The Senate met at 2 p.m. and was called to order by the Honorable BENJAMIN L. CARDIN, a Senator from the State of Maryland.

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

Let us pray.

Eternal God, our provider, give to our lawmakers provisions for their daily needs. Give them grace to keep Your commandments, to accept Your guidance, to stay on Your path, and to walk in Your light. Lord, give them stamina to run until they reach their goal and to be true to You until the very end. Make them this day wise with Your wisdom and strong with Your strength. Help them to believe in Your power so that they may be certain that You are able to do for them more than they can ask or imagine.

We pray in Your merciful Name. Amen.

PLEDGE OF ALLEGIANCE
The Honorable BENJAMIN L. CARDIN led the Pledge of Allegiance, as follows:

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

APPOINTMENT OF ACTING PRESIDENT PRO TEMPORE
The PRESIDING OFFICER, the clerk will please read a communication to the Senate from the President pro tempore (Mr. INOUYE).

The legislative clerk read the following letter:

U.S. SENATE,
PRESIDENT PRO TEMPORE,
WASHINGTON, DC, May 21, 2012.

To the Senate:

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

DANIEL K. INOUYE,
President pro tempore.

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

RECOGNITION OF THE MAJORITY LEADER
The ACTING PRESIDENT pro tempore. The majority leader is recognized.

FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT—MOTION TO PROCEED

Mr. REID. Mr. President, I now move to Calendar No. 400, S. 3187.

The ACTING PRESIDENT pro tempore. The clerk will report the motion.

The legislative clerk read as follows:

Motion to proceed to Calendar No. 400, 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.

SCHEDULE

Mr. REID. Mr. President, we are now on the motion to proceed to the FDA user fees bill. At 4:30 the Senate will proceed to executive session to consider the nomination of Paul Watford to be U.S. Circuit Judge for the Ninth Circuit. At 5:30 there will be a cloture vote on the Watford nomination. If we are able to confirm his nomination, we should expect a second vote on the motion to proceed to the FDA user fees legislation.

OBSERVATIONISM REPEATED

Mr. President, this week the Senate must complete work on legislation that will enact crucial reforms that will prevent drug shortages and bring lifesaving medicines to market more quickly. Senators HARKIN and ENZI, a Democrat and a Republican, worked very hard to bring this legislation to the floor. I am cautiously optimistic that the spirit of bipartisanship will continue because Democrats cannot pass this legislation without the cooperation of our Republican colleagues. I certainly hope they will allow us to advance this bill this evening without additional delay caused by another filibuster. I would like Senators from both parties to be free to offer relevant amendments to improve a worthy bill, but before we can get to work on this legislation we cannot afford more delays to stop their filibuster. Americans living with cancer and other life-threatening illnesses are watching closely to see whether the Senate is capable of moving to quick action to ease shortages of crucial medicines or whether we will once more be paralyzed by Republican obstructionism.

Americans have seen that obstruction time and time again this Congress. They are frustrated with the slow pace of Senate action to reauthorize the Violence Against Women Act, Iran sanctions, and on legislation to stop interest rates from doubling on student loans. Earlier this month Republicans blocked an attempt to keep higher education affordable for 7 million students. But Democrats have not given up. I hope our Republican colleagues will come to their senses and allow us to prevent this crisis that affects 7 million young men and women before it is too late.

Republican obstruction and infighting has also stalled critical new sanctions on Iran. For 2 months Democrats have worked to resolve Republican objections to this bipartisan measure which passed out of the Banking Committee unanimously. The stakes couldn’t be higher. Sanctions are a key tool to stopping Iran from obtaining a nuclear weapon, threatening Israel, and jeopardizing U.S. national security. We cannot afford more delays to putting stronger sanctions in place. I hope my Republican colleagues will see
The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

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

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

The legislative clerk proceeded to call the roll.

Ms. MIKULSKI. Mr. President, I ask unanimous consent that the call of the quorum be rescinded.

The PRESIDING OFFICER (Mr. COONS). The Senator from Maryland.

Ms. MIKULSKI. Mr. President, I come to the floor to lend my voice to asking my colleagues to vote for the motion to proceed to the FDA Safety and Innovation Act. Like the Presiding Officer, who is from Delaware, where its excellent private sector and public sector have been the hallmark of innovation, I represent a State that is absolutely critical to the innovation economy.

Those of us from Maryland know life science innovation is one of the important economic engines in our economy both today and in the future. We are the home to flagship government agencies such as the National Institutes of Health, the FDA, and iconic internationally branded universities that do research and move it into clinical practice at Johns Hopkins and the University of Maryland. There are also lots of thriving biotech companies and some medical device companies where life science is often part of the lifeblood of the Maryland economy, and it is also part of the lifeblood of the American economy.

Think of what we do. We come up with new biological products, new pharmaceuticals, new medical devices that not only save and improve lives but also enable them to help people in our own country. Because they are FDA approved—the gold standard for safety and efficacy—they can sell these products and help them get out of the way, and where did they get out of the way? Where should their government help them? We need effective regulation, not strangulation; we need to increase communication in order to speed the drug review process; we need to increase competition; we need to increase the number of new biological products approved since 1992 for everything from the dreaded "C" words such as cancer or cardiovascular disease, to infectious disease, to the dreaded "A" words such as Alzheimer’s, which we are working on, and others. It has allowed the FDA to have more scientists and staff, and for that it is giving value to the private sector to be able to decrease review times. We reduced the review times from 2 years in 1992 to 1.1 years today.

We had excellent hearings. They were very civil, very content rich. But I also thought we needed to do. I asked them whether their government helped them where their government helped them where they went out to the major biotech companies and heard from over 25 different companies about what they thought we needed to do. I asked them whether their government helped them where their government hurt them, where should their government go? And did they need a more muscular government, meaning moving things ahead. They had great ideas. It was fantastic.

What I heard was we have to reauthorize PDUFA quickly, and we must make the improvements to the programs. We need to improve the drug review process; we need to increase communication in order to speed the drug review process. We have made sure we have increased a number of mandatory performance requirements between FDA and the life science product sponsors. I say life science because it is bio, it is pharma, it is medical devices, and some things that are both. PDUFA V,
which this is—it is the fifth time—allows us to use biomarkers to decrease development time by helping to demonstrate therapeutic benefit more quickly. It requires FDA to develop a dedicated program for drug development and training. We face a turnover, and there are a lot of reasons for that which I will come back to. But we want to make sure those young people who are so smart in science know how to work to have the science evaluated in a timely way. This is absolutely critical.

We have also incentivized the development of drugs for rare diseases. Particularly for parents of children with very unique and poignant, heart-breaking diseases, we would require FDA to develop guidance related to advancing and facilitating increased outreach to patient representatives, not only to the industry but to those who represent the patient advocacy groups. Again, we seek to develop training and certificate programs within FDA on how to review drugs for rare diseases.

I could go through the many benefits of PDUFA. We have done all here in the MDUFA, the medical device act, and we do recognize a new PDA. So there are several bills in this bill. But we have to act. There has to be a sense of urgency. This is a different bill than many other bills, they keep on going, but with the PDUFA and the other user fee legislation, it will be sunset if we do not pass them by October. One might say, Well, we will wait until October. We will deal with it on the cliff. We can’t do that, because of the impact on both the people in the private sector and those in the public sector. Failure to reauthorize in a timely manner would have catastrophic effects on FDA’s ability to carry out its important role. If the user fee agreement expires, patients, public health, and industry would be affected. This isn’t Senator BARR speaking, this is what our leading business and public health advocates are telling us. If we don’t reauthorize, the user fees sunset, so that means U.S. pharmaceutical industries, which support 4 million jobs, would be adversely affected. There would be no FDA to work with.

In 2010, Maryland private life science companies supported over 25,000 jobs. These companies are true innovators. On average, it takes a new medicine 10 to 15 years to develop. If we fail to reauthorize PDUFA, which ensures an efficient, consistent, and predictable regulatory environment, our private sector will lose out. We are going to lose out to Europe and we are going to lose out to China. China is stealing our patients as we speak. It will have a terrible consequence on patients as tens of millions of them rely on drugs and biologics and medical devices.

We know we have legislation that works; we have a legislative framework that works and now we need to get to work. If we do not pass this bill, and reauthorize these major programs, what will happen is we will need to send out RIF notices. We won’t do it, but Dr. Mary Hamburg, the FDA CEO, the Commissioner, will have to, starting in July and August, send out RIF notices to 4,000 Federal employees at FDA. Furthermore, she indicated that the important lab techs and others who keep FDA going. This is no fooling around. I say to my colleagues. This isn’t: Let’s wait for the cliff. We will come to the brink if we do not reauthorize. We’re going to look at the role of PDA. If one thinks one is going to lose their job, that is what they are going to be preoccupied with. They are not going to be occupied with looking at these clinical trials and moving their advances forward.

We have worked so hard on this legislation. The private sector has worked hard to find a sensible center, and so has Dr. Mary Hamburg and her team. Our committee has worked so well. We can do this. We have the will. If we want to stay ahead in the global economy, it has to include passing this legislation.

Everybody talks about stopping China. China isn’t going to do, but I know we can stop ourselves if we don’t pass legislation that promotes innovation in our country and public sector jobs in a partnership with government.

I conclude by urging my colleagues to vote for the motion to proceed.

I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Mr. President, I thank the Senator from Maryland, Ms. Mikulski, for her passion and understanding and intense work on this particular bill. Of course, she extends her passion and intense work on any bill she is involved in. I am so pleased this bill has gone to committee and has had the time for the committee to work on it. We have a very bipartisan approach on the bill and a very reasonable way to do it.

I rise to support the Food and Drug Administration Safety and Innovation Act of 2012, and I appreciate Senator Mikulski making the opening statement. This bill will reauthorize FDA’s drug and medical device user fee programs, authorize new user fees for generic drugs and biosimilars, and make a small number of targeted bipartisan policy reforms at the same time.

This legislation represents over a full year of work by the HELP Committee. Fridays have been dedicated to coming up with solutions on this for over a year, and it has paid off. It reflects the information we have learned from hundreds of meetings with patients, with industry, with outside experts, and with the FDA. More importantly, it reflects both the ideas and the feedback we have gotten from every member of the HELP Committee, and a lot of our work outside the HELP Committee. The HELP Committee approved this bill by a voice vote on April 25 and reported the bill out of committee on May 7.

This bill will make important changes to how FDA does business. Thanks to the efforts of Senators Burr and Coburn, the bill now includes new requirements that will make FDA more accountable and transparent. A fundamental principle of management is that one has to be able to measure performance if one wants to improve it. The ideas of Senators Burr and Coburn will help provide those measurements and, as a result, Americans will get better access to safe, innovative medical devices and medicines.

The bill will also modernize how the FDA inspects foreign facilities to better account for the global nature of drug manufacturing. It will allow FDA to prioritize and target riskier oversized facilities, which will help prevent the recurrence of the problems with drugs such as heparin.

This bill will also improve how FDA regulates medical devices. For the past several years, FDA premarket review of medical devices has involved significant delay and unpredictability. This has threatened American manufacturing jobs which we are going to have to migrate overseas because of the unfavorable regulatory environment here in the United States. It has also threatened patient access to new therapies. I believe this bill will reverse those trends.

