to be a Commissioner of the United States Parole Commission for a term of six years.

NOMINATIONS PLACED ON THE SECRETARY'S DESK

IN THE AIR FORCE

PN1541 AIR FORCE nomination of Tonya R. Everleth, which was received by the Senate and appeared in the Congressional Record of April 23, 2012.

PN1542 AIR FORCE nominations (2) beginning CRAIG W. HINKLEY, and ending CHAD A. SPELLMAN, which nominations were received by the Senate and appeared in the Congressional Record of April 23, 2012.

PN1543 AIR FORCE nominations (2) beginning JOHANN S. WESTPHALL, and ending ELIESA A. ING, which nominations were received by the Senate and appeared in the Congressional Record of April 23, 2012.

PN1544 AIR FORCE nominations (15) beginning MARK J. BATCHO, and ending FREDERICK C. WEAVER, which nominations were received by the Senate and appeared in the Congressional Record of April 23, 2012.

PN1586 AIR FORCE nomination of Robert M. Ague, which was received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1587 AIR FORCE nominations (5) beginning LESLIE A. WOOD, and ending MATTHEW L. SMITH, which nominations were received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1588 AIR FORCE nominations (66) beginning NATHAN BARRY ALHOLINNA, and ending CRAIG M. ZIEMBA, which nominations were received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1639 AIR FORCE nomination of James J. Renda, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1640 AIR FORCE nomination of August S. Hein, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1641 AIR FORCE nominations (3) beginning CHRISTOPHER J. MATHEWS, and ending TIMOTHY K. WILLIAMS, which nominations were received by the Senate and appeared in the Congressional Record of May 14, 2012.

IN THE ARMY

PN1547 ARMY nomination of Israel Mercado, Jr., which was received by the Senate and appeared in the Congressional Record of April 23, 2012.

PN1548 ARMY nominations (3) beginning FRANCIS J. EVON, JR., and ending MARK S. WELLMAN, which nominations were received by the Senate and appeared in the Congressional Record of April 23, 2012.

PN1558 ARMY nomination of Chadwick B. Fletcher, which was received by the Senate and appeared in the Congressional Record of April 25, 2012.

PN1589 ARMY nominations (2) beginning Rhanda J. Brockington, and ending Vickie M. Schnackel, which nominations were received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1590 ARMY nominations (2) beginning Richard A. Daniels, and ending Daniel J. Holdwick, which nominations were received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1591 ARMY nominations (2) beginning Andrew C. Gallo, and ending Christa M. Lewis, which nominations were received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1592 ARMY nomination of John C. Moffitt, which was received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1593 ARMY nomination of Mimms J. Mabee, which was received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1594 ARMY nomination of Jonelle J. Knapp, which was received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1595 ARMY nomination of Robert E. Bessey, which was received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1596 ARMY nomination of Laurel A. Thurston, which was received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1597 ARMY nomination of Tina M. Morgan, which was received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1598 ARMY nominations (2) beginning KARL W. HUBBARD, and ending BENJAMIN N. HOFFMAN, which nominations were received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1599 ARMY nominations (7) beginning JOANN B. COUCH, and ending RICHARD J. YOON, which nominations were received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1642 ARMY nomination of Ricardo A. Bravo, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1643 ARMY nomination of Matthew W. Moffitt, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1644 ARMY nomination of Nathaniel V. Chittick, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1645 ARMY nomination of Lauri M. Zike, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1646 ARMY nomination of Timothy A. Crane, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1647 ARMY nomination of Ryan L. Jerke, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1648 ARMY nomination of Matthew R. Sun, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1649 ARMY nominations (3) beginning GREGORY P. CHANEY, and ending LAWRENCE E. SCHLOEGL, which nominations were received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1650 ARMY nominations (4) beginning AMY F. COOK, and ending PAUL S. TAMARIBUCHI, which nominations were received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1651 ARMY nominations (36) beginning MICHAEL I. ALLEN, and ending MATTHEW S. WYSOCKI, which nominations were received by the Senate and appeared in the Congressional Record of May 14, 2012.

FOREIGN SERVICE

PN1375 FOREIGN SERVICE nominations (14) beginning Robert E. Drapcho, and ending Robert P. Schmidt, Jr., which nominations were received by the Senate and appeared in the Congressional Record of February 13, 2012.

PN1407 FOREIGN SERVICE nominations (235) beginning Kathryn E. Abate, and ending Timothy J. Riley, which nominations were received by the Senate and appeared in the Congressional Record of February 29, 2012.

IN THE MARINE CORPS

PN1334 MARINE CORPS nominations (362) beginning MARTIN L. ABREU, and ending ROBERT C. ZYLA, which nominations were received by the Senate and appeared in the Congressional Record of February 1, 2012.

IN THE NAVY

PN1304 NAVY nomination of John D. Wilshusen, which was received by the Senate and appeared in the Congressional Record of January 31, 2012.

PN1339 NAVY nomination of Peter J. Oldmixon, which was received by the Senate and appeared in the Congressional Record of February 1, 2012.

PN1421 NAVY nomination of Guillermo A. Navarro, which was received by the Senate and appeared in the Congressional Record of February 29, 2012.

PN1446 NAVY nomination of Raymond J. Houk, which was received by the Senate and appeared in the Congressional Record of March 12, 2012.

PN1474 NAVY nomination of Jason D. Weddle, which was received by the Senate and appeared in the Congressional Record of March 19, 2012.

PN1549 NAVY nomination of Andrew J. Strickler, which was received by the Senate and appeared in the Congressional Record of April 23, 2012.

PN1550 NAVY nomination of Andrew K. Ledford, which was received by the Senate and appeared in the Congressional Record of April 23, 2012.

PN1551 NAVY nominations (14) beginning JOHN L. GRIMWOOD, and ending ROBYN M. TREADWELL, which nominations were received by the Senate and appeared in the Congressional Record of April 23, 2012.

PN1552 NAVY nominations (41) beginning DARIUS V. AHMADI, and ending SCOTT D. WOODS, which nominations were received by the Senate and appeared in the Congressional Record of April 23, 2012.

PN1600 NAVY nomination of Matthew F. Phelps, which was received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1626 NAVY nomination of Eric J. Skalski, which was received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1627 NAVY nomination of Ted J. Steelman, which was received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1628 NAVY nomination of David A. Moore, which was received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1652 NAVY nomination of Steven J. Porter, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

LEGISLATIVE SESSION

The PRESIDING OFFICER. Under the previous order, the Senate resumes legislative session.

UNANIMOUS CONSENT AGREEMENT—EXECUTIVE CALENDAR

Mr. REID. I ask unanimous consent that on Monday, June 4, 2012 at 5 p.m., the Senate proceed to executive session to consider Calendar No. 613; that there be 30 minutes of debate equally divided in the usual form; that upon the use or yielding back of that time, the Senate proceed to vote, with no intervening action on the nomination; the motion to reconsider be considered made and laid on the table, with no intervening action or debate; that no further motions be in order; that any further statements be printed in the RECORD; that the President be immediately notified of the Senate's action and the Senate then resume legislative session.

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

INTERNATIONAL PROTECTING GIRLS BY PREVENTING CHILD MARRIAGE ACT OF 2011

Mr. REID. I ask unanimous consent the Senate proceed to consideration of Calendar No. 412, S. 414.

The PRESIDING OFFICER. The clerk will report the bill by title.

The assistant legislative clerk read as follows:

A bill (S. 414) to protect girls in developing countries through the prevention of child marriage, and for other purposes.

