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,

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—so that we 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
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 reasonables 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 the 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. And then changed the law for few 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 increase in 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 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. 3167, which the clerk will report.

The assistant legislative clerk read as follows:

A bill (S. 3167) 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 biologics, and for other purposes.

Pending:

Durbin/Blumenthal amendment No. 2127, to require manufacturers of dietary supplements to test for and report any contaminants in their 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 Tobacco Products 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 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 Tobacco Products Evaluation and Research be connected to an evaluation of the employee’s contribution to goals under the user fee agreements.

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. 2141, 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 states of 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.

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. McCaskill, for Mr. McCain] proposes an amendment numbered 2107.

Mr. McCaskill. 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 United States prescription drugs (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 subchapter 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) has been 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

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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 approved the pharmacy 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) is 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) permits 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 that 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 importation programs.

Let me give an example—this recently came up—of the activities of the pharmaceutical companies in the for-
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 medications as 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 Canadian pharmacist; the prescribed drug must be for personal and strength as a prescription drug approved by the Secretary; 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 donation 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 for patients; the pharmacy will only 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 living 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 no 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 medicines 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 unnecessarily 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 someone will have the 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 surprised 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. MCCONNELL. Mr. President, I suggest the absence of a quorum.

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

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

The assistant legislative clerk proceeded to call the roll.

Mr. MCCAIN. Mr. President, I suggest we move 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 amendment. I 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 you, my colleagues, to please come over and call up their amendments so we can debate them and move ahead 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.

Mr. MCCONDEL. Mr. President, 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 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 an 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 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 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. These are 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 been following with great interest 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 ammunition 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 Army 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 knew he 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 that it 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 for 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 his physical fitness program 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 marking 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.

Senator Menendez 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 feel 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 here in the few days before Memorial Day, to recognize his enormous sacrifice on behalf of this Nation.

I yield the floor.

The ACTING PRESIDENT pro temore., 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 puts in place the mechanisms 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.

It seems that, once again, despite 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, 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 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 implication that has—allowing counterfeit and dangerous products into our country.

This amendment would ostensibly only allow 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 does not provide the FDA with any additional resources to monitor the drugs coming 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 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 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—a written 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 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.

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 Markets Integrity 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 allow 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 development that has always made the United States great.

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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 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 the world over is 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 in all America, it would also keep 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 importation. A list of approved pharmacies...
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 change 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. One specific advantage of this amendment would give 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 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 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, the Canadian Interagency for Public Health, and the 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.

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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.
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 valid or patentable. It 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 patent lawsuit, the parties negotiate to preserve their exclusivity rights. For instance, a 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 evincing 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...
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. And I am absolutely convinced 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 is that, 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 cost. 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 is 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 the only way they would 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 as Canadians. 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. It 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? 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. U.S. 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 report of 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 foreign and domestic pharmacies. That, in turn, would 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 same medications as we do. They are made in the same company. 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, 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 drugs. 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 pays more for 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 a very important step that we take this step. It is paying 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 the American consumer can take advantage of.

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 the following amendment:

Mr. WHITEHOUSE, and Mr. SCHUMER, proposes, by adding at the end the following:

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

"(4) PURCHASE OF DRUGS.—For purposes of section 502 of title 5, United States Code, this subsection shall be included a statute described in section 52(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 Department of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2002 (Public Law 107–177; 115 Stat. 748); and

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

(b) REQUIREMENTS.—The Attorney General and the Secretary of Health and Human Services shall consider in developing these recommendations the—

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

(2) use of existing or new standards, 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 the 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.—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 Natural Resources 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) Certification. 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 agreements with other agencies 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 Schedules I and II)

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. AMENDMENTS 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:

“(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:

“(1) 2-(2,5-Dimethoxy-4-

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

(iii) 3-(1-naphthyl)phenyl 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 naphthyl ring to any extent.

(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not substituted on 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-(1H,3S)-3-

hydroxyacyclohexanol or CP-47,497 (C-homo-

log);’’

‘‘(ii) 5-(1,1-dimethyloctyl)-2-(1H,3S)-3-

hydroxyacyclohexanol or CP-47,497 (C-homo-

log);’’

‘‘(iii) 1-phenyl-3-(1-naphthyl)indole (JWH-018 and AM678);’’

‘‘(iv) 1-(1-naphthyl)-3-(1-naphthyl)indole (JWH-073);

‘‘(v) 1-ethyl-3-1-(naphthyl)indole (JWH-019);

‘‘(vi) 1-[2-(4-morpholinyl)ethyl]-3-[1-naph-

thyl]indole (JWH-220);

‘‘(vii) 1-phenyl-3-(2-

methoxycyclacetyl)indole (JWH-250);

‘‘(viii) 1-phenyl-3-[4-(methoxy)-benz-

zoyl]indole (SR-19 and RCS-4);’’

‘‘(ix) 3-(1-naphthoyl)indole (JWH-981); and

‘‘(x) 1-pentyl-3-(4-methyl-1-naph-

thyl]indole (JWH-122);’’

‘‘(xi) 1-pentyl-3-(4-chloro-1-naphthyl)indole (JWH-388);’’

‘‘(xii) 1-(5-fluoropropyl)-3-[1-

naphthyl]indole (AM2201);

‘‘(xiii) 1-phenyl-3-[2-

iodobenzoyl]indole (AM6949);

‘‘(xiv) 1-(2-

iodobenzoyl)indole (SR-19 and RCS-8); and

‘‘(xv) 1-pentyl-3-[2-

chlorophenylacetyl]indole (JWH-263).’’

(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:

‘‘(1) 4-methylmethcathinone (Mephedrone),

‘‘(2) 3,4-methylenedioxy-vanvaleron (MDPV),

‘‘(3) 2-(2,5-Dimethoxy-4-

(ethyl)ethanamine (2C-E).

‘‘(4) 2-(2,5-Dimethoxy-4-

(methyl)ethanamine (2C-D).

‘‘(5) 2-(4-Chloro-2,5-

(dimethoxy)ethanamine (2C-C).

‘‘(6) 2-(4-Iodo-2,5-

(dimethoxy)ethanamine (2C-I).

‘‘(7) 2-(4-Ethylthio)-2,5-

(dimethoxy)ethanamine (2C-T-2).

‘‘(8) 2-(4-[4-isopropylthio]-2,5-

(dimethoxy)ethanamine (2C-T-4).

‘‘(9) 2-(2,5-Dimethoxyphenethyl)ethanamine (2C-H).

‘‘(10) 2-(2,5-Dimethoxy-4-nitro-

phenethyl)ethanamine (2C-N).

‘‘(11) 2-(2,5-Dimethoxy-4-n-

propylphenethyl)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. 812(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, provides 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 individual 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 something 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. 2123 be withdrawn.

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

AMENDMENT NO. 214, AS MODIFIED

Mr. LEAHY. Mr. President, I commend you 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, including 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 public information.

For more than four decades, the Freedom of Information Act has been an indispensable 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 senator from New Mexico.

AMENDMENT NO. 211

(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. 211.

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. KLOBUCAR, Mr. MERKLEY, and Mr. SANDERS, proposes an amendment numbered 211.

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

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

The amendment (No. 211), as modified, was agreed to.

The PRESIDING OFFICER. The amendment (No. 211), as modified, was agreed to.

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, KLOBUCAR, MERKLEY, and Mr. 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 practice that is the 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 brand-name pharmaceutical companies and generic manufacturers.

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-name Lipitor had earned $12.7 billion in sales the year before.

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 $295.1 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.

I actually received 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 brand-name companies to develop innovative new medicines. Unfortunately, pay-for-delays 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, the 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.

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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-name Lipitor had earned $12.7 billion in sales the year before.

According to the bill I sent to the FDA Deputy Commissioner 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 cost of 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 paid for 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 profi- ligacy, health care providers 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 profi- ligacy” because insurers and health care providers say there is a strong effort to reduce medical costs under control.

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 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 profits 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
tivity 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 under-
planeed and underfunded.

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 accumula-
tion 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 micro-
processors, all of which are necessary
precursors to what Saverin and his co-
horts created via Facebook.

And let’s not forget, a non-corrupt
legal system, which decided a case in
which the American worker would love to
have the proper capital gains rate, which dis-
proportionately goes to the highest in-
come 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 Cal-
ifornia—defy on their nation’s love for
tax dodging is un-American.’’

Really? Silly me. I thought that re-
nouncing 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 defini-
tion—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
write about 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; discrimina-
tory. It targeted a particular race of
people—the Jewish people—and—pun-
ished 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 re-
side permanently in a foreign country.
It is the act of renouncing one’s U.S.
citizenship—for the purpose of avoiding
taxes—that trigger our bill.

Our proposal is the only 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.

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

Mr. Saverin is, in essence, an eco-

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 odious, but it is in a bunch of these
right-wing blogs.

On right wing blogs of course it is absurd.

And when a view this irrational has
overaken one end of the political spec-
trum, it has serious, negative con-
sequences for our ability to solve our
nation’s problems.

If those on the other side of the nego-
tiating table are this obsessive on
taxes—that they consider their mini-

tization a higher priority than pre-
serving 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 Repub-
licans have for years claimed that def-
icit reduction was their top priority.

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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 came 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 the far right’s idolatry on taxes. Now it was defense spending, right?

Thought we had finally figured out a mechanism that would ensure all taxes. But sometimes, as with the tax cuts, this is not just about the size of government. It is 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 the tax cuts, this 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 spaws. 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 and others like it, that drowns out all other values that guide our actions.

Thank you. I yield the floor.

The PRESIDING OFFICER. The senior Senator from Wisconsin?

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. 419, 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 we 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. But patients who 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. It will authorize the FDA to collect almost $600 million in user fees over 5 years. The FDA can use these additional resources to 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 new devices.

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 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. 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 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 running the 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 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 bill it 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 ADHD since she was 14. Like most people with severe ADHD, she must take her medicine at a certain time every day to keep her ADHD 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 that a drug is easy 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 shortages.

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 of any expected drug shortages.

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 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 running the providers, and pharmacists are working around the clock to ensure patients maintain access to drugs and safe treatments.

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This winter, thanks to open communication between the FDA and drug companies, the FDA successfully avoided a shortage of methotrexate, a vital cancer medication. The FDA collaborated with Illinois-based generic drug manufacturer, Hospira, to increase production of this life-saving drug when another company halted production. Requiring 6 months advance notice of a 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 or other drugs. Adulterated and counterfeit drugs can have deadly consequences, yet the penalty for committing these crimes is less than the penalty for selling a counterfeit designer perfume.

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 new drugs 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, 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. But 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 vitamins, minerals and other substances, 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 dietary supplements. I want to make clear what this is about.

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 what children are taking? We have asked 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 matter was ordered to be printed in the RECORD, as follows:


DEAR SENATOR DURBIN: The Center for Science in the Public Interest is pleased to support your 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 require registration with the FDA. Much more real 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.

CHUCK BELL, Director, Programs Consumers Union.

IOANA RUSU, Regulatory Counsel Consumers Union.

Mr. DURBIN. I ask my colleagues when this vote comes before us, before another death that turns out to be 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.

Mr. VITTER. Madam President, I rise to strongly support the upcoming Bingaman-Vitter amendment, which is basically an amendment form that Bingaman-Vitter 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 drug manufacturer to restrict 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 deals 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 not 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 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 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 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, 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 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. 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. 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, 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 they do not lead to higher costs. In fact, some settlements can actually expedite generic drugs coming to market. According to
The years 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. CRAP) and the Senator from Texas (Mr. HU Pas)

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
Bingaman
Boxer
Brown (01)
Cardin
Conrad
Durbin
Feinstein
Franken
Gillibrand

NAYS—67

Alexander
Ayotte
Barrasso
Baucus
Beigh
Bennet
Blumenthal
Boozman
Brown (MA)
Burr
Cantwell
Carper
Casey
Chambliss
Coats
Cuburn
Cochran
Collins
Coons
Corker
Corzine
DeMint
Enzi

Blumenthal
Crapo

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.

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 for is that the agency that has oversight of our fisheries 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.

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

Alaska
Ayotte
Baucus
Blumenthal
Coons
Coats
Carper
Brown (OH)
Boozman
Barrasso
Alexander
Gillibrand
Feinstein
Durbin
Collins
Cochran
Coburn
Cantwell
Boxer
Begich
Ayotte
Akaka
 NOT VOTING—4
Blumenthal
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 and Innovation Act that addresses a growing public threat in Tennessee and Connecticut across our 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 be 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 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 Wurmser 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. It is in the fight we have 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 additions. This crime, of course, has doubled by 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, local and 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 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 a State 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’ intelligence.

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 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 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.

I would say that our amendment has no effect on direct spending or revenues over the 10-year period. The amendment I want to mention also has to do with substance abuse—about the dangers of what we unfortunately all hear 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 that, Madam Secretary, 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 Settings done.

I am particularly proud to support this bill because of what it 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 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 neuro-muscular disease and is the leading genetic cause of infant deaths. Of course, of course, there are 200,000 babies born that family every year. 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 Burnett 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.

Currently, the FDA is currently underpay 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, which 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 included 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.

If we pass the TREAT Act, 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 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 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 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 of the same opinion leaders 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 the resources and revenue 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 complicity, compassionate human need, there is greed. Where there is greed, there are 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 do we know 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 130 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 public health. 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 a quorum.

I yield the floor.

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 our constituents. It is clear that the FDA is working to bring generics to market now are generic, and over the last decade consumers have saved $331 billion on their drug costs as a result. There is clearly a balance in the system, and mechanisms within that system work 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.

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

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

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

Mr. HARKIN. 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.

Mr. HARKIN. I suggest the absence of a quorum.

The clerk will call the roll.

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

Mr. HARKIN. Without objection, it is so ordered.

Mr. CARPER. Without objection, it is so ordered.

The clerk will call the roll.

Mr. CARPER. I ask unanimous consent to call the roll.

Mr. CARPER. I ask unanimous consent to call the roll.

Mr. HARKIN. I suggest the absence of a quorum.

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

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

Mr. HARKIN. Without objection, it is so ordered.

The clerk will call the roll.

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

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

The clerk will call the roll.

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

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

AMENDMENT NO. 2131

Mr. CARPER. Madam President, we have three counties in Delaware.
southernmost county is called Sussex County. Several years ago, I was privi-
egated to visit a Methodist Church there and speak as a lay speaker to try to en-
courage people to become mentors.

The minister that day was a great old guy named John Seely who, I now de
ceeed, 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 coun-
try is they want us to work togeth-
her—well, maybe the two main things are they want us to work togeth-
her—they want, Democracy and Repub-
licans 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 environ-
ment for job creation and job preserva-
tion. They want us to do things that are going to encourage the cre-
ation 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 the recent history. We have had kind of an an-
alogue system, and to bring it into the digital age.

Patent reform was another signifi-
cant step forward earlier this year, where we said enough of this patent pa-
trol—people who come in after some-
one 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 legis-
lation, if you are first to file, you are first to file, and that is your patent.

Other examples of bipartisan legis-
lation we worked on, in one case the Transportation bill—land transpor-
tation: 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 transpor-
tation needs and make sure the 3 mil-
lion people who are working on trans-
portation and transit projects across the country don’t 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 Rep-
resentatives will pass the bill—they need to—to confer too, and help fix that problem. But there is good bipartisan legislation here to ef-
flect 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 ex-
amples.

In terms of actually doing things that help create jobs and preserve jobs, every one of the items I just mentioned does create a nurturing environ-
ment for job creation and job preserva-
tion. In the coming weeks, we also want to work on agricultural legis-
alation—a bipartisan bill, again, out of the Agriculture Committee that will help farmers and workers 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 legis-
lation helps to bolster the home build-
ing capacity of an industry 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 an-
other bipartisan piece of legislation, as we know, the Food and Drug Adminis-
tration Safety and Innovation Act, af-
fectionately known by its acronym, I don’t like acronyms, but I love this one. It is called PDUFA. So it is the Food and Drug Administra-
tion has the resources they need to do their job. As the other bills passed by the Senate I just talked about, this bill helps to create a more nurturing environ-
ment for those businesses to thrive.

What 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 there are some problems 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 suc-
cess of 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 their job. But we need some additional help, and this legis-
lation would do that, paid for by the in-
dustries that are seeking the consider-
ation 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 de-
vice industries to help cover the FDA’s costs for reviewing new drugs and med-
ical 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 af-
fectionately 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 begin to lay off. I am afraid the FDA would lose 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 thera-
pies, as well as pharmaceutical and medical device industry jobs and America’s global leadership in bio-
medical 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 systems 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 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 of 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 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 at some time go by, even if 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, so 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 competitive drug market 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 today 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 drugs and medicines are to our 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 and ineffective 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, true story, 99 percent of Canadian drugs and medicines are 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.

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.
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 wish to begin by touching upon 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 drugs 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 wish 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 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 painkillers 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, six of them were 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 forced to pain killers and their child was born addicted to drugs. He wanted more than anything to be a hardworking 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 base- ment 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 21 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 talk 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 the state of West Virginia, has done 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 West Virginia 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 addicted to 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 West Virginians and all our year-old girls out there 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 that this 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 Ken- tucky. Mr. Paul, followed by Senator McCaIN’s amendment, Senator SANDERs’ amendment, Senator DURBUn’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 in this committee 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 amendment. So I thank all the committee members 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 phar- macists 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 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 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 amend- ments rapidly and move to final pas- sage this afternoon.

I yield the floor.

The PRESIDING OFFICER. The Senator from Iowa.

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 to address this bill in exchange for those 7 minutes.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

AMENDMENT NO. 243

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

I rise in opposition to the Paul amendment. I oppose it for several rea- sons. Perhaps the most important rea- son is that this is a drug bill. This bill deals with drugs and devices. It does not deal with dietary su- pplements 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 the one we have. This bill is 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 that bill, this 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 back- seat to anyone in support for the vitamin, mineral, and supple- ment industry and their products. Sen- ator 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 im- plemented correctly since that time.

But the Paul amendment would go way too far. It is not consensus policy. In fact, it is very dangerous to the dietary supplement industry. I would note that the Natural Products Association, United National Products Alliance, and the Council on Respon- sible Nutrition, all three are big um- brella groups that oppose the Paul amendment. This would open this indus- try 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 do is allow people to sell products in their garages mixing it up and sell- ing 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 amend- ment.

I yield the floor.
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. BLMUMENTHAL), the Senator from California (Mrs. HUTCHISON), 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 any other Senators in the Chamber desiring to vote?

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

[Roll Call Vote No. 107 Leg.]

**YEAS—78**

Alexander
Barrasso
Baucus
Begich
Bingaman
Blumenthal
Brown (MA)
Burr
Casey
Chambliss
Coats
Collins
Conrad
Corker
Coons
Corker
Ayotte
Boozman
Coburn
Coryn
Crapo

**NAYS—15**

Avery
Boosman
Bennett
Bingaman
Boxer
Brown (OH)
Collins
Conrad
DeMint
DeMint
DeMint
Franken
Graham
Graeme
Heller
Johnson (SD)
Kentucky
Kohl
Leak
Lee

[Roll Call Vote No. 108 Leg.]

**YEAS—43**

Alexander
Barrasso
Baucus
Begich
Bingaman
Boxer
Brown (MA)
Burr
Casey
Chambliss
Coats
Collins
Corker
Coons
Corker

**NAYS—54**

Allen
Alexander
Ayotte
Barrasso
Baucus
Begich
Bingaman
Boxer
Brown (MA)
Burr
Casey
Chambliss
Coats
Collins
Corker
Coons
Corker

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 on 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 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 misconduct in addition, such liability may not reflect fraud. The amendment would discourage the development of new cures for patients. If manufacturers 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. KIRK. I ask for the yeas and nays.

The PRESIDING OFFICER. The amendment is rejected.

Mr. DURBIN. I thank the Chair.

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 a new and large number 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.

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

Mr. BURREN. Mr. President, I ask unanimous consent to withdraw the Burr amendment No. 2130.

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 PRESIDING OFFICER. All time given on the other side.

Mr. DURBIN. Mr. President, I ask unanimous consent to have the same amendment that was imported into the United States, to register your product, the ingredients of it, or 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 a new and large number 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.

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

Mr. BURREN. Mr. President, I ask unanimous consent to withdraw the Burr amendment No. 2130.

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.

Mr. BURREN. I thank the Chair.

The clerk will call the roll.

The PRESIDING OFFICER. The Senator from Connecticut (Mr. BLUMENTHAL) is necessarily absent.

The following Senators are not voting: 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:

[Roll Call Vote No. 109 Leg.]

YEAS—9

Bennet
Brown (OH)
Durbin
NAYS—88

Akaka
Alexander
Ayotte
Barrasso
Baucus
 Begich
Bingaman
Blumenthal
Boozman
Blunt
Boozman
Boxer
Brown (MA)
Burr
Cantwell
Cardin
Carper
Casey
Chambliss
Coats
Coons
Collins
Conrad
Cooney
Corcoran
Cornyn
Crapo
DeMint
Enzi
Feinstein
Gil目的地
Blumenthal
Hutchison
Kirk

NOT VOTING—3

The PRESIDING OFFICER. Under the previous order requiring 60 votes
The motion was agreed to. 

Mr. HARKIN. Madam President, I move to consider 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 that 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 we 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 fails 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, impair the Secretary's 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).

Mr. HARKIN. The managers' amendment to S. 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.

The Secretary to withdraw an accelerated approval if the required studies fail to verify and describe the predicted effect on the surrogate endpoint or predicted clinical outcome, i.e., verification of the predicted clinical benefit. In addition, the bill now requires 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 amendment requires that FDA determine that a surrogate or clinical endpoint is reasonably likely to predict 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 506(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 note 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)(2) 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 opioid drugs by tightening restrictions on hydrocodone. Opioid 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, 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 increase in 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.
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 to 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 the problem of requiring all manufacturers 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, and would 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 undertaken by the FDA and industry to develop a transitional pathway for the regulation of emergency medications. 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 diagnostic pathway and steps taken related to increasing patient access. 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 profit best in the much larger adult population.

With respect to mechanical obstacles, young children often cannot swallow low 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 make recruiting 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 may hesitate to treat 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 BPCA was enacted, it allows the 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 of 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 was enacted, 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 renews 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.

Furthermore, 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 increased, and I believe that little has been 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 of. And they have taken advantage—from adulteration, to counterfeiting, to cargo theft, to manufacturing drugs in unsanitary conditions, to mislabeled cargo. 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 thousands of 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 2008, 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 of these products 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, Madam President, under 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 manufacturer 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 admission 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, the 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 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 public health. This legislation will promote competition in the marketplace and save the public 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...
I78 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 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's formulary that a drug is not 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.

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 horrific 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 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, reducing the harm for cancer and the 1.5 million 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 authorize 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. Everyone 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 abandon the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient sec-
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. KNUCKLE).

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.]

Sec. 101. Short title.
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.

TITLES I—FEES RELATING TO DRUGS
Sec. 101. Short title.
Sec. 102. Authority to assess and use drug fees.
Sec. 103. Reauthorization; reporting requirements.
Sec. 104. Sunset dates.
Sec. 105. Effective date.
Sec. 106. Amendment with respect to misbranding.
Sec. 107. Savings clause.

TITLES II—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS
Sec. 101. Short title; finding.
Sec. 102. Fees relating to biosimilar biological products.
Sec. 103. Reauthorization; reporting requirements.
Sec. 104. Sunset dates.
Sec. 105. Effective date.
Sec. 106. Savings clause.
Sec. 107. Conforming amendment.

TITLES III—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS
Sec. 101. Short title; finding.
Sec. 102. Fees relating to biosimilar biological products.
Sec. 103. Reauthorization; reporting requirements.
Sec. 104. Sunset dates.
Sec. 105. Effective date.
Sec. 106. Savings clause.
Sec. 107. Conforming amendment.

TITLES IV—FEES RELATING TO MEDICAL DEVICES
Sec. 101. Permanent.
Sec. 102. Written requests.
Sec. 103. Communication with Pediatric Review Committee.
Sec. 104. Access to data.
Sec. 105. Ensuring the completion of pediatric studies.
Sec. 106. Pediatric study plans.
Sec. 107. Reauthorizations.
Sec. 108. Report.
Sec. 109. Technical amendments.
Sec. 110. Relationship between pediatric labeling and new clinical investigation exclusivity.
Sec. 111. Pediatric rare diseases.

TITLES V—MEDICAL DEVICE REGULATORY IMPROVEMENTS
Sec. 101. Reclassification procedures.
Sec. 102. Condition of approval studies.
Sec. 103. Postmarket surveillance.
Sec. 104. Sentinel.
Sec. 105. Condition of approval studies.
Sec. 106. Clinical holds on investigational device exemptions.
Sec. 107. Unique device identifier.
Sec. 108. Clarification of least burdensome standard.
Sec. 109. Custom devices.
Sec. 110. Agency documentation and review of certain decisions regarding devices.
Sec. 111. Good guidance practices relating to devices.
Sec. 112. Modification of de novo application process.
Sec. 113. Humanitarian device exemptions.
Sec. 114. Reauthorization of third-party re-review and inspections.
Sec. 115. 510(k) device modifications.
Sec. 116. Health information technology.

TITLES VI—DRUG SUPPLY CHAIN
Subtitle A—Drugs Supply Chain
Sec. 101. Registration of domestic drug establishments.
Sec. 102. Registration of foreign establishments.
Sec. 103. Identification of drug excipient information with product listing.
Sec. 104. Electronic system for registration and listing.
Sec. 105. Risk-based inspection frequency.
Sec. 106. Records for inspection.
Sec. 107. Failure to allow foreign inspection.
Sec. 108. Exchange of information.
Sec. 109. Enhancing the safety and quality of the drug supply.
Sec. 110. Accreditation of third-party auditors for drug establishments.
Sec. 111. Standards for admission of imported drugs.
Sec. 112. Notification.
Sec. 113. Protection against intentional adulteration.
Sec. 114. Enhanced criminal penalty for counterfeiting drugs.
Sec. 115. Extraterritorial jurisdiction.
Sec. 116. Compliance with international agreements.

Subtitle B—Pharmaceutical Distribution Integrity
Sec. 117. Short title.
Sec. 118. Securing the pharmaceutical distribution supply chain.
Sec. 119. Independent assessment.

TITLES VII—GENERATING ANTIBIOTIC INCENTIVES NOW
Sec. 101. Extension of exclusivity period for drugs.
Sec. 102. Priority review.
Sec. 103. Fast track product.
Sec. 104. GAO study.
Sec. 105. Clinical trials.
Sec. 106. Regulatory certainty and predictability.

TITLES VIII—DRUG APPROVAL AND PATIENT ACCESS
Sec. 101. Enhancement of accelerated patient access to new medical treatments.
Sec. 102. Breakthrough therapies.
Sec. 103. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments.
Sec. 104. Accessibility of information on prescription drug container labels by visually-impaired and blind consumers.
Sec. 105. Risk-benefit framework.
Sec. 106. Independent study on medical innovation impact model.
Sec. 107. Orphan product grants program.
Sec. 108. Reporting of inclusion of demographic subgroups in clinical trials and data analysis in applications for drugs, biologics, and devices.

TITLES IX—OTHER PROVISIONS
Subtitle A—Reauthorizations
Sec. 101. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.
Sec. 102. Reauthorization of the Critical Path Public-Private Partnerships.

Subtitle B—Medical Gas Product Regulation
Sec. 101. Regulation of medical gas products.
Sec. 102. Regulations.
Sec. 103. Applicability.

Subtitle C—Miscellaneous Provisions
Sec. 101. Advisory committee conflicts of interest.
Sec. 102. Guidance document regarding product promotion using the Internet.
Sec. 103. Electronic submission of applications.
Sec. 104. Combating prescription drug abuse.
Sec. 105. Tanning bed labeling.
Sec. 1126. Optimizing global clinical trials.