The bill reflects the concerns I have heard in my meetings with committee members regarding the current shortages of vital and lifesaving drugs. Senator Bruner, Senator Casey, Senator Alexander, Senator Bennet, and Hatch should be thanked for all the work they put into the drug shortage proposal. The new notification and coordination requirements are important steps that will help prevent future drug shortages.

The bill also enjoys broad support. We have received numerous letters of support from industry, patient groups, consumer groups, and a whole raft of our stakeholders. We also worked to guarantee that any mandatory spending generated by the bill would be fully offset. Over the past several weeks, we have developed offsets to pay for those provisions that produce mandatory spending. As a matter of fact, according to the Congressional Budget Office, this bill will reduce the Federal deficit.

Chairmanarkin and I have worked very hard to make this bill as bipartisan and uncontroversial as possible. We tried to avoid controversy because we understand this bill needs to get done. If we don’t reauthorize the drug and device user fee programs before to new medical therapies, and America’s global leadership in biomedical innovation. We are talking about 4 million jobs overall and 2,000 to 4,000 that
Mr. KYL. Mr. President, I ask unanimous consent to speak as in morning business.

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

THE ECONOMY

Mr. KYL. Mr. President, what I would like to talk about this afternoon is a bit about the President’s economic record. I am sure Americans have noticed the President barely mentions the cooperation Senator HARKIN has provided, the leadership he has provided on the bill, and the way his staff members and myself have worked together for at least a year in regular meetings with all members of the committee. So I think a lot of the controversy that could come up with a bill like this has been taken care of. I am hoping it has so people will not have to execute it.

I thank the Chair and yield the floor.

The PRESIDING OFFICER. The Senator from Arizona.

Mr. KYL. Mr. President, I ask unanimous consent to speak as in morning business.

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

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The PRESIDING OFFICER. The Senator from Arizona.

Mr. KYL. Mr. President, I ask unanimous consent to speak as in morning business.

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

THE ECONOMY

Mr. KYL. Mr. President, what I would like to talk about this afternoon is a bit about the President’s economic record. I am sure Americans have noticed the President barely mentions the cooperation Senator HARKIN has provided, the leadership he has provided on the bill, and the way his staff members and myself have worked together for at least a year in regular meetings with all members of the committee. So I think a lot of the controversy that could come up with a bill like this has been taken care of. I am hoping it has so people will not have to execute it.

I thank the Chair and yield the floor.

The PRESIDING OFFICER. The Senator from Arizona.

Mr. KYL. Mr. President, I ask unanimous consent to speak as in morning business.
Americans—including many small businesses—if it is not patched or repealed. Well, small business cannot afford this, what has been called “taxmageddon” and its devastating consequences.

I will hope, instead of this to-do list the President is sending us, he would take up the cause of preventing this big tax increase at the end of the year and help the small businesses and families that need that help.

Firstly, any tax unanimous consent to have printed in the Record at the conclusion of my remarks a piece in National Review Online by Larry Kudlow dated May 17 called “Extend the Bush Tax Cuts Now.”

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

(See exhibit 1.)

Mr. KYL. In this piece, Larry Kudlow, a noted economist, notes that with respect to this “taxmageddon”—the increase in everybody’s taxes at the end of this year—it is the uncertainty of it all that is preventing the investment by business which would create the jobs we would all like to see. I would just like to quote three paragraphs and a couple sentences in a fourth.

The uncertainty over the Bush tax cuts already has caused a number of business leaders to threaten a hiring freeze and a dampening of investment until they can figure out the after-tax cost of capital and rate of return on investment. Hiring has slowed noticeably in recent months. And a number of Wall Street economists are marking down the economic recovery even more, suggesting that the 3 percent growth at the end of last year, which faltered to 2 percent growth in the first quarter, could be even less in the period ahead.

Then he goes on to say:

A bunch of CEOs have even formed their own march on Washington. Eighteen of them just wrote to Treasury man Timothy Geithner, begging him to oppose tax-rate hikes on dividends—

Which would go from 15 to 45 percent—and capital gains (from 15 to near 30 percent).

..."Equity capital is the blood of investment and job creation for U.S. companies."

That is what these CEOs wrote in the letter to Treasury Secretary Geithner.

Kudlow goes on to say:

..."And they argued that the administration’s tax hike plans would do great harm to American competitiveness and capital formation."

Then he quotes the Ernst & Young firm to say this:

..."The top U.S. integrated tax rate on corporate profits and dividends is on course to hit 26 percent, significantly higher than all other OECD countries—"

Those are the developed countries of the world—
as well as Brazil, Russia, India, and China.

Capital gains would rise to 35.7 percent.

In other words, he is pointing out that not only would these higher tax rates hurt the business climate, they would harm the families because of the individual tax rate, marginal rate increases, but raising the dividends and capital gains taxes would be even more detrimental because we are asking companies in America to compete with firms all over the world, and their rate would be much higher with this tax increase than the rate in all of the other developed countries, as well as countries with the same approach to tax rates over here.

How can American businesses compete in that situation?

Then, finally, Kudlow notes the effect of all this uncertainty on what matters most to most Americans; that is, the fact that they cannot get work. He says:

"Bizarrely, some 25 million people have vanished from the labor force—from unemployment, underemployment, or simply dropping out altogether. And half of U.S. households are now on some form of federal-transfer payment assistance. So as we pay so many people not to work, we’re sapping the vitality of the economy."

This is absolutely true. With half of the people in the country on some form of Federal assistance, with 25 million people having just vanished from the labor force not even looking for work anymore, under employment, or simply dropping out altogether, how can the economy recover?

The uncertainty over the Bush tax cuts already has caused a number of business leaders to threaten a hiring freeze and a dampening of investment until they can figure out the after-tax cost of capital and rate of return on investment. Hiring has slowed noticeably in recent months. And a number of Wall Street economists are marking down the economic recovery even more, suggesting that the 3 percent growth at the end of last year, which faltered to 2 percent growth in the first quarter, could be even less in the period ahead.

A bunch of CEOs have even formed their own march on Washington. Eighteen of them just wrote to Treasury man Timothy Geithner, begging him to oppose tax-rate hikes on dividends (from 15 to 45 percent) and capital gains (from 15 to near 30 percent).

..."And they argued that the administration’s tax-hike plans would do great harm to American competitiveness and capital formation."

According to accounting firm Ernst & Young, the top U.S. integrated tax rate on corporate profits and dividends is on course to hit 68.6 percent, significantly higher than all other OECD countries, as well as Brazil, Russia, India, and China. Capital gains would rise to 35.7 percent.

And Speaker Boehner knows this. So he’s been asking for a tax cut reform, first and foremost to get supply-side tax reform at the top of the congressional agenda well before the election. Similarly, House budget chairman Paul Ryan is suggesting at least a six-month extension of the Bush tax cuts, so as not to disrupt business. (By the way, the Ryan tax-and-spending reform budget got 41 votes in the Senate, while Obama’s budget got 0.)

In a recent interview, former top Obama economic adviser Larry Summers told me the U.S. recovery is going “ahead of schedule.” Really? But former Obama economist Austan Goolsbee gives a more realistic assessment by referring to a subpar 2 percent forecast that is way too slow to spark faster job creation.

Bizarrely, some 25 million people have vanished from the labor force—from unemployment, underemployment, or simply dropping out altogether. And half of U.S. households are now on some form of federal-transfer payment assistance. So as we pay so many people not to work, we’re sapping the vitality of the economy.

Mitt Romney recently gave a fine speech, blasting Obama’s profligate spend-and-borrow policies. He described “a frantic fire of debt sweeping across Iowa and the nation,” and he tied our new federal debt to the “trepid recovery.”

But after spending alone, while important, is not going to solve the economic-growth problem. Yes, moving spending to 20 percent of GDP from 24 percent will free up private resources. But lower interest rates on the extra dollar earned and invested is a more powerful economic-growth tool. Romney should push his 20 percent tax-rate reduction plan. That would add liquidity to fight deflation, and would provide new economic-growth incentives.
As for John Boehner’s goal of an early extension of the Bush tax cuts, it’s going to be an uphill climb. Democrats want to raise taxes, not cut them. But at least the GOP will have a coherent growth-jobs message. They can tell the public how important it is to avoid falling off the massive tax cliff which looms ahead. Deflationary fears can ease. And they’re likely to make it plain that the GOP has a growth message in these perilous economic times, while the Obama Democrats do not.

The PRESIDING OFFICER. The Senator from Louisiana.

Ms. LANDRIEU. Mr. President, I was not here to hear all of my colleagues’ remarks. I know there is a lot of concern about the end of the year and what might happen to try to balance our budget and give us a solid platform on which this economy could grow. But one of the things that is holding us up is the Republicans’ refusal to put any new revenues on the table. They have been adamant and wrong and headstrong about it.

They have been very obstructionist in this way—by not being willing to put a penny of new revenue on the table. As a result, we have come to a standoff because the income coming into the national Treasury to support this government is at the lowest level since President Eisenhower was President. So they can come to the floor all day long and criticize the President, criticize the Democrats, but in the last 2 years, we have put out 12 trillion of cuts and reductions to some very important programs on the table.

Some of us have even been willing to say, yes; we know we have to reform Social Security and Medicare and Medicaid. We have also been willing to speak those words which are not easy. Yet not one single Republican leader, not one on either side, the House or the Senate, not one has come to this floor in public. Now, I have heard them say it in private meetings. So what they are saying is, we are not going to be able to extend the tax cuts that cost money.

I hope we can do something so we can extend some tax cuts to small businesses, which I came to talk about—and you, Mr. President, know this well. Instead of giving some of the biggest tax breaks to companies that are the biggest in the world and put all of their jobs overseas, I wish the Republicans would start talking about tax relief to businesses right here at home on Main Street. That is what I want to talk about today.

(The further remarks of Ms. LANDRIEU are printed in today’s RECORD under “Morning Business.”)

Ms. LANDRIEU. I wish to extend the floor and suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

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

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

The bill clerk proceeded to call the roll.

Mr. WYDEN. Mr. President, I ask unanimous consent to speak as in morning business.

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

THE INTERNET

Mr. WYDEN. Mr. President, I believe the development of the Internet, its networks, and the digital economy are one of the great achievements of our age.

The Internet links humanity together, facilitating economic growth, bringing education and health resources to remote regions, reshaping societies and advancing human rights.

While networks foster innovation, job creation, and political and social progress, networks can also be used by actors with nefarious motives. It is in our national interest to deter, detect, and destroy real and viable cyber threats, to protect Americans and preserve the benefits of the Internet.

Americans must not be afraid to go online.

The Internet works not just because it is open to all but because it is found on the principle of trust. Users trust that their browsing is not monitored and cataloged by spammers, and not for their advertisers, not for scammers, and not for the government. Congress’s effort to develop a comprehensive approach to cybersecurity must not erode that trust. When Americans go online to consume digital services and goods, they must believe and know with some certainty that their privacy is adequately protected.

The President’s refusal to put any new revenues on the table is the Republicans’ refusal to put any necessary incentives for operators of critical networks to keep their networks secure.

More than that, they would allow law enforcement to look for evidence of future crimes, opening the door to a dystopian world where law enforcement evaluates your Internet activities for the potential that you might commit a crime.