There being no objection, the Senate proceeded to consider the bill.

Ms. SNOWE. Mr. President, I rise today to urge that the Senate pass S. 414, the ''Protecting Girls by Preventing Child Marriage Act.'' As the Senate prepares to approve this bipartisan measure, we should take a moment to acknowledge and reflect upon the critical impact this legislation will have on the estimated 100 million girls in developing countries who are at risk of being married as children over the next decade.

The harmful practice of forced child marriage often exacerbates social, economic, and political instability in the developing world, and can prohibit smooth economic and political transition.

For example, Afghanistan's high female illiteracy rates and maternal mortality rates are among the most significant obstacles standing in the way of long-term progress and stability. Without ending child marriage, which remains one of the many underlying catalysts of these poor outcomes, the road ahead for women in Afghanistan will be all the more grueling. And women in Afghanistan are by no means alone in the struggle the discriminatory norms that perpetuate child marriage also prohibit full participation of women in the economic and political life in many other regions of the world.

According to the United Nations Children's Fund—UNICEF—an estimated 60,000,000 girls between the ages of 20 through 24 were married before they turned 18. The Population Council estimates that the number will increase by 100 million over the next decade if current trends continue. In addition to denying these tens of millions of women and girls their dignity, child marriage continues to endanger their health. Marriage at an early age puts girls at greater risk of dying as a result of childbirth. Pregnancy and childbirth complications are the leading cause of death for women 15 to 19 years old in most Third World countries.

Furthermore, women and girls are the world's greatest untapped resources. Studies conducted by the Food and Agricultural Organization—FAO—have confirmed that women are the main-stay of small scale agriculture, farm labor, and day-to-day family subsistence accounting for half of the world's food production.

However, child marriage continues to be a barrier to the improvement of society and the development of these young women. And, unfortunately, early marriages continue to pull girls out of school and prohibit them from gaining vital skills to engage in income generating activities, actively participate in efforts to shape their communities, and often block their ability to achieve food security.

I am heartened to see the United States Senate affirm the United States' commitment to promote the basic human rights of all individuals and through this small step improve the lives of millions of girls by passing this bill today.

Before closing, let me briefly commend my friend and colleague, Senator DURBIN of Illinois. He has been a leader on this topic for a number of years and

I have been privileged to work with him on this bill. Once the Senate completes action on this bill, I hope that the U.S. House will able to quickly approve it and send it to the White House for signature by President Obama.

Mr. REID. I ask the bill be read a third time and the Senate proceed to a voice vote on passage of the bill.

The PRESIDING OFFICER. The question is on the engrossment and third reading of the bill.

The bill (S. 414) 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 pass?

The bill (S. 414) was passed, as follows:

S. 414

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 ''International Protecting Girls by Preventing Child Marriage Act of 2011''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Child marriage, also known as ''forced marriage'' or ''early marriage'', is a harmful traditional practice that deprives girls of their dignity and human rights.

(2) Child marriage as a traditional practice, as well as through coercion or force, is a violation of article 16 of the Universal Declaration of Human Rights, which states, ''Marriage shall be entered into only with the free and full consent of intending spouses''.

(3) According to the United Nations Children's Fund (UNICEF), an estimated 60,000,000 girls in developing countries now ages 20 through 24 were married under the age of 18, and if present trends continue more than 100,000,000 more girls in developing countries will be married as children over the next decade, according to the Population Council.

(4) Between ½ and ¾ of all girls are married before the age of 18 in Niger, Chad, Mali, Bangladesh, Guinea, the Central African Republic, Mozambique, Burkina Faso, and Nepal, according to Demographic Health Survey data.

(5) Factors perpetuating child marriage include poverty, a lack of educational or employment opportunities for girls, parental concerns to ensure sexual relations within marriage, the dowry system, and the perceived lack of value of girls.

(6) Child marriage has negative effects on the health of girls, including significantly increased risk of maternal death and morbidity, infant mortality and morbidity, obstetric fistula, and sexually transmitted diseases, including HIV/AIDS.

(7) According to the United States Agency for International Development (USAID), increasing the age at first birth for a woman will increase her chances of survival. Currently, pregnancy and childbirth complications are the leading cause of death for women 15 to 19 years old in developing countries.

(8) Most countries with high rates of child marriage have a legally established minimum age of marriage, yet child marriage persists due to strong traditional norms and the failure to enforce existing laws.

(9) Secretary of State Hillary Clinton has stated that child marriage is ''a clear and unacceptable violation of human rights'', and that ''the Department of State categorically denounces all cases of child marriage as child abuse''.

(10) According to an International Center for Research on Women analysis of Demographic and Health Survey data, areas or regions in developing countries in which 40 percent or more of girls under the age of 18 are married are considered high-prevalence areas for child marriage.

(11) Investments in girls' schooling, creating safe community spaces for girls, and programs for skills building for out-of-school girls are all effective and demonstrated strategies for preventing child marriage and creating a pathway to empower girls by addressing conditions of poverty, low status, and norms that contribute to child marriage.

SEC. 3. CHILD MARRIAGE DEFINED.

In this Act, the term ''child marriage'' means the marriage of a girl or boy, not yet the minimum age for marriage stipulated in law in the country in which the girl or boy is a resident or, where there is no such law, under the age of 18.

SEC. 4. SENSE OF CONGRESS.

It is the sense of Congress that—

(1) child marriage is a violation of human rights, and the prevention and elimination of child marriage should be a foreign policy goal of the United States;

(2) the practice of child marriage undermines United States investments in foreign assistance to promote education and skills building for girls, reduce maternal and child mortality, reduce maternal illness, halt the transmission of HIV/AIDS, prevent gender-based violence, and reduce poverty; and

(3) expanding educational opportunities for girls, economic opportunities for women, and reducing maternal and child mortality are critical to achieving the Millennium Development Goals and the global health and development objectives of the United States, including efforts to prevent HIV/AIDS.

SEC. 5. STRATEGY TO PREVENT CHILD MARRIAGE IN DEVELOPING COUNTRIES.

(a) ASSISTANCE AUTHORIZED.—

(1) IN GENERAL.—The President is authorized to provide assistance, including through multilateral, nongovernmental, and faith-based organizations, to prevent the incidence of child marriage in developing countries through the promotion of educational, health, economic, social, and legal empowerment of girls and women.

(2) PRIORITY.—In providing assistance authorized under paragraph (1), the President shall give priority to—

(A) areas or regions in developing countries in which 40 percent or more of girls under the age of 18 are married; and

(B) activities to—

(i) expand and replicate existing community-based programs that are successful in preventing the incidence of child marriage;

(ii) establish pilot projects to prevent child marriage; and

(iii) share evaluations of successful programs, program designs, experiences, and lessons.

(b) STRATEGY REQUIRED.—

(1) IN GENERAL.—The President shall establish a multi-year strategy to prevent child marriage and promote the empowerment of girls at risk of child marriage in developing countries, which should address the unique needs, vulnerabilities, and potential of girls under age 18 in developing countries.

(2) CONSULTATION.—In establishing the strategy required by paragraph (1), the President shall consult with Congress, relevant Federal departments and agencies, multilateral organizations, and representatives of civil society.

(3) ELEMENTS.—The strategy required by paragraph (1) shall—

(A) focus on areas in developing countries with high prevalence of child marriage;

(B) encompass diplomatic initiatives between the United States and governments of developing countries, with attention to human rights, legal reforms, and the rule of law;

(C) encompass programmatic initiatives in the areas of education, health, income generation, changing social norms, human rights, and democracy building; and

(D) be submitted to Congress not later than one year after the date of the enactment of this Act.