Sec. 1127. Advancing regulatory science to promote public health innovation.

Sec. 1128. Drug development and testing.

Sec. 1129. Patient participation in medical product discussions.

Sec. 1130. Strategic integrated management plan.

Sec. 1131. Drug development and testing.

Sec. 1132. Patient participation in medical product discussions.

Sec. 1133. Nanotechnology regulatory program.

Sec. 1134. Online pharmacy report to Congress.

Sec. 1135. May 25 May 25 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. Reports by small businesses.

Sec. 1139. Protections for the commissioned corps of the public health service act.

Sec. 1140. Recommendations 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.

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 (U.S.C. 301 et seq.) or of the Controlled Substances Act (21 U.S.C. 801 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 “incuriously” and inserting “unexpectedly.”

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 last sentence of paragraph (1), by striking “fiscal year 2008” and inserting “fiscal year 2013”;

(B) in paragraph (1), in clauses (1) and (i) of subparagraph (A), by striking “subsection (c)(5)” each place such term appears and inserting “subsection (c)(4)”; and

(C) in the following clause (i) in paragraph (2)(A)—

(i) by striking “subsection (c)(5)” and inserting “subsection (c)(4)”; and

(ii) by striking “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)(C), in clauses (i) and (ii)—

(i) by striking “subsection (c)(5)” and inserting “subsection (c)(4)”;

(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

(E) by amending subparagraph (B) to read as follows:

“(B) EXCLUSION.—A prescription drug product shall not be assessed a fee under subparagraph (A) if such product—

(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(s); and

(II) is not in the list of discontinued products compiled under section 505(j)(7); and

(iii) the same product as another product that was approved under an abbreviated application filed under section 505(s) on or before the date 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 “$492,783,000” and inserting “$492,783,000; and”;

(iii) in paragraph (2), in subparagraphs (A) and (B)—

(I) by striking “subsection (c)(5)” and inserting “subsection (c)(4);” and

(II) 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 fiscal year by the amount equal to the sum of—

(A) one;

(B) the average annual percent change in the consumer price index for all urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of all costs other than personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, and

(C) the average annual percent change in the consumer price index for all urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 fiscal years, and

(D) the dollar amount equal to the inflation adjustment for fiscal year 2013 (as determined under paragraph (3)(A)); and

(E) the dollar amount equal to the workload adjustment for fiscal year 2013 (as determined under paragraph (3)(B));”;

(2) WORKLOAD ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, after the fees revenues established in subsection (b) are adjusted for a fiscal year for a fiscal year in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload for the review of human drug applications, as described in subsection (c)(5) of this section, and the total number of active commercial investigational new drug applications (adjusted for changes in review activities, as described in the 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 under paragraph (1)."

"(C) The Secretary shall contract with an independent accounting or consulting firm to periodically review the adequacy of the adjustment in accordance with 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)."

"(D) In paragraph (4)—

(i) by striking “fiscal years 2008 through 2013” and inserting “fiscal years 2013 through 2016”; and

(ii) by striking “fiscal year 2011” and inserting “fiscal year 2016”;

(iii) by striking “fiscal years 2008 through 2013” and inserting “fiscal years 2013 through 2016”; and

(iv) by striking “fiscal year 2012” and inserting “fiscal year 2017”.

"(E) The Secretary shall, if warranted, adopt appropriate changes to the methodology. If the Secretary adopts changes to the methodology based on the first review shall be effective for the first fiscal year for which fees are set after the Secretary adopts such changes and each subsequent fiscal year.

"(F) REPORTING REQUIREMENTS.—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 for collection of user fees 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 fiscal year, the reduction in such balances shall be made.

"(G) ANNUAL FEE SETTING.—For fiscal year 2017, 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, the amount under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).

"(H) 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

"(I) in paragraph (3), by striking “fiscal years 2008 through 2012” and inserting “fiscal years 2013 through 2016”.

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 help expedite the 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.

“(a) Section 737 (21 U.S.C. 379j) is amended—

(1) in paragraph (9), by striking “incurred” after “expenses”;

(2) in paragraph (10), by striking “October 1, 2001” and inserting “October 1, 2011”;

(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 USE DEVICES FEE.

(a) Types of Fees.—Section 738(a) (21 U.S.C. 379j(a)) is amended—

(1) in paragraph (1), by striking “fiscal year 2007” and inserting “fiscal year 2015”;

(2) in paragraph (2)(A)—

(A) in the matter preceding clause (i)—

(i) by striking “subsections (d) and (e)” and inserting “subsections (a), (d), (e), and (f)”;

(ii) by striking “October 1, 2002” and inserting “October 1, 2012”; and

(iii) by striking “subsections (c)(1)” and inserting “subsections (c)(1) and (2)”; 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 (i)” 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 under this title.”;

(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:

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“(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. 379f(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 base inflation adjustment under subsection (b) and the adjustments provided under this 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 specified in such subsection.

“(B) ANNUAL ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—For fiscal year 2014 and each subsequent fiscal year, the product of—

(i) the base inflation adjustment under subparagraph (C) for such fiscal year; and

(ii) the adjustment to the base inflation adjustment under subparagraph (D) for the fiscal years preceding such fiscal year, beginning with fiscal year 2014.

“(D) ADJUSTMENT TO BASE FEE AMOUNTS.—For each of the fiscal years 2014 through 2017, the base fee amounts specified in subsection (b) shall be adjusted as needed, on a uniform percentage 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 the fiscal years 2014 through 2017, after the base fee amounts specified in subsection (b)(2) are adjusted under paragraph (2)(D), the 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).

“(4) FEE WAIVER OR REDUCTION.—Section 738 (21 U.S.C. 379f) 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 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(b)(1)(A) (21 U.S.C. 379f(b)(1)(A)), as redesignated by subsection (d)(1), is amended by striking “$255,720,000” and inserting “$280,587,000”.

“(f) CREDITING AND AVAILABILITY OF FEES.—Section 738(b)(1) (21 U.S.C. 379f(b)(1)), as redesignated by subsection (d)(1), is amended—

(1) in paragraph (1), by striking “ Fees authorized under “Subject to paragraph (2)(C), fees authorized”:

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) in the phrase “shall be retained”, striking “shall be retained” and inserting “subject to subparagraph (C), shall be collected and available”; and

(ii) in clause (1)—

(I) by striking “collected and” after “shall only be”; and

(II) by striking “fiscal year 2002” and inserting “fiscal year 2010”;

(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.”.

“(g) FEE WAIVER OR REDUCTION.—For each of 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”.

“4. CONFORMING AMENDMENTS.—Section 515(c)(4)(A) (21 U.S.C. 360e(c)(4)(A)) is amended by striking “738(e)” and inserting “738(h)”.

SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) REAUTHORIZATION.—Section 738(b)(21 U.S.C. 379f–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 738(a) (21 U.S.C. 379–1(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. 379 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 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 (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 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:

"(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(b)).

"(c) Objectives Specified.—The objectives specified in this subsection with respect to the activities under subsection (b), the goals referred to in section 738(a)(1).

"(d) Internal Controls.—The Secretary shall establish 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 1 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 ASSOCIATE 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. 741A. DEFINITIONS.

"For purposes of this part:

"(1) The term 'abbreviated new drug application'—

"(A) means an application submitted under section 505(j), an abbreviated new drug application submitted under section 507 (as in effect on August 17, 1962) for the purpose of securing a new drug application for 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.

"(B) means the activities following the 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.

"(8) The term 'human generic drug activities' means the activities necessary for the review of generic drug submissions, including review of drug master files referenced in such submissions.

"(B) The issuance of—

"(1) approval letters which approve abbreviated new drug applications or supplements to such applications; or

"(2) 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—

"(1) sets forth in detail the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve such deficiencies; or

"(2) 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:

"(2) Collecting, developing, and reviewing safety information on approved drugs, including adverse event reports.

"(2) Developing and using improved adverse-event data-collection systems, including information technology systems.

"(3) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

"(4) Implementing and enforcing section 506(c) (relating to postapproval studies and clinical evaluations and, where appropriate, decisions to withdraw approval.

"(5) Regulatory science activities related to generic drugs.

"(6) The term 'postmarket pharmacovigilance' drug' has the meaning given to the term 'postmarket pharmacovigilance drug' in section 202(i)(1), except that paragraph (1)(B) of such section shall not apply.

"(7) 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 committees and contractors;

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

"(C) research, development, 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 ACCESS AND USE HUMAN GENERIC DRUG FEES.

(a) Types of Fees.—Beginning in fiscal year 2015, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) On-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 on-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).

(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 or that owns a Type II active pharmaceutical ingredient drug master file, the drug master file must be deemed available for reference by the Secretary.

(B) 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 a drug master file fee for a Type II active pharmaceutical ingredient drug master file, the person shall not be required to pay a submission fee for a Type II active pharmaceutical ingredient drug master file referenced in such a generic drug submission.

(ii) the Secretary may determine, in accordance with criteria to be established by the Secretary, that a drug master file has not failed an initial completeness assessment, in accordance with criteria to be published by the Secretary, and is available for reference.

(3) Fiscal Year 2013. For fiscal year 2013, such fees shall be due on the later of—

(i) 30 calendar days after publication of the notice required in clause (i) of subparagraph (C); 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.

(B) 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); or

(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 fiscal year 2013, the Secretary shall publish a notice in the Federal Register 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

(iv) the fees established under subparagraph (A) shall be established under subsection (d).

(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.

(A) IN GENERAL.—Each applicant that submits a generic drug submission that is pending or approved to produce one or more finished dosage forms of a human generic drug that contains 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 to produce one or more finished dosage forms of a human generic drug shall be assessed an annual fee for each such facility.

(B) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (d).

(B) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (d).
"(2) FISCAL YEARS 2014 THROUGH 2017.—For each of fiscal years 2014 through 2017, the fees under subsection (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 last business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this subsection for such year.

"(3) DATES 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 via that gateway that such submission 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 closed, but 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.—For fiscal year 2013—

"(A) the Secretary shall establish, by October 1, 2012, the amount to be derived from fees under subsection (a) (relating to active pharmaceutical ingredient facilities), based on the revenue amounts established under subsection (b); and

"(B) the amount equal to the fee master file fee established in subsection (a)(2) for such submission.

"(2) 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 consumer price index for all urban consumers during the most recently preceding 12-month period, for 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-PA region) during the most recently preceding 4 fiscal years; and

"(D) 14 percent shall be derived from fees under 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 such each such facility, site, or organization. The notice required by this paragraph shall specify the type of information to be submitted and the format and procedures for submission of such information.

"(2) REQUIRED SUBMISSION OF FACILITY IDENTIFICATION.—Each person that owns or is responsible for an active pharmaceutical ingredient facility fee and active pharmaceutical ingredient fee for a fiscal year, based on the revenue amounts established under subsection (b).

"(3) FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT FACILITIES.—

"(A) the Secretary shall establish, by October 1, 2012, the one-time generic drug backlog fee for generic drug applications pending on October 1, 2012, the one-time generic drug backlog fee for such fiscal year and the active pharmaceutical ingredient fee under subsection (c) for such fiscal year, based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).

"(4) 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) the amount equal to the final year fee established in subsection (a)(2) for such submission.

"(5) 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.

"(e) IDENTIFICATION OF FACILITIES.—

"(1) PROVISION OF NOTICE; DEADLINE FOR COMPLIANCE.—Not later than October 1, 2012, the Secretary shall publish in the Federal Register a notice requiring that 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 format and procedures for submission of such information.

"(2) REQUIRED SUBMISSION OF FACILITY IDENTIFICATION.—Each person that owns or is responsible for an active pharmaceutical ingredient facility fee and active pharmaceutical ingredient fee for a fiscal year, based on the revenue amounts established under subsection (b).

"(3) CONTENTS OF NOTICE.—At a minimum, the information required by paragraph (2) shall include—

"(A) identification of a facility identified or intended to be identified in an approved or pending application for a master file; and

"(B) whether the facility manufactures active pharmaceutical ingredients or finished dosage forms, or both.

"(4) CONTENTS OF NOTICE.—At a minimum, the information required by paragraph (2) shall include—

"(A) whether the facility manufactures active pharmaceutical ingredients or finished dosage forms, or both; and

"(B) whether the facility manufactures drugs that are not generic drugs.
subparagraph (B) shall submit to the Secretary information concerning the ownership, name, and address of the site or organization.

(1) REFERENCES AND ORGANIZATIONS.—A site or organization is described in this subparagraph if it is identified in a generic drug submission and is:

(i) a sponsor in which a bioanalytical study is conducted;

(ii) a clinical research organization;

(iii) a contract analytical testing site; or

(iv) a contract repackager site.

(2) NOTICE.—The Secretary may, by notice published in the Federal Register, specify the sites for which 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 504(h) 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 fee being due on each subsequent new drug application 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.—(i) Failure to pay the fee under subsection (a)(2)(A) 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.

(ii) 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.

(iii) The Secretary shall notify the sponsor of the 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.

(B) NONRECEIVABLE FOR NONPAYMENT.—(i) If an abbreviated new drug application or supplement to an abbreviated new drug application submitted on or after October 1, 2012, references a drug master file that has not been paid or the facility is removed from all generic drug submissions that refer to the facility.

(ii) NONRECEIvable FOR NONPAYMENT.—(i) The Secretary shall notify the sponsor of the new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of section 505(j)(5)(A).

(3) DRUG MASTER FILE FEE.—

(A) IN GENERAL.—The fees authorized by this subsection are payable to the Secretary for 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 if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

(B) LIMITATION.—(i) In general.—Fees authorized under subparagraph (a)(3) 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) 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 appropriation Acts.

(4) 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 (a)(3) as adjusted under subsection (c), if applicable, or as otherwise affected under paragraph (2) of this subsection.

(5) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a)(3) on or before the due date for such fee, the Secretary shall credit such amounts to the fee account and remain available until expended.

(6) USE OF DRUG ADMINISTRATION SALARIES AND EXPENSES FOR HUMAN GENERIC DRUG ACTIVITIES.—The sums transferred shall be available solely for human generic drug activities.

(7) 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 appropriation 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 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.
SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) Authorization.—The amendments made by section 302 cease to be effective on January 31, 2018.

(b) Reporting Requirements.—The amendments made by section 303 cease to be effective on January 31, 2018.

SEC. 305. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or 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:

"(a) If it is a drug containing 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 activities"; and

(B) by striking the period at the end and inserting "are activities";

(2) by adding at the end the following:

"(2) objectives specified in this subsection are—

(A) with respect to the activities under subsection (b)(1), the goals referred to in section 738A(a)(1); and

(B) 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 303(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 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 12 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 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 71 (21 U.S.C. 379f et seq.) is amended, by adding after section 712, as added by title III of this Act, the following:

"(1) Authorization.—The amendments made by section 302 cease to be effective on October 1, 2017.

(2) Reporting Requirements.—The amendments made by section 303 cease to be effective on January 31, 2018.

SEC. 305. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or 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.".
**PART 8—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS**

**SEC. 744G. DEFINITIONS.**

"For purposes of this part:

(1) The term ‘adjustment factor’ applicable to a particular fiscal year that is in 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 or references a product that is a blood product for topical application licensed before September 1, 1992, or a large volume parenteral drug 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 business entity if, directly or indirectly—

(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’ means—

(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 any study results.

(9) The term ‘costs of resources allocated for the process for the review of biosimilar biological product applications’ means the expenses within 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 (including contractors) 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 ‘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 not necessary, consistent with the best interests of public health; 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.

(11) The term ‘financial hold’ includes an affiliate of such person.

(12) The term ‘financial hold’ applies to—

(A) the activities necessary for the review of the biosimilar biological product applications; and

(B) any costs of resources allocated for the process for the review of biosimilar biological product applications.

(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 requesting that the Secretary take action to support a biosimilar biological product application, and supplements:

(A) The activities necessary for the review of submissions requesting that the Secretary take action to support a biosimilar biological product application, and supplements.

(B) Activities related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or identify 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(h) (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 ‘transition rule’ means a request to the Secretary to approve a change in a biosimilar biological product application for a new product that has been approved, including a supplement requesting that the Secretary determine that the biosimilar biologic 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 an approved investigational new drug application described under clause (ii) or a clinical protocol for an investigational new drug protocol described under clause (iii) shall pay a biosimilar biological product application and supplement 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 for a product that is consistent with such protocol described in section 351(k), 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.

(b)(1)(A) The initial biosimilar biological product development fee shall be due by the earlier of the following:

(1) Not later than 5 days after the Secretary grants a request described under section 351(k)(1), 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.

(2) 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:

(1) Not later than 60 days after the date of the enactment of the Biosimilars User Fee Act of 2012.
support a biosimilar biological product application.

“(D) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting, the Secretary shall not provide a biosimilar biological product development meeting regarding the product for which fees are owed.

“(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 the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application.

“(B) REDUCTION IN FEES.—Notwithstanding section 505(i)(2) of the Biologics Price Competition 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 for the time when such biosimilar biological product application was submitted, by the cumulative amount of fees paid under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

“(C) PAYMENT DEADLINE.—Any fee required by subparagraph (A) shall be due on 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 an investigational drug application that 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 any portion 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, unless the fee is waived under subsection (c).

“(G) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—

“(I) 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 establishment fee.

“(II) ASSESSMENT IN FISCAL YEARS.—The establishment fee shall be assessed at the time when such biosimilar biological product establishment that is listed in the application does not engage in the manufacture of the biosimilar biological product during such fiscal year.

“(B) ASSESSMENT IN FISCAL YEARS.—The establishment fee shall be assessed at the time when such biosimilar biological product establishment that is listed in the application does not engage in the manufacture of the biosimilar biological product during such fiscal year.

“(C) DUE DATE.—The annual establishment 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 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 year for which such fees applies.

“(D) EFFECT OF FAILURE TO PAY BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

“(i) NO BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT PROGRAM FEES.—If a person fails to pay any initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), a reactivation fee as required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting regarding the product for which fees are owed.

“(ii) NO REIMBURSEMENT FOR FILING OR SUBMISSION.—If a person has failed to pay any 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 refund any 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 refund any initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

“...
per biosimilar biological product establishment, notwithstanding the number of bio-
similar biological products manufactured at the establishment, subject to clause (ii).

(ii) The fees under subsection (a)(2)(A) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a human drug application described in section 738a(a)(1)(A)(i) for that fiscal year.

(E) BIOSIMILAR BIOLOGICAL PRODUCT EST-

ABLATION FEE.—The biosimilar biological product development 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 processing of biosimilar biological product applications.

(c) Application Fee Waiver for Small Biosimilar Biological Product

(i) Waiver of Application Fee.—The Secretary shall grant to a person who is granted such a waiver, the small business or its affiliate shall pay—

(A) an annual fee established under subsection (b)(1)(F); and

(B) all supplement fees for all supplement to biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business; and

(C) one fee per product per year. The biosimilar biological product application fee shall be paid only once for each product for each fiscal year.

(ii) Application fees paid under this subsection shall be transferred from the Food and Drug Administration account of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(iii) Effective Date.—The provisions of this subsection shall—

(A) apply to fees paid under this subsection after the enactment of the Food and Drug Administration Act providing for the collection and obligation of fees for such year under this section.

(b) Fee Setting and Amounts

(i) Establishment Fee.

The Secretary shall, within 30 days after it is due, such fees shall be paid only once for each product for each fiscal year.

(ii) Fee Setting and Amounts.

The 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) 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, fees authorized by this section for fiscal year 2013 may be collected and shall be credited to such account and remain available until expended.

(e) Collection of Unpaid Fees.

(i) In General.—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 parent or a subsidiary that is itself a small business.

(ii) 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 parent or a subsidiary that is itself a small business.

(iii) Application Fee Waiver for Small Biosimilar Biological Product

(A) Waiver of Application Fee.—The Secretary shall grant to a person who is granted such a waiver, the small business or its affiliate shall pay—

(i) the first business day on or after October 1 of each such fiscal year; and

(ii) the first business day after the enactment of the Food and Drug Administration Act providing for the collection and obligation of fees for such year under this section.

(B) Due Date.—The biosimilar biological product establishment fee for the fiscal year shall be due on the later of—

(i) the first business day on or after October 1 of each such fiscal year; and

(ii) the first business day after the enactment of the Food and Drug Administration 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 establishment fee shall be paid only once for each product for each fiscal year.

(D) Fee Setting and Amounts.

(i) Establishment Fee.

The Secretary shall, within 30 days after it is due, such fees shall be paid only once for each product for each fiscal year.

(ii) Fee Setting and Amounts.

The fees authorized by this section for fiscal year 2013 may be collected and shall be credited to such account and remain available until expended.

(f) Collection of Unpaid Fees.

(i) 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 shall be available only if appropriated such fiscal year.

(ii) 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.

(iii) Crediting and Availability of Fees.

(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 compile and 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 carrying out the goals and objectives described in section 401(b) of the Biosimilar User Fee Act of 2012 during 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 employees in the Food and Drug Administration and 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 (except as provided in subsection (c)) no less than $30,000,000, 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 2012 may be collected and shall be credited to such account and remain available until expended.

(e) 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 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 this subsection (a) within 30 days after it is due, such fees 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 fees collected under this subsection (a), a person shall submit to the Secretary a written request for such waiver or refund not later than 180 days after such fees are due.

(h) Construction.—This section may not be construed to require that the number of full-time equivalent positions in the Depart-

ment of Health and Human Services, 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 en-

gaged.
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 to initial pediatric study plans, agreed initial pediatric study plans, agreed initial pediatric study plans, and any changes made to the recommendations in response to such views and comments.

(a) AUTHORIZATION.—The amendment made by section 402 shall cease to be effective October 1, 2017.

(b) FILING REQUIREMENTS.—The amendment made by section 403 shall cease to be effective January 31, 2018.

(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.—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.

(2) IN GENERAL.—The Secretary shall conduct, with an independent accounting or consulting firm to study the workload volume and fee assessments associated with the process for the review of biosimilar biological product applications.

(3) FINAL RESULTS.—Not later than September 30, 2013, the Secretary shall publish, for public comment, interim results of the study described under paragraph (1).

(4) REAUTHORIZATION.—Not later than June 25, 2016, the Secretary shall publish, for public comment, the final results of the study described under paragraph (1).

(d) STUDY.—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; and

(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.

SEC. 504. SUNSET DATES.

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); and

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

(b) by inserting after subparagraph (A) the following:

(1) on or before October 1, 2012; or

(ii) the applicant submits a new timeline for studies or other conditions described in subsection (d) unless the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(i) the Secretary shall provide public notice in the Federal Register of such extension or retraction of the specified date; and

(ii) the application for such extension or retraction shall be submitted to the Secretary not less than 90 days prior to the date that the deferral would expire.

Not later than 3 years after the date of enactment of this Act, the Secretary shall

(a) issue pediatric studies of drugs as the Secretary determines that the conditions described in the preceding sentence in a manner consistent with how the Secretary makes such an extension.

(b) make public the information described in the proceeding sentence in a manner consistent with how the Secretary makes such an extension.

(c) as the Secretary determines such an extension, the specified date shall be the extended date.

(d) 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 applicant submits a new timeline for studies or other conditions described in subsection (d) unless the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(ii) the applicant submits a new timeline for studies or other conditions described in subsection (d) unless the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(iii) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(iv) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(v) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(vi) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(vii) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(viii) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(ix) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(x) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(xi) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(xii) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(xiii) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(xiv) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(xv) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(xvi) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(xvii) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(xviii) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(xix) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(xx) the Secretary determines that the conditions described in this subparagraph (I) continue to be met; and

(2) in paragraph (1), by striking ''on or before October 1, 2012,''; and

(3) in subsection (c), by adding at the end the following:

(i) PROVISIONS RELATING TO THE FOOD AND DRUG ADMINISTRATION.—The amendments made by section 401 shall cease to be effective October 1, 2017.

(b) EFFECTIVE DATE.

SEC. 504. SAVINGS CLAUSE.

Effective January 31, 2018.

 بلا فراغات في النص الطبيعي.
“(III) Projected completion date for pediatric studies.

“(IV) The reason or reasons why a deferral or deferral extension continues to be necessary.

“(II) in clause (i)—

“(I) by inserting ‘‘, as well as the date of each deferral or deferral extension, as applicable,’’ and that applicable requirements apply to an agreed initial pediatric study plan may be amended at any time. The requirements of paragraphs (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).

“(3) DEFINITIONS.—In this section—

“(A) IN GENERAL.—Section 505B (21 U.S.C. 355c) is amended to read as follows:

“(A) IN GENERAL.—Subsection (e) of section 505B (21 U.S.C. 355c) is amended by—

“(B) in paragraph (1), by inserting ‘‘DEFERRAL EXTENSIONS, after ‘‘DEFERRALS,’’; and

“(C) in the paragraph heading, by inserting ‘‘DEFERRAL EXTENSIONS, after ‘‘DEFERRALS,’’; and

“(II) by inserting ‘‘deferral extensions,’’ after ‘‘deferrals’’.

“(B) to revoke the license for a biological product, as well as the date of 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).

“(3) EFFECTIVE DATES.—This section—

“(A) IN GENERAL.—Subsection (e) of section 505B (21 U.S.C. 355c) is amended—

“(B) to insert ‘‘deferral extensions, after ‘‘deferral’’, and

“(C) in the paragraph heading, by inserting ‘‘DEFERRAL EXTENSIONS, after ‘‘DEFERRALS,’’; and

“(II) by inserting ‘‘deferral extensions,’’ after ‘‘deferrals’’.

“(B) in paragraph (1), by inserting ‘‘DEFERRAL EXTENSIONS, after ‘‘DEFERRALS,’’; and

“(C) in the paragraph heading, by inserting ‘‘DEFERRAL EXTENSIONS, after ‘‘DEFERRALS,’’; and

“(II) by inserting ‘‘deferral extensions,’’ after ‘‘deferrals’’.

“(B) in paragraph (1), by inserting ‘‘DEFERRAL EXTENSIONS, after ‘‘DEFERRALS,’’; and

“(C) in the paragraph heading, by inserting ‘‘DEFERRAL EXTENSIONS, after ‘‘DEFERRALS,’’; and

“(II) by inserting ‘‘deferral extensions,’’ after ‘‘deferrals’’.

“(B) in paragraph (1), by inserting ‘‘DEFERRAL EXTENSIONS, after ‘‘DEFERRALS,’’; and

“(C) in the paragraph heading, by inserting ‘‘DEFERRAL EXTENSIONS, after ‘‘DEFERRALS,’’; and

“(II) by inserting ‘‘deferral extensions,’’ after ‘‘deferrals’’.


“(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 group, 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); and

“(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.

“(III) if the Secretary determines that no meeting is necessary, shall notify the applicant and provide written comments of the Secretary as to whether such request meets the applicable requirements in subsection (a)(3), or fails to submit a request for approval of a pediatric formulation described in subsection (a)(2), and that applicable requirements apply to an agreed initial pediatric study plan may be amended at any time. The requirements of paragraphs (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).

“(2) AGreed initial pediatric study plan and activities—

“(A) IN GENERAL.—Subsection (e) of section 505B (21 U.S.C. 355c) is amended by—

“(B) 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 response of the Secretary shall include a recommendation from the Secretary as to whether such request meets the standards under paragraphs (3) or (4) of subsection (e).

“(5) AMENDMENTS TO THE PLAN.—At the initiation of the Secretary or the applicant, the

“(D) which is for the duration of the Best Pharmaceuticals for Children Act of 2007” and inserting “for the duration of the Best Pharmaceuticals for Children Act of 2007”. SEC. 507. REAUTHORIZATIONS.