In establishing this massive new regime, these bills fail to create the necessary incentives for operators of critical networks to keep their networks secure.

It is a fundamental principle of cybersecurity policy that any network whose failure could result in a loss of
life or significant property should be physically isolated from the Internet. Unfortunately, many of our critical network operators have violated this principle in order to save money or streamline operations. This sort of gross negligence ought to be the first target of our cybersecurity legislation, not the privacy of individual Americans.

Congress could target this behavior with yet one more rule book and one more bureaucratic command. The cybersecurity contractors in full employment program. I am not, however, convinced this is a problem that requires that kind of solution.

At the same time, Congress should not allow our critical network operators to ignore best practices with impunity. It is vital they understand that any liability for a preventable cyber attack is their responsibility. There is not going to be a governmental bailout after the fact in the cybersecurity area. Board of directors and executive directors must be vigilant and understand the risks to their investments. Executives must understand that ignoring critical cyber threats in the interest of cost savings and convenience will leave them personally exposed.

Internet providers and backbone operators clearly have a role in this fight. When they detect abnormal network activity or have a user violating their contract in a way that constitutes a cyber attack, they should inform our cyber defense officials. If it is necessary to grant them immunity to share this kind of information, the Congress could grant it—narrowly and with careful consideration.

Mr. President, there would be bipartisan support for the proposition that the Federal Government also has a significant role that does not necessarily require billing taxpayers for legions of private cybersecurity contractors. The Department of Defense, the Department of National Intelligence, Homeland Security, and the Justice Department—four major parts of our government—all have cybersecurity specialists. The Congress ought to be promoting the cyber capabilities of these agencies and providing the resources that are needed to protect these networks. These Federal agencies should do a better job of consulting the private Internet companies to better understand the attacks that are occurring across the net.

Some of these steps may require legislation, but many can be carried out by responsible actors in the public and private sector without waiting for the Congress to act. However, the legislation that they can and should include cybersecurity legislation that passed the other body leads our country away from the kind of commonsense approach to cybersecurity I have outlined this afternoon.

As they stand, these bills are an overreaction to a legitimate and understandable fear. The American people are going to respond by limiting their online activities. That would be a recipe to stifle speech, innovation, job creation, and social progress. I believe these bills will encourage the development of an industry that profits from fear and whose currency is Americans’ private data. These bills create a cyber security industry that does not exist. They are interested in preserving the problem to which it is the solution.

In terms of the process, the Senate ought to proceed in a way that is as open and collaborative as the Internet itself. It is the Senate’s role to protect. On substance, any cybersecurity bill must contain specific and clear descriptions of what types of data and when such data can be captured, with whom it can be shared, and under what circumstances. Anything not specifically covered ought to remain private. Privacy in the cybersecurity arena should be the default not the exception. Legal immunity to corporations that share information should be the exception not the rule and void if privacy protections or contracts are disregarded.

The Congress and the public must have the ability to know how any cybersecurity program that is established will be implemented. That means routine public and unclassified reports and hearings to examine whether there were any unintended privacy or civil liberty impacts caused by the program. No secret law, Mr. President.

Mr. President, Mr. Bad Internet policy is increasingly premised on false choices. Earlier this year, during the consideration of the Protect IP Act and the Stop Online Piracy Act, the Congress was told again it had a false choice. The Congress was told either it could protect intellectual property or it could protect the integrity of the Internet. This was a false choice. I and others said so at the time because achieving one should not and does not require sacrificing the other.

No Congress should be asked once again to make a false choice—a choice between cybersecurity and privacy—and I don’t think these two are mutually exclusive. I think we can have both. Our job is to write a cybersecurity bill that protects America’s security and the fundamental right to privacy of our people. There is no sound policy reason to sacrifice the privacy rights of law-abiding American citizens in the name of cybersecurity. It is my intent to fight any legislation that would force Members of the Senate to make that choice.

Mr. President, with that I yield the floor.

The PRESIDING OFFICER. The Senator from Indiana is recognized.

Mr. COATS. Mr. President, I rise today to talk about the Food and Drug Administration Safety and Innovation Act. I believe we are going to have a cloture vote on this bill tonight, and I am pleased that all early indications are it will pass and we will move forward on this bill.

There has been considerable time spent drafting this legislation. It gained bipartisan support both in House and Senate committees, and it is moving through what I would call a regular process. We haven’t seen too much of that in the last year and a half or so. This is the regular process. For those who say Congress can’t get anything done, hopefully our work on this bill will take us a very significant step forward in terms of being able to provide and bring to patients, doctors, administrators, and others across the Nation new drugs, new treatments, and new medical devices for Americans. If we can do that, we can preserve better health, prevent potential terminal situations, and provide better drug availability and device availability. So I think it is very important that this legislation goes forward.

I am pleased we have gotten to this point on a bipartisan basis. I think we have an opportunity for the work of the Senate, and those in the House as well for bringing the bill along on a parallel track.

The whole idea of this legislation is to continue to provide the safest, most effective and most efficient drugs and devices for Americans and people around the world. These are two very important industries in which the United States has had the leading edge as providers and we don’t want to lose that. It has meant a lot for our economy, and it has meant a lot for Americans. I think the passage of this bill will continue what has been a remarkable nearly three decades’ worth of innovation that has taken place both in the biopharmaceutical industry as well as the medical device industry.

Part of this bill deals with drug shortages. I have talked to a number of doctors—my staff has been traveling the State talking to medical providers—and there is an alarming number of drug shortages in critical drugs, particularly those designed to deal with more rare instances of health problems and yet, obviously, important to those people who are suffering from those incidences of disease or health threats.

It was reported to me that last year FDA received a record number of drug shortage reports—more than 250—involving critical drugs used in surgery, emergency care, and oncology. The problem continues today, but the this bill addresses that and, hopefully, will move us forward significantly in terms of dealing with this current problem.

In Fort Wayne—my hometown in Indiana—Parkview Health’s pharmacy director said nearly 80 percent of hospitals consistently face shortages in drugs needed for emergencies, including cardiac and diabetic prescriptions. This bill incorporates significant reporting requirements to the FDA that I hope will help mitigate this critical problem that we need to figure out ways to further address this, but this can be an important first step.
The whole concept has been somewhat unique in the Federal Government; that is, the makers of the products essentially pay a fee to a regulatory agency for the regulatory agency to conduct the work necessary to gain approval to sell their drugs on the market. A situation that is sort of a cornucopia of new innovations in drugs and medical devices. Yet they have been delayed by the bureaucracy or the inability of the FDA to move in an efficient, effective way to run the process.

The biopharmaceutical industry has basically said: Look, we are willing to put up between $3.5 billion and $4 billion in new user fees—I believe it is over a 5-year period of time—which will account for nearly 60 percent of the funding designated by the Center for Drug Evaluation and Research. In exchange for putting up these fees, the FDA has agreed to new performance goals and process improvements that will reduce the time it takes drugs to reach the market.

So the key is to provide the funds necessary to hire the right people and put the right procedures in place to expedite the study and approval of safe, effective, efficient drugs that have been sent to the FDA for approval so we can get them into the market. Of course, the ultimate goal is to get them not only into the market but use them to provide health and safety benefits for the American people.

The Medical Device User Fee Act is also part of this. In Indiana, we have not only a very large biopharmaceutical company and a number of affiliated companies, we also have a vibrant and dynamic medical device industry. That industry employs over 20,000 Hoosiers directly and many more indirectly with good-paying jobs. Many of these companies are right on the leading edge of new innovation and new developments included in the legislation that we will be voting on is a 5-year agreement known as the Medical Device User Fee Act that improves the regulatory pathway for medical devices.

This is the medical device equivalent of the pharmaceutical user fee. Device companies have worked with the FDA, again in an agreement where each side contributes. The medical device manufacturers will contribute user fees to go to the FDA toward product development and innovation and reward innovators and innovator of medical devices. California, Florida, Illinois, Massachusetts, New Jersey, New York, Ohio, Pennsylvania, Texas, and Wisconsin will all suffer potential job losses if this medical device tax is imposed.

We are not taking it up in this bill so as not to try to derail the bill. I understand an agreement has been made that it would be set aside. I know Senator HATCH, on our side, is looking for a way to move all these things up in another vehicle, and I want to support that. I encourage my colleagues to take a look at the impact of that fee on our ability as a nation to be the leader in innovation and export of medical devices.

I thank Senators HARKIN and ENZI for shepherding the Food and Drug Administration Safety and Innovation Act through the committee. I believe this legislation will help improve patients' access to new medical technology, and it will protect American jobs and improve the FDA so that America can remain a global leader in biomedical innovation. I encourage my colleagues in the Senate to support this important legislation. I yield the floor.

The PRESIDING OFFICER. The Senator from Minnesota.

Ms. KLOBUCHAR. Mr. President, I think the Senator from Indiana for his words.

We both are from States that have a lot of jobs involved in medical devices, and, in fact, this bill is something we worked on very hard. I am the cochair of the medical device caucus in the Senate. This has been our top priority, to try to move those FDA rules along, and this bill does that. It is an agreement—a rare agreement—between government and industry, which is something both parties want. We would like to move those approvals along for the patients, long-suffering patients who should have access to medical devices, and then also for the industry, where we have seen way too much venture capital money go to devices such as Europe simply because that process moves faster. So this is a very good bill, and I am so pleased we have bipartisan support.

I see that the Senator from Wyoming, Mr. Enzi, has come into the Chamber, and both he and Senator HARKIN deserve a lot of praise.

I wish to focus today on one piece of this bill, something I have worked very hard on, and it really came out of things I heard in my State. I heard it from pharmacists literally 2 years ago, things I have heard from patients. I got together with our staff. I see that our legislative director, Rose Baumann, and Andrew Hu, who did a lot of work on this bill, are here today. We went and talked to all kinds of people involved. We talked to pharmaceutical companies to try to figure out what was going wrong with drug shortages; we talked to the people who were suffering the most—the patients; we talked to the pharmacists who said: What would work here? And the FDA told us that, in fact, when they did get early notification from pharmaceutical companies that there was going to be some kind of shortage, it helped. They were able to avert that shortage. They have done it successfully over 100 times, and they have done it many times with some key drugs. And the earlier notice they have, the better it is for everyone because they can, in fact, avert the drug shortage, and that is what this is about.

I will tell you that, for me, this whole bill and this whole provision really comes down to a little boy named Axel Zirbes, a young boy with bright eyes and a big smile. Because of leukemia, this little boy, when I saw him, had no hair on his head. He and his family were thrown into a panic about 1 year ago when they learned that an essential drug—cytarabine—was in short supply and might not be available. I went and talked to the pharmacists. That boy just found out he was diagnosed with leukemia and was supposed to start treatment, and the doctor says: You know...
what, we don’t know if you should start it—you should start it immediately, but we don’t have this critical cancer drug, this critical leukemia drug.

They decided they would take Axel to Coon Rapids, where the drug was likely available, and just when they were making those plans to go there, they found out that some of the drug had been located and that Axel could come in for his treatments. Well, that never happened, not in the United States of America. And so to a family of a little 4-year-old boy, both parents working hard to make sure their child could have health care and then this happens. It makes no sense.