(c) REPORT.—Not later than three years after the date of the enactment of this Act, the President should submit to Congress a report that includes—

(1) a description of the implementation of the strategy required by subsection (b);

(2) examples of best practices or programs to prevent child marriage in developing countries that could be replicated; and

(3) an assessment, including data disaggregated by age and sex to the extent possible, of current United States funded efforts to specifically prevent child marriage in developing countries.

(d) COORDINATION.—Assistance authorized under subsection (a) shall be integrated with existing United States development programs.

(e) ACTIVITIES SUPPORTED.—Assistance authorized under subsection (a) may be made available for activities in the areas of education, health, income generation, agriculture development, legal rights, democracy building, and human rights, including—

(1) support for community-based activities that encourage community members to address beliefs or practices that promote child marriage and to educate parents, community leaders, religious leaders, and adolescents of the health risks associated with child marriage and the benefits for adolescents, especially girls, of access to education, health care, livelihood skills, microfinance, and savings programs;

(2) support for activities to educate girls in primary and secondary school at the appropriate age and keeping them in age-appropriate grade levels through adolescence;

(3) support for activities to reduce education fees and enhance safe and supportive conditions in primary and secondary schools to meet the needs of girls, including—

(A) access to water and suitable hygiene facilities, including separate lavatories and latrines for girls;

(B) assignment of female teachers;

(C) safe routes to and from school; and

(D) eliminating sexual harassment and other forms of violence and coercion;

(4) support for activities that allow adolescent girls to access health care services and proper nutrition, which is essential to both their school performance and their economic productivity;

(5) assistance to train adolescent girls and their parents in financial literacy and access economic opportunities, including livelihood skills, savings, microfinance, and small-enterprise development;

(6) support for education, including through community and faith-based organizations and youth programs, that helps remove gender stereotypes and the bias against girls used to justify child marriage, especially efforts targeted at men and boys, promotes zero tolerance for violence, and promotes gender equality, which in turn help to increase the perceived value of girls;

(7) assistance to create peer support and female mentoring networks and safe social spaces specifically for girls; and

(8) support for local advocacy work to provide legal literacy programs at the community level to ensure that governments and

law enforcement officials are meeting their obligations to prevent child and forced marriage.

SEC. 6. RESEARCH AND DATA.

It is the sense of Congress that the President and all relevant agencies should, as part of their ongoing research and data collection activities—

(1) collect and make available data on the incidence of child marriage in countries that receive foreign or development assistance from the United States where the practice of child marriage is prevalent; and

(2) collect and make available data on the impact of the incidence of child marriage and the age at marriage on progress in meeting key development goals.

SEC. 7. DEPARTMENT OF STATE'S COUNTRY REPORTS ON HUMAN RIGHTS PRACTICES.

The Foreign Assistance Act of 1961 is amended—

(1) in section 116 (22 U.S.C. 2151n), by adding at the end the following new subsection:

''(g) The report required by subsection (d) shall include, for each country in which child marriage is prevalent, a description of the status of the practice of child marriage in such country. In this subsection, the term 'child marriage' means the marriage of a girl or boy, not yet the minimum age for marriage stipulated in law or under the age of 18 if no such law exists, in the country in which such girl or boy is a resident.''; and

(2) in section 502B (22 U.S.C. 2304), by adding at the end the following new subsection:

''(j) The report required by subsection (b) shall include, for each country in which child marriage is prevalent, a description of the status of the practice of child marriage in such country. In this subsection, the term 'child marriage' means the marriage of a girl or boy, not yet the minimum age for marriage stipulated in law or under the age of 18 if no such law exists, in the country in which such girl or boy is a resident.''.

Mr. REID. I now ask the motion to reconsider be laid on the table, there be no intervening action or debate, and any statements related to this measure be printed in the RECORD as if read.

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

AUTHORIZING THE ARCHITECT OF THE CAPITOL TO ESTABLISH BATTERY RECHARGING STATIONS

Mr. REID. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of Calendar No. 44, S. 739.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 739) to authorize the Architect of the Capitol to establish battery recharging stations for privately owned vehicles in parking areas under the jurisdiction of the Senate at no net cost to the Federal Government.

There being no objection, the Senate proceeded to the bill.

Mr. LEVIN. Mr. President, I am very pleased that the Senate today is passing legislation that would allow the Senate to continue its leadership of our country toward a clean-energy future. This bill provides the authority for the Architect of the Capitol to provide for charging of batteries for privately owned vehicles in parking areas under the jurisdiction of the Senate and, of great importance, at no cost to the Federal Government.

Plug-in hybrid and electric vehicles offer great potential in meeting our goal of reducing greenhouse gas emissions, and auto manufacturers are moving toward developing a broad choice of electric-drive vehicles. Batteries and components are now being manufactured in the U.S., and we are developing the supply chain necessary to support these home-grown technologies. But in addition to making the vehicles and components available, we also need to take steps to ensure the infrastructure exists to make these vehicles desirable and accessible to consumers. Increased use of plug-in hybrid and electric vehicles will bring changes in how we think about cars and driving. Instead of looking for gas stations, drivers will need to have places where they can replenish the batteries that power their vehicles.

This bill will ensure that the Senate leads by example as we transition to that cleaner-energy future. It will ensure that the capability to charge plug-in hybrid and electric vehicles will exist in the Senate—at no cost to the taxpayer. I am a proud owner of a Chevrolet Volt, but I also want to ensure that the taxpayers do not subsidize the cost of my or anyone else's use of electricity to power these vehicles.

I appreciate the efforts and support of the cosponsors of this bill—Senators ALEXANDER, SCHUMER, KERRY, MURKOWSKI, BINGAMAN, STABENOW, and MERKLEY—and the great assistance of the staffs of Senators SCHUMER and ALEXANDER on the Rules Committee in getting this bill passed. It has been our explicit intention to ensure there would be no cost to the taxpayer in providing access to electricity for those wishing to charge their vehicle batteries in the parking areas of the Senate, but I am pleased that we were able to include language to clarify any questions in that regard.

Mr. SCHUMER. Mr. President, I rise today to discuss S. 739, a bill which authorizes the Architect of the Capitol, AOC, at no cost to the Federal government, to create and install electric vehicle recharging stations in Senate parking facilities.

This bill likely would have never seen the light of day it were it not for the perseverance and hard work of my good friend Senator LEVIN. He worked tirelessly to make this bill a reality, and I am so proud to stand with him. This bill was drafted with bipartisan support. Senator ALEXANDER and I join Senators KERRY, MURKOWSKI, BINGAMAN, MERKLEY and STABENOW in supporting this bill sponsored by Senator LEVIN.

It bears repeating: This bill creates a program that will not cost the Federal government one dime. S. 739 funds the installation and maintenance of the charging stations by billing the individuals who use the plug-in stations. S. 739 works on a simple premise: the more people who drive electric cars on campus, the more plug-in stations the AOC will install. S. 739 insures that the demand for plug-in stations will match the number of dues paying participants who fund the program.

This bill is needed as more and more people decide to buy electric cars. Currently, the Architect does not have the authority to install plug-in stations on the Capitol campus. This bill fixes that problem in a smart, cost effective manner.

Mr. REID. Mr. President, I ask unanimous consent that a Levin amendment be agreed to, the bill, as amended, be read a third time and passed, the motion to reconsider be laid upon the table, with no intervening action or debate, and any statements related to the bill be printed in the RECORD.