“(a) PEDIATRIC ADVISORY COMMITTEE.—Sec-
(d) DEMONSTRATION GRANTS TO IMPROVE PEDIATRIC DEVICE AVAILABILITY.—Section 305(e) of the Pediatric Medical Device Safety and Improvement Act (Public Law 110-85; 42 U.S.C. 284m(e) through 284m(2) and (3)) is amended by striking `$36,000,000 for each of fiscal years 2008 through 2012` and inserting `$45,000,000 for each of fiscal years 2013 through 2017`.

(e) 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 the section” and all that followed 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 test-
ed in pediatric populations and properly la-

eted for use in children.

(b) CONTENTS.—The report under sub-
section (a) shall include—

(1) the number and importance of drugs and biological products for children for which studies have been requested or re-
quired (as of the date of such report) under section 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 bio-

logical products in the improvement of the health of children;

(2) the number of required studies under such section 505B that have not met the ini-
tial deadline provided under such section, in-
cluding—

(A) the number of deferrals and deferral ex-
densions granted and the reasons such exten-
sions were granted; and
(B) the number of waivers and partial waivers granted; and

(C) the number of letters issued under sub-
section (d) of such section 505B;

(3) the number of requests issued, declined, and referred to the National Insti-
tutes of Health under such section 505A since the date of enactment of this Act (including the recommendations and the rejection of such requests), and a de-
scription and status of referrals made under subsection (d) 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 re-

sult of the review by such Committee of ad-

verse events reports; and

(6) the number and current status of pedi-

atric disease high risk projects;

(7) the number and importance of drugs and biological products for children that are not being tested for use in pediatric popu-

lation programs for pediatric study require-
ments;

(8) the existence of pediatric plans submitted and agreed to as identified in the marketing application under such sections 505A and 505B and section 409I of the Public Health Service Act;

(9) the possible reasons for the lack of test-
ing reported under paragraph (7); and

(10) the number of drugs and biological products for which testing is being done (as of the report) and for which each a-

beling 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 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 appro-
riate studies of 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.

(c) C ONTENTS.—The report under sub-
section (a) shall include—

(1) in subsection (k)(2), by striking ''sub-

section (or supplement) receives a standard re-

view'' after ''after the date of the submission

of such product''; and

(2) in subsection (o)(2), by amendment sub-
cparsp; (B) (i) in the first sentence, by inserting ''par-
tial'' before “waiver is granted”;

(ii) in the second sentence, by striking ‘‘either a full or’’ and inserting ‘‘such a’’;

(3) in subsection (g), in the matter preceding subparagraph (A), by inserting “After providing notice and all that follows through ‘‘studies,”’’ and inserting ‘‘The’’;

(4) in subsection (h),—

(A) by inserting “an application (or supple-

ment to an application) that contains” after “date of submission of”; and

(B) by inserting “, if the application (or supplement) receives a priority review, or more than 360 days after the date of sub-
mision of an application (or supplement to an application) that contains a pediatric as-
sessment under this section, if the applica-
tion (or supplement) receives a standard re-
vew,” after “under this section.”;

(c) INTERNAL REVIEW COMMITTEE.—The heading of section 505C (21 U.S.C. 355c) is amended by inserting “AND DEFERRAL EX-
tENSIONS” after “DEFERRALS”.

(d) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS AND BIOLOGICAL PROJECTS IN FDNSA.—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 striking “for a” 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”; and

(iii) in subparagraph (B), by striking “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”;

(2) in paragraph (4)(C)—

(A) in the first sentence, by inserting “partial” before “waiver is granted”; and

(B) in the second sentence, by striking “either a full or” and inserting “such a”;

(3) in subsection (g), in the matter preceding subparagraph (A), by inserting “After providing notice and all that follows through ‘‘studies,”’’ and inserting ‘‘The’’;

(A) in paragraph (1)(A), by inserting “that receives a priority review or 330 days after the date of the submission of an application on that product that is not already under review” after “after the date of the submission of the application or supplement”; and

(B) in paragraph (2), by striking the “the label of such product” and inserting “the labeling of such product”;

(4) in subsection (h),—

(A) by inserting “an application (or supple-

ment to an application) that contains” after “date of submission of”; and

(B) by inserting “, if the application (or supplement) receives a priority review, or more than 360 days after the date of sub-
mision of an application (or supplement to an application) that contains a pediatric as-
sessment under this section, if the applica-
tion (or supplement) receives a standard re-
vew,” after “under this section.”;

(c) INTERNAL REVIEW COMMITTEE.—The heading of section 505C (21 U.S.C. 355c) is amended by inserting “AND DEFERRAL EX-
tENSIONS” after “DEFERRALS”.

(d) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS AND BIOLOGICAL PROJECTS IN FDNSA.—Section 505B (21 U.S.C. 355c) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by inserting “of this Act,” after “Cosmetic Act,”;

(B) in subparagraph (A)(i), by inserting “or section 351(k) of this Act” after “Cosmetic Act,”;

(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 subsections (d)(1)(E)(ii), (d)(3)(E)(ii), and (j)(5)(F) of section 505 of the Federal Food, Drug, and Cosmetic Act, or applicable twelve-year period referred to in section 351(k)(7) of the Biologics Price Competition and Innovation 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.”

(2) in paragraph (2)—
(A) in the heading, by striking “FOR DRUGS LACKING EXCLUSIVITY”; and
(B) in the text of section 515(a) 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 515(m) of this Act”;

(2) FOUNDATION OF NATIONAL INSTITUTES OF HEALTH ADVISORY COMMITTEE.—Section 15(a) of the Best Pharmaceuticals for Children Act (Public Law 107–90) is amended by striking “subparagraph (C)”—
(A) in subparagraph (A)—
(i) by striking “section 360c(a)” and inserting “section 355(c)”; and
(B) in subparagraph (C)—
(i) in the paragraph heading, by striking “subsection (C)” and inserting “subsection (C)”; and
(ii) by striking “October 22, 1998,” and inserting “October 22, 2004,”

(2) in paragraph (1), by striking “subsequent determinations or subpopulations.”

(2) in paragraph (3)—
(A) in subparagraph (B), by striking “or” and inserting “or”;
(B) in subparagraph (C)—
(i) by striking “(ii)” and inserting “(ii)”; and
(ii) by striking “exclusive in pediatric populations or subpopulations” and inserting “exclusive in pediatric populations or subpopulations.”

SEC. 510. RELATIONSHIP BETWEEN PEDIATRIC LABELING AND NEW CLINICAL INVESTIGATION EXCLUSIVITY.

(a) IN GENERAL.—Section 505 (21 U.S.C. 355) is amended by adding at the end 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) In general.—If a 180-day period under section 505(c)(5)(B)(i) or (j)(5)(F)(iv) of this section, 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 under section 505(j), the 180-day period shall be extended from—

(2) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B) and moving clause “Section 360c” 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 referred to in section 505(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a)(2)) is amended by—

(1) in the heading, by striking “subsection (A)” 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 striking “class (iii) and (iv) of section 505(c)(3)(E)” and inserting “class (iii) and (iv) of section 505(c)(3)(E) or after ‘Notwithstanding’”; and

(4) in paragraph (3)—

(A) in subparagraph (B), by striking “that differ from adult formulations” and inserting “demonstrates that the product is safe or effective in pediatric populations or subpopulations.”

(b) APPLICATION.—Notwithstanding any provision of section 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355b) stating that a provision applies beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007 or 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. 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 the need to encourage and accelerate the development of new therapies for pediatric rare diseases.

(b) REPORT.—Not later than 180 days after the date of this Act, 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. 3513(e)(1)) is amended by—

(A) in the heading, by striking “Regulation promulgated” and inserting “Regulation promulgated”;

(B) in subparagraph (A), by striking “under section 513(e)” and inserting “under section 513(e)”; and

(C) by striking “(I) in the heading, by striking “Regulation promulgated” and inserting “Regulation promulgated”;

(2) APPLICABILITY OF OTHER PROVISIONS.—In the case of a device reclassified under section 513(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(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 513(a)(1) applies to an administrative order issued with respect to such 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 “not being issued under subsection (b) or (c)” and inserting “not being issued under subsection (b) or (c)”; and

(B) in subsection (c)(1)—

(i) in paragraph (1)—

(I) by striking “(1) In general.” and inserting “(1) In general.”;

(II) in paragraph (2)—

(aa) by striking “(A) The Commissioner shall promulgate a regulation promulgated under section 515(a)(1) of such Act and section 515(a)(1) of such Act with respect to such device in the same manner such section 513(a)(1) applies to an administrative order issued with respect to such device reclassified after the date of enactment of this Act.” and inserting “by administrative order following publication of a proposed reclassification order in the Federal Register, a meeting of a device classification panel described in paragraph (1)(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subsection (c)(1)(B) of chapter II 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, unlawful, but unlikely to advance the public health."

(ii) in paragraph (2)—

(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 such order";

and

(2) A proposed order required under paragraph (1) shall contain—

(a) a statement that a regulation required under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act 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, as defined in such section, or a proposed order issued under subsection (b);

(i) in paragraph (1)—

(B) by striking "promulgation of such regulation" and inserting "an order issued"; and

(ii) in subclause (ii), by striking "provision for premarket approval" and inserting "issuance of such order";

and

(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, as defined in such section, or a proposed order issued under subsection (b);

(1) by striking "an order issued" and inserting "a regulation promulgated" and inserting "an order issued"; and

(ii) by striking a regulation promulgated and inserting "an order issued";

and

(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 consult with outside stakeholders, including patients, providers, and 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. 809. RECALLS.

(a) ASSESSMENT OF DEVICE RECALL INFORMATION.—

(1) IN GENERAL.—

(A) ASSESSMENT PROGRAM.—The Secretary of Health and Human Services (hereafter 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 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(e)) and (b); and

(ii) information required to be reported to the Secretary regarding a correction or removal of a device under section 510(g) of such Act (21 U.S.C. 360(g));

(B) USE.—The Secretary shall use the assessment of information described under paragraph (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 frequently recalled;

(C) the causes of device recalls; and

(D) any other information that the Secretary determines appropriate.

(b) AUDIT CHIEF 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 510(k), section 510(e), section 510(b), or to a requirement under section 510(k) of such Act (21 U.S.C. 360(i)) has performed an effective recall under such section or an effective correction or removal action under such section 510(g), respectively.

SEC. 602. CONDITION OF APPROVAL STUDIES.


(1) by striking "(ii)" and inserting "(ii)(I)"; and

(2) by adding at the end the following:

(III) by striking "or" and inserting "and the"

SEC. 603. POSTMARKET SURVEILLANCE.

Section 522 (21 U.S.C. 360i) is amended—

(1) in subsection (a)(1)(A), in the manner preceding clause (i), by inserting "provides for postmarket 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 period;

SEC. 604. SENTINEL.

Section 519 (21 U.S.C. 360i) is amended by adding at the end the following:

"(d) EFFECTIVE JANUARY 1, 2016.—"
(d) TERMINATION OF RECALL.—The Secretary shall document the basis for the termination by the Food and Drug Administration (1) an individual device recall ordered under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(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. 360(g)).

SEC. 606. CLINICAL HOLD ON INVESTIGATIONAL DEVICE EXEMPTIONS.

SEC. 607. UNIQUE DEVICE IDENTIFIER.

Section 519(i) (21 U.S.C. 360(i)) is amended by— (1) striking “(D) Whenever” and inserting “(D) whenever” and (2) by adding at the end the following: “(i) For purposes of clause (i), the term ‘necessatory’ 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) This section shall take effect on the date of enactment of this Act.

SEC. 510(K).—Section 513(i)(1)(D) (21 U.S.C. 360(i)(1)(D)) is amended—

SEC. 609. CUSTOM DEVICES.

Section 520(b) (21 U.S.C. 360(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) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of professional practice of such physician or dentist (or other specially qualified person so designated); or

(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 components or distributed devices.

(2) LIMITATION.—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 in any year of a particular device type, provided that such replication otherwise complies with this section; and

(C) the sponsor 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).

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.

(1) DOCUMENTATION AND REVIEW FOR DEVICES.—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 section 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.

(2) REVIEW OF DENIAL.—“(I) 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 organizational level at which the decision to deny the clearance of the report or approval of the application is made.

(II) SUBMISSION OF REQUEST.—A person requesting a supervisory review under paragraph (I) 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.

(III) TIMEFRAME.—“(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall schedule an in-person or teleconference review under this subsection no later than 45 days after the request is made under paragraph (I), 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.

Paragraph (c) of section 701(b)(1) (21 U.S.C. 371(b)(1)) is amended— (1) by striking “(C) For guidance documents” and inserting “(C)(i) For guidance documents”;

(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 or policy or 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. 360(f)(2)) is amended— (1) by redesignating subparagraphs (B) and (C) as subparagraphs (C) and (D), respectively; and

(2) by adding at the end the following: “(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 included in 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 such classification, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommendation.

“(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 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 746A(b).

(b) Not later than 2 years after the date of enactment of this Act, 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 require special controls, as described in subsection (a)(1)(B), and 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;

(3) the impact that paragraph (4) of such section 520(m) (as so redesignated) has on access to and in any State engaged in the manufacture, distribution, or sale of such devices.

(c) REPRESENTATIVES.—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, stakeholders in the health care industry, including mobile applications, that promotes innovation and protects patient safety.

(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. 377d-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. 501. REGISTRATION OF DOMESTIC DRUG ESTABLISHMENTS.

(a) IN GENERAL.—Section 510(m) (21 U.S.C. 360m) is amended—

(1) in paragraph (6), by inserting ``(c)" after ``(A);"

(2) in paragraph (7), by striking ``regarding a device and inserting ``regarding a device described in paragraph (6)(A)(i)"; and

(3) in paragraph (8), by striking ``(B)'' and inserting ``(B)''.

(b) THIRD PARTY INSPECTIONS.—Section 704(g)(11) (21 U.S.C. 374g(11)) is amended by striking ``2012'' and inserting ``2017''.

SEC. 510(k) DEVICE MODIFICATIONS.

(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 Coordinator for Health Information Technology, and the Chairman of the Federal Communications Commission, shall submit to the Committee on Health, 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.—In general—

(1) creating a working group that includes representatives of patients, consumers, health care providers, stakeholders in the health care industry, including mobile applications, that promotes innovation and protects patient safety.

(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, stakeholders in the health care industry, including mobile applications, that promotes innovation and protects patient safety.

(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. 377d-1), as amended by section 1121, shall not apply to the working group under this section.

SEC. 614. REAUTHORIZATION OF THIRD-PARTY REVIEW AND INSPECTIONS.

(a) Thru—

(1) in section 526(c) (21 U.S.C. 366m(c)) is amended by striking "2012" and inserting "2017".

(b) THIRD PARTY INSPECTIONS.—Section 704(g)(11) (21 U.S.C. 374g(11)) is amended by striking "2012" and inserting "2017".

SEC. 615. 510(k) DEVICE MODIFICATIONS.

(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 Coordinator for Health Information Technology, and the Chairman of the Federal Communications Commission, shall submit to the Committee on Health, 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.—In general—

(1) creating a working group that includes representatives of patients, consumers, health care providers, stakeholders in the health care industry, including mobile applications, that promotes innovation and protects patient safety.

(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, stakeholders in the health care industry, including mobile applications, that promotes innovation and protects patient safety.

(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. 377d-1), as amended by section 1121, shall not apply to the working group under this section.

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 Coordinator for Health Information Technology, and the Chairman of the Federal Communications Commission, shall submit to the Committee on Health, 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.—In general—

(1) creating a working group that includes representatives of patients, consumers, health care providers, stakeholders in the health care industry, including mobile applications, that promotes innovation and protects patient safety.

(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, stakeholders in the health care industry, including mobile applications, that promotes innovation and protects patient safety.

(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. 377d-1), as amended by section 1121, shall not apply to the working group under this section.
(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;

(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 excipient manufacturer;

(c) within the United States, shall, through electronic means in accordance with the criteria of the Secretary—

(1) upon first engaging in any such activity, immediately submit a registration to the Secretary that includes—

(i) with respect to drugs, the information described under subsection (b)(1); and

(ii) 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 506(c) (21 U.S.C. 352(c)) is amended by striking “in any State”.

(b) REGISTRATION OF FOREIGN DRUG ESTABLISHMENTS.—Section 510(c) (21 U.S.C. 360(c)) 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—

(1) with respect to drugs, the name and place of business of such person, all such establishments, the unique facility identifier of each such establishment, and 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 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 excipient manufacturer;

(2) with respect to devices, the information described under paragraph (1); and

(3) by adding at the end the following:

‘‘(3) REGULATORY INFORMATION. The Secretary shall, upon request from the Secretary of the Treasury or the Secretary of Commerce, provide to the Secretary confirmation of the request.’’.

(2) ELECTRONIC DATABASE.—Not later than February 1 of each year, the Secretary shall submit to Congress a report that describes the electronic database that shall be used by the Secretary to link with other relevant databases to the Food and Drug Administration in order to identify and inform risk-based inspections under section 801(r)."

SEC. 703. RISK-BASED INSPECTION FREQUENCY.

Section 704 (21 U.S.C. 360(j)) is amended to read as follows:

(1) in section 704—

(A) by adding at the end the following:

‘‘(3) RISK-BASED SCHEDULE FOR DRUGS.—The Secretary shall, upon request from the Secretary of the Treasury or the Secretary of Commerce, provide to the Secretary confirmation of the request.’’;

(B) by adding at the end the following:

‘‘(4) RISK FACTORS.—In establishing the risk-based schedule under paragraph (3), the Secretary shall consider the following factors:

(A) The cumulative risk associated with an establishment for purposes of establishing a risk-based schedule under paragraph (3), the Secretary shall consider whether the drugs manufactured, prepared, propagated, compounded, or processed by such establishment are drugs described in section 503(b).

(B) The number of domestic and foreign establishments registered pursuant to this section in the previous fiscal year;

(C) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed by such establishment;

(D) The certifications described under sections 801(n) and 809 for the establishment;

(E) Whether the establishment has been inspected in the preceding 2 years;

(F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of establishing an inspection schedule.

(2) EFFECT OF STATUSES.—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).

(3) ANNUAL REPORT ON INSPECTIONS OF ESTABLISHMENTS.—Not later than February 1 of each year, the Secretary shall submit a report to Congress regarding—

(A) the number of domestic and 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 inspected in the previous fiscal year;

(C) the percentage of the budget of the Food and Drug Administration used to fund the inspections described under subparagraph (A).

(4) PUBLIC AVAILABILITY OF ANNUAL REPORTS.—The Secretary shall make the report required under paragraph (3) available to the public at the Internet site of the Food and Drug Administration.’’.

SEC. 706. RECORDS FOR INSPECTION.

Section 706(a) (21 U.S.C. 371(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 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 the person.

(B) Such records or other information that the Secretary is entitled to inspect under this section from a person that owns or operates an establishment 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 the person.

(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. AUTHORITY TO ALLOW FOREIGN INSPECTION.

Section 801(a) (21 U.S.C. 331(a)) is amended by adding at the end the following:

‘‘Notwithstanding any other provision of this section, 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, 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 707 (S.3588) is amended—

(1) by striking "CONFIDENTIAL INFORMATION" and all that follows through "The Secretary" and inserting "CONFIDENTIAL INFORMATION";

(a) CONTRACTORS.—The Secretary;

(b) by adding at the end the following:

"(c) ABILITY TO RECEIVE AND PROTECT CONFIDENTIAL INFORMATION OBTAINED FROM FOREIGN GOVERNMENTS.—

"(1) IN GENERAL.—The Secretary shall not be required to disclose under section 522 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 under a memorandum of understanding voluntarily and on the condition that the information not be released to the public; and

(B) the information is covered by, and subject to the protection of, a 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 522 of title 5, United States Code and section 318(f)(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 subsection authorizes any official to withdraw any of the non-disclosure requirements described in subparagraph (A), not to receive information from Congress or information required to be disclosed pursuant to an order of a court of the United States.

(4) 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:

(A) 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 such information from disclosure. Responsibility for this certification shall not be delegated to any officer or employee other than the Commissioner.

(B) WRITTEN AGREEMENT.—The written agreement under this subsection shall include a commitment by the foreign government to protect information exchanged under this agreement from disclosure without the written permission of the Secretary and until the sponsor gives written permission for disclosure or the Secretary makes a declaration of a public health emergency pursuant to section 301 of the Public Health Service Act that is relevant to the information.

(C) 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 this subsection, information described in section 301(j) in the following circumstances:

(A) Information concerning the inspection of a facility pursuant to section 301(e)(2) of the Public Health Service Act that has been certified under paragraph (1) and that has executed a written agreement under this subsection shall be considered a statute by which Congress authorizes the Secretary to enter into an agreement under this subsection.

(B) Information not described in subparagraph (A) may be provided to a foreign government in accordance with the criteria described in subsection (c)(1), that is eligible to be considered for disclosure to conduct drug safety and quality audits.

(D) ACCREDITATION SYSTEM.—

(1) RECOGNITION OF ACCREDITATION BODIES.—

(A) 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 establish a system for the recognition of accreditation bodies that accredit third-party auditors to conduct drug safety and quality audits.

(B) DIRECT ACCREDITATION.—

(iv) IN GENERAL.—If, by the date that is 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act, 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;

(b) updated lists as needed to ensure the list held by the Secretary is accurate.

(3) RECOGNITION OF ACCREDITATION BODY.—

(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 be required to establish such standards in accordance with the criteria described in subsection (c)(1), that is eligible to be considered for disclosure to conduct drug safety and quality audits.

(B) ACCREDITATION SYSTEM.—

(1) RECOGNITION OF ACCREDITATION BODIES.—

(A) 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 establish a system for the recognition of accreditation bodies that accredit third-party auditors to conduct drug safety and quality audits.

(2) DIRECT ACCREDITATION.—

(iv) IN GENERAL.—If, by the date that is 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act, 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;

(b) updated lists as needed to ensure the list held by the Secretary is accurate.

(3) RECOGNITION OF ACCREDITATION BODY.—

(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 be required to establish such standards in accordance with the criteria described in subsection (c)(1), that is eligible to be considered for disclosure to conduct drug safety and quality audits.

(B) ACCREDITATION SYSTEM.—

(1) RECOGNITION OF ACCREDITATION BODIES.—

(A) 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 establish a system for the recognition of accreditation bodies that accredit third-party auditors to conduct drug safety and quality audits.

(B) DIRECT ACCREDITATION.—

(iv) IN GENERAL.—If, by the date that is 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act, 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;

(b) updated lists as needed to ensure the list held by the Secretary is accurate.

(3) RECOGNITION OF ACCREDITATION BODY.—

(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 be required to establish such standards in accordance with the criteria described in subsection (c)(1), that is eligible to be considered for disclosure to conduct drug safety and quality audits.
"(ii) set forth procedures for the periodic renewal of the accreditation of accredited third-party auditors.

(C) REQUIREMENT TO PROVIDE RESULTS AND REPORT.—An accreditation body shall—

"(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 reviews 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 reviews 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 of eligible entities and may employ audit agents to conduct drug safety and quality audits, but must ensure that such audit agents comply with all requirements under this Act. The Secretary shall promptly revoke, after the opportunity for an informal hearing, the accreditation of an accredited third-party auditor.

"(i) if the Secretary determines, based on evidence presented, that—

"(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 satisfies the requirements set forth in paragraph (A); or

"(ii) under such other conditions as the Secretary may require.

"(4) REACCREDITATION.—The Secretary shall establish procedures to restate the accreditation of a third-party auditor for which accreditation has been revoked under paragraph (3).

"(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.

"(B) CONFLICTS OF INTEREST.—

"(A) ACCREDITATION BODIES.—A recognized accreditation body shall—

"(i) not own, manage, or control by any person that owns or operates a third-party auditor to be accredited by such body; and

"(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 own, managed, or controlled by any person that owns or operates a third-party auditor to be accredited by such auditor; and

"(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 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.

"(B) ADDITIONAL BASIS FOR REVOCATION OF ACCREDITATION.—The Secretary may revoke accreditation from an accredited third-party auditor if the Secretary finds 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) 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); and

(2) shall periodically, or at least once every 4 years, evaluate the performance of each accredited third-party auditor, through the recovery audit process for 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 806(r) of such 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 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) 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 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 for their adherence to 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 to authorize the program.

SEC. 711. STANDARDS FOR ADMISSION OF IM- PORTS.

Section 801 (21 U.S.C. 331) is amended—

(1) in subsection (o), by striking ‘‘drug or’’; and

(2) by adding at the end following:

‘‘(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 only as determined, in consultation with appropriate stakeholder groups, that there is insufficient access to an accredited third-party auditor; and

(5) the Secretary, be satisfied—

(1) the extent to which drug safety and quality audits 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) of such Act (as added by section 711).

(2)Whether the Secretary has been able to access drug safety and quality audit reports completed by accredited third-party auditors.

(3) Whether accredited third-party auditors accredited under such section 809 have adhered to the conflict of interest provisions set forth in such section.

(4) The extent to which the Secretary has audited recognized accreditation bodies (as defined under such section 809) for their adherence to the requirements of such section 809.

(5) 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.

(6) Recommendations to Congress regarding the accreditation program under such section 809, including whether Congress should continue to authorize the program.

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(5) the Secretary, be satisfied—

(1) the extent to which drug safety and quality audits 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) of such Act (as added by section 711).

(2) Whether the Secretary has been able to access drug safety and quality audit reports completed by accredited third-party auditors.

(3) Whether accredited third-party auditors accredited under such section 809 have adhered to the conflict of interest provisions set forth in such section.

(4) The extent to which the Secretary has audited recognized accreditation bodies (as defined under such section 809) for their adherence to the requirements of such section 809.

(5) 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.

(6) Recommendations to Congress regarding the accreditation program under such section 809, including whether Congress should continue to authorize the program.

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‘‘(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 only as determined, in consultation with appropriate stakeholder groups, that there is insufficient access to an accredited third-party auditor; and

(5) the Secretary, be satisfied—

(1) the extent to which drug safety and quality audits 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) of such Act (as added by section 711).

(2) Whether the Secretary has been able to access drug safety and quality audit reports completed by accredited third-party auditors.

(3) Whether accredited third-party auditors accredited under such section 809 have adhered to the conflict of interest provisions set forth in such section.

(4) The extent to which the Secretary has audited recognized accreditation bodies (as defined under such section 809) for their adherence to the requirements of such section 809.

(5) 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.

(6) Recommendations to Congress regarding the accreditation program under such section 809, including whether Congress should continue to authorize the program.

SEC. 711. STANDARDS FOR ADMISSION OF IM- PORTS.

Section 801 (21 U.S.C. 331) is amended—

(1) in subsection (o), by striking ‘‘drug or’’; and

(2) by adding at the end following:

‘‘(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 only as determined, in consultation with appropriate stakeholder groups, that there is insufficient access to an accredited third-party auditor; and

(5) the Secretary, be satisfied—

(1) the extent to which drug safety and quality audits 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) of such Act (as added by section 711).

(2) Whether the Secretary has been able to access drug safety and quality audit reports completed by accredited third-party auditors.

(3) Whether accredited third-party auditors accredited under such section 809 have adhered to the conflict of interest provisions set forth in such section.

(4) The extent to which the Secretary has audited recognized accreditation bodies (as defined under such section 809) for their adherence to the requirements of such section 809.

(5) 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.

(6) Recommendations to Congress regarding the accreditation program under such section 809, including whether Congress should continue to authorize the program.
‘(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 568 of the Federal Food, Drug, and Cosmetic Act (as added by paragraph (1)) to a wholesaler, except as provided for in 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 COUNTERFEIT DRUGS.

(a) FDAAA.—Section 303(b) (21 U.S.C. 333(b)) of section 713 is amended by adding at the end the following:

‘(8) Notwithstanding subsection (a)(2), any person who knowingly and intentionally violates section 301 shall be imprisoned for not more than 20 years or fined not more than $4,000,000, or both.’