There is the story of Mary McHugh Morrison, who joined me at a forum I held on this topic in Edina, MN. Mary is a woman whose cancer had, unfortunately, returned after a shortage of Doxil. That is a chemotherapy drug that had kept her ovarian cancer at bay. Last year, a shortage interrupted her chemotherapy regimen. Mary struggled to find remaining vials of Doxil and then struggled with the ethical dilemmas of using the drug she found when others would not be able to use it. She literally talked at the forum about how she had personally called people, used connections, tried to find those vials, and she realized that when she got those drugs, other people wouldn’t have them.

Again, this can’t be happening in the United States of America. She shared her experience with us. And because of a few delays in treatment, Mary’s doctor told her that her tumor had, unfortunately, returned and that she was then no longer responding to that drug. This past February, CT scans, unfortunately, showed that Mary’s tumor size had doubled. She was immediately accepted into a clinical trial at the Mayo Clinic and began treatment. Fortunately, she is so far responding well and her health is improving.

These shortages are happening all over this country. Every single Senator in this Chamber has heard about one of them. You heard Senator Coats from Indiana talking about what he had heard. So the fact that we heard this first in Minnesota I don’t think is any surprise. We have an active State. We have people who believe you can still make money. We have people who believe you can still do the right thing. Mary McHugh Morrison, who joined me at a forum I held on this topic in Edina, MN.

The number of drug shortages has more than tripled over the last 6 years, jumping from 61 drug products—remember, there are thousands of shortages, but this is 61 different drug products in 2005 to more than 200 drug product shortages in 2011.

A survey by the American Hospital Association found that virtually every hospital in the United States has experienced shortages of critical drugs in the past 6 months. More than 80 percent reported delays in patient treatment due to shortages.

For some of these drugs, no substitutes are available or, if they are, they are less effective and may involve greater risk of adverse side effects. The chance of medical errors also rises as providers are forced to use second- or third-tier drugs that they are less familiar with using.

A survey conducted by the American Hospital Association showed that nearly 100 percent of their hospitals experienced a shortage—100 percent. Another survey conducted by Premier Health System showed that 89 percent of its hospitals and pharmacists experienced shortages that may have caused a medication safety issue or an error in patient care.

It is clear that there are a large number of contributing factors that have resulted in these unprecedented shortages. Experts cite a number of factors: market consolidation, poor business incentives, manufacturing problems, production delays, unexpected increases in demand for a drug, inability to procure raw materials, and even the influence of the gray market. Literally, people are trying to make money off of this now. They hear there is a shortage, and they buy up the supply and then sell it at a higher price. Financial decisions in the pharmaceutical industry are also a major factor. Many of these medications are in short supply because the companies have simply stopped production. They decided it wasn’t worth their profit to keep producing them. Mergers in the drug industry have narrowed the focus of product lines. As a result, some products are discontinued or production is moved to different sites, leading to delays. Even in rare cases, made by only a few companies, a decision by any one drug company can have a large impact. That would make sense.

To help correct a poor market environment or to prevent gray market drug shortages from contaminating our medication supply chain, we must address the drug shortage problem at its root. Last year I introduced the Preserving Access to Life-Saving Medications Act with Senator Blumenthal with the support of Senator Collins and others. This is a bipartisan bill that would require drug manufacturers to provide early notification to the FDA whenever there is a factor that may lead to a shortage. We also had support from the Presiding Officer, as well as Senator Blumenthal of Connecticut and many other people from across the Senate.

This bill will help the FDA take the lead in working with pharmacy groups, drug manufacturers, and health care providers to better prepare for impending shortages, more effectively manage shortages when they occur, and minimize their impact on patient care. And that is why I am pleased to include my early notification provision from my bill is included in the Food and Drug Administration Safety and Innovation Act, the one that Senator Coats and I were just discussing and that we are debating today.

I thank Senator Harkin and Senator Enzi for their leadership on the HELP Committee in bringing this legislation forward and including my provision. In a bipartisan manner, the HELP Committee brought together working groups to address a wide range of issues, from medical device innovation to drug shortages. In the drug shortage working group, we spoke with experts from patient groups, providers, drug manufacturers, and the FDA to try to find an appropriate solution.

Ultimately, the legislation now includes many policies that I believe will help address shortages. In addition to the early-notification requirement, again, the FDA is going to be able to lead in our oversight efforts, and if they can’t find something in our own country they can look at local or international sources. You simply can’t keep these patients waiting for their treatment.

In addition, the bill directs the FDA to improve communications inside and outside its walls, requires more robust record-keeping and reporting, and asks for studies on how pricing factors impact drug shortages. This bill represents a step forward in our ability to prevent these shortages—a strong step forward. With manufacturers providing early notification, the FDA’s drug shortage team can then appropriately use their tools to prevent shortages from happening. As I mentioned, in the last 2 years, the FDA, with more information, has successfully prevented nearly 200 drug shortages. Imagine the hundreds of thousands and millions of patients that has helped. So we need to extend it. That is why this bill.

One such example is the recent shortage of methotrexate. This is a very common drug used in chemotherapy to
treat cancers such as leukemia. For me, the most devastating part about the shortage is that I heard about it from the Zirbes family—the family of this little 4-year-old boy who had to suffer through the shortage of cytotoxic agents earlier. Only this time, the FDA took quick action. Once it learned of this potential shortage and worked with other manufacturers to boost production and helped stop the bleeding before this became a major crisis. That is an example of what can happen with early notification. They are allowed to then go to other manufacturers and find the people who can make the drug to get it to the hospital, to get it to the patients. And today, with strong cooperation between the FDA and pharmaceutical manufacturers, methotrexate is available for patients who rely on it just like that little 4-year-old boy Axel Zirbes.

Together with Senator CASEY, we were able to work with the HELP Committee to bring bipartisan legislation to address this crisis. The bipartisan legislation we introduced the Preserving Access to Life-Saving Medication Act. That is why we were able to work with the HELP Committee to bring bipartisan legislation to address this crisis. The bipartisan legislation we introduced the Preserving Access to Life-Saving Medication Act. That is why we were able to work with the HELP Committee to bring bipartisan legislation to address this crisis.

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

The PRESIDING OFFICER. The clerk will call the roll.

Mr. HARKIN. Mr. President, after many months of bipartisan negotiation, the Senate will proceed this evening to vote on the motion to proceed to consideration of the Food and Drug Administration Safety and Innovation Act of 2012. I hope it will receive an overwhelming vote so we can move ahead with it and dispense with the bill. The reasons this bill is important are the product of excellent bipartisan collaboration on the Health, Education, Labor, and Pensions Committee which I chair. All Senators on the committee have been involved. Going back almost a year, we spent working together. Different Senators had different interests and different concerns. They and their staffs on both sides were invited, Republican and Democrat, to be involved in those working groups to put this bill together.

The bill passed overwhelmingly out of our committee—actually by voice vote, with only two reserving their "no" votes. So it had overwhelming support on both sides in our committee.

The bill, of course, reauthorizes important FDA user fee agreements. It modernizes the FDA’s medical product authority to help boost American innovation and ensure patients have access to the therapies they need. The backbone of this legislation is the user fee agreements that FDA has negotiated with industry. We must remember that a sizable part of FDA’s budget comes from user fees that the industry agrees to pay, that allows the FDA to hire the staff and resources they need to review applications. We need to reauthorize this bill to implement those agreements in a third of current levels—from 30 months to 10 months—and will improve the speed with which generic products are made available to patients. This will generate significant savings in our health care system. In the last decade, from 2001 to 2010, it saved the U.S. health care system more than $931 billion.

This agreement will ensure we continue to see those savings and that patients will have access to cheaper drugs when they need them. It also obviously means taxpayers will be saving money because many of these drugs come through both Medicaid and Medicare.

The agreement is expected to save more rapidly than they have been in the past, it will mean taxpayers will save a significant amount of money in the future.

This agreement also authorizes another new section, the biosimilars user fee agreement, which will further spur innovation by shepherding the biologic industry as it matures.

These agreements are vital to FDA’s ability to do its job, to the medical products industry’s ability to survive some very challenging economic times, but, most importantly, to the patients who are the primary beneficiaries of this longstanding and valuable collaboration between FDA and industry. As I have said in the past, these agreements work with our staffs, with FDA, with the industry, and with consumer groups, I think they have crafted win-win agreements that they stand behind. So industry is behind this bill, the FDA is behind this bill, and hundreds of groups throughout our country have been supporting it. They have done their job and now it is time for us to do ours.

It is absolutely imperative that we authorize these user fee agreements because drugs available the FDA will lose about 60 percent of its drug center budget and 20 percent of its device center budget. It will have to lay off nearly 2,000 employees, which would grind the drug and device approval processes to an unacceptably slow pace, with devastating consequences for patients, jobs, for the industry, and further innovations both in drugs and devices. We cannot let that happen, and that is why for more than a year we have worked very closely in our committee.

I see the ranking member, Senator ENZI, is here. We and our staffs have worked together. As I said, we set up
these working groups in our committee. They were not divided along any kind of partisan lines. They were set up along interest groups so we had both Democratic and Republican Senators and their staffs working together for your vote.

I am sure I can speak for Senator Enzi when I say all along our aim has been to ensure that in addition to the user fee agreements and all the other things, this is the product of a consensus, bipartisan, policy-making process that we were involved in for the betterment of the beneficiaries. It was an open and transparent process. We had input not only from our members but other Senators were also involved as they had interest in this bill. Throughout negotiations on this bill the stakeholder community-at-large was involved.

Again, I can assure everyone that this legislation benefited greatly from all of the diverse input from Senators on both sides, industry stakeholders, consumer groups, and patient groups. It is a result of concerted efforts to define our common interests, and I believe these efforts will directly benefit patients and the U.S. biomedical industry.

Very briefly, I want to say as a broad stroke that this bill authorizes key user fee agreements for both drugs and medical devices. It streamlines the device approval process while again enhancing patient protections.

We do one other thing. We modernize the FDA’s global drug supply chain authority so we have a better handle on and better information and knowledge of where our products are coming from. Of the drugs manufactured in this country, 80 percent of the ingredients come from abroad. In the past we have not had a tight handle on where they were coming from and what kind of manufacturing processes were involved. This bill closes that up. It gives the FDA a much better authority over that and much better input from where the drugs come from to make sure they follow good manufacturing practices. It spurs innovation and incentivizes drug development for life-threatening conditions.

We reauthorized the pediatric trial program and improved it so we have specific trial programs for pediatric drugs. Children are not just small adults. What may work for an adult in terms of a drug, we don’t just cut the drug in half and give it to a child. Sometimes it takes specialized, specific kinds of drugs for children that are not something an adult gets. So this reauthorizes and improves those trials for children.

Senator Enzi and I and others in our committee wanted to do something about preventing and mitigating drug shortages, so we have provisions in this bill that will do that and help prevent and mitigate these drug shortages by making sure the FDA gets timely information from manufacturers if there is going to be any interruption at all in the supply chain. Also I believe this bill increases FDA’s accountability and transparency.

That is sort of a broad-brush stroke of what is in this bill. I will be over in the next day perhaps getting into some more of the specifics. It is imperative that we adapt to your new medical and technological and scientific advances. Things move very rapidly in this area and we want to make sure we get the drugs and devices approved as quickly as possible, but always with keeping patient safety foremost. That is the single most important thing to make sure that patient protections will remain key. Keeping pace with the biomedical landscape that changes so rapidly is the aim of this bill, to ensure the drugs coming from abroad are safe, and to take appropriate measures to protect our patients.