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

The amendment (No. 2155) was agreed to, as follows:

(Purpose: To improve oversight over the program and ensure no subsidy is received by Senators and employees)

On page 4, strike lines 14 through 19, and insert the following:

(e) REPORTS.—

(1) IN GENERAL.—Not later than 30 days after the end of each fiscal year, the Architect of the Capitol shall submit a report on the financial administration and cost recovery of activities under this section with respect to that fiscal year to the Committee on Rules and Administration of the Senate.

(2) AVOIDING SUBSIDY.—

(A) DETERMINATION.—Not later than 3 years after the date of enactment of this Act and every 3 years thereafter, the Architect of the Capitol shall submit a report to the Committee on Rules and Administration of the Senate determining whether Senators and covered employees using battery charging stations as authorized by this Act are receiving a subsidy from the taxpayers.

(B) MODIFICATION OF RATES AND FEES.—If a determination is made under subparagraph (A) that a subsidy is being received, the Architect of the Capitol shall submit a plan to the Committee on Rules and Administration of the Senate on how to update the program to ensure no subsidy is being received. If the committee does not act on the plan within 60 days, the Architect of the Capitol shall take appropriate steps to increase rates or fees to ensure reimbursement for the cost of the program consistent with an appropriate schedule for amortization, to be charged to those using the charging stations.

The bill (S. 739), as amended, was ordered to be engrossed for a third reading, was read the third time, and passed, as follows:

S. 739

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. BATTERY RECHARGING STATIONS FOR PRIVATELY OWNED VEHICLES IN PARKING AREAS UNDER THE JURISDICTION OF THE SENATE AT NO NET COST TO THE FEDERAL GOVERNMENT.

(a) DEFINITION.—In this Act, the term ''covered employee'' means—

(1) an employee whose pay is disbursed by the Secretary of the Senate; or

(2) any other individual who is authorized to park in any parking area under the jurisdiction of the Senate on Capitol Grounds.

(b) AUTHORITY.—

(1) IN GENERAL.—Subject to paragraph (3), funds appropriated to the Architect of the Capitol under the heading ''CAPITOL POWER PLANT'' under the heading ''ARCHITECT OF THE CAPITOL'' in any fiscal year are available to construct, operate, and maintain on a reimbursable basis battery recharging stations in parking areas under the jurisdiction of the Senate on Capitol Grounds for use by privately owned vehicles used by Senators or covered employees.

(2) VENDORS AUTHORIZED.—In carrying out paragraph (1), the Architect of the Capitol may use 1 or more vendors on a commission basis.

(3) APPROVAL OF CONSTRUCTION.—The Architect of the Capitol may construct or direct the construction of battery recharging stations described under paragraph (1) after—

(A) submission of written notice detailing the numbers and locations of the battery recharging stations to the Committee on Rules and Administration of the Senate; and

(B) approval by that Committee.

(c) FEES AND CHARGES.—

(1) IN GENERAL.—Subject to paragraph (2), the Architect of the Capitol shall charge fees or charges for electricity provided to Senators and covered employees sufficient to cover the costs to the Architect of the Capitol to carry out this section, including costs to any vendors or other costs associated with maintaining the battery recharging stations.

(2) APPROVAL OF FEES OR CHARGES.—The Architect of the Capitol may establish and adjust fees or charges under paragraph (1) after—

(A) submission of written notice detailing the amount of the fee or charge to be established or adjusted to the Committee on Rules and Administration of the Senate; and

(B) approval by that Committee.

(d) DEPOSIT AND AVAILABILITY OF FEES, CHARGES, AND COMMISSIONS.—Any fees, charges, or commissions collected by the Architect of the Capitol under this section shall be—

(1) deposited in the Treasury to the credit of the appropriations account described under subsection (b); and

(2) available for obligation without further appropriation during—

(A) the fiscal year collected; and

(B) the fiscal year following the fiscal year collected.

(e) REPORTS.—

(1) IN GENERAL.—Not later than 30 days after the end of each fiscal year, the Architect of the Capitol shall submit a report on the financial administration and cost recovery of activities under this section with respect to that fiscal year to the Committee on Rules and Administration of the Senate.

(2) AVOIDING SUBSIDY.—

(A) DETERMINATION.—Not later than 3 years after the date of enactment of this Act and every 3 years thereafter, the Architect of the Capitol shall submit a report to the Committee on Rules and Administration of the Senate determining whether Senators and covered employees using battery charging stations as authorized by this Act are receiving a subsidy from the taxpayers.

(B) MODIFICATION OF RATES AND FEES.—If a determination is made under subparagraph (A) that a subsidy is being received, the Architect of the Capital shall submit a plan to the Committee on Rules and Administration of the Senate on how to update the program to ensure no subsidy is being received. If the committee does not act on the plan within 60 days, the Architect of the Capitol shall take appropriate steps to increase rates or fees to ensure reimbursement for the cost of the program consistent with an appropriate schedule for amortization, to be charged to those using the charging stations.

(f) EFFECTIVE DATE.—This Act shall apply with respect to fiscal year 2011 and each fiscal year thereafter.

PROVIDING FOR THE RELEASE OF THE REVERSIONARY INTEREST

Mr. REID. Mr. President, I ask unanimous consent that the Agriculture Committee be discharged from further consideration of H.R. 2947 and the Senate proceed to its consideration.

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

The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (H.R. 2947) to provide for the release of the reversionary interest held by the United States in certain land conveyed by the United States in 1950 for the establishment of an airport in Cook County, Minnesota.

There being no objection, the Senate proceeded to consider the bill.

Mr. REID. Mr. President, I ask unanimous consent that the bill be read the third time and passed, the motion to reconsider be laid upon the table, with no intervening action or debate, and any related statements be printed in the RECORD.

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

The bill (H.R. 2947) was ordered to a third reading, was read the third time, and passed.

ALLOWING OTHERWISE ELIGIBLE ISRAELI NATIONALS TO RECEIVE E–2 NONIMMIGRANT VISAS

Mr. REID. Mr. President, I ask unanimous consent that the Judiciary Committee be discharged from further consideration of H.R. 3992 and the Senate proceed to its consideration.

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

The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (H.R. 3992), to allow otherwise eligible Israeli nationals to receive E–2 nonimmigrant visas if similarly situated United States nationals are eligible for similar nonimmigrant status in Israel.

There being no objection, the Senate proceeded to consider the bill.

Mr. REID. Mr. President, I ask unanimous consent that the bill be read a third time and passed, the motion to reconsider be laid upon the table, with no intervening action or debate, and any statements related to the matter be printed in the RECORD.

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

The bill (H.R. 3992) was ordered to a third reading, was read the third time, and passed.

NATIONAL POST-TRAUMATIC STRESS DISORDER AWARENESS DAY

Mr. REID. I ask unanimous consent that the Judiciary Committee be discharged from further consideration of S. Res. 455.

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

The clerk will report the resolution by title.

The assistant legislative clerk read as follows:

A resolution (S. Res. 455) designating June 27, 2012, as ''National Post-Traumatic Stress Disorder Awareness Day.''

There being no objection, the Senate proceeded to consider the resolution.

Mr. REID. I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, the motions to reconsider be laid upon the table, with no intervening action or debate, and any statements be printed in the RECORD.