(b) TTRA.—Section 223(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 $5,000,000, 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, or imprisoned not more than 30 years.

(B) Revisals.—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 shall—

(i) if an individual, be fined not more than $8,000,000, imprisoned not more than 20 years, or both; and

(ii) if a person other than an individual, be fined not more than $20,000,000.

(c) SENTENCING.—

(1) DIRECTIVE TO SENTENCING COMMISSION.—Pursuant to its authority under section 306 (3)(8)(B)(ii) 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 323(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 are approved by the state where the offense was committed and account for the potential and actual harm to the public resulting from the offense;

(C) assure reasonable consistency with other relevant guidelines and with other sentencing guidelines;

(D) account for any additional aggravating or mitigating circumstances that might justify a sentence in excess of the generally applicable sentencing ranges;

(E) make any necessary conforming changes to the sentencing guidelines; and

(F) assure that the recommended sentence 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 and the 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 Treaty 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 B—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 is machine-readable and human-readable, and the expiration date of a product. The data carrier shall be printed with a numerical identifier (SNI), the lot number, the expiration date of a product. The data carrier contains information that is 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 public databases.

‘(2) 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 4% years after the date of enactment of this Act, must maintain RxTEC data for product intended to be introduced into interstate commerce.

‘(2) CHAIN OF CUSTODY REQUIREMENTS.—A manufacturer must maintain RxTEC data that associate unit and lot level data for each individual saleable unit of product and homogenous case introduced in interstate commerce; and

‘(3) RxTEC DATA.—(i) The business name and address of the immediate previous source, if applicable, and the immediate subsequent recipient of the product;

‘(ii) the name and address of the immediate previous source, if applicable, and the immediate subsequent recipient of the product; and

‘(iii) the name and address of the immediate previous source, if applicable, and the immediate subsequent recipient of the product.

‘(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 importer of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

‘(1) apply RxTEC to the individual saleable unit and homogeneous case of product intended to be introduced into interstate commerce;

‘(2) 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

‘(3) 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) the brand name or 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 transaction information to the

May 24, 2012

CONGRESSIONAL RECORD — SENATE S3591

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 THROUGH THE ESTABLISHMENT OF AN RxTEC SYSTEM.

(a) MANUFACTURER REQUIREMENTS.—

(1) PRODUCT TRACING.—A manufacturer, not later than 4% 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 homogeneous case of 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 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 importer of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

(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 name and address of the immediate previous source, if applicable, and the immediate subsequent recipient of the product; and

(iv) the National Drug Code number of the product;
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) RxTEC data by lot; 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, regarding such product.

‘‘(G) notify the Secretary, in consultation with the Secretary, of any steps taken pursuant to subsection (f) or (g) of this section.

‘‘(F) notify the Secretary, in consultation with the Secretary, regarding such product.

‘‘(H) distribute, not later than 4 1⁄2 years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section—

‘‘(1) RxTEC data to the immediate saleable unit level data to cases or pallets.

‘‘(2) 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 product introduced in interstate commerce, including RxTEC data received for such products and for which a repackager applies a new RxTEC; and

‘‘(3) any guidance the Secretary issues regarding high-risk scenarios that could increase the risk of a suspect product entering the pharmaceutical distribution supply chain.

‘‘(I) notify the Secretary, in consultation with the Secretary, of any steps taken pursuant to subsection (f) or (g) of this section.

‘‘(J) notify the Secretary, in consultation with the Secretary, regarding such product.

‘‘(K) distribute, not later than 5 1⁄2 years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section—

‘‘(1) RxTEC data to the immediate saleable unit level data to cases or pallets.

‘‘(2) 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 product introduced in interstate commerce, including RxTEC data received for such products and for which a repackager applies a new RxTEC; and

‘‘(3) any guidance the Secretary issues regarding high-risk scenarios that could increase the risk of a suspect product entering the pharmaceutical distribution supply chain.

‘‘(L) notify the Secretary, in consultation with the Secretary, of any steps taken pursuant to subsection (f) or (g) of this section.

‘‘(M) notify the Secretary, in consultation with the Secretary, regarding such product.

‘‘(N) distribute, not later than 5 1⁄2 years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section—

‘‘(1) RxTEC data to the immediate saleable unit level data to cases or pallets.

‘‘(2) 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 product introduced in interstate commerce, including RxTEC data received for such products and for which a repackager applies a new RxTEC; and

‘‘(3) any guidance the Secretary issues regarding high-risk scenarios that could increase the risk of a suspect product entering the pharmaceutical distribution supply chain.

‘‘(O) notify the Secretary, in consultation with the Secretary, of any steps taken pursuant to subsection (f) or (g) of this section.

‘‘(P) notify the Secretary, in consultation with the Secretary, regarding such product.

‘‘(Q) distribute, not later than 5 1⁄2 years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section—

‘‘(1) RxTEC data to the immediate saleable unit level data to cases or pallets.

‘‘(2) 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 product introduced in interstate commerce, including RxTEC data received for such products and for which a repackager applies a new RxTEC; and

‘‘(3) any guidance the Secretary issues regarding high-risk scenarios that could increase the risk of a suspect product entering the pharmaceutical distribution supply chain.
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 lot level data from a registered manufacturer, repackager, or wholesaler;

(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) the product is a 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) maintain, in wholesale distribution where a change of ownership has occurred between non-affiliated entities, the previous owner, if the product was a product of a licensed or registered manufacturer, repackager, or wholesale distributor, upon confirming that a product does not have the standing numerical identifier or lot number, consistent with this section, and expiration date assigned by the Secretary, and 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 a patient; and

(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.

(3) LIMITATIONS.—Nothing in this section shall—

(A) prevent a wholesaler from removing a wholesale distributor on behalf of the dispensers and wholesalers who in good faith removed data for a direct trading partner and provided access to such information to such trading partner or the Secretary, routine monitoring of a suspect product at the request of a trading partner or the Secretary; and

(B) require nor restrict the use of additional data carrier technologies; or

(C) provide for the collection of information other than that reasonably available and appropriate.

(4) EXPIRE.—This section shall expire—

(A) 7 years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a wholesaler, 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 wholesaler to verify product at the unit level; or

(ii) require a wholesaler to adopt specific technologies or business systems for compliance with this section.

(5) ENSURING FLEXIBILITY.—The requirements under this section shall—

(A) require the maintenance and transmission only of information that is reasonably available and appropriate; and

(B) be based on current scientific and technological capabilities and shall neither require nor restrict the use of additional data carrier technologies.

(6) RIGHTS OF WHOLESALE DISTRIBUTORS.—Any 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.

(7) EXPIRE.—This section shall expire—

(A) 12 months after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

(i) receive only products encoded with RxTec lot level data from a registered manufacturer, repackager, or wholesale distributor selling the drug product to the dispenser;

(ii) 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 subsequent recipient of such product if the unit is not in a sealed homogeneous case; and

(iii) require nor restrict the use of additional data carrier technologies.
“(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 60 days after the submission of a complete application under section 505(b) for such drug. The Secretary shall, not later than 60 days after the submission of that application, provide a period of not less than 60 days for comments on the proposed regulation.

(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 recommendations and any additional, more detailed or focused assessments and any additional, more detailed or focused assessments.

(3) 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) recommendations 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 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.

(6) CONTRACTORS.—The Secretary shall—

(a) analyze the recommendations for improvement opportunities identified in the assessment, develop and implement a corrective action plan, and ensure it is effective;

(b) 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

(c) incorporate the results of the assessment in a Good 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. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS.

(a) EXTENSION.—If the Secretary approves an application pursuant to section 505(b) 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 (ii) 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, unless the application 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, 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
"(e) REGULATIONS.—

"(1) General provisions.—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) consult an advisory committee to make recommendations to the Secretary concerning 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) Authority to promulgate 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 enterococci;

"(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 pathogens identified and listed by the Secretary under paragraph (2) that has the potential to pose a serious threat to public health, such as—

"(i) an assessment of any underlying regulatory issues related to qualified infectious disease products, including qualified infectious disease biological products and antifungal products; and

"(ii) 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; and

"(II) percentage of success or failure at each phase of clinical trials; and

"(III) public versus private funding levels of the trials for each drug;

"(2) ISSUES FOR REVIEW.—At a minimum, the issues for review under paragraph (1) shall include 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 term 'qualified infectious disease product' as defined in section 505(b)(1) is defined in this section, nothing in this section shall be construed to repeal or otherwise affect the guidance documents of the Food and Drug Administration for the conduct of clinical trials with respect to antibacterial and antifungal drugs; and

"(b) APPLICATION.—Section 524A of the Federal Food, Drug, and Cosmetic Act, as added by section 801, shall be applied only with respect to a drug that is first approved under section 505 of the Public Health Service Act (42 U.S.C. 262).

"(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 that is designed 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.

"(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 new 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 issues for review under paragraph (1) shall include—

"(B) as appropriate, revising such guidance documents to reflect new 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.).
§ 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

(a) ACCELERATED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS, INCLUDING A FAST TRACK PRODUCT.

(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, fast track the drug for the approval of the drug under section 505(i) or section 351(a)(5) of the Public Health Service Act upon a determination that the drug meets the criteria, the Secretary shall designate the drug as a fast track product.

(b) ACCELERATED APPROVAL OF A DRUG FOR A SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION, INCLUDING A FAST TRACK PRODUCT.

(1) 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 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'.

(2) EVIDENCE.—The evidence to support that an endpoint is reasonably likely to predict clinical benefit under subparagraph (A) may include epidemiological, biochemical, pathological, therapeutic, pharmacologic, or other evidence developed using biomarkers, for example, or other scientific methods or tools.

(3) 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 study the effect of the approved drug on the disease, or other condition, in order to describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

(B) That the sponsor submit copies of all preclinical materials and 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.

(4) ADMINISTRATION.—The Secretary shall 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 the development and availability to patients of treatments for serious or life-threatening diseases or conditions while maintaining safety and effectiveness of such treatments.

(5) EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS. Section 506 of the Federal Food, Drug, and Cosmetic Act is amended to read as follows:

"(a) ACCELERATED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

SEC. 201. ENHANCEMENT OF ACCELERATED PATIENT ACCESS TO NEW MEDICAL PRODUCTS.

(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.

(B) Regulatory impediments to 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.

(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product.

(A) The Secretary shall designate the drug as a fast track product if the drug meets the criteria described in paragraph (1).

(B) The Secretary and the FDA shall submit to Congress a strategy and implementation plan with respect to the requirements of this section as the ‘Secretary’ 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;

(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 ensuring 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 that have information on the types of exclusivity granted for each product, consistent with the information published under section 505E(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355E(g)(1));

(4) the number of such qualified infectious disease products 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.

(2) LIMITATION.—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 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’.

(3) EVIDENCE.—The evidence to support that an endpoint is reasonably likely to predict clinical benefit under subparagraph (A) may include epidemiological, biochemical, pathological, therapeutic, pharmacological, or other evidence developed using biomarkers, for example, or other scientific methods or tools.

(4) 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 study the effect of the approved drug on the disease, or other condition, in order to describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

(B) That the sponsor submit copies of all preclinical materials and 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.

(5) 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.

(6) PRELIMINARY REPORT.—Not later than 1 year 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 that have information on the types of exclusivity granted for each product, consistent with the information published under section 505E(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355E(g)(1));

(4) the number of such qualified infectious disease products 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 INFECTION PROD—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.
product fails to verify and describe such ef-
fect or benefit.

"(c) other evidence demonstrates that the product is not safe or effective under the conditions of use.

"(d) the sponsor disseminates false or mis-
leading 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 deter-
mines that the preliminary evaluation of clini-
cal data submitted by the sponsor, that a fast track product may be effective, the Secre-
tary shall evaluate for filing, and may consult with appropriate portions of, an applica-
tion 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 applica-
tion complete; and

"(B) pays any fee that may be required under section 736.

"(2) exception.—Any time period for re-
view of human drug applications that has been established by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees col-
lected 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 appro-
priate persons a description of the provisions of this section and of the availability of accelerated ap-
proval 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 reason-
sably likely to predict clinical benefit for serious or life-threatening conditions for which significant unmet medical needs exist.

(e) In General.—

"(1) purpose.—The amendments made by this section 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) 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).

"(2) Guidance.—

(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 issue guidance implementing the amendments made by this section. In deve-
loping such guidance, the Secretary shall spe-
cifically consider issues arising under the ac-
celerated approval and fast track processes under section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (d) of section 505(i) or section 351(a) of the Public Health Service Act.

(b) Designation.—

"(2) in subsection (f)(1), as so redesignated,

"(A) Designation of a Drug as a Break-
through Therapy.—

"(1) in general.—The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of a drug designated as a breakthrough therapy, 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 evidence as substantial treatment effects observed early in clinical development. In this sec-
tion, such a drug is referred to as a ‘break-
through therapy.’

"(2) in subsection (f)(2), as so redesignated.

"(B) Designation of a Drug as a Break-
through 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 evidence as substantial treatment effects observed early in clinical development. In this sec-
tion, such a drug is referred to as a ‘break-
through therapy.’

"(ii) holding meetings with the sponsor and the review team throughout the development of the drug;

"(iii) involving senior managers and ex-
perienced review staff, as appropriate, in a col-
laborative, 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 prac-
tical, when scientifically appropriate, such as by minimizing the number of patients ex-
posed to a potentially less efficacious treat-
ment.

(2) in subsection (f)(1), as so redesignated.

"(A) in General.—

"(1) Designation of a Breakthrough Therapy.—

"(2) by redesignating subsection (a) through (c) as subsections (b) through (d), re-
spectively;

"(3) by inserting before subsection (b), as so redesignated,

"(4) in subsection (f)(1), as so redesignated.

"(B) R eport.—Beginning in fiscal year 2013, the Secretary shall annually prepare an R eport to the Congress, the O ffice of the Secretary, the O ffice of the Inspector General, the O ffice of the Assis-
tant Secretary for Planning and Evaluation, and the G eneral Accounting Office, summarizing the information required under section 505(i) or section 351(a) of the Public Health Service Act.

"(C) in subsection (f)(1), as so redesignated.

"(D) Designation of a Breakthrough Therapy.—

"(1) in general.—The Secretary shall designate a 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 evidence as substantial treatment effects observed early in clinical development. In this sec-
tion, such a drug is referred to as a ‘break-
through therapy.’

"(2) in subsection (f)(2), as so redesignated.

"(E) Redesignation.—

"(1) in general.—The Secretary shall, at the request of the sponsor of a drug, redesignate a drug as a breakthrough therapy, 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 evidence as substantial treatment effects observed early in clinical development. In this sec-
tion, such a drug is referred to as a ‘break-
through therapy.’

"(B) in subsection (f)(2), as so redesignated.

(b) Guidance.—

"(1) in general.—

"(i) by redesignating subsection (a) through (c) as subsections (b) through (d), re-
spectively;

"(ii) by redesignating subsection (d) as sub-
section (f);

"(iii) by inserting before subsection (b), as so redesignated,

"(a) in General.—

"(1) Designation of a Breakthrough Therapy.—

"(2) in subsection (f)(1), as so redesignated.

(b) Guidance.—

"(1) in general.—

"(i) by redesignating subsection (a) through (c) as subsections (b) through (d), re-
spectively;

"(ii) by redesignating subsection (d) as sub-
section (f);

"(iii) by inserting before subsection (b), as so redesignated,

"(a) in General.—
(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.

(3) 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, 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.

(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 conduct, and the Secretary shall ensure that opportunities exist, a comprehensive review of the processes described in section 506(a)(3), including updating good review management practices to reflect breakthrough therapies.

SEC. 903. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC RESOURCES.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by subsection (a)(3), 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 RESOURCES.

(a) IN GENERAL.—For the purpose of promoting the efficiency of and informing the review by the Food and Drug Administration of new 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 minimum, for consultations with 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 biological products for rare diseases and drugs and biological products that are genetically targeted, including the topics described in subsection (c), with the extent to which barriers to accessibility can be addressed.

(b) EXTERNAL EXPERTS.—For purposes of subsection (a), experts are those who possess scientific or medical training in that the Secretary lacks with respect to one or more rare diseases.

(c) TOPIC AND 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 patients;

(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 shall 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 Secretary’s legal right for a consultation on any matter with a particular expert or stakeholder. Nothing in this section shall be construed to alter any consultations on any matter with a 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.

(f) OTHER REQUIREMENTS.—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 with a particular expert or stakeholder. Nothing in this section shall be construed to alter the Secretary’s legal right for a consultation on any matter with a 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 composed of the following, which the Secretary may designate 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 (including the elderly, and industry groups representing stakeholders, including retail, mail order, and independent community pharmacies), and individuals representing the elderly, and industry groups representing stakeholders, including retail, mail order, and independent community pharmacies, and individuals who are blind or visually impaired.

(b) WORKING GROUP.—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 information on prescription drug container labels.

(B) PUBLIC AVAILABILITY.—The best practices developed under subparagraph (A) may be disseminated through public 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.

(c) CONFORMING CHANGES.—In developing and issuing the best practices under paragraph (3)(A), the working group shall consider—

(1) the use of—

(i) Braille;

(ii) auditory means, such as—

(I) "talking bottles" that provide audible container label information;

(III) digital voice recorders attached to the prescription drug container; and

(III) radio frequency identification tags;

(3) enhanced visual means, such as—

(I) alternative font sizes or large font, "duplicate" labels that are affixed or matched to a prescription drug container;

(II) high-contrast printing; and

(III) sans-serif font;

(4) other relevant alternatives as determined by the working group;

(5) 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

(6) such other factors the working group determines to be appropriate.

(d) INFORMATION CAMPAIGN.—Upon completion of the development of 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.

(e) FACA WAIVER.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the working group.

(f) GAO STUDY.—

(1) IN GENERAL.—Beginning 18 months after the submission of the final report on such best practices under subsection (a)(3), the Comptroller General of the United States shall conduct a review of the extent to which pharmacists 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 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.

(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) In our opinion ‘‘prescription drug container label’’ means the label with the directions for use that is affixed to the prescription drug container by the pharmacist and dispenses on the label.

SEC. 905. RISK-BENEFIT FRAMEWORK.

Section 505(d)(1) (21 U.S.C. 355(d)) is amended by adding at the end the following: ‘‘The Secretary shall implement a structured risk-benefit 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 MODELS.

(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 of 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 innovation incentive programs for 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) Model 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.

(D) Summaries.—The study conducted under subsection (a) shall include consideration of each of the following:

(1) Whether a system of large innovation inducement prizes would work as a replacement for the existing product monopoly/patent-based system, as in effect on the date of enactment of this Act.

(2) Whether 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 expand access to new products and improve health outcomes.

(4) 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.

(5) Whether there would be major advantages in rewarding the incremental impact of innovations, as benchmarked against existing products.

(6) Whether open-source dividend prizes could be managed, and whether such prizes would increase access to knowledge, materials, data and technologies.

(7) Whether the creation of competitive intermediaries for interim research prizes would provide an acceptable solution to the valuation challenges for interim prizes.

(8) Whether a system of large innovation inducement prizes could work as a replacement for the existing product monopoly/patent-based system.

SEC. 907. ORPHAN PRODUCT GRANTS PROGRAM.

(a) Reauthorization of Program.—Section 5(c) of the Orphan Drug Act (21 U.S.C. 350c) is amended by striking ‘‘2008 through 2012’’ and inserting ‘‘2013 through 2017’’.

(b) Human Clinical Testing.—Section 5(d)(1)(A)(ii) of the Orphan Drug Act (21 U.S.C. 350e(b)(1)(A)(ii)) is amended by striking ‘‘after the date such drug is designated under section 520 of such Act’’ and inserting ‘‘on or before 15 months after the date of enactment of this Act’’.

SEC. 908. REJECTION 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 of Food and Drugs, 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) Content 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 in accordance with the Food and Drug Administration requirements and guidance for Industry. The report shall address how the Food and Drug Administration makes available such data, including 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, and ethnicity is presented in applications for new drug applications for new molecular entities under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)), and by section 351 of the Public Health Service Act (42 U.S.C. 262(b)), including sex, age, race, and ethnicity information as of the date of enactment of this Act.

(C) A description and evaluation of the extent to which demographic data subset analyses on sex, age, and ethnicity is included in applications for new drug applications for new molecular entities under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)), and by section 351 of the Public Health Service Act (42 U.S.C. 262(b)), including sex, age, race, and ethnicity information as of the date of enactment of this Act.

(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 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 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 by subsection (a) 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, clinicians, and researchers; and

(D) a determination with respect to each recommendation identified in subparagraph (A) through (C) that distinguishes between program types referred to in subsection (a)(2)(B) insofar as the applicability of each such recommendation to each type of program.

(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-saving;

(B) life-sustaining;

(C) intended for use in the prevention of a debilitating disease or condition;

(D) a sterile injectable product; or

(E) in emergency medical care or during surgery;

(2) that is not a radio pharmaceutical drug product, a human tissue replaced by a replacement 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 REVIEW. 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—

(1) expedite the review of a supplement to a 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 drug shortage;

(2) expedite an inspection or reinspection of an establishment that could help mitigate or prevent such drug shortage.

(d) Task Force and Strategic Plan—

(A) IN GENERAL.—

(1) 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 subparagraph (B) shall include—

(I) plans for enhanced interagency and intra-agency 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 investigating the impact of drug shortages on research and clinical trials.

(B) TIMING.—Not later than 1 year after the date of enactment of the 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 issuing of an enforcement 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 in subsection (a), the Secretary shall communicate with the appropriate office of the Food and Drug Administration with expertise regarding drug shortages regarding whether the notification letter could cause, or exacerbate, a shortage of the drug.

(3) ACTION.—If the Secretary determines, after the communication described in subparagraph (a), that the notification letter could cause, or exacerbate, a shortage of a drug described under subsection (a), then the Secretary shall evaluate the information 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.

(6) 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 notifications submitted to the Secretary under subsection (a) in each calendar year.

(C) A list of the known factors contributing to the drug shortages described in subparagraph (B).

(D) A list of major actions taken by the Secretary to prevent or mitigate the drug shortages described in subparagraph (B).

(E) The number of communications with the appropriate office of the Food and Drug Administration with expertise regarding drug shortages regarding whether the notification letter could cause, or exacerbate, a shortage of the drug.

(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 applications for which the Secretary expedited review under subsection (c)(1) in each calendar year.

(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) COMMUNICATION.—The Secretary shall be 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 include information on the basis 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.

(1) DEFINITIONS.—For purposes of this section—

(A) the term ‘drug’—

(1) means a drug (as defined in section 201(g)) that is intended for human use; and

(2) 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 (b);

(B) the term ‘drug shortage’ or ‘shortage’, with respect to a drug, means a period of time when the demand or projected demand for such drug within the United States exceeds the supply of the drug;

(C) 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.

(2) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute information on drug shortages and on the permanent discontinuation of the drugs described in this section to appropriate pharmaceutical and patient organizations.

(3) RULE FOR VACCINES.—If the Secretary applies this section to vaccines pursuant to subparagraph (A), the Secretary—

(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 implementing this section.

(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) if the Secretary meets the requirements of the following:

(B) EFFECT OF NOTIFICATION.—The submission of a notification to the Secretary of Health and Human Services (referred to in this title as the ‘Secretary’) may not be the basis for, or the subject of, any action by the Department of Health and Human Services (referred to in this title as the ‘Department’) to require compliance with the requirements of 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 an intention of promotion to 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 guidelines or policies issued under such Act related to drugs intended for human use, and the practices of the Food and Drug Administration regarding enforcing an Act related to manufacturing of such drugs, to identify any such regulations, guidelines, policies, or practices that cause, exacerbate, prevent, or mitigate drug shortages, 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 manufacturer, distributors, group purchasing organizations, and providers) on competition, access to drugs, and pricing of drugs; and

(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 title 3 (the 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, and the Secretary.

TITLE XI—OTHER PROVISIONS

Subtitle A—Reauthorizations

SEC. 1101. REAUTHORIZATION OF PROVISION RELATING TO DRUG SHORTAGES AND STOCK- OUTS.

(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 in its place--"(II)the request does not contain the information required under paragraph (1) or otherwise lacks sufficient information to permit the Secretary to determine that the drug product is a designated medical gas product; or

(2) granting the request would be contrary to public health.

(3) EFFECT OF CERTIFICATION.—(A) IN GENERAL.—There are no designated medical gas products approved 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) Carbon dioxide for use in hyperoxia challenge testing.

(iii) Nitrous oxide for anesthetics.

(iv) Carbon dioxide for use in extracorporeal membrane oxygenation therapy or respiratory support.

(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.

(B) 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)(B), under clause (iii) or (iv) of section 505(c)(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.

(C) Any designation of exclusivity for a designated medical gas product as defined and determined by the Secretary to be contrary to public health.

(D) INAPPLICABILITY OF EXCLUSIVITY PROVISIONS.—

(i) EFFECT ON INELIGIBILITY.—No designated medical gas product deemed appropriate by the Secretary under section 505A, applicable to such indication for use for such gas product or combination of products has not expired.

(ii) EFFECT ON CERTIFICATION.—No period of exclusivity under section 505(c), 505(j), or the extension of any such period under section 505A, on the basis of such deemed exclusive approval.

(iii) 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 a drug shall prohibit, limit, or otherwise affect the submission, grant, or renewal of a certification under this section, except as provided in paragraph (3)(A)(ii)(VIII).

(iv) WITHDRAWAL, SUSPENSION, OR REVOCATION OF APPROVAL.—(A) IN GENERAL.—Nothing in this subsection 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 requirements of this subsection are not met or that the certification contains any material omission or falsification.

(2) PRESCRIPTION REQUIREMENT.—

(A) IN GENERAL.—A designated medical gas product shall be subject to section 505(b)(1) unless the Secretary exercises the authority provided in section 505(b)(3) to remove such gas product from the requirements of section 505(b)(1). The Secretary is not authorized to take action pursuant to another provision of this Act relating to use of medical products in emergencies.

(B) EXCEPTION FOR OXYGEN.—

(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.

(C) LABELING.—For oxygen provided pursuant to subparagraph (A), the requirements established in section 505(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.

(D) REQUIREMENTS 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 be subject to the assessed fees under section 739(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, establish such regulations as the Secretary determines to be necessary in order to carry out the purposes of this Act.

(b) AMENDED REGULATIONS.—If the Secretary determines that changes to the Federal drug regulations in title 21, Code of Federal Regulations that the Secretary determines to be necessary under this 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.

(a) 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 cases listed in subparagraphs (A) through (G) of section 575(c) of such Act (as added by section 1111), or any mixture of any such gases, for an indication that is listed, prescribed, or used in a manner different from that specified in subclauses (I) through (VII) of section 578(a)(3)(i) of such Act (as added by section 1111); and

(b) not later than 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.

(a) ADVICE TO SECRETARY.—Notwithstanding any provisions of this Act or section 351 of the Public Health Service Act, the Secretary shall—

(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

(b) EXCEPTION.—In the guidance under paragraph (1), the Secretary may—

(1) by inserting paragraph (1) of this subsection; and

(c) 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 and conditions that are addressed by such 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.

(3) EXCEPTION.—This subsection shall not apply to submissions described in section 561. (b) DEVICES.

(i) IN GENERAL.—Beginning after the issuance of final guidance implementing this paragraph, pre-submissions and submissions under section 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 that include an electronic copy of such pre-submissions or submissions.