I believe we have a good compromise. Neither Democrats nor Republicans got everything they wanted in this bill. As I have said before, I didn’t get all of what I wanted and I am sure others didn’t either, but that is the process of a consensus. And where we could not achieve consensus, we didn’t allow those differences to distract us from the important goal of producing a bill that everyone could support.

Again, it is a true bipartisan bill that is broadly supported by the patient groups and industry. I have letters from over 100 groups outlining their support. To name a few: the Pew Charitable Trusts, the Pharmaceutical Manufacturers Association, the Generic Pharmaceutical Industry, the Biotech Industry Organization, BIO, the American Academy of Pediatrics, Advanced Medical Technology Association, American Foundation for the Blind, and many more. Those are just a sampling of over 100 groups.

Mr. President, I ask unanimous consent that the list of those groups be printed in the RECORD at the conclusion of my remarks.

Mr. HARKIN. We are expecting that there will probably be some amendments to this bill, and that is fine. That is the way the Senate should operate. We expect all amendments to this bill will be relevant to the bill. I hope Senators on both sides of the aisle who want to see this bill passed expeditiously would keep that in mind. If there is a relevant amendment and Senator feels they want to bring that up, that is fine. That is the way the Senate should operate.

I hope nonrelevancy amendments which have nothing to do with the bill will not be promoted on the Senate floor. That would only slow the bill down and put us into some untenable position on the Senate floor in terms of getting this bill expeditiously done.

We cannot allow unrelated, partisan disagreements or Presidential-election year politics to interfere with this bill and keep us from doing our job. So amendments that are offered must be relevant to the bill, and we must pass it now.

The clock is ticking. Everything ends by the end of this summer. We are out of here in August. We have the 4th of July break and Memorial Day break coming up. In order for us to go to conference with the House and work out any differences we may have and get this back here so we can finish it by late June or early July—I hope we could even finish this by late June so there would not be any disruptions at all in the FDA and their planning for the future or in the--

I urge my colleagues to join in the bipartisan spirit of cooperation that we have witnessed in the HELP Committee over the last year. Let us come together to pass this legislation that is critical importance to the American people.

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

SUPPORT FOR PROVISIONS IN THE FDA SAFETY AND INNOVATION ACT

A. Philip Randolph Institute; Ablitech, Inc.; Academy of General Dentistry; Academy of Managed Care Pharmacy; Action Administration CP; Advisory Committee on Technology Association; AFL-CIO, Maryland and DC Chapter; AIDS Alliance for Children, Youth, and Families; AIDS Delaware; AIDS Foundation of Greater Philadelphia; Alexion Pharmaceuticals; Allegheny Conference of Community Development; Alliance of AIDS Services—Carol; Alzheimer’s Association—Capital of Texas Chapter; Alzheimer’s Association—Indiana Chapter; Alzheimer’s Association; American Academy of Allergy, Asthma, and Immunology; American Academy of Health Technology Association; American Academy of Pediatrics; American Academy of Periodontology; American Association for Cancer Research, Inc.; American Cancer Society Cancer Action Network; American Cancer Society—Allegheny Division; American Cancer Society—Alliance for Children; American Cancer Society—Orange County; American College of Clinical Pharmacy; American College of Dentistry; American College of Gastroenterology; American College of Gastroenterology—National Capital; American College of Physicians; American College of Physicians—Association; American Dental Association; American Dental Association; American Diabetes Association; American Dental Association; American Foundation for the Blind; American Hospital Association; American Law Foundation—Allegheny Division; American Medical Association; American Pediatric Society; American Pharmacists Association; American Printing House for the Blind; American Psychiatric Association; American Public Health Association; American Public Health Association; American Public Health Association; American Thoracic Society; Amgen; Analtech; ARCA Biopharma; Arthritis Foundation; Association for Community Cancer Centers; Association of Medical School Pediatric Department Chairs; AstraZeneca Pharmaceuticals LP; Augmenta Biologics; Bayer Healthcare; BHGR Law; BIO; BioCrossroads; Biogen Idec; BioHouston; BioNJ;
BioOhio; BioRelix, Inc.; Biotech Vendor Services; Black Mental Health Alliance of Delaware; Blood Bank of Delmarva; Bloomington Life Sciences; Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Vetmedica, Inc.; Boehringer Ingelheim-Vetmedica, Inc.; Boudreaux; Boudreaux Brothers Construction; Boyertown Chamber of Commerce.

Cambridge Chamber of Commerce; CARE Therapeutics; CARO Corporation; Central Connecticut Chambers of Commerce; Cerebral Palsy Association of Eastern Massachusetts; Chamber of Commerce of Eastern Connecticut; Children’s Defense Fund; Children’s Hospital Association; Citizens Opposed to Additional Spending and Taxes (COAST); Cleveland Clinic; Connecticut Association of Business & Industry; Connecticut Business & Industry Council; Connecticut Association of Commerce and Industry; Connecticut Chamber of Commerce; Connecticut Coalition of Texans with Disabilities; Colorado Association of Commerce and Industry; Colorado Bioscience Association; Colorado Gerontological Society; Commerce and Industry Association of NJ; Community Health Charities of Iowa; Connecticut AIDS Resource Coalition; Connecticut Business & Industry Association (CTBIA).

Connecticut Retail Merchants Association; Connecticut State Building and Construction Trades Council; Connecticut United for Research and Education (CURE); CT Board of Education; CT Center for Public Managers; CT Department of Economic Development; CT Health Care; CT Hospital & Health Care Association; CT Hospital Association; CT Municipal Officials Association; CT Office of Early Childhood; CT Office of Early Childhood Development; CT School Counseling Association; CT Small Business Development Council; CT State Board of Education; CT State Library; CT United Way; CT United Way; CT Workforce Readiness Council; CT Women’s Infrastructure Fund.

Connecticut Statewide Organized Labor; Council of Pediatric Subspecialties; CT BEACON; Cubist; D’Souza and Associates; David M. Rubenstein Family Foundation; Dayton/Ohio Area Chamber of Commerce; DC Area Chamber of Commerce; Delaware County Chamber of Commerce; Delmarva Chamber of Commerce; Dinosaur Country Chamber of Commerce; Down East NC; Dun & Bradstreet.

East End Group, LLC; Easter Seals of Maryland; East Tennessee Chamber of Commerce; East Texas Economic Development District; Eastern Connecticut Business Roundtable; Eastern Shore Community College; Eastern Shore Economic Development Organization; Eastern Shore Regional Chamber of Commerce; Develop Indy; Dun & Bradstreet.

Ezra et Yeshayahu Chamber of Commerce of Massachusetts; Economic Alliance Snohomish County; Eli Lilly and Company; Elizabeth Glaser Pediatric AIDS Foundation; Endocyte; Engineered BioPharmaceuticals; Epilepsy Foundation of Greater Chicago; Exemplar Genetics; Farmington Chamber of Commerce; Feed Energy Company; Fort Wayne Chamber of Commerce; Generic Pharmacy Association; GlaxoSmithKline; GlycoMimetics; Grand Rapids Area Chamber of Commerce; Greater Boston Chamber of Commerce; Greater New Haven Chamber of Commerce.

HealthHV; Healthcare Institute of New Jersey (HIJ); Hematology/Oncology Pharmacy Institute; Here–Just For You; HMS; Hollingsworth; Holyoke Community College; Hood Cancer Center; Howard University; Huntington County Cancer Coalition; IBF Scientific; Illinois Bio; Illinois Biotechnology Industry Organization (IBIO); Illinois Chamber of Commerce Healthcare Council; Illinois Manufacturers’ Association; Illinois Science and Technology Corporation; Incyte; Indianapolis & Marion County Metropolitan Medical Center; Iowa Academy of Family Physicians; Iowa Biotech Association; Iowa Nurses Association; Johns Hopkins Medicine; Johnsson & Johnson; Joy’s House; Junior Achieve- ment of Central Maryland; Junior Achievement of Delaware; Junior Blind of America; Juvenile Diabetes Research Foundation; Kala- Juvenile Diabetes Awareness Coalition; Kolltan Pharmaceuticals, Inc.; Lampl Light; Lauren’s Fund; Leukemia & Lymphoma Society Iowa and Nebraska; Life Science Greenhouse of Central Pennsylvania; LifeScience Alley; Lighthouse International; Lupus Alliance of America—Michigan Indiana Affiliate; Lupus Foundation of America; Lupus Foundation of America-DC/MĐ/VA Chapter; Lupus Foundation of America, Connecticut Chapter; Lupus Foundation of America, DC/MĐ/Va Chapter; Lupus Foundation of America, New York Chapter; Lupus Foundation of California; Lupus Foundation of Florida; Lupus Foundation of Georgia; Lupus Foundation of Illinois; Lupus Foundation of Michigan; Lupus Foundation of New Jersey; Lupus Foundation of Northern California; Lupus Foundation of Ohio; Lupus Foundation of Pennsylvania; Lupus Foundation of Southern California; Lupus Foundation of Washington, D.C.; lupusfoundationofwisconsin; Lupus Foundation of Wisconsin; Lupus Society of Illinois; Lupus Society of Virginia; Mental Health America of Colorado; Mental Health America of Greater Tarrant County; Mental Health America of Illinois; Mental Health America of Indiana; Mental Health Association of Connecticut; Merck; Metro Denver Economic Development Corporation; MichBio; Michigan Chamber of Commerce; Michigan Council of the Blind and Visually Impaired; Michigan Manufacturers Association; Middlesex County Chamber of Commerce; Midwest Business Group on Health; Mid-State Alliance; Micron; Mylan.

NAAAC Crewe Chapter; NAMU Illinois; Nation- ally for Mental Illness—Gulf Coast; National Alliance for Mental Illness—Metropolitan Houston; National Alliance for Mental Illness—Texas; National Alliance on Mental Illness; National Alliance on Mental Illness, Michigan; National Association of Chain Drug Stores; National Association of Manufacturers; National Association of Pediatric Nurse Practitioners; National Dental Association; National Federation of the Blind; National Kidney Foundation of Indiana; National Organization for Rare Disorders; National Parkinson Foundation; National Processing Solutions; National Research Center for Women & Families.

NC Autism Society; NC Bio NC Chamber; NC Psychological Association; Neurofibromatosis of the Mid-Atlantic; Neurofibromatosis of the Mid-Atlantic; New Jersey Business and Industry Association (NJBIA); New Jersey Chamber of Commerce; New Jersey Laborers’ Union; New Jersey Life Science Vendors Alliance (NJLBSVA); New Jersey State League of Municipalities; Newark Senior Center; NH Healthcare Advocate Volunteer Force (NJ Have); North Carolina Association for Biomedical Research; North Carolina Arthritis; North Carolina Biotechnology Association; North Carolina Medical Society; North Carolina Office of Science, Technology & Bio- technology & Biomedical Association.

Washington Global Health Alliance; Washington State Department of Commerce; Washington State University Tri-Regional Chamber of Commerce; We Work For Health; We Work For Health New Jersey; WellDoc, Inc.; Western Economic Council; Western Michigan University; Westside Health; Wolcott Chamber of Commerce; Worcester Chamber of Commerce; Wright Runstad & Company.