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

The resolution (S. Res. 455) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 455

Whereas the brave men and women of the United States Armed Forces, who proudly serve the United States, risk their lives to protect the freedom of the United States and deserve the investment of every possible resource to ensure their lasting physical, mental, and emotional well-being;

Whereas more than 2,000,000 servicemembers have deployed overseas as part of overseas contingency operations since the events of September 11, 2001;

Whereas the military has sustained an operational tempo for a period of time unprecedented in the history of the United States, with many servicemembers deploying multiple times, placing them at high risk of PTSD;

Whereas according to the Armed Forces Health Surveillance Center, approximately 90,000 servicemembers who have returned from overseas contingency operations have been clinically diagnosed with PTSD;

Whereas the Department of Veterans Affairs reports that—

(1) since 2002, more than 217,000 of the more than 750,000 veterans of overseas contingency operations who have sought care at a Department of Veterans Affairs medical center have been diagnosed with PTSD; and

(2) in fiscal year 2011, more than 475,000 of the nearly 6,000,000 veterans from all wars who sought care at a Department of Veterans Affairs medical center received treatment for PTSD;

Whereas many cases of PTSD remain unreported, undiagnosed, and untreated due to a lack of awareness about PTSD and the persistent stigma associated with mental health issues;

Whereas PTSD significantly increases the risk of depression, suicide, and drug- and alcohol-related disorders and deaths, especially if left untreated;

Whereas perceived or actual symptoms of PTSD or other mental health issues create unique challenges for veterans seeking employment;

Whereas the Departments of Defense and Veterans Affairs have made significant advances in the prevention, diagnosis, and treatment of PTSD and the symptoms of PTSD, but many challenges remain; and

Whereas the establishment of a National Post-Traumatic Stress Disorder Awareness Day will raise public awareness about issues related to PTSD, reduce the stigma associated with PTSD, and help ensure that those

suffering from the invisible wounds of war receive proper treatment: Now, therefore, be it

Resolved, That the Senate—

(1) designates June 27, 2012, as ''National Post-Traumatic Stress Disorder Awareness Day'';

(2) supports the efforts of the Secretary of Veterans Affairs and the Secretary of Defense to educate servicemembers, veterans, the families of servicemembers and veterans, and the public about the causes, symptoms, and treatment of post-traumatic stress disorder (referred to in this resolution as ''PTSD''); and

(3) respectfully requests that the Secretary of the Senate transmit a copy of this resolution to the Secretary of Veterans Affairs and the Secretary of Defense.

RELATIVE TO THE DEATH OF THE HONORABLE E. JAMES ABDNOR

Mr. REID. I ask unanimous consent to proceed to S. Res. 475.

The PRESIDING OFFICER. The clerk will report the resolution by title.

The assistant legislative clerk read as follows:

A resolution (S. Res. 475) relating to the death of the Honorable E. James Abdnor, former United States Senator and Congressman from the State of South Dakota.

There being no objection, the Senate proceeded to consider the resolution.

Mr. REID. I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, and the motions to reconsider be laid upon the table.

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

The resolution (S. Res. 475) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 475

Whereas James Abdnor was born in Kennebec, South Dakota, on February 13, 1923, and was the son of an immigrant from Lebanon who peddled and homesteaded in Lyman County, South Dakota;

Whereas James Abdnor enlisted in the United States Army during World War II, farmed in Kennebec after graduating from the University of Nebraska in 1945, and later taught and coached in neighboring Presho;

Whereas James Abdnor served as Chairman of the Lyman County Young Republicans in 1950, Chairman of the State Young Republicans from 1950 to 1952, and Farm Chairman of the Young Republican National Federation from 1953 to 1955;

Whereas James Abdnor served as the First Assistant Chief Clerk of the South Dakota House of Representatives during the legislative sessions of 1951, 1953, and 1955;

Whereas James Abdnor was elected to the South Dakota Senate in 1956, where he served until his election as the 30th Lieutenant Governor of the State of South Dakota, a position he served in from 1969 through 1971;

Whereas James Abdnor was elected to the United States House of Representatives for the 93rd United States Congress in 1972 and served a total of 4 consecutive terms, representing the Second Congressional District of South Dakota;

Whereas James Abdnor served on the Committee on Public Works of the House of Representatives, the Committee on Veterans' Affairs of the House of Representatives, and the Select Committee on Aging of the House of Representatives;

Whereas James Abdnor was elected to the United States Senate for the 97th United States Congress in 1980 and was appointed Chairman of 3 subcommittees on his first day, including the Subcommittee on Treasury, Postal Service, and General Government of the Committee on Appropriations of the Senate, the Subcommittee on Water Resources of the Committee on Environment and Public Works of the Senate, and the Subcommittee on Agriculture and Transportation of the Joint Economic Committee;

Whereas James Abdnor was appointed Vice Chairman of the Joint Economic Committee and served on the Committee on Indian Affairs of the Senate;

Whereas James Abdnor was a voice for the rural United States in Congress, where he advocated for family farms and small business, rural water systems and electrification, a balanced budget, and small-town values;

Whereas James Abdnor was appointed by President Ronald Reagan to serve as the Administrator of the United States Small Business Administration from 1987 to 1989 following his service in the United States Congress;

Whereas James Abdnor will be remembered for his humble service to his constituents, dedication to the youth of South Dakota, and defining influence on South Dakota politics; and

Whereas the hallmarks of James Abdnor's public service were his integrity, kindness, respect for the common man, and love for South Dakota: Now, therefore, be it

Resolved, That—

(1) the Senate expresses profound sorrow and deep regret regarding the death of the Honorable James Abdnor, former member of the United States Senate and House of Representatives for the State of South Dakota, on May 16, 2012;

(2) the Senate respectfully requests that the Secretary of the Senate communicate this resolution to the House of Representatives and transmit an enrolled copy of this resolution to the family of the deceased; and

(3) when the Senate adjourns today, the Senate stand adjourned as a further mark of respect to the memory of the Honorable James Abdnor.

MEASURE READ THE FIRST TIME

Mr. REID. There is a joint resolution at the desk, and I ask for its first reading.

The PRESIDING OFFICER. The clerk will read the joint resolution by title for the first time.

The assistant legislative clerk read as follows:

A joint resolution (S. J. Res. 41) expressing the sense of Congress regarding the nuclear program of the Government of the Islamic Republic of Iran.

Mr. REID. I ask for a second reading, the purpose of which is to place this joint resolution on the calendar under the provisions of rule XIV, but after having said that, I object to my own request.

The PRESIDING OFFICER. Objection is heard.

The joint resolution will be read the second time on the next legislative day.

SIGNING AUTHORITY

Mr. REID. I now ask unanimous consent that from Friday, May 25, through Monday, June 4, Senator LEAHY be authorized to sign duly enrolled bills or joint resolutions.

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

APPOINTMENT AUTHORITY

Mr. REID. Mr. President, I ask unanimous consent that notwithstanding the upcoming recess or adjournment of the Senate, the President of the Senate, the President pro tempore, and the majority leader and minority leader be authorized to make appointments to commissions, committees, boards, conferences, or interparliamentary conferences authorized by law, by concurrent action of the two Houses, or by order of the Senate.

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

ORDERS FOR FRIDAY, MAY 25 THROUGH MONDAY, JUNE 4, 2012

Mr. REID. Mr. President, I ask unanimous consent that when the Senate completes its business today, it adjourn and convene for pro forma sessions only with no business conducted on the following dates and times and that following each pro forma session, the Senate adjourn until the next pro forma session: Friday, May 25, at 2:30 p.m.; Tuesday, May 29, at 11 a.m.; and Thursday, May 31, at 12 p.m.; and that the Senate adjourn on Thursday, May 31 until 2 p.m. on Monday, June 4; that following the prayer and pledge, the Journal of proceedings be approved to date, the morning hour be deemed expired, and the time for the two leaders be reserved for their use later in the day, and that the majority leader be recognized; further, that at 5 p.m., the Senate proceed to executive session under the previous order.