(3) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

(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 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 submit a report to the Committee on Appropriations of the House of Representatives and the Committee on Appropriations of the Senate on prescription drug monitoring programs and the initiatives of the Food and Drug Administration on the findings of the review under subsection (a). Such report shall include findings and recommendations—

(1) how best to leverage and build upon existing Federal and federally funded data assets such as prescription drug monitoring program data and the sentinel initiative of the Food and Drug Administration under section 566(c)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(c)(3)), as it relates to collection of information relevant to adverse events, patient safety, and patient outcomes, to create a centralized database for information sharing and analysis;

(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 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 adding after section 7420 the following:

SEC. 7445. ELECTRONIC FORMAT FOR SUBMISSIONS.

(a) DRUGS AND BIOLOGICS.—In general—

(i) 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), (c), (d), (e), or (f) 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—

(1) by striking paragraph (1), the Secretary may—

(III) the use in the event of oxygen deficiency or use in emergency resuscitation, when administered by properly trained personnel.

(VII) the event of the use of oxygen deficiency or use in emergency resuscitation, when administered by properly trained personnel.

(W) LABELING.—For oxygen provided pursuant to subparagraph (A), the requirements established in section 505(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.

(X) REQUIREMENTS 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 be subject to the assessed fees under section 739(a) on the basis of such deemed approval.

ARTICLE V

CONGRESSIONAL RECORD—SENATE
May 24, 2012

S3602

SEC. 11212. ADVISORY COMMITTEE CONFLICTS OF INTEREST.

SEC. 11213. COMBATING PRESCRIPTION DRUG ABUSE.

SEC. 11214. COMBATING PRESCRIPTION DRUG ABUSE.
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 requiring that the word "tanning" be used on tanning beds or on labels that are affixed to tanning beds to ensure that individuals are informed of the potential adverse health effects of exposure to ultraviolet radiation from tanning beds, 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 facilitate uniform and 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, 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 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), as amended by section 104, 738A (as amended by section 204), 744C (as added by section 333), and 744I (as added by section 403) of such Act, the Secretary shall—

(1) consider whether the data used in support of such application were conducted outside the United States, including in the European Union, are inadequate for the purpose of making a determination of approval, clearance, or licensure; and

(2) conduct such investigations as may be necessary to support such findings.

(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 of approval, clearance, or licensure, or of a device or drug pursuant to an application submitted under this Act, 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’), acting through the Commissioner, 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) 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 provisions of 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.

(c) ANNUAL PERFORMANCE REPORTS.—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.

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 priorities and goals of the Food and Drug Administration, including results-oriented goals, strategies, milestones, performance measures; and
"(B) the efforts to finalize and approve a comprehensive inventory of the information technology systems of the Food and Drug Administration that includes information technology requirements for each existing system, including the system function or purpose, status information, and a progress report on the development of the information technology strategic plan; and

(2) contain a description of 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 regulatory science for medical products; and

(c) ANNUAL PERFORMANCE REPORTS.—As part of the annual performance reports submitted to Congress under sections 738B(a) (as amended by section 104), 738A(a) (as amended by section 204), 744C(a) (as added by section 333), and 744I(a) (as added by section 403) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Secretary, for each of fiscal years 2014 through 2017, shall annually report on the progress made in implementing the strategy and goals set forth in paragraph (4) of such Act and in paragraph (5) of such Act, including reporting on specific metrics identified under paragraph (4) of such Act; and

(2) the integration and adoption of advances in regulatory science goals as set forth in paragraph (5) of such Act; 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, and the progress made in advancing the regulatory science goals outlined in the Medical Device User Fee Agreement commitment letter.

(d) THE EXTENT TO WHICH THE FOOD AND DRUG ADMINISTRATION HAS UTILIZED THE INFORMATION TECHNOLOGY STRATEGIC PLAN.—In the annual report required under subparagraph (A) of paragraph (2), the Comptroller General of the United States, as appropriate, shall detail the extent to which the Food and Drug Administration has utilized the information technology strategic plan.
(2) develop—

(A) a documented enterprise architecture program management plan that includes the tasks, activities, and timeframes associated with developing and maintaining the enterprise architecture and addresses how the enterprise architecture program management will be performed in coordination with other management disciplines, such as strategic planning, capital planning and investment control, and performance management; and

(B) a skills inventory, needs assessment, gap analysis, and initiatives to address skill gaps as part of a strategic approach to information technology human capital planning.

(b) 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) that identifies the 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 strategic information technology strategic plan, including the results-oriented goals, strategies, milestones, and performance measures identified in subsection (a)(1); and

(2) the effectiveness of the comprehensive information technology strategic plan described in subsection (a)(1), including the results-oriented goals and performance measures; and

(3) to 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 Chairman of the Committee on Energy and Commerce of the House of Representatives, and set forth in the Congressional Record:

"(1) the number of such applications that met the goals identified for purposes of 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 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—

"(A) the number of such applications that were subject to a refuse-to-file action;</p>
agreed to comply with the terms of the notice.

(2) Written notice.—For purposes of this subsection, the Secretary shall, within a reasonable time, consider a request to issue a written notice to authorize the supply of a covered drug for purposes of testing as described in paragraph (1), and the Secretary shall issue a written notice to each eligible drug developer for purposes of testing if—

(A) the eligible drug developer has agreed to comply with all conditions the Secretary considers necessary;

(B) in the event the eligible drug developer is conducting bioequivalence or other clinical studies, 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 compatible with 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;

(C) the eligible drug developer is in compliance with all applicable laws and regulations related to such testing, including any applicable laws 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 under subsection (f) or, a drug, including a biological product licensed under section 351(a) of the Public Health Service Act, that is subject to 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.

(4) Violation and penalties.—For purposes of subsection (b)(2) and sections 391, 303U(c)(4), 502(y), and 505(p), it shall be a violation of this subsection, and the Secretary may impose any penalty prescribed by law, for a covered drug that has not 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 for the conduct of an investigation with respect to an eligible drug developer, and the Secretary shall provide 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.

(5) Liability.—Unless the holder of the application for 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), 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 section 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 claims.

(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 conduct of an investigation with respect to a drug obtained under this subsection, and the eligible drug developer shall 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 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 any drug developer that receives a written notice from the Secretary that the holder of an application for a covered drug to an eligible drug developer for purposes of testing

(C) the eligible drug developer is in compliance with all applicable laws and regulations related to such testing, including any applicable laws related to Investigational New Drug Applications or informed consent.

(D) Additional required element.—The Secretary shall require as an element of each 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.

(E) Effect on other law.—Notwithstanding the provisions of this subsection, nothing in this Act, the antitrust laws, or section 351 of the Federal Trade Commission Act, or the Sherman Act (15 U.S.C. 1 and 2), 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.

(F) Technical and conforming amendments.—

(1) Section 505(s)(2) (21 U.S.C. 355(c)(2)) is amended by striking ‘‘(e)’’ and ‘‘(f)’’ and inserting ‘‘(e), (f), and (k)’’.

(2) Section 502(y) (21 U.S.C. 352(y)) is amended by striking ‘‘(d), (e), or (f) of section 505(c), or (d), (e), or (f) of section 506–1’’ and inserting ‘‘(d), (e), (f), or (k) 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. 506C. PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSIONS.

(a) IN GENERAL.—The Secretary shall develop and implement a program to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions, including—

(1) fostering participation of a patient representative who may serve as a special government employee in appropriate agency meetings with local 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 or personal beneficial interest under section 208(a) of title 18, United States Code.’’.

SEC. 1013. NANO TECHNOLOGY 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 National Science Foundation, the National Institutes of Health, and other appropriate Federal agencies, shall establish within the Food and Drug Administration a Nanotechnology Regulatory Science Program (referred to in this Act as the ‘‘program’’) to enhance scientific knowledge regarding nanomaterials included or intended for inclusion in products regulated under this Act.

(b) Program purposes.—The purposes of the program established under subsection (a) may include—

(1) developing 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 unique 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 nanomaterials and nanomaterials that might contribute to toxicity;

(4) promoting and participating in collaborative efforts to further the understanding of the safety of measurement and detection methodologies 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 fostering the expertise, for monitoring the production and presence of nanomaterials in domestic and imported products regulated under this Act, on the unique aspects of nanomaterials that might contribute to toxicity.

(7) Developing scientific expertise on nanomaterials within the Food and Drug Administration, including fostering the expertise, for monitoring the production and presence of nanomaterials in domestic and imported products regulated under this Act, on the unique aspects of nanomaterials that might contribute to toxicity.

(8) in cooperation with other Federal agencies, developing and organizing information using databases and models that will facilitate the identification of unique principles and characteristics regarding the behavior of classes of nanomaterials with biological systems and disseminating scientific information and data related to the interactions of nanomaterials with biological systems;

(9) in cooperation with other Federal agencies, developing and organizing information using databases and models that will facilitate the identification of unique principles and characteristics regarding the behavior of classes of nanomaterials with biological systems and disseminating scientific information and data related to the interactions of nanomaterials with biological systems;
“(B) coordinating and integrating the strategic plan with activities of 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;

“(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 1031 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) acts 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 the owners and operators of pharmacy Internet websites;

(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 such websites; and

(7) laws, policies, and activities that would educate consumers about how to distinguish legitimate pharmacy 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;

(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 take steps, in consultation with the Office of Minority Health of the Food and Drug Administration, to provide links to any other appropriate webpage, and seek public comment on the proposed information plan. SEC. 1136. 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 small businesses to prevent medication and device errors.

(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 small business involvement in 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 (21 U.S.C. 379g et seq.), 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. 379g et seq.);

(6) the number of small businesses submitting applications and receiving approval for solicited grant applications from the Food and Drug Administration;

(7) the number of small businesses submitting applications and receiving approval for unsolicited grant applications from the Food and Drug Administration;

(8) barriers small businesses encounter in the drug and medical device approval process;

(9) recommendations for changes in the user fee structure to help alleviate generic drug shortages.

SEC. 1137. ENSURING ADEQUATE INFORMATION REGARDING PHARMACEUTICALS FOR ALL POPULATIONS, PARTICULARLY UNDERREPRESENTED SUB-POPULATIONS, INCLUDING RACIAL ETHNIC HEALTH DISPARITIES.

(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 professionals and patient representatives on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

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 small businesses to prevent medication and device errors.

(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 small business involvement in 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 (21 U.S.C. 379g et seq.), 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. 379g et seq.);

(6) the number of small businesses submitting applications and receiving approval for solicited grant applications from the Food and Drug Administration;

(7) the number of small businesses submitting applications and receiving approval for unsolicited grant applications from the Food and Drug Administration;

(8) barriers small businesses encounter in the drug and medical device approval process;

(9) recommendations for changes in the user fee structure to help alleviate generic drug shortages.

SEC. 1139. PROTECTIONS FOR THE COMMISIONED CORPS OF THE PUBLIC HEALTH SERVICE ACT.

(a) In General.—Section 221(b) 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 Communicable Disease Prohibition of Retalatory Personnel Actions.”

(b) CONFORMING AMENDMENT.—Section 301 of the Public Health Service Act (42 U.S.C. 213(a)) is amended by adding at the end the following:

“For purposes of paragraph (18) of subsection (a), the term ‘Inspector General’ 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(i) of the Public Health Service Act (42 U.S.C. 290aa-3); and

(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(i); and

(4) the term ‘Secretary’ means the Secretary of Health and Human Services.

(b) Proposed Rulemaking.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with representatives of the pharmaceutical industry and representatives of the medical research community, shall issue a proposed rule for the purpose of—

(1) proposing to amend the definition of ‘applicable clinical trial’ in section 402(i) of such Act, as added by section 1140, to—

(2) requiring all applicable clinical trials that involve investigational drugs, devices, biologics, and/or procedures to be registered before the first enrollment of a subject in the trial, and to include at least the following information...

(3) requiring all registrants to submit to appropriate databases their reports on clinical trial results in a timely manner, and to include at least the following information...

(4) requiring all registrants to submit, within 90 days of the completion of an applicable clinical trial, their oral and written responses to any queries submitted by the Director, as required by section 402(i) of such Act; and

(5) requiring all registrants to submit, within 90 days of the completion of an applicable clinical trial, their oral and written responses to any queries submitted by the Director, as required by section 402(i) of such Act.

(c) Reports.—Not later than 1 year after the date of enactment of this Act, the Secretary shall—

(1) submit to Congress an initial report on the implementation of the proposed rulemaking pursuant to section 1140(b), that includes—

(2) a summary of comments received and sources of comment...
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).

(2) Final rule—Not later than 150 days after the issuance of the notice of proposed rulemaking under paragraph (1), the Secretary, acting through the Director, shall issue a final rule on the registration of applicable clinical trials by responsible parties under 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 401(b)(1), including—

(A) an assessment of legal, technical, financial, and programmatic challenges that may impact interoperability of State prescription monitoring programs in order to reduce fraud, diversion, and abuse of prescription drugs.

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

(A) information on the rate of compliance and non-compliance (by category of sponsor, category of drug, and phase I, 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) the reporting of such trials under such section; and

(iii) the completeness of the reporting of the required data under such section; and

(B) an assessment of the promulgation and implementation 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) in 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 801(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) 100 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoinquinoline alkaloid of opium; or

(ii) not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 30 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts, subparagraph (C) shall not apply and such compound, mixture, or preparation shall not be subject to control under such Schedule I;''.

SEC. 1142. COMPLIANCE DATE FOR RULE RELATING TO SUNSCREEN DRUG PRODUCTS OVER-THE-COUNTER HUMAN USE.

In accordance with the final rule issued by the Commissioner of Food and Drug entitled "Labeling and Effectiveness for Sunscreen Drug Products for Over-the-Counter Human Use; Delay of Compliance Dates" (77 Fed. Reg. 27591 (May 11, 2012)), a product subject to such final rule on or before May 24, 2012, 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. 1142A. RECOMMENDATIONS ON INTEROPERABILITY STANDARDS.

(a) In General.—The Attorney General and the Secretary of Health and Human Services shall consider the following in facilitating 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 Department of 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. 282(j)).

(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 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 Department of 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. 282(j)).

(c) Recommendations.—The Attorney General and the Secretary of Health and Human Services shall consider the following in facilitating 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 Department of 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. 282(j)).

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) Cannabinomimetic Agents.—Schedule I, as in effect on the date of enactment of this Act, to the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end the following:

"(d) In paragraph (1):"

"(i) "Cannabinomimetic 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:

"(A) 2-(3-hydroxyoctyl)cyclohexyl)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,

"(B) 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 naphthyl or naphthyl ring to any extent,

"(C) 3-(1-naphthyl)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 naphthyl ring to any extent,

"(D) 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,

"(E) 3-phenylactylindole 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 naphthyl ring to any extent,

"(F) 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, whether or not substituted on the naphthyl ring to any extent,

"(G) (1-naphthylmethane) 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,

"(H) (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;"

"(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-(2-phenyl-5-ethoxy-4-piperidinyl)acetyl]indole (CP-47,497) (CBO[homo-]human uses)"

"(iii) 1-pentyl-3-(1-naphthyl)indole (JWH–018 and AM676)"
Mr. REID. Madam President, I move to reconsider the vote and move to lay the matter on the table.

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 were it not for 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.

I want to thank the staff of the Senate for their tireless and diligent work on this bill. 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

RACHEL PYROR—BLUMENTHAL
JESSICA McNIECE, CHRISTINE EVANS—MIKULSKI
DEIDRE FRUH—CASEY
ANDREW Hu—KLOBUCAR
HANNAH KATCH, WHITNEY Brown—FRANKEN
JENNIFER DeANGELIS—WHITEHOUSE
SOPHIE KASTMOW—SANDERS
ROHINI Kosoglu, Sally Mayes—BENNETT
SUSANLEXER—MERKLEY
JOSHUA Teitelbaum—HAGAN
SANDRA Wiklns—BINGAMAN
JENNIFER Boyer—ROBERTS
HAYDEN Rhudy—HATCH
MARYSumpter Lipinski—ALEXANDER
CHRISTOPHER Bowlin—McCain
ANNA Abram, Margaret Coulter—Burr
ANNA Oswalt—Corker
AMA DA Makki—Murkowski

GENERATING ANTIBIOTIC INCENTIVES NOW

RACHEL PYROR—BLUMENTHAL
HANNAH KATCH, WHITNEY Brown—FRANKEN
SOPHIE KASTMOW—SANDERS
SUSANLEXER—MERKLEY
ROHINI Kosoglu—BENNETT
JOSHUA Teitelbaum—HAGAN
SANDRA Wiklns—BINGAMAN
MATT Prowler, Deidre Fruh—CASEY
CHRISTINE Evans, Jessica McNiece—MIKULSKI
MARGARET Coulter/Anna Abram—Burr
AMA DA 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 (SBC/PRE)

PAULA Berg—Murray
KATE Mevis—Reed
ROHINI Kosoglu, Sally Mayes—Bennett
JESSICA McNiece, Christine Evans—Mikulski
DEIDRE Fruh, Matt Prowler—Casey
HANNAH Katch, Whitney Brown—Francken
SOPHIE Kastmow—Sanders
ANNA Abram, Margaret Coulter—Burr
MARY Sumpter Lapinski, NICOLAS Magallanes—Alexander
JENNIFER Boyer—Roberts
TYLER Thompson—Issakson
AMA DA Makki—Murkowski
HAYDEN Rhudy, Paul Williams—Hatch

DRUG SUPPLY CHAIN

ROHINI Kosoglu—Bennett
JENNIFER DeAngelis, Justin Florence—Whitehouse
ANNA Abram—Burrr
ERIKA Smith—Grassley

Mr. HARKIN. On that note, I specifically thank the staff of Ranking Member ENZI’s office. I thank Frank Macchiola, Chuck Clapton, Keith Flanagan, Melissa Pfaff, Grace Stuntz, Katy Spangler, and Riley Swinehart. I
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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, our press secretary, 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 Lavel, 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 legislative 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 with 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 pass when we already have one contest, waiting for our Democratic minutes of debate equally divided and the previous order, there will be 10.

The legislative clerk will report.

Mr. MRUROBI, and Ms. AYOTTE, proposes an amendment to get a result. 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. This 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.

Mr. McCONNEL. 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 amendment is as follows:

(A) IN GENERAL.—Section 4002 of the Patient Protection and Affordable Care Act (42 U.S.C. 300t) is repealed.

(b) RESCISSION OF UNOBLIGATED FUNDS.—Of the funds made available by such section for the purpose of complying with the 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

Mr. McCONNEL. Madam President, 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 amendment is as follows:

(A) IN GENERAL.—Section 4002 of the Patient Protection and Affordable Care Act (42 U.S.C. 300t) is repealed.

(b) RESCISSION OF UNOBLIGATED FUNDS.—Of the funds made available by such section for the purpose of complying with the 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
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. Eszti and me to get things done, frankly, we are confronted now with two votes. Which way do we want to go? What is the proposal? It 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, smoke-free environments, 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 diabetest 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 from 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 $9.3 billion on the health care bill. We can give back to the students enough money to pay for this freezing of the rate.

We will not tax the small businesses. 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 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 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. The time 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 in July.

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.
Mr. REID. Mr. President, I understand the importance and value of a good education. The majority leader is recognized.

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 bill (H.R. 5740), as amended, was read the third time and was read the third time.

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.

Mr. NOWAKOWSKI (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

NAY—43

Mr. President, while our efforts are 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. The struggle 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 screeching 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 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.

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.

Mr. NOWAKOWSKI (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

NAY—43
The PRESIDENT: The PRESIDENT 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 PRESIDENT: 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 PRESIDENT 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 accord-ance 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. Laun-tenberg, Jeff Bingaman, Sheldon Whitehouse, John F. Kerry, Kent Con-rad, 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 PRESIDENT 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 PRESIDENT 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 pol-lution 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 tempera-tures 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 a 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 Oceanogra-phy found.

Science Daily reports:

Black carbon aerosols and tropospheric ozone, both humanmade pollutants emitted predominantly in the Northern Hemisphere’s low-to-mid-latitude.

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 poleward, impacting regional agriculture, economy, and society.

The American people have not been taken in by the campaign of propa-ganda that primarily the polluting in-dustries 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 then the sound legen-dary 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 cli-mate change—I quoted an article ear-lier, describing how over time the facts have proven his initial predictions ac-curate—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 ensure 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 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 pre-tend 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 cal-led back to the United States his rec-o mmendation. 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 his-tory will be made if America fails to recog-nize 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 re-gret 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 delayed back its expressions of interest and concern on this issue, probably for the practical reason that the Re-publican-controlled House does not...
want to deal with this issue at all. Perhaps, 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 go to fish with their grandfather 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 species called 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. One verse to another.

Well, landings of winter flounder in Rhode Island have crashed catastrophically. The reason? The mean winter temperature of Narragansett Bay is up about 4 degrees. That is enough of an ecosystem shift that had the winter flounder 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, and doubt should not 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 tell our grandchildren now that we are discharging into the atmosphere.

Of course, 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 Pen- sion Committee 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 unani- mous vote. 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—eloquent 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, 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, it is too late. 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. I remember 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 size was like 30-pound fish. Then there was a picture taken in the early 1980s—no, it is down to maybe 15 pounds. Same pictures, same pier, same dock and everything, and now the catch is down to tiny little fish. Same place, same ocean, same waters.

The article went on to point out how, if you think of our future, 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.

As the Chairman points out, by the time we look 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.

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. Scientists are not good at propaganda. It is not why they went to graduate school. They did not get 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 you are not even a 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 Senator for his recognition.

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.

Mr. Abdnor represented the state from 1974 to 1995. He was a successful farmer who had served as a state senator and in the U.S. House of Representatives before winning a seat in the Senate.

Mr. Abdnor was a strong advocate for conserving and protecting the natural resources of the country. He was a strong supporter of the federal government's role in managing public lands and resources.

He also had a strong commitment to the people of South Dakota. He fought for greater federal funding for rural development and infrastructure, and he was a strong advocate for the state's agricultural industry.

Mr. 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 when I first arrived in 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 met Jim, his 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 under 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 is an American story. It started as the tale of an immigrant who headed for the land of opportunity. That immigrant, Jim’s father Sam Abdelnour, wanted to escape the growing economic crisis in 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 farmer 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 the United States Senate. 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 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 use of recharge wells in Watertown, Edmunds, and Brown counties in north central South Dakota that began in 1983.

The question of water was never far from Jim’s mind. It had a lot 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. Jim’s 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 grew wheat, but like the Abdnors would do 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 spent 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.

Jim was the go-to guy for people in South Dakota. He was a champion for local control. As the son of a small businessman, Jim was sensitive to the encroachment of Federal regulations and the question of 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 said 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 estimated the Federal debt at $7 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. Jim votes that probably cost him his Senate seat. But Jim Abdnor had the moral courage to make the tough decisions.

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 encroachment of Federal regulations and the question of 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.

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Jim wasn’t afraid to make hard votes to fix our problems. Jim 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 urge the Senate to allow this resolution to pass swiftly.
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 senators on the other side of this 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 it may be 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. 406, that all after the enacting clause be stricken and the language of S. 295, 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 without further 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. 5652
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 3 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 bringing the debate to a close, and Republicans consented to limiting ourselves to just two amendments—just two. Our Democratic colleagues also added a provision for 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-Grasley 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 agreed to help them with 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 amendment: 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 and the text of the Senate-passed Violence Against Women bill, S. 295, 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 amendments 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 conferences 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. It, in fact, is the only way 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, last month, the Senate voted 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 agreed to help them with 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 amendment: 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 and the text of the Senate-passed Violence Against Women bill, S. 295, 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 amendments 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.

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The PRESIDING OFFICER. Objection is heard.

REMEMBERING BILL STEWART

Mr. MANCHIN. Mr. President, before I speak today about the bill before us, I want to congratulate 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 Virginia 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.
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 15 years as the 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 nation and is uniquely compatible with big names like Ken Norton, chief of staff, and Harris, co-founder of the College of the Enneagram. Berea College is the first college to engage all of its students in a service learning experience.

Dr. Shinn’s leadership has been recognized in this capacity since 1994. In a letter to the 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, and students have been instrumental in this transition. Shinn’s leadership has been characterized by his focus on a Christian ethic of service and its historic mission to promote the causes of Christ.

Dr. Shinn is a magna cum laude graduate of Baldwin-Wallace College and a Rhodes scholar at 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 the first 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 institutionalized a decisionmaking process and engaged 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 $150 million for endowments to fund student scholarships, undergraduate research, a new technology program for students, a study abroad program, an entrepreneur program, and other key initiatives. I know that Larry and his wife Nancy, are looking forward to extended time with their children and grandchildren during their pending retirement. I ask unanimous consent that 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, PLUS, PLUS (By Tim Jordan)

Berea College President Dr. Larry D. Shinn announced today that he will be retiring from the College, effective June 30, 2012. Dr. Shinn said that during his time in this position, he has observed in this capacity since 1994. In a letter to the 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, and students have been instrumental in this transition. Shinn’s leadership has been characterized by his focus on a Christian ethic of service and its historic mission to promote the causes of Christ.

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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, as we know it in America could not exist without their heroism.

On Memorial Day, we honor service-members 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 our 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, 117 Kentucky service-members 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. SGF 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 venerable 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 a 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 form, he was asked if he was safe or alive. 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 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, does his selfless act give us any indication 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, 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.

So I hope this Memorial Day, people will heed the advice of SGF 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 the Civil War, 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 American tradition of Memorial Day—or 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, publishers, and editors of the 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 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 1866, Congress and President Lyndon Johnson declared that Waterloo was 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 1917, Congress passed legislation to make Memorial Day a national holiday and by its 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 331 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 song which is as 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. That every name and 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 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 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 447,000.”

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 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. Our fallen service men and women 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 adequate number of mental health professionals 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 service members who believe that seeking mental health care will affect 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, 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 fell 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 Alaskans, this day brings us near our roots. We spent 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 ago, 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 gratitude, our respect and our admiration. 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 country. As we honor them 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 who gave his life 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 defend our debt to 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 have fallen recently 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 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 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 mil-
lion 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
cooal-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 home-
port of Ludington, MI, to Manitowoc,
WI, every summer. But they need to be
reminded of this: It is the last coal-
fi red ferry in the United States, and
every year it dumps another 500 tons of
cast off into Lake Michigan. Think
of historic significance than EPA regu-
lation.

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
cast-off coal ash into Lake Michigan.
Think about that for a moment—500 tons of
cast off 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 con-
cerned about coal ash because it con-
tains 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 behav-
ior that will just make this problem
worse?

If the Badger’s owners had only re-
cently 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.

Many people on 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
cast-off 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 reason-
able effort to stop dumping coal ash
into the lake. Instead, they are doing
to things they can 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 Transporta-
tion Act to exempt all vessels of his-
toric significance from environmental
regulation.

The national historic landmark desig-
nation was created to commemorate
properties that have special signifi-
cance in American history. The desig-
nation has been appropriately used to
protect sites including the home of
President Abraham Lincoln in Spring-
field, IL, and the S.S. Milwaukee Clip-
per, a retired steamer 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 Sala-
zar to oppose the designation of the
Badger as a national historic landmark.
I also urge everyone here in this
body to join me in opposing language
in the House Coast Guard and Maritime
Transportation Act that would exempt “vessels of historic significance” from EPA regu-
lation.

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strategy, the Badger’s owner came to
Washington to talk to me.
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for an EPA permit to continue dumping
cast-off coal ash into Lake Michigan.
Think about that for a moment—500 tons of
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
"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 unaltering in their appre-
ciation 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, in-
cluding the more than 70 military per-
sonnel from Mississippi who have died
in the service of our Nation in Iraq, Af-
ghanistan and around the world over the
past decade.

For the RECORD, I offer the names of
these brave Mississippians who have
died since the Nation commemorated
Memorial Day last year:
SGT Christopher R. Bell, 21, of Gold-
en, who died June 4, 2011.
SFC Billy E. Sutton, 42, of Tupelo,
SFC Stacy O. Johnson, 35, of Rollins,
under 9/11.