I yield the floor. The PRESIDENT pro tempore. The Senator from Wyoming.

Mr. ENZI. Mr. President, I thank the chairman for his remarks and wish to be associated with them. It has been a very bipartisan process that has resulted in this bill coming to the floor. I am hoping there will only be relevant amendments and that there will be few of those. Every amendment has the potential for disrupting the entire bill. This has been a very inclusive process that has led to this legislation. Over a year ago staff began to meet with stakeholders on the policy issues that are addressed in S. 3187. Starting in the spring of 2011, staff from Republican and Democratic offices on the Health, Education, Labor and Pensions Committee began holding meetings. The groups proceeded to meet every week for several months. They met with stakeholders and discussed policy solutions that each member thought would solve the problem. After much discussion of the benefits, costs, and possible unintended con- sequences, members agreed to a list of policy concepts. If it was not a consen- sus on a particular policy, then it
was not included. The chairman mentioned the importance of consensus, and that is what we worked on.

As this process progressed, my staff met with the Republican staff on the HELP Committee for at least 2 hours every week to keep them informed of everything that happened. I personally met with the members of the committee before the markup to make sure I understood their priorities. No one office got the entirety of what they wanted. However, we did find the 80 percent solution we could all agree could help solve whatever policy the group was working on.

What we see before us now is the outcome of the hard work of these groups. The bill passed the committee by a voice vote. The bill reflects the work of every member of the Health, Education, Labor, and Pensions Committee. All of them have at least one provision included in this legislation, and many members of the committee worked with us to find consensus measures that addressed their priorities as well.

This legislation is a model for how the process can and should work no matter what the political environment. This went to committee, it was worked in committee, it is now at the Senate floor, and I hope my colleagues will join me in supporting this truly bipartisan provision that reduces the debt and ensures that the United States will maintain its leadership in the innovation of safe and effective biomedical products.

I yield the floor.

EXECUTIVE SESSION

NOMINATION OF PAUL J. WATFORD, OF CALIFORNIA, TO BE UNITED STATES CIRCUIT JUDGE FOR THE NINTH CIRCUIT

The PRESIDING OFFICER. Under the previous order, the Senate will proceed to executive session to consider the following nomination which the clerk will report.

The legislative clerk read the nomination of Paul J. Watford, of California, to be United States Circuit Judge for the Ninth Circuit.

The PRESIDING OFFICER. Under the previous order, there will be 1 hour of debate equally divided and controlled in the usual form.

The Senator from Vermont.

Mr. LEAHY. I am glad we are finally able to debate and vote on the nomination of Paul Watford of California to fill a judicial emergency vacancy on the Ninth Circuit. As the distinguished Presiding Officer knows, it was 3½ months ago that we voted Mr. Watford out of committee. We had not been able to get an agreement to debate or vote on this nomination since it was approved a few days after the Majority Leader was forced to file cloture to get an up-or-down vote on one of President Obama’s judicial nominations.

Thankfully enough, Senate Republicans came forward to say they are not going to delay a vote or to continue a filibuster. We ought to just have an up-or-down vote, which we always used to do. Hopefully, we will not vote to prolong a filibuster, but vote up or down, and I think those Republicans who came forward and said enough of the cloture votes, let’s vote.

This nominee, Paul Watford, is highly qualified. In fact, he has the highest qualifications for the Ninth Circuit. He shouldn’t be filibustered. He should not require a cloture vote. He is a nominee with impeccable credentials and qualifications. He served as a Federal prosecutor and is now a highly regarded appellate lawyer in private practice. He served as a law clerk at the United States Supreme Court and at the United States Court of Appeals for the Ninth Circuit. The ABA Standing Committee on the Federal Judiciary gave Paul Watford the highest possible rating, saying they would give it to him unanimously. He also has the strong support of his home State Senators, Senator Feinstein and Senator Boxer. He has widespread support across the spectrum, including known conservatives and two former Presidents of the Los Angeles chapter of the Federalist Society, as well as Judge Alex Kozinski, a conservative Reagan appointee who is now Chief Judge of the Ninth Circuit. By any traditional measure, Paul Watford is the kind of judicial nominee who should be confirmed easily by an overwhelming vote—a vote of both Republicans and Democrats.

I had hoped after the agreement between the Democratic and Republican Senate leadership to begin finally considering the backlog of judicial nominations from last year that the Senate was at last returning to regular order. The refusal of Senate Republicans to consent to a debate and vote on this nomination for more than 3½ months, however, again required the Majority Leader to file cloture to end another Republican filibuster.

Senator Republicans continue to apply what they have admitted is a “new standard” to President Obama’s judicial nominees. From the beginning of the Obama administration, Senate Republicans abandoned the standards and arguments they used to sayshould block his judicial nominations. During the administration of the last President, a Republican, they insisted that filibusters of judicial nominees were unconstitutional. They threatened the “nuclear option” in 2005 to guarantee up-or-down votes for each of President Bush’s judicial nominations. Many Republican Senators declared that they would never support the filibuster of a judicial nomination.

Senate Republicans reversed course and filibustered President Obama’s judicial nominations. In one instance, that of Judge David Hamilton of Indiana. They tried to prevent an up-or-down vote on that nomination even though he was nominated by President Obama after consultation with the most senior and longest-serving Republican in the Senate, SenatorDick Lugar of Indiana, who strongly supported the nomination. Fortunately, the Senate rejected that unjustified filibuster and Judge Hamilton was confirmed with Senator Lugar’s support.

Senate Republicans previously engaged in misguided filibusters last year of Goodwin Liu’s nomination to the Ninth Circuit and Caitlin Halligan’s nomination to the D.C. Circuit. Each of these nominees is a highly qualified lawyer we should encourage to join the Federal bench. There were certainly no “extraordinary circumstances” for filibustering their nominations. Senate Republicans filibustered them anyway, setting a new and unfortunate standard for the Senate. Those filibusters demonstrated that any nominee can be filibustered based on concocted controversies and baseless claims. That was unfortunate and unwise. Senate Republicans have already succeeded in preventing confirmation votes on five of President Obama’s judicial nominees who were blocked from a Senate vote after being voted out of the Senate Judiciary Committee.

Paul Watford is the kind of person we want in our Federal judiciary. This is the kind of person when we talk about the Federal courts, we can say here is a judge we can look up to and who can inspire others who seek to be judges. He is not a nominee against whom a partisan filibuster would be justifiable, and I thank some of those Republican Senators who called me this weekend who said they would oppose a Republican filibuster. I thank them for that, because what they are doing is what is best for the Senate. By allowing a vote, they are doing the best for the Ninth Circuit but, even more importantly, they are doing what is best for the independence of our Federal judiciary. Because if one is going to vote to try to block somebody as qualified as Paul Watford, one is basically saying they care who the nominee is, they are going to block it, and that is not the message we should send if we are going to have an independent Federal judiciary in this country.

He has a mainstream record. He demonstrates legal excellence and experience at the top of his profession. He clerked at the United States Supreme Court for Justice Ruth Bader Ginsburg and on the Ninth Circuit for now-Chief Judge Alex Kozinski, a conservative appointee of President Ronald Reagan. Over his 17-year legal career, Paul Watford has worked on briefs in nearly 20 cases before the United States Supreme Court, and has argued numerous cases before the Ninth Circuit Court of Appeals as well as the California appellate courts. As a Federal prosecutor in California, Mr. Watford handled prosecutions involving immigration and drug offenses, firearms trafficking, and major frauds.
So he should be on the Ninth Circuit, and I am delighted, as I make a pre-
liminary nose count, that he will be confirmed as a judge of the Ninth Cir-
cuit. When confirmed, he will be only the second African-American judge
serving on the Ninth Circuit, joining Judge Johnnie Rawlinson of Nevada on the
bench. And I will not be surprised when he is confirmed, because of his work as a
tough but very fair prosecu-ictor. It is no surprise that he had support from conservatives as well as liberals
who had what they call a blind spot, as a while, his nomination was being held
up and we couldn’t get a vote.

Two former presidents of the Los An-
geles Chapter of the Federalist Society
wrote to the Judiciary Committee in
support of Mr. Watford. Jeremy Rosen
wrote:

Everyone who knows Paul (whether they
are conservative or liberal, or somewhere in between) recognizes that he possesses the
qualities that are needed in an appellate
judge. While I find myself in somewhat
frequent disagreement with the President on
many issues (and an active supporter of one
of his nominees) I remain unanimous in our view that Paul pos-
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He is all the qualities that an appellate judge ought to have: intellectual brilliance, thoughts that
are moderate, collegiality, an ability to
civilly and productively with colleagues of all ideological stripes, and a
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Henry Weissman, another former
Federal Society chapter President,
that he has “never seen any hint
of politics in Mr. Watford’s lawyering”,
and that he has “every confidence that,
as a judge, Mr. Watford would apply
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As Chief Justice Roberts noted dur-
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represent clients. They do not stand in their client’s shoes and they should not
have their client’s legal positions used

against them. It is time to abandon the crude and inaccur-
cate litmus tests being applied to
President Obama’s nominees. Let’s
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could ever be confirmed to the Federal
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practice, of course they are going to
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resent some issues where others may,
as individual Senators, feel they would
rather be on the other side of the issue.

But how quickly would our legal sys-
tem break down if lawyers could only
represent one side of an issue, or when
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One of the most valued legal systems
in the world would disinte-
grate.

As an attorney in private practice
Paul Watford has advocated positions
well within the mainstream of legal arg-
ument. There were only two cases on
which he worked in which the hundreds
and possibly thousands in
which he has been involved, that were
criticized by Committee Republicans.

In one, the well-known law firm with
which he worked, the Supreme Court
sentenced thousands of people to
groups challenging the controversial
Arizona immigration law, and won a
preliminary injunction against certain
provisions for violating the Constitu-
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fairly and impartially in cases involving the death penalty. He also answered that he believes the death penalty an acceptable form of punishment and that he would have no difficulty faithfully applying the Supreme Court's precedent in that regard. How this point of view that as justifying opposition is beyond me.

Our legal system is an adversary system that is predicated upon legal advocacy from both sides. No nominee should be allowed to be disqualified by the views of the clients. That has always been our tradition. I hope it always will be our tradition, on behalf of the client, is critical to the fair lawyer with the particular views of the client. We did not engage in tit for tat when the presidency changed. During the Bush administration, the Senate proceeded to confirm seven of the nine Ninth Circuit nominees of President Bush. Four of President Bush's Ninth Circuit nominees were confirmed during this first 4-year term: Judge Richard Clifton, Judge Jay Bybee, Judge Consuelo Callahan, and Judge Carlos Bea.

By contrast, Senate Republicans have been opposing our moving forward to consider and confirm Paul Watford and Andrew Hurwitz, who are both strongly supported by their home State Senators, to fill judicial emergency vacancies. Senate Republicans have already successfully filibustered the nominations of Goodwin Liu, who also had the strong support of his home State Senators.