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

PROGRAM

Mr. REID. It is my intention to resume the motion to proceed to S. 3220, the paycheck fairness bill, when the Senate convenes on Monday, June 4. There will be a rollcall vote on confirmation of the Hillman nomination.

ADJOURNMENT UNTIL FRIDAY, MAY 25, 2012, AT 2:30 P.M.

Mr. REID. Mr. President, if there is no further business to come before the Senate, I ask unanimous consent that it adjourn under the provisions of S. Res. 475 as a further mark of respect to the memory of the late Senator James Abdnor of South Dakota.

There being no objection, the Senate, at 7:21 p.m., adjourned until Friday, May 25, 2012, at 2:30 p.m.

NOMINATIONS

Executive nominations received by the Senate:

STATE JUSTICE INSTITUTE

JONATHAN LIPPMAN, OF NEW YORK, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE STATE JUSTICE INSTITUTE FOR A TERM EXPIRING SEPTEMBER 17, 2012, VICE ROBERT A. MILLER, TERM EXPIRED.

JONATHAN LIPPMAN, OF NEW YORK, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE STATE JUSTICE INSTITUTE FOR A TERM EXPIRING SEPTEMBER 17, 2015. (REAPPOINTMENT)

NUCLEAR REGULATORY COMMISSION

ALLISON M. MACFARLANE, OF MARYLAND, TO BE A MEMBER OF THE NUCLEAR REGULATORY COMMISSION FOR THE REMAINDER OF THE TERM EXPIRING JUNE 30, 2013, VICE GREGORY B. JACZKO, RESIGNED.

DEPARTMENT OF STATE

GRETA CHRISTINE HOLTZ, OF MARYLAND, A CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF MINISTER-COUNSELOR, TO BE AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE SULTANATE OF OMAN.

ALEXANDER MARK LASKARIS, OF MARYLAND, A CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF COUNSELOR, TO BE AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE REPUBLIC OF GUINEA.

MARCIE B. RIES, OF THE DISTRICT OF COLUMBIA, A CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF CAREER-MINISTER, TO BE AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE REPUBLIC OF BULGARIA.

OFFICE OF GOVERNMENT ETHICS

WALTER M. SHAUB, JR., OF VIRGINIA, TO BE DIRECTOR OF THE OFFICE OF GOVERNMENT ETHICS FOR A TERM OF FIVE YEARS, VICE ROBERT IRWIN CUSICK, JR., TERM EXPIRED.

IN THE ARMY

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. HOWARD B. BROMBERG

DISCHARGED NOMINATIONS

The Senate Committee on Foreign Relations was discharged from further consideration of the following nomination by voice vote and the nomination was confirmed:

DAVID J. LANE, OF FLORIDA, FOR THE RANK OF AMBASSADOR DURING HIS TENURE OF SERVICE AS U.S. REPRESENTATIVE TO THE UNITED NATIONS AGENCIES FOR FOOD AND AGRICULTURE.

The Senate Committee on Health, Education, Labor, and Pensions was discharged from further consideration of the following nominations by voice vote and the nominations were confirmed:

PUBLIC HEALTH SERVICE NOMINATIONS BEGINNING WITH JOSEPH R. FONTANA AND ENDING WITH JOY A. MOBLEY, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON APRIL 26, 2012.

PUBLIC HEALTH SERVICE NOMINATIONS BEGINNING WITH MARY J. CHOI AND ENDING WITH MEGHAN M. ZOMORODI, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 15, 2012.

CONFIRMATIONS

Executive nominations confirmed by the Senate May 24, 2012:

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

MATTHEW FRANCIS MCCABE, OF PENNSYLVANIA, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE CORPORATION FOR NATIONAL AND COMMUNITY SERVICE FOR A TERM EXPIRING OCTOBER 6, 2013.

SECURITIES INVESTOR PROTECTION CORPORATION

ANTHONY FRANK D'AGOSTINO, OF MARYLAND, TO BE A DIRECTOR OF THE SECURITIES INVESTOR PROTECTION CORPORATION FOR A TERM EXPIRING DECEMBER 31, 2011.

ANTHONY FRANK D'AGOSTINO, OF MARYLAND, TO BE A DIRECTOR OF THE SECURITIES INVESTOR PROTECTION CORPORATION FOR A TERM EXPIRING DECEMBER 31, 2014.

GREGORY KARAWAN, OF VIRGINIA, TO BE A DIRECTOR OF THE SECURITIES INVESTOR PROTECTION CORPORATION FOR A TERM EXPIRING DECEMBER 31, 2013.

INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT

SARA MARGALIT AVIEL, OF CALIFORNIA, TO BE UNITED STATES ALTERNATE EXECUTIVE DIRECTOR OF THE INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT FOR A TERM OF TWO YEARS.

THE JUDICIARY

ROY WALLACE MCLEESE III, OF THE DISTRICT OF COLUMBIA, TO BE AN ASSOCIATE JUDGE OF THE DISTRICT OF COLUMBIA COURT OF APPEALS FOR THE TERM OF FIFTEEN YEARS.

DEPARTMENT OF ENERGY

ADAM E. SIEMINSKI, OF PENNSYLVANIA, TO BE ADMINISTRATOR OF THE ENERGY INFORMATION ADMINISTRATION.

FEDERAL ENERGY REGULATORY COMMISSION

ANTHONY T. CLARK, OF NORTH DAKOTA, TO BE A MEMBER OF THE FEDERAL ENERGY REGULATORY COMMISSION FOR THE TERM EXPIRING JUNE 30, 2016.

JOHN ROBERT NORRIS, OF IOWA, TO BE A MEMBER OF THE FEDERAL ENERGY REGULATORY COMMISSION FOR THE TERM EXPIRING JUNE 30, 2017.

THE JUDICIARY

MARGARET BARTLEY, OF MARYLAND, TO BE A JUDGE OF THE UNITED STATES COURT OF APPEALS FOR VETERANS CLAIMS FOR THE TERM OF FIFTEEN YEARS.

CORAL WONG PIETSCH, OF HAWAII, TO BE A JUDGE OF THE UNITED STATES COURT OF APPEALS FOR VETERANS CLAIMS FOR THE TERM OF FIFTEEN YEARS.

DEPARTMENT OF STATE

MICHAEL A. RAYNOR, OF MARYLAND, A CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF COUNSELOR, TO BE AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE REPUBLIC OF BENIN.

SCOTT H. DELISI, OF MINNESOTA, A CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF MINISTER-COUNSELOR, TO BE AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE REPUBLIC OF UGANDA.

MAKILA JAMES, OF THE DISTRICT OF COLUMBIA, A CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF COUNSELOR, TO BE AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE KINGDOM OF SWAZILAND.

DEPARTMENT OF DEFENSE

JESSICA LYNN WRIGHT, OF PENNSYLVANIA, TO BE AN ASSISTANT SECRETARY OF DEFENSE.

JAMES N. MILLER, JR., OF VIRGINIA, TO BE UNDER SECRETARY OF DEFENSE FOR POLICY.