Mr. BLUMENTHAL. Mr. President, I
will offer the names of three brave
Mississippians who have died since the
Nation commemorated Memorial Day
last year:
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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 went viral, 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.”

And then, you know, that town was really easy to manage for the next few years.

Armendariz’s point was that making examples of certain businesses or industries would serve as a deterrent to ensure compliance. But in 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 “nuisance is when someone accidentally tells the truth.”

I know first-hand that Mr. Armendariz’s view is a truthful representation of how many small business owners feel. 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 failing 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 Bob Latham, who runs a small Internet sales company in Greenville, S.C. Mr. Latham started his business in 2005 and was preparing 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 imported soap.

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—it’s dedication to junking his entire shipment—when he tried to work with the agency.

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 no 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 worked 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.

As Bob Latham crystallized 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 that successful 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—such as Walmart—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 business.

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 Hender son State University Small Business Development Technology 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 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 and 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 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 relationship 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 that he is waiting out of bounds area for the Nebraska governor to sign the 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. And throughout his tenure, he strived to ensure fairness in the military justice system and remained vigilant so that military standards continued 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 a long and happy retirement 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 aide 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 then-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 become my first hire.

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. Denise and I spent a great deal of time together, working and socializing. One of Denise’s favorite traditions was our annual picnic at the Lake. 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 a 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 Nebraska 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 serving our 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 as Officer Candidate School in Newport, RI. Bryan successfully completed the rigorous nuclear pipeline and attended the 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 Integration 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 extremely decorated, exemplifying his strong work ethic and commitment to service. 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, Natasa, 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 of the women and men who wear the uniform of our armed services, and they deserve our support.

The invaluable sacrifices of our service members 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 service members 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 our 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 works at the world-renowned 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 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 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 efforts 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.

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 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.

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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, we have had an increase in rates 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 personal and statewise interest, for my gratitude to the volunteers of this Foundation and enter into the CONGRESSIONAL RECORD, a comprehensive summary that the accomplishment and impact that this Foundation has achieved from 2000 to 2012 for the families of my state and our nation. I would like 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 force to educate the public about 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, as a national organization 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 Foundation 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 to convey the initiative's messages within their States and nationally through State policy briefings, outreach to and through the media, broad distribution of materials through the media, 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 designates 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 their views and messages about their state's underage drinking prevention initiatives, and also taking the lead when needed. The Leadership membership has always been uniquely qualified to help move the conversation around underage drinking to a higher level and broader audience. Its niche has been successful in a relatively short time. Many organizations and experts in the field of prevention view the Governor as the household drinking as key in placing childhood and underage drinking front and center on the national agenda. Often in collaboration with national and statelevel initiatives, the Leadership Foundation has accomplished our purpose by voicing concerns in national conversations on related issues; providing ongoing support towards the creation of a national agenda. Often in collaboration with national and statelevel initiatives, the Leadership Foundation has accomplished our purpose by voicing concerns in national conversations on related issues; providing ongoing support towards the creation of a national agenda. Often in collaboration with national and statelevel initiatives, the Leadership Foundation has accomplished our purpose by voicing concerns in national conversations on related issues; providing ongoing support towards the creation of a national agenda. Often in collaboration with national and statelevel initiatives, the Leadership Foundation has accomplished our purpose by voicing concerns in national conversations on related issues; providing ongoing support towards the creation of a national agenda. Often in collaboration with national and statelevel initiatives, the Leadership Foundation has accomplished our purpose by voicing concerns in national conversations on related issues; providing ongoing support towards the creation of a national agenda.
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 addition, several products were developed 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 the arrest of a driver convicted of driving under the influence of alcohol and alcohol-related offenses. The Surgeon General participated in a town hall meeting on the University of Oregon campus and addressed four prevention and treatment professionals in the state. The Surgeon General also hosted the Surgeon General's visit to Montana that included a three-day visit that included numerous presentations at the Enforcing Underage Drinking Laws (EUDL) Conference.

Since 2000, the Leadership Foundation has also been invited to present at a variety of national, state, and local conferences. These included numerous presentations at the Leadership Initiative into the Leadership Foundation after leaving the Governor's Residence. Recipients of the Hope Award have been Hope Taft, First Lady Emeritus of Ohio and current President of the Foundation, and Karen Baldacci, First Spouse of Vermont. The Leadership Foundation is recognized for their outstanding efforts through The Racicot Leadership Award, and The Hope Award. In 2010, the Leadership Foundation Board of Directors created the Raccoit Leadership Award to be given annually to a sitting First Spouse who had made significant accomplishments in his/her state on underage drinking prevention efforts. Recipients of the Raccoit Leadership Award have been First Lady Mikey Hoeven who served as co-chair of the Raccoit Leadership Foundation and was recognized for her work. In addition, the Surgeon General has been invited to present at a variety of national, state, and local conferences when he/she is a member of the foundation's board of directors.
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 anti-drug drinking efforts, 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 (YRBS) survey was administered, 50.8% of youth in grades 9-12 reported current alcohol use in the past month. In 2009 the latest survey results 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 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 ten-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 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 causes a host of neurocognitive, 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 Association). The website, with the First Spouse convenor, 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 regulatory 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 50's 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 grow. 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 1986 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 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 an officer 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 Citizens. 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 the 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 assist them in 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, may encourage 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 small towns. 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 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 200 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 for 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 same can be said for American culture. 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 the 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 Dr. 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 his 20-year-old mother joined her 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 1968, 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.
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–A397) 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 Dock 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 “Fishing Zones Off West Coast States; West Coast Salmon Fisheries; 2012 Management Measures” (RIN2018–X329) 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 “Fishing Zones of the Northeastern United States; Northeast Multispecies Fishery; Interim Final Rule; Repatriation” (RIN9668–X378) 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 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 Comment Period” (RIN2120–AK65) (Docket No. FAA–2012–04019) received in the Office of the President of the Senate on May 15, 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 “Federal Class E Airspace; Boyne City, MI” (RIN2120–AA46) (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–6251. 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, IN” (RIN2120–AA46) (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–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; Southport, NC, and Establishment of Class E Airspace; Oak Island, NC” (RIN2120–AA46) (Docket No. FAA–2011–0559) 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 “Establishment of Class E Airspace; Sandusky, OH, and Revocation of Class E Airspace: Cuyahoga, OH” (RIN2120–AA46) (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–6254. 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; Piscataway, NJ” (RIN2120–AA46) (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–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; Willcox, AZ, and Revocation of Class E Airspace: Cochise, AZ” (RIN2120–AA46) (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.
transmitting, pursuant to law, the report of a rule entitled “Airworthiness Directives; Pratt and Whitney Turbofan Engines” ((RIN2120–AA64) (Docket No. FAA–2007–27203)) 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–2011–0966)) 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; 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–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; 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–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; 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–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; Bombardier Inc. Airplanes” ((RIN2120–AA64) (Docket No. FAA–2011–0780)) 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–2011–1206)) 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” ((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; Empresa Brasil de Aeronautica S.A. (EMBRAER) Airplanes” ((RIN2120–AA64) (Docket No. FAA–2011–20)) 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; Turbomeca S.A. Turbo shaft 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–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; Luna C69b and Installed on Airbus Airplanes” ((RIN2120–AA64) (Docket No. FAA–2012–0011)) 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–2012–0022)) 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; 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–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; General Dynamics Corporation Engine Support International” ((RIN2120–AA64) (Docket No. FAA–2012–0322)) 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. Turbo shaft Engines” ((RIN2120–AA64) (Docket No. FAA–2012–0030)) 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; S32 Support Services GmbH Airplanes” ((RIN2120–AA64) (Docket No. FAA–2011–3138)) 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; 328 Support Services GmbH Airplanes” ((RIN2120–AA64) (Docket No. FAA–2011–3123)) 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; Cessna Citation Spirit” ((RIN2120–AA64) 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; General Electric–Alco Steam Turbine Engines,” 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, a report entitled “Achloribenzolar–S–methyl; Time–Limited Pesticide Tolerances” ((PRL No. 9369–3) 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 “Swap Dealer,” “Major Swap Participant,” “Major Swap” ((RIN2120–AA64) received in the Office of the President of the Senate on May 15, 2012; to the Committee on Commerce, Science, and Transportation.
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–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 and Resources, Office of the Secretary of Defense, transmitting, pursuant to law, the report of a rule entitled “Defense Federal Acquisition Regulation Supplement; Contracting with the Canadian Government” (DAR 89–01–0012) 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 of defense that was originally declared in Executive Order 13199 relative to the risk of nuclear proliferation created by the advent of nuclear weapons-related 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 “Flood Insurance Premium Rate Information (FIRI)-I” (Docket No. FEMA–2012–0007) 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 67) (Docket No. FEDERAL REGISTER 1–2012–0003) 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–2012–0005) 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 Chairman and Managing Director, Farm Credit System Insurance Corporation, 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 (LNG) and the Committee on Energy and Natural Resources.”

EC–6301. A communication from the Secretary of Energy, 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 Secretary, Office of Energy Efficiency and Renewable Energy, Department of Energy, transmitting, pursuant to law, the report of a rule entitled “Loan Guarantees for Projects That Employ Innovative Technologies” (RIN1001–AB52) 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, a rule entitled “Partial Approval and Promulgation of Implementation Plans; Washington: Infrastructure Requirements for the 1997 8-Hour Public Standard and Annual Gasoline 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. 9673–9) 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 Implementing Plans for Air Quality Standards in Minnesot (Rev. Rul. 2012–15) received in the Office of the President of the Senate on May 22, 2012; to the Committee on Finance.

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 Implementation Plan; South Coast Rule 1315” (FRL No. 9669–4) 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 Inter-Area development, Nuclear Regulatory Commission, transmitting, pursuant to law, the report of a rule entitled “Export and Import of Nuclear Equipment and Material; Exports of Nuclear Technology and Facilities; Nuclear Safeguards Samples” (RIN3150–A704) 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 Secretary, Under Secretary of Defense (Acquisition, Technology, and Logistics), transmitting, pursuant to law, the report of a rule entitled “Amendment of Americans with Disabilities Act to Specify a Specified Compliance Date for Certain Requirements Related to Existing Pools and Spas Provided by State and Local Governments” (RIN1190–0025) 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 Commission, transmitting, pursuant to law, the Commission’s 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 Commission, transmitting, pursuant to law, the Farm Credit System Insurance Corporation’s fiscal year 2011 annual report relative to the Notification and Federal Employee Anti-discrimination 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 Office of the Comptroller of the Currency’s fiscal year 2011 annual report relative to the National Credit Union Administration Act of 2002; 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
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, from the date of his confirmation.

(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, Mr. MINK, lady, Mr. MURRAY, and Mr. TESTER):

S. 3253. 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. JOHANNES):

S. 3235. A bill to amend title 38, United States Code, to require, as a condition on the issuance of benefits or licenses, and for other purposes; to the Committee on Veterans’ Affairs.
S. 3248. A bill to designate the North American bison as the national mammal of the United States; to the Committee on the Judiciary.

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. BROWN of Massachusetts (for himself, Mr. BERECKI, and Mr. RISCH):

S. 3250. A bill to amend the DNA Analysis Backlog Reduction Act of 2000 to provide for Debbie Smith grants for auditing 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. HAYDEN, Ms. AYOTTE, Mr. BARRASSO, Mr. BLUMENTHAL, Mr. CORNYN, Mr. RISCH, Mr. COCHRAN, Mr. UDALL of Colorado, Mr. CROMITI, Mr. JOHNSON of Wisconsin, Mr. NELSON of Florida, Mr. TOOMEY, Mr. WICKER, Mr. LEE, Mr. COONS, Mr. GRAHAM, Ms. LANDRIEU, and Mr. BARRASSO):

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. AYOTTE, Mr. BLUMENTHAL, Mr. BOOZMAN, Mr. BROWN of Massachusetts, Mr. BROWN of Ohio, Mr. BURR, Ms. CANTWELL, Mr. CARDIN, Mr. CARPER, Mr. CASEY, Mr. CHAMBLISS, Mr. COATS, Mr. COURNOYER, Mr. COLINS, Mr. CONRAD, Mr. COONS, Mr. CORKER, Mr. CORNYN, Mr. CRAMER, Mr. DEMINT, Mr. DURBIN, Mr. ENZI, Ms. FEINSTEIN, Mr. FRANKEN, Mr. GRASSLEY, Mr. GRAHAM, Mr. GRASSLEY, Ms. HAGAN, Mr. HARKIN, Mr. HELLER, Mr. HOVEN, Mrs. HUTCHISON, Ms. AISCH, Mr. INOUYE, Mr. ISAKSON, Mr. JOHANNES, Mr. JOHNSON of Wisconsin, Mr. KERRY, Mr. KIRK, Ms. KLOBUCHAR, Mr. KOHL, Mr. KYRIS, Ms. LANDRIEU, Mr. LEAHY, Mr. LEE, Mr. LIEVIN, Mr. LIEBERMAN, Mr. LUGAR, Mr. MANCHIN, Mr. MCCAIN, Mrs. MCCASKILL, Mr. MENENDEZ, Mr. MURKOWSKI, Mr. NELSON of Nebraska, Mr. NELSON of Florida, Mr. PAUL, Mr. POMPEO, Mr. PEYTON, Mr. ROCKEFELLER, Mr. ROCKFELLER, Mr. RUBIO, Mr. SANDERS, Mr. SCHUMER, Mr. SESSIONS, Mr. SHAHEEN, Mr. SHELY, Ms. SNOWE, Ms. STABENOW, Mr. Tester, Mr. TOOMEY, Mr. UDALL of Colorado, Mr. UDALL of New Mexico, Mr. VITTER, Mr. WARNER, Mr. WEHR, Mr. WHITEHOUSE, Mr. WICKER, and Mr. WYDEN):

S. Res. 475. 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 Foreign Relations.

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. BERICH, Mr. BENNET, Mr. BINGHAM, Mr. BLUMENTHAL, Mr. BLUNT, Mr. BOOZMAN, Mr. BOXER, Mr. BROWN of Massachusetts, Mr. BROWN of Ohio, Mr. BURR, Ms. CANTWELL, Mr. CARDIN, Mr. CARPER, Mr. CASEY, Mr. CHAMBLISS, Mr. COATS, Mr. COYNE, Mr. COLINS, Mr. CONRAD, Mr. COONS, Mr. CORKER, Mr. CORNYN, Mr. CRAPO, Mr. DEMINT, Mr. DURBIN, Mr. ENZI, Ms. FEINSTEIN, Mr. FRANKEN, Mr. GRASSLEY, Mr. GRAHAM, Mr. GRASSLEY, Mrs. HAGAN, Mr. HARKIN, Mr. HELLER, Mr. HOVEN, Mrs. HUTCHISON, Ms. AISCH, Mr. INOUYE, Mr. ISAKSON, Mr. JOHANNES, Mr. JOHNSON of Wisconsin, Mr. KERRY, Mr. KIRK, Ms. KLOBUCHAR, Mr. KOHL, Mr. KYRIS, Ms. LANDRIEU, Mr. LEAHY, Mr. LEE, Mr. LIEVIN, Mr. LIEBERMAN, Mr. LUGAR, Mr. MANCHIN, Mr. MCCAIN, Mrs. MCCASKILL, Mr. MENENDEZ, Mr. MURKOWSKI, Mr. NELSON of Nebraska, Mr. NELSON of Florida, Mr. PAUL, Mr. POMPEO, Mr. PEYTON, Mr. ROCKEFELLER, Mr. ROCKFELLER, Mr. RUBIO, Mr. SANDERS, Mr. SCHUMER, Mr. SESSIONS, Mr. SHAHEEN, Mr. SHELY, Ms. SNOWE, Ms. STABENOW, Mr. Tester, Mr. TOOMEY, Mr. UDALL of Colorado, Mr. UDALL of New Mexico, Mr. VITTER, Mr. WARNER, Mr. WEHR, Mr. WHITEHOUSE, Mr. WICKER, and Mr. WYDEN):

S. Res. 473. A resolution commending Royalty 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. BERICH, Mr. 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 Foreign Relations.

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. BERICH, Mr. BENNET, Mr. BINGHAM, Mr. BLUMENTHAL, Mr. BLUNT, Mr. BOOZMAN, Mr. BOXER, Mr. BROWN of Massachusetts, Mr. BROWN of Ohio, Mr. BURR, Ms. CANTWELL, Mr. CARDIN, Mr. CARPER, Mr. CASEY, Mr. CHAMBLISS, Mr. COATS, Mr. COYNE, Mr. COLINS, Mr. CONRAD, Mr. COONS, Mr. CORKER, Mr. CORNYN, Mr. CRAPO, Mr. DEMINT, Mr. DURBIN, Mr. ENZI, Ms. FEINSTEIN, Mr. FRANKEN, Mr. GRASSLEY, Mr. GRAHAM, Mr. GRASSLEY, Mrs. HAGAN, Mr. HARKIN, Mr. HELLER, Mr. HOVEN, Mrs. HUTCHISON, Ms. AISCH, Mr. INOUYE, Mr. ISAKSON, Mr. JOHANNES, Mr. JOHNSON of Wisconsin, Mr. KERRY, Mr. KIRK, Ms. KLOBUCHAR, Mr. KOHL, Mr. KYRIS, Ms. LANDRIEU, Mr. LEAHY, Mr. LEE, Mr. LIEVIN, Mr. LIEBERMAN, Mr. LUGAR, Mr. MANCHIN, Mr. MCCAIN, Mrs. MCCASKILL, Mr. MENENDEZ, Mr. MURKOWSKI, Mr. NELSON of Nebraska, Mr. NELSON of Florida, Mr. PAUL, Mr. POMPEO, Mr. PEYTON, Mr. ROCKEFELLER, Mr. ROCKFELLER, Mr. RUBIO, Mr. SANDERS, Mr. SCHUMER, Mr. SESSIONS, Mr. SHAHEEN, Mr. SHELY, Ms. SNOWE, Ms. STABENOW, Mr. Tester, Mr. TOOMEY, Mr. UDALL of Colorado, Mr. UDALL of New Mexico, Mr. VITTER, Mr. WARNER, Mr. WEHR, 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 Congress— man 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.
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 Ryan 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. 3982

At the request of Mr. Rubio, the name of the Senator from Idaho (Mr. Crazo) was added as a cosponsor of S. 3982, 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. 3293

At the request of Mr. Lautenberg, the names of the Senator from New Jersey (Mr. Menendez) and the Senator from Georgia (Mr. Isakson) and the Senator from North Carolina (Mr. Burr) were added as cosponsors of S. 3293, a bill to amend the Internal Revenue Code to make permanent the exclusion of the fundable portion of the child tax credit.

S. 3201

At the request of Mr. Cantwell, the names of the Senator from Iowa (Mr. Harkin) and the Senator from Arizona (Mr. Udall) were added as cosponsors of S. 3201, 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. 1141

At the request of Mr. Cardin, the names of the Senator from Wisconsin (Mr. Johnson) and the Senator from Maryland (Mr. Cardin) were added as cosponsors of S. 1141, 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. 1406

At the request of Mr. Baucus, the name of the Senator from Illinois (Mr. Durbin) was added as a cosponsor of S. 1406, 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. 1766

At the request of Mr. Johanns, his name was added as a cosponsor of S. 1766, 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. 1969

At the request of Ms. Cantwell, the name of the Senator from Iowa (Mr. Harkin) was added as a cosponsor of S. 1969, 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 Georgia (Mr. Menendez) was added as a cosponsor of S. 1993, a bill to posthumously award a Congressional Gold Medal to Mickey Rooney in recognition of his 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 increased 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 Oregon (Mr. Wyden) 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.

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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 Ryan 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.

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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 increased 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 Oregon (Mr. Wyden) 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.
(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. 45
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 Ms. LANDRIEU, the names of the Senator from Alaska (Mr. BINGGELI), 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. 210
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. 216
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 states have low classen 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.

This legislation is necessary 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 timetable 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 joining 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 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 redesigning subsections (b), (c), (d), (e), (f), and (g) as subsections (f), (g), (h), (i), (j), and (k), respectively;

(3) by redesigning subsections (h) and (i) as subsections (l) and (o), respectively;

(4) by redesigning subsections (j), (k), and (l) as subsections (r), (s), and (t), respectively;

(5) by redesigning 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) ENVIRONMENTAL ENRICHMENTS.—

"(1) 'Eggs from free-range hens' to indicate that the egg-laying hens in 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) '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 for human consumption, in commerce, but does not include an open barn or other fixed structure without internal caging devices.

"(f) by inserting after subsection (k), 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.

"(o) 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.

"(B) beginning 15 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 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 106 square inches of individual floor space per brown hen and 94 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 14 years after the date of enactment of the Egg Products Inspection Act Amendments of 2012, a minimum of 110 square inches of individual floor space per brown hen and 102 square inches of individual floor space per white hen.

"(ii) The term ‘feed-withdrawal molting’ means the practice of preventing food 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:

"(1) Existing caging devices.—All existing 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.

"(2) New caging devices.—All new 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, a minimum of 110 square inches of individual floor space per brown hen and 102 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 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 and until the date that is 14 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 82 square inches of individual floor space per white hen.

"§ 7A. Housing and treatment of egg-laying hens.
``(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 a minimum of 25 square inches of individual floor space per white hen.

``(3) CALIFORNIA CAGING DEVICES.—All caging devices in California must provide egg-laying hen space per bird with a minimum of 144 square inches of individual floor space per brown hen and 25 square inches of individual floor space per white hen.

``(A) beginning January 1, 2015, and through December 31, 2020, 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) beginning January 1, 2021, a minimum of 144 square inches of individual floor space per brown hen; 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 UNREINCRIBLABLE CAGHS.—No person shall build, construct, implement, or operate 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 put 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 that were 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 derived from egg-laying hens not in commercial egg production or to an egg handler who either sells, offers or exchanges, or holds for sale, any eggs on or 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 a minimum of 25 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 125 square inches of individual floor space per brown hen and 25 square inches of individual floor space per white hen.

``(c) FINAL CONVERSION PHASE.—As of December 31, 2029, all egg-laying hens confined to 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 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 by January 1, 2028, the Secretary shall require that each installation of existing caging devices placed into operation prior to January 1, 1995, be replaced with new devices not in commerce.

``(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).

``(g) Importations.—Section 17 of the Egg Products Inspection Act of 1970 (21 U.S.C. 1047) is amended in 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 redesigning 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 housed or treated in violation of any provision of section 7A, or

``(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 any eggs or egg products derived from egg-laying hens unless the egg-laying hens are—

``(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)” after ‘‘Before any violation of this chapter is reported by the Secretary”.'
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 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 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:

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.

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 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.

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 the economy has grown, there has been 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 and programs affecting SCORE chapters, we can ensure that entrepreneurs in all areas of our economy are served by high-quality mentoring services. Specifically, this bill is aimed at increasing the oversight for organization and oversight of the SCORE program.

While some may argue that funding for SCORE should be increased, I believe it is not the answer to our recovery. 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 the members of SCORE’s total 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 60 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 that the National Director of SCORE and the CEO shall 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 the expenses of the SCORE Advisory Board to 65 percent of the aggregate expenses incurred by SCORE chapters and mentoring services.

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:

SEC. 1. SHORT TITLE. This Act may be cited as the “SCORE Program Improvement Act of 2012.”

SEC. 2. DEFINITIONS. In this Act—

(a) the term “Administration” and “Administrator” mean the Small Business Administration and the Administrator thereof, respectively;

(b) 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));

(c) the term “SCORE Advisory Board” means the SCORE Advisory Board established under section 101 of this Act;

(d) the term “SCORE chapter” means a chapter of the Service Corps of Retired Executives;

(e) the term “small business concern” has the meaning given that term under section 3 of the Small Business Act (15 U.S.C. 631).

SEC. 101. ESTABLISHMENT OF SCORE 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) shall be employees or employees of small business concerns or members of an association that represents small business concerns;

(3) Promotion.—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 the provisions 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.

(3) Initial meetings.—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.

(4) Meetings.—The SCORE Advisory Board shall meet—

(A) not less frequently than semiannually; and

(B) 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 other projects 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).

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 of the responsibilities of the SCORE Advisory Board described in section 4.

(c) Information from Federal Agencies.—The SCORE Advisory Board may secure such information as the SCORE Advisory Board considers necessary to carry out this Act. Upon request of the Chairman of the SCORE Advisory Board, any 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 may receive 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 ADMINISTRATIVE PROVISIONS TO THE SCORE ADVISORY BOARD.

(a) Provision.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply with respect to the SCORE Advisory Board.

(b) Funding.—The expenses of the SCORE Advisory Board, including expenses relating to personnel services described in subsection (a), 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. §739(b)(1)(B)).

TITLE II—FINANCIAL REFORMS

SEC. 201. REAUTHORIZATION.

Section 20 of the Small Business Act (15 U.S.C. 637) is amended—
(1) by redesignating subsection (j) as subsection (f); and
(2) by adding at the end the following:

"SEC. 202. CHIEF EXECUTIVE OFFICER OF SCORE.

(a) LIMITION 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 in 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—
(1) 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 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—
(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. HOVEN, Mr. THUNE, Mr. BENNET, Mr. UDALL of Colorado, Mr. MORA, Mr. UDALL of New Mexico, Mr. JOHNSONS, 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. The American Bison, or the American buffalo, is a species native to North America and I am 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 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 the bison on its official seal for 94 years and the buffalo nickel played an important role in modernizing our currency in the 20th century. At one point in American history, bison were brought in to graze outside the original Smithsonian building here in Washington, DC.

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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-Qaeda and the Talibans 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 322 victims 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, children 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 for International Rotary, a global association that was founded in 1905 in Chicago, Illinois, is currently headquartered in Eagan, Minnesota, and has 1.2 million members in more than 170 countries;

Whereas Rotary International and its member clubs (commonly known as “Rotarians”) have contributed more than $1 billion and volunteered countless hours in the global fight against polio;

Whereas the Federal Government is the leading contributor 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 immi-

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. JOHNSEN 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, Ms. Feinstein, Mr. Franken, Mrs. Gillibrand, Mr. Graham, Mr. Grassley, Mrs. Hagans, Mr. Harkin, Mr. Hatch, Mr. Herrmann, 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. McCaин, Mrs. McCaskill, Mr. Menendez, Mr. Merkley, Ms. Mikulski, Mr. Moran, Ms. Murray, 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, 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. Whitmer, Mr. Wyden, and Mr. Wyden) submitted the following resolution:

Resolved, That the Senate recognizes—
(1) the significance of May 2012 as Asian-Pacific American Heritage Month and the Congressional Asian Pacific American Caucus, a bicameral caucus of Members of Congress advocating on behalf of Asian-Americans and Pacific Islanders, is comprised of a record high 41 Members in 2012;
(2) the 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; and
(3) the Asian-American and Pacific Islander community enhances the rich diversity of, and strengthens, the United States.

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 access to resources, both in the Federal Government, and continue to advance in the political landscape of the United States; and
Whereas 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.

Whereas James Abdnor was elected to the United States Senate for the State of South Dakota in 1972 and served a total of 4 consecutive terms, representing the 93rd United States Congress in 1972, and the 94th United States Congress in 1973 through 1974; and
Whereas James Abdnor served as Chairman of the Young Republican National Federation from 1953 to 1955; and
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; and
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; and
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; and
Whereas James Abdnor served on the Committee on Public Works on 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; and
Whereas James Abdnor was elected to the United States Senate for the 97th United States Congress in 1983 and was appointed Chairman of 3 subcommittees on his first day, including the Subcommittee on Treasury, Postal Service, and Governmental Operations of 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 served as 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 small farms and small business, rural water systems and electrification, a balanced budget, and small-town values;
Whereas James Abdnor was appointed by President George W. Bush, as the Administrator of the United States Small Business Administration; and
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 wisdom, 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 Sergeant at Arms shall cause the flag to be flown at half-staff as a 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. Bennet, 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. 731, 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:

[Congressional Record - Senate, May 24, 2012, page S3640]
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. 300a–11) is repealed.