I urge Senators to show that we can work together to reduce the vacancies that are burdening the Federal judiciary. Do what some of my friends on the Republican side of the aisle have said to me, which is to move forward to vote for this nominee. They should also help the millions of Americans who rely on our Federal courts who seek justice. We can show we intend to do that. We can start right here by voting to confirm this good man, Paul Watford, who is a highly qualified nominee to the Ninth Circuit Court of Appeals, and say to the American people we believe in justice for everybody here.

EXHIBIT 1

BARTLIT BECK HERMAN PALENCHER & SCOTT LLP

Re Paul Watford.

Hon. HARRY REID,
Majority Leader, U.S. Senate, Hart Senate Office Building, Washington, DC.

Hon. LENORE J. LEAHY,
Chairman, Committee on the Judiciary, U.S. Senate, Russell Senate Office Building, Washington, DC.

Hon. MITCH MCCONNELL,
Minority Leader, U.S. Senate, Russell Senate Office Building, Washington, DC.

Hon. CHARLES GRASSLEY,
Ranking Member, Committee on the Judiciary, U.S. Senate, Hart Senate Office Building, Washington, DC.

DEAR SENATORS: We write to provide our enthusiastic support for Paul Watford's nomination to serve on the United States Court of Appeals for the Ninth Circuit.
We have known Paul personally and professionally for nearly twenty years, having met him in 1994 when we served together as clerks to Judge Kozinski on the Ninth Circuit. Of all the men and women we worked with during those intense years, we learned a lot about Paul’s approach to legal issues, his attitudes about legal rules and precedents, and the most important aspect of his demeanor when confronted with competing views of what the law is or should be.

Paul is intelligent, thoughtful, balanced and fair—don’t expect him to succeed by polemic or partisan views. As a serious student of the law, his instinct is to look for the answer dictated by precedent, not his personal views. And even in the context of debate, he maintains an even keel, demonstrating a temperament that is well-suited to the act of judging.

Others can and no doubt will speak to Paul’s obvious qualifications, including his demonstrable intelligence and distinguished professional career. We can speak, from both sides of the political aisle, on what the law is or should be.

Paul has the experience, skills and demeanor well-suited for the bench. He clerked for two distinguished judges, as a federal prosecutor, and as a lawyer in private practice. With very different political viewpoints and represents clerks from the chambers of every Justice on the Supreme Court during the OT96 term. We are unanimous in our view that Paul possesses all the qualities characteristic of the most highly regarded jurists in this country. He has the ability to listen to and consider fairly all points of view, a calm temperament, and a prodigious work ethic. We respectfully request that the Senate take a vote to confirm him to the Ninth Circuit.

Sincerely,

Julia Ambrose, David Barron, Stuart Benjamin, Yochai Benkler, Steve Chansonnier, Nancy Combs, Jeff Robbins, Charlie Dungan, Ward Farnsworth, Ann L. Luisa, David Frelinghuysen, Shawn Fagan, Sean Gallagher, Heather Gerken, Craig Goldblatt, Mark Harris, Julie Katzenmoyer, Joseph Kennedy, Mary Kaye Kelly Klas, Laurie Allen Mullig, Eileen Mullennix, Kate Moore, Jennifer Newstead, Gretchen Rubin, Kevin Ruskj, Maria Simon, Paul Simon, Dana Ulyot, Paul Weiser, Mike Wishnie, Michael Wong, Ernie Young.

Hon. HARRY REID,
Majority Leader, U.S. Senate, 522 Hart Senate Office Building, Washington, DC

Hon. PATRICK J. LEAHY,
Chairman, Committee on the Judiciary, U.S. Senate, 433 Russell Senate Office Building, Washington, DC

Hon. MITCH MCCONNELL,
Minority Leader, U.S. Senate, 361A Russell Senate Office Building, Washington, DC

Hon. CHARLES GRASSLEY,
Ranking Member, Committee on the Judiciary, U.S. Senate, 135 Hart Senate Office Building, Washington, DC

DEAR MAJORITY LEADER REID, MINORITY LEADER LEAHY, AND RANKING MEMBER GRASSLEY: We write in support of Paul Watford’s nomination to be a Judge on the United States Court of Appeals for the Ninth Circuit. All of us served as law clerks at the Supreme Court during the same year that Paul clerked for Justice Ruth Bader Ginsburg (the October 1986 Term of the Court). During that time, some of us worked with Paul directly in Justice Ginsburg’s chambers; others of us worked directly with Paul on cases that we were assigned to in common; and all of us got to know Paul. Based on what we have seen, and what we know of Paul’s career in the years since, we believe that Paul is a superb choice to be a Judge on the Ninth Circuit. Paul would be well suited to support Chief Judge Kozinski’s nomination and to bring it to a vote expeditiously.

Paul came to the Supreme Court after clerking for Circuit Judge Alex Kozinski, a Reagan appointee, and after attending UCLA Law School. His path to a Supreme Court clerkship reflected his work ethic and legal acumen. At the Supreme Court, Paul brought those qualities to bear in analyzing difficult legal problems and finding ways to explain them clearly and sensibly. He worked with Paul, won respect from everyone he worked with. Paul invariably got along well with his peers, was always a superb listener, and treated everyone with kindness and respect.

The most important aspect of Paul’s demeanor when confronted with competing views of what the law is or should be is that he will make an excellent judge.

We urge the Senate to bring Paul’s nomination to a vote and to vote to confirm.

Very truly yours,

MARK S. OUWELEN.
O’Connor (OT 1993); David A. Schwartz, Irell & Manella LLP, Judge Alex Kozinski, (1988–1989); Kathryn H. Ku, Munger, Tolles & Olson LLP, Judge Alex Kozinski (2003-2004); Joshua Lipsher, Gibson, Dunn & Crutcher LLP, Judge Alex Kozinski (2005-2006), Justice Antonin Scalia (OT 2006); Laura Nelson, Judge Alex Kozinski (1985-1986); Mark Overbeck, Hon. Chief Judge, U.S. District Court for the Central District of California, where he served as Co-Chair of the American Bar Association’s Appellate Practice Committee, and he is a member of the Judicial Council’s Magistrate Selection Panel.

The American Bar Association has given him their highest rating—unanimously well qualified.

Mr. Watford has earned the respect of attorneys who know his work. For example, Daniel Collins, who clerked for Justice Scalia and served as an attorney in both Bush administrations, said this about Mr. Watford:

He just embodies the definition of judicial temperament—very level-headed and even-keeled. . . . I don’t think he’ll approach the job with any kind of agenda other than to do what is right and consistent with precedent and he understands it.

And Jeremy Rosen, a partner at Horvitz & Levy and former president of the Los Angeles Lawyers Chapter of the Federalist Society, said Mr. Watford is a nominee many conservatives could support:

I know he has the respect of anyone who has come into contact with him. He is exceptionally bright and well qualified. . . .

I ask unanimous consent to have printed in the RECORD letters from

GRASSLEY: I write this letter in support of the nomination of Paul Watford to the United States Court of Appeals for the Ninth Circuit. Having known Paul on a professional basis for a number of years, and can personally attest to his reputation for being remarkably intelligent, insightful and even-handed, he is highly regarded within his firm, amongst his clients, and within the wider legal community for his exceptional skills as an appellate practitioner. More importantly, he is remarkably sincere and friendly, and working with him is always a pleasure.

Paul enjoys an exemplary record as an attorney. He clerked for Judge Alex Kozinski of the Ninth Circuit, and later for Justice Ruth Bader Ginsburg on the Supreme Court of Appeals, then clerked for Justice Ruth Bader Ginsburg on the Ninth Circuit Court of Appeals. He has served as Co-Chair of the American Bar Association’s Appellate Practice Committee, and he is a member of the Judicial Council’s Magistrate Selection Panel.

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I ask unanimous consent to have printed in the RECORD letters from
Daniel Collins, Jeremy Rosen, Eugene Volokh and Henry Weissmann immediately following my remarks.

The PRESIDING OFFICER. Without objection, it is so ordered. (See exhibit 1.)

Mr. WATFORD. In conclusion, Mr. Watford is a talented lawyer who has earned the respect of his peers for his work in the public and private sectors. He will be a great addition to the federal bench, and I urge my colleagues to join me in voting for him today.

Los Angeles, CA, May 18, 2012.

Re Nomination of Paul J. Watford as Circuit Judge, United States Court of Appeals for the Ninth Circuit.

HON. PATRICK J. LEAHY. Chairman, U.S. Senate, Committee on the Judiciary, 433 Russell Senate Office Building, Washington, DC.

Member, Committee on the Judiciary, 135 Hart Senate Office Building, Washington, DC.

Mitch McConnell, Republican Leader, U.S. Senate, 317 Russell Senate Office Building, Washington, DC.

Chuck Grassley, Ranking Member, U.S. Senate, Committee on the Judiciary, Dirksen Senate Office Building, Washington, DC.

Dear Senators:

I write to express my strong support for the confirmation of Paul J. Watford to be a Circuit Judge on the United States Court of Appeals for the Ninth Circuit. Having known and worked with Paul for more than eight years at Munger Tolles & Olson LLP in Los Angeles, I am confident that he has the skills, judgment, temperament, and integrity to be an outstanding appellate judge. Paul and I come from opposite ends of the political spectrum. I have been a conservative Republican for my entire adult life. I am a member and supporter of the Federalist Society, and I served in the Justice Department in Washington, D.C. during the Administrations of both George H.W. Bush and George W. Bush. Despite our political differences, I firmly support Paul's nomination because I believe that he understands and respects the crucial distinction between law and politics. I say that based on years when I observed how he approached the legal precedent and how he analyzes complex legal arguments.

During our time together at Munger, Tolles, I have frequently consulted Paul on many difficult legal issues, and he has served many times as a “moot court” judge helping me to prepare for oral arguments. Given Paul's brilliance and honesty, I know that he can always count on him to quickly spot the weak points in a legal argument and to give me a frank and professional assessment of the arguments he presents. Few traits are more important in a Circuit Judge than a willingness to adhere faithfully to precedent, and I have always been impressed by the thoroughness, objectivity, and candor that Paul brings to bear in his evaluation of the relevant body of law in any given area.

I strongly agree that judges must respect the precedent of their office and should not attempt to implement a personal or ideological agenda from the bench. I believe that Paul understands those limits. While he and I may have differences on some jurisprudential issues, I have always been impressed by the even-handed and measured approach he brings to bear in analyzing legal problems. I feel that on the bench, Paul can perform his duty best to fairly reach the correct answer under the law as he sees it.

To my mind, another indication of Paul’s fairmindedness, and of his ability to separate law and politics, is the wide range of the matters on which he has worked. Paul has grappled with many of the most interesting legal matters in the firm, and that has unsurprisingly led him to work on important matters involving controversial issues that may generate strong emotions on one or the other end of the political spectrum. I do not think that Paul’s work on these or any other cases can be viewed as suggesting that he has an ideological agenda that would distort his approach to the law on the bench. Indeed, one of the more controversial cases that Paul worked on was Mohammad v. Jeppesen Dataspace Inc., in which I represented the defendant company, which was accused by the plaintiffs (who were represented by the ACLU) of respecting the CIA in carrying out its alleged “extraordinary rendition” program. That Paul has shown a willingness to work, with great professionalism, on such a diverse set of important matters seems to me to dispel any concern that his approach to judging would be anything other than evenhanded. Paul has always struck me as a lawyer’s lawyer and as refreshingly oblivious to “political” concerns. On the bench, he’d be a judge’s judge.