FRANK KENDALL III, OF VIRGINIA, TO BE UNDER SECRETARY OF DEFENSE FOR ACQUISITION, TECHNOLOGY, AND LOGISTICS.

ERIN C. CONATON, OF THE DISTRICT OF COLUMBIA, TO BE UNDER SECRETARY OF DEFENSE FOR PERSONNEL AND READINESS.

DEREK H. CHOLLET, OF NEBRASKA, TO BE AN ASSISTANT SECRETARY OF DEFENSE.

KATHLEEN H. HICKS, OF VIRGINIA, TO BE A PRINCIPAL DEPUTY UNDER SECRETARY OF DEFENSE.

EXECUTIVE OFFICE OF THE PRESIDENT

JOSEPH G. JORDAN, OF MASSACHUSETTS, TO BE ADMINISTRATOR FOR FEDERAL PROCUREMENT POLICY.

DEPARTMENT OF DEFENSE

KATHARINA G. MCFARLAND, OF VIRGINIA, TO BE AN ASSISTANT SECRETARY OF DEFENSE.

IN THE AIR FORCE

THE FOLLOWING AIR NATIONAL GUARD OF THE UNITED STATES OFFICER FOR APPOINTMENT IN THE RESERVE OF THE 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. MICHAEL D. DUBIE

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES AIR FORCE TO THE GRADE INDICATED UNDER TITLE 10, U.S.C., SECTION 624:

To be brigadier general

COL. BOBBY V. PAGE

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 general

GEN. PHILIP M. BREEDLOVE

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT AS THE VICE CHIEF OF STAFF, UNITED STATES AIR FORCE, AND APPOINTMENT TO THE GRADE INDICATED WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, U.S.C., SECTIONS 8034 AND 601:

To be general

LT. GEN. LARRY O. SPENCER

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. NOEL T. JONES

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., SECTIONS 12203 AND 12212:

To be brigadier general

COL. WAYNE A. ZIMMET

IN THE ARMY

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

MAJ. GEN. THEODORE C. NICHOLAS

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. FRANCISCO A. ESPAILLAT

THE FOLLOWING ARMY NATIONAL GUARD OF THE UNITED STATES OFFICER FOR APPOINTMENT IN THE RESERVE OF THE ARMY TO THE GRADE INDICATED UNDER TITLE 10, U.S.C., SECTIONS 12203 AND 12211:

To be major general

BRIG. GEN. WILLIAM R. PHILLIPS II

THE FOLLOWING NAMED OFFICERS FOR APPOINTMENT IN THE RESERVE OF THE ARMY TO THE GRADES INDICATED UNDER TITLE 10, U.S.C., SECTIONS 12203 AND 12211:

To be major general

BRIGADIER GENERAL LESLIE J. CARROLL
BRIGADIER GENERAL BRYAN R. KELLY
BRIGADIER GENERAL PETER S. LENNON
BRIGADIER GENERAL GARY A. MEDVIGY
BRIGADIER GENERAL DAVID W. PUSTER
BRIGADIER GENERAL MEGAN P. TATU
BRIGADIER GENERAL DANIEL L. YORK
BRIGADIER GENERAL JAMES V. YOUNG, JR.

To be brigadier general

COLONEL DOUGLAS F. ANDERSON
COLONEL DANNY C. BALDWIN
COLONEL WILLIAM P. BARRIAGE
COLONEL LEANNE P. BURCH
COLONEL MITCHELL R. CHITWOOD
COLONEL STEPHEN K. CURDA
COLONEL ARLAN M. DEBLIECK
COLONEL CHRIS R. GENTRY
COLONEL NORMAN B. GREEN
COLONEL LEWIS G. IRWIN
COLONEL PHILLIP S. JOLLY
COLONEL ROBERT A. KARMAZIN
COLONEL TROY D. KOK
COLONEL WILLIAM S. LEE
COLONEL TAMMY S. SMITH
COLONEL MICHAEL S. TUOMEY

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. MICHAEL T. FLYNN

IN THE MARINE CORPS

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES MARINE CORPS 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. THOMAS D. WALDHAUSER

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT TO THE GRADE OF LIEUTENANT GENERAL IN THE UNITED STATES MARINE CORPS WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, U.S.C., SECTION 601:

To be lieutenant general

MAJ. GEN. JON M. DAVIS

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES MARINE CORPS 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. ROBERT E. SCHMIDLE, JR.

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES MARINE CORPS 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. TERRY G. ROBLING

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES MARINE CORPS RESERVE TO THE GRADE INDICATED UNDER TITLE 10, U.S.C., SECTION 12203:

To be brigadier general

COL. BURKE W. WHITMAN

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES MARINE CORPS RESERVE TO THE GRADE INDICATED UNDER TITLE 10, U.S.C., SECTION 12203:

To be major general

BRIG. GEN. JAMES M. LARIVIERE

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT TO THE GRADE OF LIEUTENANT GENERAL IN THE UNITED STATES MARINE CORPS WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, U.S.C., SECTION 601:

To be lieutenant general

LT. GEN. JOHN M. PAXTON, JR.

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES MARINE CORPS 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. JOHN A. TOOLAN, JR.

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES MARINE CORPS RESERVE TO THE GRADE INDICATED UNDER TITLE 10, U.S.C., SECTION 12203:

To be brigadier general

COL. PAUL K. LEBIDINE

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES MARINE CORPS 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. ROBERT B. NELLER

IN THE NAVY

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES NAVY TO THE GRADE INDICATED WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, U.S.C., SECTION 601:

To be admiral

VICE ADM. WILLIAM E. GORTNEY

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES NAVY TO THE GRADE INDICATED WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, U.S.C., SECTION 601:

To be vice admiral

REAR ADM. KURT W. TIDD

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES NAVY TO THE GRADE INDICATED WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, U.S.C., SECTION 601:

To be vice admiral

VICE ADM. DAVID H. BUSS

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES NAVY TO THE GRADE INDICATED WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, U.S.C., SECTION 601:

To be vice admiral

REAR ADM. MICHELLE J. HOWARD

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES NAVY TO THE GRADE INDICATED WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, U.S.C., SECTION 601:

To be vice admiral

REAR ADM. THOMAS H. COPEMAN III

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES NAVY TO THE GRADE INDICATED WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, U.S.C., SECTION 601:

To be vice admiral

VICE ADM. RICHARD W. HUNT

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES NAVY TO THE GRADE INDICATED UNDER TITLE 10, U.S.C., SECTION 624:

To be rear admiral (lower half)

CAPT. JOHN F. KIRBY

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES NAVY TO THE GRADE INDICATED UNDER TITLE 10, U.S.C., SECTION 624:

To be rear admiral (lower half)

CAPT. BRIAN B. BROWN

JAMES MADISON MEMORIAL FELLOWSHIP FOUNDATION

DREW R. MCCOY, OF MASSACHUSETTS, TO BE A MEMBER OF THE BOARD OF TRUSTEES OF THE JAMES MADISON MEMORIAL FELLOWSHIP FOUNDATION FOR A TERM EXPIRING JANUARY 27, 2016.

PAULINE R. MAIER, OF MASSACHUSETTS, TO BE A MEMBER OF THE BOARD OF TRUSTEES OF THE JAMES MADISON MEMORIAL FELLOWSHIP FOUNDATION FOR A TERM EXPIRING NOVEMBER 17, 2017.

UNITED STATES PAROLE COMMISSION

CHARLES THOMAS MASSARONE, OF KENTUCKY, TO BE A COMMISSIONER OF THE UNITED STATES PAROLE COMMISSION FOR A TERM OF SIX YEARS.