(b) RESCISSION OF UNOBLIGATED FUNDS.—Of the funds made available by such section 4002, the unobligated balance is rescinded.


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 S. 739, to authorize the Architect of the Capitol to establish battery recharging stations for privately owned vehicles in parking facilities in 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.

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. 4015(e)) is amended by striking “any properties within any single” and inserting “any properties within any single”.

(b) PHASE-OUT OF SUBSIDIZED PREMIUM RATES.—Section 1308(e)(2) of the National Flood Insurance Act of 1968 (42 U.S.C. 4016(a)) is amended by striking “the earlier of the date of enactment into law of an Act that specifically amends the date specified in this section or May 31, 2012” and inserting “July 31, 2012”.

(c) EFFECTIVE DATE.—The first increase in chargeable risk premium rates for 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 thereafter, 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).".

SEC. 3. COMPLIANCE WITH PAY-WITH.

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 of Michigan) 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 facilities in the jurisdiction of the Senate at no net cost to the Federal Government; as follows:

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 2:15 p.m., to conduct a hearing entitled “Programs and Services for Native Veterans.”

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

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.

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., to conduct a hearing entitled “Deterrence: The Global Implications of Poaching in Africa.”

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

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–626 of the Dirksen Senate Office Building, at 2:15 p.m., to conduct an executive business meeting.

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

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 1:00 p.m., to conduct a hearing entitled, “Iran Threat Reduction Act of 2011.”

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

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 2:15 p.m., to conduct a hearing entitled, “The Iran Sanctions, Accountability, and Human Rights Act of 2012.”

The PRESIDING OFFICER. Without objection, it is so ordered.
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 Iran's Revolutionary Guard Corps

Sec. 211. Imposition of sanctions with respect to the provision of vessels or shipping services to transport certain goods related to proliferation or suicide attacks.

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 Subsidiaries 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 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 prohibition on foreign persons that engage in certain transactions with Iran's Revolutionary Guard Corps.

Sec. 312. Determinations of whether the National Petroleum Company and the Iranian National Oil Company are agents or affiliates of Iran's Revolutionary Guard Corps.

Sec. 313. Expansion of measures that prohibit financial transactions with Iran's Revolutionary Guard Corps.

Sec. 314. Expanding measures that prohibit financial transactions with persons who engage in censorship or other related activities against citizens of Iran.

Sec. 315. Additional measures to promote human rights in Iran.

Sec. 316. Expanded consideration of requests for authorization of certain human rights, humanitarian-, and development-related activities with respect to Iran.

Sec. 317. Comprehensive strategy to promote Internet freedom and access to information in Iran.

Sec. 318. Sense of Congress on political prisoners.

TITLE IV—MEASURES RELATING TO HUMAN RIGHTS ABUSES IN IRAN

Subtitle A—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.

Sec. 405. Additional measures to promote human rights in Iran.

Sec. 406. Expedited consideration of requests for authorization of certain human rights, humanitarian-, and development-related activities with respect to Iran.

Sec. 407. Comprehensive strategy to promote Internet freedom and access to information in Iran.

Sec. 408. Sense of Congress on political prisoners.

TITLE V—MISCELLANEOUS

Sec. 501. Exclusion of citizens of Iran seeking to purchase or sell goods or services.

Sec. 502. Technical correction.

Sec. 503. Interdiction of certain financial assets of Iran.

Sec. 504. Report on membership of Iran in international organizations.

Sec. 505. Increased capacity 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. Sense of the Congress.

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. Sanctions of persons with respect to persons who engage in censorship or other forms of repression in Syria.

Sec. 705. Waiver.

Sec. 706. Termination.

TITLE II—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 under mining and destabilizing its neighbors and other countries; and

(2) to fully implement all multilateral and bilateral sanctions against Iran, as part of larger sanctions regimes.
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 cease development and dismantle its ballistic missile and conventional 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 capabilities, while effectively achieving the 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 when it comes to Iran’s 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 to 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
(E) 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 law, or support described in this subparagraph are not agreed to impose such sanctions or measures;
(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 other measures to further the policy set forth in section 101 and a description of those measures; and
(2) 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 of a 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 that the United States should take all necessary measures to preserve robust information-sharing activities.

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 multilateral 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; and
(2) an identification of the countries that have not agreed to impose such sanctions or measures;

(c) UNILATERAL SANCTIONS.—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—

(1) the joint venture is established on or after January 1, 2002; and
(2)(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.

(d) 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 DEVELOPMENT OF PETROLEUM SECTORS OF IRAN.

Section 5(a) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) 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 1 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, supplies, provisions, services, technology, or support described in subparagraph—

(B) goods, services, technology, or support described.—Goods, services, technology, or support described in this subparagraph are 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 within Iran;
(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 PETROLEUM FACILITIES 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 any 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 $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 (A) and (B), respectively, and inserting after such clauses, as so redesignated, 2 ems to the right;

(B) by striking “a person has, on or after.” and inserting before “a person”—

“(A) on or after.”;

(C) in subparagraph (A)(ii), as redesignated, by striking the period and inserting “;”;

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 Act, 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:

“(A) 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) 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)(i) if the person participating in the joint venture terminates 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 corporative officer or a shareholder or a person holding 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:

“(C) CREDIBLE INFORMATION.—The term ‘credible information’, with respect to a person—

“(i) 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 government organization;

“(D) 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.—Section 104(c)(2)(B) of the Comprehensive Iranian 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:—

“(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) in the case of 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...
194 of the Comprehensive 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. 210. AGENCY OBTAINED COMPANIES FOR VIOLATIONS OF SANCTIONS BY FOREIGN SUBSIDIARIES.

(a) Definition.—In this section:

(1) ENTITY.—The term ‘entity’ means a partnership, association, trust, joint venture, corporation, or other organization.

(2) The term ‘own or control’ means, with respect to an entity—

(A) to hold more than 50 percent of the equity interests of value in the entity; or

(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 publish a notice that the annual or quarterly report that identifies an 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 Heads of the International Atomic Energy Agency between the United Nations, signed June 26, 1947, and entered into force November 21, 1947. (c) Restrictions on Visas and Adjustments in Immigration Status.—Except as provided in subsection (d), 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 Heads of the International Atomic Energy Agency between 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 VICTIMIZATION OF SPECIALIZED FINANCIAL MESSAGING SERVICES TO THE CENTRAL BANK OF IRAN OR 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;

(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, 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) 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 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) 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 paragraphs (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) 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.

(2) FORM OF REPORT.—A report submitted under paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

(3) AUTHORIZATION OF THE IMPOSITION OF SANCTIONS.—

(a) IN GENERAL.—Except as provided in paragraph (1) and subsection (b), the President may impose sanctions pursuant to section 104(c) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)) if—

(1) the Central Bank of Iran; and

(2) a financial institution identified under 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:

(i) the person is subject to a sanctions regime under its governing foreign law that requires the person to cease doing business with 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 the person to cease doing business with 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) the group of financial institutions under that governing foreign law are in the United States, and the person is a non-U.S. national foreign person if such property and interests in property are in the United States, or are or come within the possession or control of a United States person.

(ii) a transaction relating to the manufacture, importation, exportation, or transfer of items needed for the development by Iran of nuclear, missile, or other weapons of mass destruction; or

(iii) a financial transaction or series of financial transactions identified under this subsection is—

(A) a transaction relating to the manufacture, importation, exportation, or transfer of items needed for the development by Iran of nuclear, missile, or other weapons of mass destruction; or

(B) a financial transaction or series of financial transactions identified under this subsection is—

(i) a transaction relating to the manufacture, importation, exportation, or transfer of items needed for the development by Iran of nuclear, missile, or other weapons of mass destruction; or

(ii) a transaction relating to the procurement or sale of goods, services, and technology related to Iran's petrochemical sector.

(iii) 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. 8513(c)(3)));

(iv) a transaction relating to the manufacture, importation, exportation, or transfer of items needed for the development of foreign persons pursuant to section 560.304 of title 31, Code of Federal Regulations (relating to the definition of the Government of Iran); and

(v) a transaction relating to the manufacture, importation, exportation, or transfer of items needed for the development of foreign persons pursuant to section 560.304 of title 31, Code of Federal Regulations (relating to the definition of the Government of Iran).

(3) E XCEPTION.—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) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(E)(ii))—

(A) the person is subject to a sanctions regime under its governing foreign law that requires the person to cease doing business with 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) the group of financial institutions under that governing foreign law are in the United States, and the person is a non-U.S. national foreign person if such property and interests in property are in the United States, or are or come within the possession or control of a United States person.

(4) PRIORITY FOR INVESTIGATION.—In identifying foreign persons pursuant to section (a)(1) as officials, agents, or affiliates of Iran's Revolutionary Guard Corps, the President shall give priority to investigating—

(a) foreign persons for which there is a reasonable basis to find that the person has conducted or attempted to conduct one or more significant transactions or activities described in subsection (c).

(b) 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, missile, or other weapons of mass destruction, including conventional weapons, including ballistic missiles;

(3) a transaction relating to the manufacture, procurement, or sale of goods, services, and technology related to Iran's petrochemical 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. 8513(c)(3)));

(6) EXCLUSION FROM UNITED STATES.—

(A) 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.)—

(i) designates for the imposition of sanctions pursuant to that Act; and

(ii) 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, or are or come within the possession or control of a United States person.

(B) PRIORITY FOR INVESTIGATION.—In identifying foreign persons pursuant to section (a)(1) as officials, agents, or affiliates of Iran's Revolutionary Guard Corps, the President shall give priority to investigating—

(1) foreign persons for which there is a reasonable basis to find that the person has conducted or attempted to conduct one or more significant transactions or activities described in subsection (c).

(2) 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, missile, or other weapons of mass destruction, including conventional weapons, including ballistic missiles;

(3) a transaction relating to the manufacture, procurement, or sale of goods, services, and technology related to Iran's petrochemical 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. 8513(c)(3)));

(6) EXCLUSION FROM UNITED STATES.—

(A) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, and as appropriate thereafter, the President shall—

(i) identify foreign persons that are officials, agents, or affiliates of Iran's Revolutionary Guard Corps; and

(ii) 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 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, or are or come within the possession or control of a United States person.

(2) AUTHORIZATION OF THE IMPOSITION OF SANCTIONS.—

(a) IN GENERAL.—Except as provided in paragraph (1) and subsection (b), the President may impose sanctions pursuant to section 104(c) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)) if—

(1) the Central Bank of Iran; and

(2) a financial institution identified under section 104(c)(2)(E) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(E)(ii)) if:

(i) the person is subject to a sanctions regime under its governing foreign law that requires the person to cease doing business with 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

(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 or a financial institution identified under such governing foreign law for purposes of that sanctions regime.
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.

(6) by the President—

(a) I N GENERAL.—Section 6(b) of the Iran Sanctions Act of 1996, as amended by subsection (a), is further amended—

(1) by striking ''Not later than 90 days'' and inserting ''the revision to subsection 303(a)(1) of United States Code''; and

(ii) in subparagraph (B), by striking ''(i)'' and inserting ''(ii)''

(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)(A) shall be submitted with respect to contracts for which solicitations are issued on or after the date that is 60 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012.

SEC. 312. DETERMINATIONS OF WHETHER THE NATIONAL IRANIAN OIL COMPANY OR THE NATIONAL IRANIAN TELECOMMUNICATIONS COMPANY ARE AGENTS OR AFFILIATES OF IRAN'S REVOLUTIONARY GUARD CORPS.

Subtitle B—Additional Measures Relating to Iran’s Revolutionary Guard Corps.

SEC. 311. EXPANSION OF PROCUREMENT PROHIBITION TO FOREIGN PERSONS ENGAGING 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 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 transacts with any Revolutionary Guard Corps or any of its official 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)—

(ii) 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 CERTIFICATIONS RELATING TO TRANSACTIONS 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)(A) shall be submitted with respect to contracts for which solicitations are issued on or after the date that is 60 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012.”.


SEC. 312. DETERMINATIONS OF WHETHER THE NATIONAL IRANIAN OIL COMPANY AND THE NATIONAL IRANIAN TELECOMMUNICATIONS 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:

“(D) DETERMINATIONS REGARDING NIOC AND NITC.—

(A) DETERMINATIONS.—For purposes of paragraphs (3)(A) and (5)(A), the Secretary shall, not later than 60 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, determine whether 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.
TITLE IV—MEASURES RELATING TO HUMAN RIGHTS ABUSES IN IRAN

Subtitle A—Expansion of Sanctions Relating to Human Rights Abuses in Iran.

SEC. 405A. 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 an updated list under paragraph (1) of persons who the President determines have knowingly engaged in, or facilitate the transfer of, goods or technologies 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.

(b) Definitions.—In this section:

(1) NIOC.—The term ‘NIOC’ means the National Iranian Oil Company.

(2) NITC.—The term ‘NITC’ means the National Iranian Tanker Company.

(3) Government of Iran.—The term ‘Government of Iran’ means the Government of the Islamic Republic of Iran.

(4) Revolutionary Guard Corps.—The term ‘Revolutionary Guard Corps’ means the Revolutionary Guard Corps of Iran.

(5) Any person.—The term ‘any person’ means any person, natural or juridical, including any entity, organization, or agency.

(6) Transactions.—The term ‘transactions’ includes, but is not limited to—

(A) the importation of goods or services by another person on behalf of the person who is the subject of a transaction;

(B) the transfer of funds, directly or indirectly, for the purpose of financing any activity described in this section;

(C) any other transaction that the President determines is another form of support for any activity described in this section.

(b)_sanctions 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 such agencies or instrumentalities) to commit serious human rights abuses against the people of Iran, including—

(1) 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

(2) sensitive technology (as defined in section 109(c)).

(2) 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 determines that the activity described in paragraph (2) for which the President would otherwise have included the person on the list; and

(3) Applications of sanctions.—The President shall not be required to impose the sanctions described in section 505(c) with respect to a person from the list required by subsection (b) if—

(A) the person is no longer engaging in, or has taken significant 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 an updated list to the appropriate congressional committees an updated list under paragraph (1) if—

(A) each time the President is required to submit an updated list to those committees under section 109(b)(1); 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 under subsection (b) 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.—The President shall impose sanctions described in section 105(c) with respect to a person on the list required by subsection (b) if—

(A) 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 person that is an agent of the Government of Iran, for use in or with respect to Iran; or

(B) 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.

(2) Exclusions.—The President may exclude from the requirements of this subsection any person—

(A) who is not a citizen of Iran; or

(B) with respect to whom the President determines that—

(i) the person is a country, an international organization, a regional organization, or an intergovernmental organization;

(3) If a contract or other agreement is entered into after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012.

(d) 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.
SEC. 401. 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.—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 an asset of the central bank or monetary institution of Iran or any entity owned or controlled by the Government of Iran.

"(2) Updates of list.—The President shall update the list submitted under paragraph (1)—

"(A) each time the President is required to update an updated list to those committees under section 105B(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 preceding part IV of title 22, Code of Federal Regulations is amended by inserting "105B" in the appropriate place.

SEC. 411. EXPEDITED CONSIDERATION OF REQUESTS FOR AUTHORIZATION OF HUMAN RIGHTS ACTIVITIES AGAINST CIVILIAN AND MILITARY, HUMAN RIGHTS, HUMANTARIAN, AND DEMOCRACY-RELATED ACTIVITIES WITH RESPECT TO IRAN.

(a) REQUIREMENT.—The Office of Foreign As-

SEC. 412. COMPREHENSIVE STRATEGY TO PROMOTE INTERNET FREEDOM AND ACCESS TO INFORMATION IN IRAN.

SEC. 413. SENSE OF CONGRESS ON POLITICAL PRISONERS.

SEC. 414. SENSE OF CONGRESS ON HUMAN RIGHTS ACTIVITIES IN IRAN.
that such foreign securities intermediary or a re-
lated 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 for such actions.
(b) PROPERTY DESCRIBED.—Property described
in this subsection is property that is identified
in and subject to the proceedings in the United
States.
(c) RULE OF CONSTRUCTION.—Nothing in this
section shall be construed to affect the avail-
ability or lack thereof, of a right to a judgment
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敌 Actors Act (50 U.S.C. App. 5(b)) or
under section 202 or 203 of the International
and 1703); and
(B) includes property that—
(i) is subject to a license issued by the United
States Government for final payment, or
disposition, of any license, or property, subject to the juris-
diction of the United States, in connection
with a transaction for which the issuance of the license has been specifically required by a provi-
sion of law other than the International Emer-
(ii) is property subject to the Vienna Conven-
tion on Consular Relations, or that enjoys equivalent privileges and immunities under the laws of the United States, and is being used ex-
clusively for diplomatic or consular purposes.
(2) FINANCIAL ASSET; SECURITIES INTER-
MEDIARY.—The terms "financial asset" and "se-
curities intermediary" have the meanings given
those terms in the Uniform Commercial Code,
but the former includes cash.
(3) IRAN.—The term "Iran" means the Gov-
ernment of the Islamic Republic of Iran, or any agency or instrumentality of that Govern-
ment.
(a) PERSON.—
(A) IN GENERAL.—The term "person" means
an individual or entity.
(B) ENTITY.—The term "entity" means a part-
nership, association, trust, joint venture, cor-
poration, group, subgroup, or other organiza-
tion.
(2) TERRORIST PARTY.—The term "terrorist
party" means the party of war or an authorization of the use of force
involving the President.
(3) FORM OF REPORT; PUBLIC AVAIL-
ABILITY.—Nothing in this Act or the amendments made
by this Act shall apply to the authorized intel-
ligence activities of the United States.
SEC. 602. APPLICABILITY TO CERTAIN INTEL-
LIGENCE ACTIVITIES.
Nothing in this Act or the amendments made
by this Act shall apply to the authorized intel-
ligence activities of the United States.
SEC. 603. RULE OF CONSTRUCTION WITH RE-
PECT TO USE OF FORCE AGAINST IRAN.
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 its nationals.
SEC. 604. TERMINATION.
The provisions of sections 211, 213, 215, 216, 217, and 501, title I, and subtitle A of title II shall terminate on the date that is 30 days after
the date on which the President makes the cer-
ification described in section 401(a) of the
Comprehensive Iran Sanctions, Accountability, and Divest-
ment Act of 2008, as added by subtitle A of title
IV of this Act.
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.
SEC. 702. IMPOSITION OF SANCTIONS WITH
RESPECT TO CERTAIN PERSONS WHO ARE RESPONSIBLE OR
COMPETENT IN HUMAN RIGHTS
ABUSES COMMITTED AGAINST CITI-
zens of Syria or their Family Members.
(a) IN GENERAL.—The President shall impose
sanctions described in subsection (c) with re-
spect to any person on the list required by sub-
section (b).
(b) LIST OF PERSONS WHO ARE RESPONSIBLE FOR OR COMPETENT IN CERTAIN HUMAN RIGHTS
ABUSES.—
(1) IN GENERAL.—Not later than 90 days after
the date of the enactment of this Act, the Presi-
dent shall submit to the appropriate congres-
sional committees a list of persons who are offi-
cials of the Government of Syria or persons act-
ing on behalf of that Government that the Presi-
dent determines have knowingly engaged in
activities described in paragraph (1) of this sub-
section, and each such person is 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 mem-
ers, regardless of whether such abuses occurred
in Syria.
(B) PUBLIC AVAILABILITY.—The list required by paragraph (1) shall be made available to the public and posted on the websites of the Department of the Treas-
ury and the Department of State.
SEC. 703. IMPOSITION OF SANCTIONS WITH
RESPECT TO THE TRANSFER OF GOODS OR TECHNOLOGY 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 sub-
section (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
activities described in paragraph (2) for
which the person was included in the list; or
(C) is owned or controlled by, or under com-
mon 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, know-
ingly engaged in the activity described in subsec-
section (c), and the President determines have
knowingly engaged in an activity described in paragraph (2) on or after such date of enactment.
(b) TYPE OF ACTIVITY DESCRIBED.—
(A) IN GENERAL.—A person engages in an ac-
tivity described in this paragraph if the person—
(i) transfers, or facilitates the transfer of,
goods or technologies described in subparagraph
(1); and
(ii) provides services with respect to goods or
technologies described in subparagraph
(1) for which the person was included in the list,
and for which the person engaged in activities described in subsection (c), and
the President determines have knowingly engaged in an activity described in paragraph (2) on or after such date of enactment.
(C) TO SYRIA; OR
SEC. 704. 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 15, 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 organiza-
tion on an annual basis.
SEC. 505. INCREASED CAPACITY FOR EFFORTS TO
COMBAT UNLAWFUL OR TERRORIST
RECEIPT OF GOODS OR SERVICES
(a) AUTHORIZATION OF APPROPRIATIONS FOR
OFFICE OF TERRORISM AND FINANCIAL INTEL-
LIGENCE AND BUREAU OF INDUSTRY AND SECU-
RITY.—Section 109 of the Comprehensive Iran
Sanctions, Accountability, and Divestment Act
of 2010 (22 U.S.C. 8517) is amended—
(1) in subsection (a)(5), by striking "2009, "2010, "2011" and inserting "2016"; and
(2) in subsection (d)(2), by striking "2013" and inserting "2016".
(b) AUTHORIZATION OF APPROPRIATIONS FOR
FINANCIAL CRIMES ENFORCEMENT NETWORK.—
Section 3106(d)(1) of title 31, United States Code, is amended by striking "and 2013" and inserting "through 2016".
(c) RULE OF CONSTRUCTION.—Nothing in this
section shall be construed to affect the avail-
ability, or lack thereof, of a right to a judgment
against a terrorist party in any proceedings other than proceedings
referred to in subsection (b).
(2) PROPERTY DESCRIBED.—Property described
in this subsection is property that is identified
in and subject to the proceedings in the United
States.
(c) RULE OF CONSTRUCTION.—Nothing in this
section shall be construed to affect the avail-
ability, or lack thereof, of a right to a judgment
against a terrorist party in any proceedings other than proceedings
referred to in subsection (b).
(2) PROPERTY DESCRIBED.—Property described
in this subsection is property that is identified
in and subject to the proceedings in the United
States.
(c) RULE OF CONSTRUCTION.—Nothing in this
section shall be construed to affect the avail-
ability, or lack thereof, of a right to a judgment
against a terrorist party in any proceedings other than proceedings
referred to in subsection (b).
(2) PROPERTY DESCRIBED.—Property described
in this subsection is property that is identified
in and subject to the proceedings in the United
States.
(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 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) for use by the Syrian armed forces, other armed elements of the Syrian Government, or any of its agencies or instrumentalities, for crimes against humanity, war crimes, genocide, or crimes against the Syrian people;

(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) EXCLUSION.—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)).

(2) contains a classified annex.

(3) FORM OF REPORT: PUBLIC AVAILABILITY.—(A) The President shall submit to the appropriate congressional committees the certification described in subsection (1) 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.

(4) 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.

(5) 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.

(6) FORM OF REPORT: PUBLIC AVAILABILITY.—(A) 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 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 restricts, 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 described in subsection (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) 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 described in 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 any such section 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 disrupted, 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 procuring 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.
Mr. BARRASSO. Mr. President, I rise to speak on the nomination of Sara Margalit Aviel, of California, 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: Calibration 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 of 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 alleviation 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 appear 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 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 usual 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 to place the following nominations on the Calendar:

- 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 other than the bills and no further motions be in order to any of the nominations; and 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 8, 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 Kazarian, 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 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 Republic of Swaziland.

Scott H. DeLisi, of Minnesota, 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 Belgium.

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.

Eric 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.

Katharine G. McFarland, 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:


The following named officer for appointment in the Reserve of the Army to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

Col. Wayne A. Zimmet

IN THE ARMY

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:

Maj. Gen. Theodore C. Nicholas

Air 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:

Brig. Gen. Leslie J. Carroll

Brigadier General Bryan R. Kelly

Brigadier General Peter S. Lennon

Brigadier General Gary A. Medivy

Brigadier General Dave W. Puster

Brigadier General Megan P. Tatun

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. Chatwood

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. Toney

In the Marine Corps

The following named officer for appointment in the United States Marine Corps to
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 brigadier general

Col. Burke W. Whitman

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 rear admiral

Capt. John F. Kirby

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 rear admiral (lower half)

Capt. Brian B. Brown

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 major general

Brig. Gen. Jean M. Larijive

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:

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

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 brigadier general


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. Robert W. Neller

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 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 H. Copeman, III

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 admiral

Vice Adm. David M. Buss

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 admiral

Vice Adm. Michelle J. Howard

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 admiral

Vice 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 admiral

Vice Adm. Jonelle J. Hunter

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. Israel A. Wood, and ending MATHEW L. SMITH, which nominations were received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1588 AIR FORCE nomination (15) beginning NATHAN R. KIM AND 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. BLACKBURN, 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 23, 2012.

PN1559 ARMY nominations (2) beginning Rhonda J. Brockington, and ending Vickie S. 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.

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 Laurell A. Treadwell, 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 JOANNA B. COUCH, and ending RICHARD J. YOUN, which nominations were received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1642 ARMY nomination of Ricardo A. Buentello, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

IN THE NAVY

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. SPELMAN, 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. WEBTHALL, 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 MATHEW L. SMITH, which nominations were received by the Senate and appeared in the Congressional Record of May 10, 2012.

PN1588 AIR FORCE nominations (15) beginning NATHAN R. KIM AND ALHOLINNA, and ending CRAIG M. ZIEMBA, which nominations were received by the Senate and appeared in the Congressional Record of May 10, 2012.
PN1649 ARMY nomination of Matthew W. Moffitt, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1650 ARMY nomination of Nathaniel V. Chittick, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1651 ARMY nomination of Lauri M. Zilke, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1652 ARMY nomination of Timothy A. Crane, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1654 ARMY nomination of Ryan L. Jerke, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1655 ARMY nomination of Matthew R. Sun, which was received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1657 ARMY nominations (3) beginning GREGORY P. CHANEY, and ending LAWRENCE E. SCHLOERGL, which nominations were received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1658 ARMY nominations (4) beginning AMY F. COOK, and ending PAUL S. TAMANAKI, which nominations were received by the Senate and appeared in the Congressional Record of May 14, 2012.

PN1659 ARMY nominations (9) beginning MICHAEL J. 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 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 E. DRAPCHO, 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. Wilson, 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. Navarrete, 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. Weidle, which was received by the Senate and appeared in the Congressional Record of March 19, 2012.

PN1458 NAVY nomination of Andrew J. Stricklin, which was received by the Senate and appeared in the Congressional Record of April 23, 2012.

PN1550 NAVY nomination of Andrew K. Leiford, 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.

PN1629 NAVY nomination of Steven J. Porter, which was received by the Senate and appeared in the Congressional Record of May 11, 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 on 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 on motions; that no other 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 CHIL MARRIAGE ACT OF 2011
Mr. REID. I ask unanimous consent that 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.

Mr. 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 to achieve dignified and democratic 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 resource in development. 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 I proceed to a 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 and read the third time 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:

SEC. 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 Institute.

(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, Burkina Faso, and Nepal, according to Demographic Health Survey data.

(5) Factors perpetuating child marriage include poverty, 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 the girls, including significantly increased risk of maternal death 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) According to the State Department, Secretary 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 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 areas with high-prevalence areas for child marriage.