IN THE AIR FORCE

AIR FORCE NOMINATION OF TONYA R. EVERLETH, TO BE LIEUTENANT COLONEL .

AIR FORCE NOMINATIONS BEGINNING WITH CRAIG W. HINKLEY AND ENDING WITH CHAD A. SPELLMAN, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON APRIL 23, 2012.

AIR FORCE NOMINATIONS BEGINNING WITH JOHANN S. WESTPHALL AND ENDING WITH ELIESA A. ING, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON APRIL 23, 2012.

AIR FORCE NOMINATIONS BEGINNING WITH MARK J. BATCHO AND ENDING WITH FREDERICK C. WEAVER, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON APRIL 23, 2012.

AIR FORCE NOMINATION OF ROBERT M. AGUE, TO BE COLONEL.

AIR FORCE NOMINATIONS BEGINNING WITH LESLIE A. WOOD AND ENDING WITH MATTHEW L. SMITH, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 10, 2012.

AIR FORCE NOMINATIONS BEGINNING WITH NATHAN BARRY ALHOLINNA AND ENDING WITH CRAIG M. ZIEMBA, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 10, 2012.

AIR FORCE NOMINATION OF JAMES J. RENDA, TO BE MAJOR.

AIR FORCE NOMINATION OF AUGUST S. HEIN, TO BE COLONEL.

AIR FORCE NOMINATIONS BEGINNING WITH CHRISTOPHER J. MATHEWS AND ENDING WITH TIMOTHY K. WILLIAMS, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 14, 2012.

IN THE ARMY

ARMY NOMINATION OF ISRAEL MERCADO, JR., TO BE LIEUTENANT COLONEL.

ARMY NOMINATIONS BEGINNING WITH FRANCIS J. EVON, JR. AND ENDING WITH MARK S. WELLMAN, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON APRIL 23, 2012.

ARMY NOMINATION OF CHADWICK B. FLETCHER, TO BE MAJOR.

ARMY NOMINATIONS BEGINNING WITH RHANDA J. BROCKINGTON AND ENDING WITH VICKIE M. SCHNACKEL, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 10, 2012.

ARMY NOMINATIONS BEGINNING WITH RICHARD A. DANIELS AND ENDING WITH DANIEL J. HOLDWICK, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 10, 2012.

ARMY NOMINATIONS BEGINNING WITH ANDREW C. GALLO AND ENDING WITH CHRISTA M. LEWIS, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 10, 2012.

ARMY NOMINATION OF JOHN C. MOFFITT, TO BE MAJOR.

ARMY NOMINATION OF MIMMS J. MABEE, TO BE COLONEL.

ARMY NOMINATION OF JONELLE J. KNAPP, TO BE MAJOR.

ARMY NOMINATION OF ROBERT E. BESSEY, TO BE MAJOR.

ARMY NOMINATION OF LAUREL A. THURSTON, TO BE MAJOR.

ARMY NOMINATION OF TINA M. MORGAN, TO BE MAJOR.

ARMY NOMINATIONS BEGINNING WITH KARL W. HUBBARD AND ENDING WITH BENJAMIN N. HOFFMAN, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 10, 2012.

ARMY NOMINATIONS BEGINNING WITH JOANN B. COUCH AND ENDING WITH RICHARD J. YOON, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 10, 2012.

ARMY NOMINATION OF RICARDO A. BRAVO, TO BE LIEUTENANT COLONEL.

ARMY NOMINATION OF MATTHEW W. MOFFITT, TO BE LIEUTENANT COLONEL.

ARMY NOMINATION OF NATHANIEL V. CHITTICK, TO BE MAJOR.

ARMY NOMINATION OF LAURI M. ZIKE, TO BE MAJOR.

ARMY NOMINATION OF TIMOTHY A. CRANE, TO BE MAJOR.

ARMY NOMINATION OF RYAN L. JERKE, TO BE MAJOR.

ARMY NOMINATION OF MATTHEW R. SUN, TO BE MAJOR.

ARMY NOMINATIONS BEGINNING WITH GREGORY P. CHANEY AND ENDING WITH LAWRENCE E. SCHLOEGL, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 14, 2012.

ARMY NOMINATIONS BEGINNING WITH AMY F. COOK AND ENDING WITH PAUL S. TAMARIBUCHI, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 14, 2012.

ARMY NOMINATIONS BEGINNING WITH MICHAEL I. ALLEN AND ENDING WITH MATTHEW S. WYSOCKI, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 14, 2012.

IN THE MARINE CORPS

MARINE CORPS NOMINATIONS BEGINNING WITH MARTIN L. ABREU AND ENDING WITH ROBERT C. ZYLA, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON FEBRUARY 1, 2012.

IN THE NAVY

NAVY NOMINATION OF JOHN D. WILSHUSEN, TO BE CAPTAIN.

NAVY NOMINATION OF PETER J. OLDMIXON, TO BE COMMANDER.

NAVY NOMINATION OF GUILLERMO A. NAVARRO, TO BE COMMANDER.

NAVY NOMINATION OF RAYMOND J. HOUK, TO BE CAPTAIN.

NAVY NOMINATION OF JASON D. WEDDLE, TO BE COMMANDER.

NAVY NOMINATION OF ANDREW J. STRICKLER, TO BE COMMANDER.

NAVY NOMINATION OF ANDREW K. LEDFORD, TO BE COMMANDER.

NAVY NOMINATIONS BEGINNING WITH JOHN L. GRIMWOOD AND ENDING WITH ROBYN M. TREADWELL, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON APRIL 23, 2012.

NAVY NOMINATIONS BEGINNING WITH DARIUS V. AHMADI AND ENDING WITH SCOTT D. WOODS, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON APRIL 23, 2012.

NAVY NOMINATION OF MATTHEW F. PHELPS, TO BE COMMANDER.

NAVY NOMINATION OF ERIC J. SKALSKI, TO BE LIEUTENANT COMMANDER.

NAVY NOMINATION OF TED J. STEELMAN, TO BE LIEUTENANT COMMANDER.

NAVY NOMINATION OF DAVID A. MOORE, TO BE LIEUTENANT COMMANDER.

NAVY NOMINATION OF STEVEN J. PORTER, TO BE COMMANDER.

FOREIGN SERVICE

FOREIGN SERVICE NOMINATIONS BEGINNING WITH ROBERT E. DRAPCHO AND ENDING WITH ROBERT P. SCHMIDT, JR., WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON FEBRUARY 13, 2012.

FOREIGN SERVICE NOMINATIONS BEGINNING WITH KATHRYN E. ABATE AND ENDING WITH TIMOTHY J. RILEY, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON FEBRUARY 29, 2012.

DEPARTMENT OF STATE

DAVID J. LANE, OF FLORIDA, FOR THE RANK OF AMBASSADOR DURING HIS TENURE OF SERVICE AS U.S. REPRESENTATIVE TO THE UNITED NATIONS AGENCIES FOR FOOD AND AGRICULTURE.

PUBLIC HEALTH SERVICE

PUBLIC HEALTH SERVICE NOMINATIONS BEGINNING WITH JOSEPH R. FONTANA AND ENDING WITH JOY A. MOBLEY, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON APRIL 26, 2012.

PUBLIC HEALTH SERVICE NOMINATIONS BEGINNING WITH MARY J. CHOI AND ENDING WITH MEGHAN M. ZOMORODI, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 15, 2012.