(11) Investments in girls' schooling, creating safe community spaces for girls, and programs 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 constitute a foreign policy goal of the United States;

(2) the practice of child marriage undermines United States investments in foreign aid and assistance to activities in 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 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 health care, education, 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 educational fees and other costs associated with educational 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) 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;

(4) assistance to train adolescent girls and their parents in financial management, access to economic opportunities, including livelihood skills, savings, microfinance, and small-enterprise development;

(5) support for education, including through community and faith-based organizations and youth programs, that helps to 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 reduce the perceived value of girls;

(6) support for peer-mentoring networks and safe social spaces specifically for girls; and

(7) assistance to create peer support and female mentoring networks and safe social spaces specifically for girls and women.

(b) ACTIVITIES SUPPORTED.—Assistance authorized under subsection (a) shall be integrated with existing United States development programs.

(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) 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) may be made available to activities in 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 health care, education, 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 educational fees and other costs associated with educational 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) 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 management, access to economic opportunities, including livelihood skills, savings, microfinance, and small-enterprise development;

(5) support for education, including through community and faith-based organizations and youth programs, that helps to 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 reduce the perceived value of girls;

(6) support for peer-mentoring networks and safe social spaces specifically for girls; and

(7) assistance to create peer support and female mentoring networks and safe social spaces specifically for girls and women.

(e) ACTIVITIES SUPPORTED.—Assistance authorized under subsection (a) may be made available to activities in 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 health care, education, 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 educational fees and other costs associated with educational 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) 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 management, access to 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 to 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 reduce the perceived value of girls;
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 minimum age for marriage 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 minimum age for marriage 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 gives the authority to 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 electric-vehicle 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 those 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 would 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 own 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 vehicles in our parking lots. As chairman 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 if it were 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 joined 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 cost the Federal government one cent. S. 739 funds the maintenance and installation 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 the 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’’ and 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 included in 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 construct, maintain and operate the stations described under subparagraph (A) 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 authorization for—

(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 Capitol shall submit a plan to the Committee on Rules and Administration of the Senate on how to end or to limit, including programs 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 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 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 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.

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 all peoples 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 personnel 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 750,000 of the more than 2,000,000 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 more than 2,000,000 veterans from all wars who sought care at a Department of Veterans Affairs medical center received treatment for 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 Departments of Defense and Veterans Affairs collaborate to bring PTSD treatment to servicemembers who sustain PTSD-related injuries;

Whereas PTSD significantly increases the risk of depression, suicide, and drug- and alcohol-related disorders and deaths, especially if left untreated;

Whereas many cases of PTSD remain 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 PTSD is recognized as a unique challenge 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 would 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 De-
fense 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 Interior and Public Works of the House of Rep-
resentatives, the Committee on 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 Congress-
man from 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 Ken-
nebec, South Dakota, on February 13, 1923, and was the son of an immigrant from Leb-
anon 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 Repub-
licans from 1950 to 1952, and Farm Chairman of the Young Republican National Federa-
tion from 1953 to 1955;

Whereas James Abdnor served as the First Assistant Chief Clerk of the South Dakota House of Representatives during the legisla-
tive sessions of 1951, 1953, and 1965;

Whereas James Abdnor was elected to the South Dakota Senate in 1956, where he served until his election as the 30th Lieuten-
ant 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 97th United States Congress in 1980 and was appointed Chairman of 3 subcommittees on his first day, including the Subcommittee on Treas-
ury, Postal Service, and General Govern-
ment of the Committee on Appropriations of the Senate, the Subcommittee on Water Re-
sources of the Committee on Environment and Public Works of the Senate, and the Subcommittee on Agriculture and Transpor-
tation of the Joint Economic Committee;

Whereas James Abdnor was appointed Vice Chairman of the Joint Economic Committee and served on the Committee on Indian Af-
fairs of the Senate;

Whereas James Abdnor was a voice for the rural United States in Congress, where he advocated for family farms and small busi-
ness, 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 Ad-
ministrator of the United States Small Busi-
ness Administration from 1987 to 1989 fol-
lowing his service in the United States Cong-
gress;

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 polit-
ics; 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 Rep-
resentatives 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 Representa-
tives 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.

ORDERS FOR FRIDAY, MAY 25

MAY 25, 2012, AT 2:30 P.M.

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 Sen-
ate, the President pro tempore, and the majority leader and minority leader be authorized to make appointments to commissions, committees, boards, conferences, or interparliamentary con-
ferences authorized by law, by concur-
rent action of the two Houses, or by order of the Senate.

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

PROGRAM

Mr. REID. It is my intention to re-
sume the motion to proceed to S. 3220, the paycheck fairness bill, when the Senate convenes on Monday, June 4. There will be a rolloca
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 LIPMAN, OF NEW YORK, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE STATE JUSTICE INSTITUTE FOR A TERM EXPIRING SEPTEMBER 17, 2014. VICE ROBERT A. MILLER, TERM EXPIRED.

JONATHAN LIPMAN, OF NEW YORK, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE STATE JUSTICE INSTITUTE FOR A TERM EXPIRING SEPTEMBER 17, 2015.

NUCLEAR REGULATORY COMMISSION

ALLISON M. MACABALAN, OF MARYLAND, TO BE A MEMBER OF THE NUCLEAR REGULATORY COMMISSION FOR THE TERM EXPIRING JUNE 30, 2013. VICE GREGORY B. JACKEO, REASSIGNED.

DEPARTMENT OF STATE

GERTA CHRISTINE BOLTZ, OF MARYLAND, A CAREER MEMBER OF THE FEDERAL SERVICE, CLASS OF MINISTER-COUNSELOR, TO BE AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE SULTANATE OF OMAN.

ALEXANDER M. LARKAR, 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.

MARGUERITE J. BIRK, OF THE DISTRICT OF COLUMBIA, A CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF COUNSELOR-APPOINTED, TO BE AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE REPUBLIC OF BULGARIA.

DEPARTMENT OF JUSTICE 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 CSUCIK, JR., TERM EXPIRED.

IN THE ARMY

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE RESERVE OF THE 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
L.T. GEN. HOWARD R. EMMERSON

DISCHARGED NOMINATIONS

The Senate Committee on Foreign Relations was discharged from further consideration of the following nominations by voice vote and the nominations were confirmed:

DAVID J. LANE, OF FLORIDA, FOR THE RANK OF AMBASSADOR DURING HIS TENURE OF SERVICE AS U.S. REPRESENTATIVE TO THE UNITED NATIONS NATIONS ACTIVITIES 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:


The Senate Committee on Appropriations was discharged from further consideration of the following nominations by voice vote and the nominations were confirmed:

NOMINATIONS BEGINNING WITH OCTOBER 4, 2013.

CONFIRMATIONS

Executive nominations confirmed by the Senate May 24, 2012:

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

MATTHEW FRANCIS MCCARTY, OF PENNSYLVANIA, TO BE A BOARD OF DIRECTORS OF THE CORPORATION FOR NATIONAL AND COMMUNITY SERVICE FOR A TERM EXPIRING OCTOBER 4, 2013.

SECURITIES INVESTOR PROTECTION CORPORATION


GREGORY KARAWAN, OF VIRGINIA, TO BE A DIRECTOR OF THE SECURITIES INVESTOR PROTECTION CORPORATION FOR A TERM EXPIRING DECEMBER 31, 2014.

INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT

SARA MARAGLIAT AVIEL, OF CALIFORNIA, TO BE UNITED STATES REPRESENTATIVE EXECUTIVE DIRECTOR OF THE INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT FOR A TERM OF TWO YEARS.

THE JUDICIARY

ROY WALLACE MULRONEY, JR., OF THE DISTRICT OF COLUMBIA, TO BE AN ASSOCIATE JUDGE OF THE DISTRICT OF COLUMBIA COURT OF APPEALS FOR THE TERM OF FIVE YEARS.

DEPARTMENT OF ENERGY

ADAM E. SIEMINSKI, OF PENNSYLVANIA, TO BE ADMINISTRATOR OF THE ENERGY INFORMATION ADMINISTRATION.

FEDERAL ENERGY REGULATORY COMMISSION


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.

SCOTTH R. DELIS, 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 BEND.

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 SWAZIлан.

DEPARTMENT OF STATE

MICHAEL A. RAYNOR, OF MARYLAND, A CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF COUNSELOR-APPOINTED, TO BE AMBASSADOR EXTRAORDINARY AND PLINNIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE REPUBLIC OF KINSHASA.

SCOTT H. DELIS, OF MINNESOTA, A CAREER MEMBER OF THE SENIOR FOREIGN SERVICE, CLASS OF MINISTER-COUNSELOR, TO BE AMBASSADOR EXTRAORDINARY AND PLINNIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE REPUBLIC OF BEND.

ERIN C. CONATON, OF THE DISTRICT OF COLUMBIA, TO BE UNDER SECRETARY OF DEFENSE FOR ACQUISITION, TECHNOLOGY, AND LOGISTICS.

DEPARTMENT OF DEFENSE

JESSICA LYNN WRIGHT, OF PENNSYLVANIA, TO BE AN ASSISTANT SECRETARY OF DEFENSE.

JAMES S. MILLER, JR., OF VIRGINIA, TO BE UNDER SECRETARY OF DEFENSE FOR POLICY.

FRANK KENDALL II, OF VIRGINIA, TO BE UNDER SECRETARY OF DEFENSE FOR PROCUREMENT POLICY.

BRIGADIER GENERAL PETER S. LENNON, OF NEBRASKA, TO BE AN ASSISTANT 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. MCCLARLAND, OF VIRGINIA, TO BE AN ASSISTANT SECRETARY OF DEFENSE.

IN THE AIR FORCE

THE FOLLOWING AIR NATIONAL GUARD OF THE UNITED STATES OFFICERS FOR APPOINTMENT IN THE RESERVE OF THE AIR FORCES 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 OFFICERS FOR APPOINTMENT IN THE RESERVE OF THE AIR FORCES TO THE GRADE INDICATED UNDER TITLE 10, U.S.C., SECTIONS 12300 AND 12211:

To be brigadier general
Col. Wayne A. Ziemm

IN THE ARMY

THE FOLLOWING NAMED OFFICERS 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:

Maj. Gen. Theodore C. Nichols

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:

Col. Francisco A. Refaillat

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., SECTIONS 6128 AND 12211:

To be brigadier general
Col. John L. Green

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 6128:

To be lieutenant general
L.T. Gen. Michael T. Flynn

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 6128:

To be lieutenant general
L.T. Gen. Thomas D. Waldhauser

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 6128:

To be lieutenant general
L.T. Gen. Jon M. Davis

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 6128:

To be general
Gen. Philip M. Breedlove

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 6128:

To be general
L.T. Gen. Larry O. Spencer

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 6128:

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 6128:

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 6128:

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 6128:

The following nominations 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:
JAMES MADISON MEMORIAL FOUNDATION


UNITED STATES PAROLE COMMISSION

CHARLIES THOMAS MASSARO, 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 S. EVERLETH, TO BE LIEUTENANT COLONEL.

AIR FORCE NOMINATIONS BEGINNING WITH CRAIG W. HINKLEY AND ENDING WITH HENRY A. SPEELMAN, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON APRIL 23, 2012.

AIR FORCE NOMINATIONS BEGINNING WITH JOHNNY S. WESTPHALL AND ENDING WITH ELIJAS E. IBU, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON APRIL 23, 2012.

AIR FORCE NOMINATIONS BEGINNING WITH MARK J. BARTCH 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 LIEUTENANT COLONEL.

AIR FORCE NOMINATIONS BEGINNING WITH LESLIE A. WOOD AND ENDING WITH THOMAS J. SMITH, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 15, 2012.

AIR FORCE NOMINATIONS BEGINNING WITH NATHAN BARRY ALBRECHT AND ENDING WITH CRAIG M. ZIEMICZ, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 15, 2012.

AIR FORCE NOMINATION OF JAMES J. KENDA, TO BE LIEUTENANT COLONEL.

AIR FORCE NOMINATION OF AUGUST S. HIN, TO BE LIEUTENANT COLONEL.

AIR FORCE NOMINATIONS BEGINNING WITH CHRISTOPHER J. MATHEWS AND ENDING WITH TIMOTHY K. GRIMWOOD, 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 NOMINATION OF CHADWICK B. FLITCHER, TO BE LIEUTENANT COLONEL.


ARMY NOMINATION OF JOHN C. MOFFITT, TO BE LIEUTENANT COLONEL.


ARMY NOMINATION OF DARUS V. ARMADO AND ENDING WITH ROBERT T. ARMSTRONG, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON AUGUST 3, 2012.

ARMY NOMINATION OF ERIC J. SKALASKI, TO BE LIEUTENANT COMMANDER.


ARMY NOMINATION OF TROY W. ALLEN AND ENDING WITH MATTHEW S. WYSOCKI, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 14, 2012.

ARMY NOMINATION OF PAUL S. TAMARIBUCHI, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 14, 2012.

ARMY NOMINATION OF JASON D. WEDDLE, TO BE COMMANDER.

ARMY NOMINATION OF ANDREW J. STRICKLER, TO BE COMMANDER.

ARMY NOMINATION OF ANDREW K. LEDFORD, TO BE COMMANDER.

ARMY NOMINATION BEGINNING WITH JOHN L. GRIMWOOD AND ENDING WITH ROBYN M. TRAWILL, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON APRIL 28, 2012.

ARMY NOMINATION BEGINNING WITH DARWIN V. ARMADO AND ENDING WITH SCOTT D. WOODS, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON APRIL 23, 2012.

ARMY NOMINATION OF ZACHARY P. MOODY, TO BE COMMANDER.

ARMY NOMINATION OF ERIC J. SKALASKI, TO BE LIEUTENANT COMMANDER.

ARMY NOMINATION OF STEVEN J. PORTER, TO BE COMMANDER.

FOREIGN SERVICE


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 JAMES D. FONTANA AND ENDING WITH NOTA M. MOLEY, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON APRIL 26, 2012.

PUBLIC HEALTH SERVICE NOMINATIONS BEGINNING WITH RAY M. CHIN AND ENDING WITH MIHORI M. ZOMORODI, WHICH NOMINATIONS WERE RECEIVED BY THE SENATE AND APPEARED IN THE CONGRESSIONAL RECORD ON MAY 15, 2012.
HIGHLIGHTS
Senate passed S. 3187, Food and Drug Administration Safety and Innovation Act, as amended.

Senate

Chamber Action
Routine Proceedings, pages S3535–S3661

Measures Introduced: Twenty bills and five resolutions were introduced, as follows: S. 3234–3253, S.J. Res. 41, and S. Res. 472–475.

Measures Reported:
S. 2061, to provide for an exchange of land between the Department of Homeland Security and the South Carolina State Ports Authority, with amendments. (S. Rept. No. 112–171)
S. 3241, making appropriations for the Department of State, foreign operations, and related programs for the fiscal year ending September 30, 2013. (S. Rept. No. 112–172)
S. 2370, to amend title 11, United States Code, to make bankruptcy organization more efficient for small business debtors.
S. 3240, to reauthorize agricultural programs through 2017.

Measures Passed:
Food and Drug Administration Safety and Innovation Act: By 96 yeas to 1 nay (Vote No. 111), Senate passed 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, after taking action on the following amendments proposed thereto:

Adopted:
Harkin (for Leahy) Modified Amendment No. 2142, to modify and limit certain exemptions to the Freedom of Information Act.
Harkin (for Portman/Whitehouse) Modified Amendment No. 2145, to facilitate the development of recommendations on interoperability standards to inform and facilitate the exchange of prescription information across State lines.

Rejected:
By 28 yeas to 67 nays (Vote No. 105), Bingaman Amendment No. 2111, 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. (Pursuant to the order of Wednesday May 23, 2012, the amendment having failed to achieve 60 affirmative votes, was not agreed to.)
By 46 yeas to 50 nays (Vote No. 106), 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. (Pursuant to the order of Wednesday May 23, 2012, the amendment having failed to achieve 60 affirmative votes, was not agreed to.)
By 78 yeas to 15 nays (Vote No. 107), Senate tabled the amendment.

Coburn/Burr Amendment No. 2131, to require an independent assessment of the Food and Drug Administration’s review of drug applications.
Harkin (for Portman/Schumer) Modified Amendment No. 2146, to amend the Controlled Substances Act to place synthetic drugs in Schedule I.
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. (By 78 yeas to 15 nays (Vote No. 107), Senate tabled the amendment.)
By 43 yeas to 54 nays (Vote No. 108), McCain Amendment No. 2107, to allow the importation by individuals of safe and affordable drugs from Canada.  
(Pursuant to the order of Wednesday May 23, 2012, the amendment having failed to achieve 60 affirmative votes, was not agreed to.)  

Pages S3536–38, S3540, S3541–42, S3543–44, S3557, S3559–61, S3562

By 9 yeas to 88 nays (Vote No. 109), 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.  
(Pursuant to the order of Wednesday May 23, 2012, the amendment having failed to achieve 60 affirmative votes, was not agreed to.)  

Pages S3536, S3540–41, S3543, S3562–63

Durbin/Blumenthal Amendment No. 2127, to require manufacturers of dietary supplements to register dietary supplement products with the Food and Drug Administration.  
(By 77 yeas to 20 nays (Vote No. 110), Senate tabled the amendment.)  

Pages S3536, S3550–53, S3563–64

Withdrawn:

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.

Pages S3536, S3547

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

Pages S3536, S3563

National Flood Insurance Program Extension Act: Senate passed H.R. 5740, to extend the National Flood Insurance Program, after agreeing to the following amendment proposed thereto:  

Reid (for Johnson (SD)) Amendment No. 2154, in the nature of a substitute.

Page S3611

International Protecting Girls by Preventing Child Marriage Act: Senate passed S. 414, to protect girls in developing countries through the prevention of child marriage.

Page S3611

Battery Recharging Stations: Senate passed 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, after agreeing to the following amendment proposed thereto:  

Reid (for Levin) Amendment No. 2155, to improve oversight over the program and ensure no subsidy is received by Senators and employees.

Page S3657

Cook County, Minnesota Airport: Committee on Agriculture, Nutrition, and Forestry was discharged from further consideration of 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, and the bill was then passed.

E–2 Nonimmigrant Visas: Committee on the Judiciary was discharged from further consideration of 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, and the bill was then passed.

National Post-Traumatic Stress Disorder Awareness Day: Committee on the Judiciary was discharged from further consideration of S. Res. 455, designating June 27, 2012, as “National Post-Traumatic Stress Disorder Awareness Day”, and the resolution was then agreed to.

Pages S3658–59

Honoring Late Former Senator Abdnor: Senate agreed to 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.

Page S3659

Measures Failed:

Stop the Student Loan Interest Rate Hike Act: By 51 yeas to 43 nays, 1 responding present (Vote No. 113), Senate rejected S. 2343, to amend the Higher Education Act of 1965 to extend the reduced interest rate for Federal Direct Stafford Loans, and pursuant to the unanimous-consent agreement of Wednesday, May 23, 2012, requiring 60 votes for passage of the bill, and the bill was returned to the calendar, after taking action on the following amendment proposed thereto:  

Pages S3609–11, S3611–12

Rejected:

By 34 yeas to 62 nays, 1 responding present (Vote No. 112), McConnell (for Alexander) Amendment No. 2153, in the nature of a substitute.  
(Pursuant to the order of Wednesday May 23, 2012, the amendment having failed to achieve 60 affirmative votes, was not agreed to.)  

Pages S3609–11

Measures Considered:

Paycheck Fairness: Senate began consideration of the motion to proceed to consideration of S. 3220, 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.

A motion was entered to close further debate on the motion to proceed to consideration of the bill, and, in accordance with the provisions of Rule XXII
of the Standing Rules of the Senate, and pursuant to
the unanimous-consent agreement of Thursday, May
24, 2012, a vote on cloture will occur at 2:15 p.m.,
on Tuesday, June 5, 2012.

Signing Authority—Agreement: A unanimous-
consent agreement was reached providing that from
Friday, May 25, 2012 through Monday, June 4,
2012, Senator Leahy be authorized to sign duly en-
rolled bills or joint resolutions.

Authorizing Leadership To Make Appoint-
ments—Agreement: A unanimous-consent agree-
ment was reached providing that, notwithstanding
the upcoming recess or adjournment of the Senate,
the President of the Senate, the President Pro Tem-
porum, and the Majority and Minority Leaders be au-
thorized to make appointments to commissions,
committees, boards, conferences, or interparlia-
tary conferences authorized by law, by concurrent ac-
tion of the two Houses, or by order of the Senate.

Pro Forma Sessions—Agreement: A unanimous-
consent agreement was reached providing that the
Senate convene for pro forma sessions only with no
business conducted on the following dates and times,
and that following each pro forma session, Senate ad-
journ until the next pro forma session: Friday, May
25, 2012 at 2:30 p.m., Tuesday, May 29, 2012 at
11 a.m., and Thursday, May 31, 2012 at 12 p.m.;
and that the Senate adjourn on Thursday, May 31,
2012 until 2 p.m. on Monday, June 4, 2012.

Hillman Nomination—Agreement: A unanimous-
consent agreement was reached providing that at 5 p.m., on Monday, June 4, 2012, Senate begin
consideration of the nomination of Timothy S. Hillman, of Massachusetts, to be United States Dis-
trict Judge for the District of Massachusetts; that
there be 30 minutes for debate equally divided in
the usual form; that upon the use or yielding back
of time, Senate vote, without intervening action or
debate on confirmation of the nomination; and that
no further motions be in order.

Nominations Confirmed: Senate confirmed the fol-
lowing nominations:

Matthew Francis McCabe, of Pennsylvania, to be
a Member of the Board of Directors of the Corpora-
tion for National and Community Service for a term
expiring October 6, 2013.

Anthony Frank D’Agostino, of Maryland, to be a
Director of the Securities Investor Protection Cor-
poration for a term expiring December 31, 2011.

Anthony Frank D’Agostino, of Maryland, to be a
Director of the Securities Investor Protection Cor-
poration 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.

Charles Thomas Massarone, of Kentucky, to be a
Commissioner of the United States Parole Commis-
sion for a term of six years.

Margaret Bartley, of Maryland, to be a Judge of
the United States Court of Appeals for Veterans
Claims for the term of fifteen years.

Sara Margalit Aviel, of California, to be United
States Alternate Executive Director of the Inter-
national Bank for Reconstruction and Development
for a term of two years.

Drew R. McCoy, of Massachusetts, to be a Mem-
er of the Board of Trustees of the James Madison
Memorial Fellowship Foundation for a term expiring
January 27, 2016.

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.

Roy Wallace McLeese III, of the District of Co-
lumbia, to be an Associate Judge of the District of
Columbia Court of Appeals for the term of fifteen
years.

Pauline R. Maier, of Massachusetts, to be a Mem-
er of the Board of Trustees of the James Madison
Memorial Fellowship Foundation for a term expiring
November 17, 2017.

Michael A. Raynor, of Maryland, to be Ambas-
sador to the Republic of Benin.

Jessica Lynn Wright, of Pennsylvania, to be an
Assistant Secretary of Defense.

James N. Miller, Jr., of Virginia, to be Under Sec-
retary of Defense for Policy.

Frank Kendall III, of Virginia, to be Under Sec-
retary 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.

Adam E. Sieminski, of Pennsylvania, to be Ad-
ministrator of the Energy Information Administra-
tion.

Anthony T. Clark, of North Dakota, to be a Mem-
er of the Federal Energy Regulatory Commiss-
ion for the term expiring June 30, 2016.

Scott H. DeLisi, of Minnesota, to be Ambassador
to the Republic of Uganda.

John Robert Norris, of Iowa, to be a Member of
the Federal Energy Regulatory Commission for the

Joseph G. Jordan, of Massachusetts, to be Admin-
istrator for Federal Procurement Policy.

Katharina G. McFarland, of Virginia, to be an As-
sistant Secretary of Defense.
Makila James, of the District of Columbia, to be Ambassador to the Kingdom of Swaziland.
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.
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.

(Prior to this action, Committee on Foreign Relations was discharged from further consideration.)

6 Air Force nominations in the rank of general.
28 Army nominations in the rank of general.
10 Marine Corps nominations in the rank of general.
8 Navy nominations in the rank of admiral.
Routine lists in the Public Health Service. (Prior to this action, Committee on Health, Education, Labor, and Pensions was discharged from further consideration.)

Nominations Received: Senate received the following nominations:
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.
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.
Allison M. Macfarlane, of Maryland, to be a Member of the Nuclear Regulatory Commission for the remainder of the term expiring June 30, 2013.
Greta Christine Holtz, of Maryland, to be Ambassador to the Sultanate of Oman.
Alexander Mark Laskaris, of Maryland, to be Ambassador to the Republic of Guinea.
Marcie B. Ries, of the District of Columbia, to be Ambassador to the Republic of Bulgaria.
Walter M. Shaub, Jr., of Virginia, to be Director of the Office of Government Ethics for a term of five years.

1 Army nomination in the rank of general.

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Committee Meetings

BEFORE THE COMMITTEE ON FOREIGN RELATIONS

Makila James, of the District of Columbia, to be Ambassador to the Kingdom of Swaziland.
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.

(Prior to this action, Committee on Foreign Relations was discharged from further consideration.)

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POACHING IN AFRICA

Committee on Foreign Relations: Committee concluded a hearing to examine the global implications of poaching in Africa, focusing on ivory and insecurity, including S. 1483, to ensure that persons who form corporations in the United States disclose the beneficial owners of those corporations, in order to prevent wrongdoers from exploiting United States corporations in ways that threaten homeland security, to assist law enforcement in detecting, preventing, and punishing terrorism, money laundering, and other misconduct involving United States corporations, and S. 2318, to authorize the Secretary of State to pay a reward to combat transnational organized crime and for information concerning foreign nationals wanted by international criminal tribunals, after receiving testimony from Iain Douglas-Hamilton, Save the Elephants, Nairobi, Kenya; Tom Cardamone, Global Financial Integrity, Washington, DC.; and John E. Scanlon, Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), Geneva, Switzerland.

INFORMATION TECHNOLOGY SPENDING REFORM

Committee on Homeland Security and Governmental Affairs: Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security concluded a hearing to examine efforts to reform information technology spending, focusing on innovating with less, after receiving testimony from Steven VanRoekel, Federal Chief Information Officer, Administrator for E-Government and Information Technology, Office of Management and Budget; David A. Powner, Director, Information Technology Management Issues, Government Accountability Office; George DeLPrete, Grant Thornton LLP, Alexandria, Virginia, on behalf of TechAmerica; Molly O’Neill, CGI Federal Inc., Baltimore, Maryland; Nick Combs, EMC Corporation, San Antonio, Texas; and Jennifer Morgan, SAP Public Services, Arlington, Virginia.

BUSINESS MEETING

Committee on the Judiciary: Committee ordered favorably reported the following business items:

S. 2076, to improve security at State and local courthouses, with an amendment in the nature of a substitute;

S. 2370, to amend title 11, United States Code, to make bankruptcy organization more efficient for small business debtors; and

The nomination of Charles Thomas Massarone, of Kentucky, to be a Commissioner of the United States Parole Commission.

INTELLIGENCE

Select Committee on Intelligence: Committee held closed hearings on intelligence matters, receiving testimony from officials of the intelligence community.

Committee recessed subject to the call.
House of Representatives

Chamber Action
The House was not in session today. The House is scheduled to meet at 10 a.m. on Friday, May 25, 2012 in pro forma session;

Committee Meetings
No hearings were held.

Joint Meetings
No joint committee meetings were held.

COMMITTEE MEETINGS FOR FRIDAY,
MAY 25, 2012
(Committee meetings are open unless otherwise indicated)

Senate
No meetings/hearings scheduled.

House
No hearings are scheduled.
Next Meeting of the SENATE

2:30 p.m., Friday, May 25

Senate Chamber

Program for Friday: Senate will meet in a pro forma session.

Next Meeting of the HOUSE OF REPRESENTATIVES

10 a.m., Friday, May 25

House Chamber

Program for Friday: The House will meet in pro forma session at 10 a.m.