Lastly, I would note that Paul has an outstanding disposition. Anyone who has met him for any length of time cannot fail to be impressed by his graciousness and professional demeanor. He is without guile. On the bench, he would epitomize judicial temperament. I recognize the importance of the decision to confirm an individual to a lifetime appointment as a federal appellate judge. I am confident that Paul offers the requisite talent, fairness, and integrity to be an excellent jurist, and I am pleased to support his confirmation.

Sincerely,

Daniel P. Collins.


Re Nomination of Paul Watford.

HON. PATRICK J. LEAHY. Chairman, Senate Judiciary Committee, Dirksen Senate Office Building, Washington, DC.

HON. CHARLES E. GRASSLEY. Ranking Member, Senate Judiciary Committee, Dirksen Senate Office Building, Washington, DC.

Dear Chairman Leahy and Senator Grassley:

I write this letter in support of the nomination of Paul Watford to the United States Court of Appeals for the Ninth Circuit. I have known Paul for over a decade, first as a colleague and then as a friendly competitor in the relatively small California appellate bar.

By way of background, I am a partner at Horvitz & Levy LLP, the largest civil appellate law firm in California. My practice primarily focuses on handling appeals in the Ninth Circuit and California appellate courts. At the outset of my career, I had the privilege of serving as a law clerk for a judge on the Ninth Circuit. I also am a member of the National Chamber Litigation Center’s California Advisory Committee and past president of the Los Angeles Chapter of the Federalist Society.

While I find myself in somewhat frequent disagreement with the President on many issues (and an active supporter of one of his opponents), I do not attempt to implement a personal or ideological agenda from the bench. I believe that Paul understands those limits. While he and I may have differences on some jurisprudential issues, I have always been impressed by the even-handed and measured approach he brings to bear in analyzing legal problems. I feel that on the bench, Paul can do his level best to fairly reach the correct answer under the law as he sees it.

To my mind, another indication of Paul’s fairmindedness, and of his ability to separate law and politics, is the wide range of the matters on which he has worked. Paul has grappled with many of the most interesting legal matters in the firm, and that has unsurprisingly led him to work on important matters involving controversial issues that may generate strong emotions on one or the other end of the political spectrum. I do not think that Paul’s work on these or any other cases can be viewed as suggesting that he has an ideological agenda that would distort his approach to the law on the bench. Indeed, one of the more controversial cases that Paul worked on was Mohammad v. Jeppesen Dataspace Inc., in which I represented the defendant company, which was accused by the plaintiffs (who were represented by the ACLU) of assisting the CIA in carrying out its alleged “extraordinary rendition” program. That Paul has shown a willingness to work, with great professionalism, on such a diverse set of important matters seems to me to dispel any concern that his approach to judging would be anything other than evenhanded. Paul has always struck me as a lawyer’s lawyer and as refreshingly oblivious to “political” concerns. On the bench, he would epitomize judicial temperament.

I recognize the importance of the decision to confirm an individual to a lifetime appointment as a federal appellate judge. I am confident that Paul offers the requisite talent, fairness, and integrity to be an excellent jurist, and I am pleased to support his confirmation.
At the same time, there is no doubt that some small but important fraction of appellate cases consists of matters on which liberal judges and conservative judges will reach different results. That is the nature of law: Law is not mathematics. Some legal questions are unsettled and not answered by statutory or constitutional text, or binding precedent. Judges decide the easy and obvious legal answer, different judges reach different results based partly on their philosophies. Paul is a moderate liberal; I am a moderate libertarian conservative; I therefore expect that, if he is confirmed, there would be some future decisions of his with which I will disagree.

Yet the current President is President Obama, not Senator McCain. The American people spoke, and they elected someone who will not nominate judges with whom Republicans like me will always agree. So, respecting as I do the voters’ choice in 2008 (though it was not my choice), I do not ask: Is this the sort of judge who shares my legal philosophy? Rather, I ask: Would he be the sort of judge whom I could respect intellectually? Would he be the sort of judge whom I could trust to be fair-minded and respectful of the legal system? Would he be obligated to follow precedent? Is he likely to be more on the moderate side rather than solidly on the left? For Paul, my answer to those questions is a definite yes.

When a Democratic President nominates a judge who is indeed well on the left, Republicans like me face a difficult question: Should we resist the nomination, or should we accept it so long as the judge appears to be excellent on the nonideological factors? I have not fully thought through this question.

But for the reasons I mentioned, that’s a question that doesn’t even come up for me in this instance. Paul is the sort of moderate Democrat who nominee that moderates and consensus-building, as well as liberals, should solidly support.

Sincerely,
HENRY WEISSMANN.

HENRY WEISSMANN.
The American economy has always been driven by innovation, and some of our most extraordinary innovations have come in the biomedical sector. In the years ahead, it is my hope, that we will see more and more new jobs in this sector. But it is crucial for certain kinds of patients or very specific diseases. In the lifecycle of innovation, this is different than the last few decades when blockbuster medications were used and then developed on a very wide scale across the world. But it is an equally impressive feat of innovation that lies in the years ahead, and one that is only possible because of amazing advances in technology, the mapping of the human genome, the disassociation across many labs and small startup businesses, of the machinery, the mechanics, and the capabilities to innovate in the discovery and development of pharmaceuticals.

We have to continue to support and encourage this kind of innovation in order to be competitive in the global economy. At the moment, the FDA continues to keep pace with many of our global competitors in terms of their review time for new drug applications, but we are at real risk of falling behind.

One recent example to which I paid close attention, the blood-thinning drug Brilinta, was manufactured by a company—was developed and discovered by a company—in my home State of Delaware, AstraZeneca. It was finally approved by the FDA in July 2011. But prior to that approval, 33 other countries, including the EU and Canada, had already approved the drug months or years before. This delay in review and approval in some certain cases can be bad for patients who rely on these medications and harm the competitiveness of the United States. So I am glad this reauthorization clears away some of the conflict in the underbrush and will reauthorize and streamline the review time for pharmaceuticals.

Not only will this provide the kind of predictability and certainty any business needs to succeed, but it helps make sure the FDA’s essential regulatory process keeps pace with scientific innovation. In my home State of Delaware, there are more than 20,000 jobs that directly rely on biomedical research and innovation. But around the country there are more than 4 million indirectly and more than 675,000 jobs that directly benefit from this area.

Frankly, it is also one of our strongest export areas of growth for the long term. So we need this reauthorization now. In my view, moving forward with this legislation also means finding the fine balance between speed and safety, between getting treatments to patients without delay, and being certain these new drugs will be effective and safe.

In a recent editorial, the Washington Post noted: This time around, the balance appears to be tilting slightly toward faster approval. That’s good.

I agree. Safety is paramount, but with today’s technology and the FDA’s century of experience, I think we can move more quickly to get innovative treatments in the hands of patients who desperately need them. The Prescription Drug User Fee Act originally passed by Congress in 1992 and reauthorized most recently allows the FDA to collect user fees from pharmaceutical manufacturers and provide a stable, consistent funding stream that has steadily decreased drug review times by nearly 60 percent. It has also provided access on a faster and more predictable timeframe to over 1,500 new medicines since it was first enacted and deserves to be reauthorized to help expedite approval for breakthrough medicines for rare and widely experienced diseases.

In closing, the FDA is the oldest, most comprehensive consumer protection agency in the Federal Government. Its relevance has not decreased with age; in fact, our researchers and scientists have made major breakthroughs in care and technologies for treatment, the FDA has continued to serve as the conduit between innovators, physicians, and patients.

We face tremendous hurdles in treating devastating diseases of all kinds. In addition to ancient puzzles such as cancer that continue to allude us, there are new challenges cropping up every day. One example would be the need for new drugs to treat increasing cases of bacterial infections, greatly resistant to conventional antibiotics, so-called superbugs. That is why I have joined my colleagues in support of the President and Senator Corker as a cosponsor of the GAIN Act, to spur development of these specific types of drugs. This is one of many examples of the kinds of innovations that will solve the medical mysteries of our day, ease the suffering of millions of Americans, secure high-wage and high-skilled jobs in the biomedical research field, and ensure our competitiveness globally.

So let’s continue working in the bipartisan spirit that has carried this reauthorization thus far and proceed to pass it without delay.

I yield the floor.

The PRESIDING OFFICER. The Senator from California.

Mrs. FEINSTEIN. Mr. President, at 5:30 we will be voting on the nomination of Paul Watford for the Ninth Circuit Court of Appeals. I would like to say a few words about him at this time.

His work in the private sector, as a Federal prosecutor, as a two-term Ninth Circuit Judge, and as an ante-petitioner on numerous Ninth Circuit appeals, arguing four of them.

In one such case, a cocaine dealer had already convinced the State court that a drug seizure had violated his fourth amendment rights. Mr. Watford prevailed on appeal in forcing the dealer to forfeit over $100,000 in drug trafficking proceeds.

In 2006, Watford rejoined Munger, Tolles & Olson where he is currently a partner. This is one of the premier appellate law firms in California. Paul Watford specializes in appellate litigation at the firm. Like most major law firms, Munger’s docket is dominated by white collar crime litigation. Thus the focus of Mr. Watford’s work has been appellate litigation for business clients. For example, he represented Verizon Communications in a consumer class action case. He represented the technology company, Rambus, in Rambus v. Intel in the Ninth Circuit. He also represented Shell Oil in an antitrust case. Mr. Watford and his colleagues at Munger won a 9-to-0 reversal on behalf of Shell Oil in the Supreme Court. He has also represented numerous other American businesses, such as Coca-Cola and Berkshire Hathaway, as well as business executives and municipal government agencies.

In total he has argued 21 cases in the appellate courts, and he has appeared as counsel in over 20 cases in the U.S. Supreme Court. So he is well equipped.
His extensive experience as a prosecutor and private practitioner, including his specialty in appellate work, will serve the Ninth Circuit extremely well. Mr. Watford is also regarded by attorneys on both sides of the aisle, including conservative Republicans who praise him for his keen intellect and fair-minded approach to the law. He has been endorsed by two former presidents of the Los Angeles chapter of the Federalist Society.

One, Jeremy Rosen, says Watford is, “open-minded and fair,” and a “brilliant person and a gifted appellate lawyer.” The other, Henry Weissman, says that although he “does not agree with President Obama on issues, [he] completely agree[s] with his nomination of Paul Watford.” So that is a good thing.

Daniel Collins, who clerked for Justice Scalia and served as an Associate Deputy Attorney General in the Bush Justice Department, says Watford “embodies the definition of judicial temperament—very level-headed and even keeled.”

Thirty-two Supreme Court clerks from the term when Watford clerked for Justice Ginsburg have written in support of his nomination. They include clerks from every Justice on the Court at that time, including all of Justice Scalia’s clerks from that year, as well as several from Justices Rehnquist, Thomas, and Kennedy. I find this telling.

A group of over 40 former clerks for Judge Kozinski have also written in support of Watford’s nomination. This group includes numerous individuals with unquestionable conservative credentials. Many clerked for Justices Rehnquist, Scalia, Alito, and Kennedy. Several, such as Steve Engel, Charles Dugan, and Ted Ulyot also served in the Bush administration, including in the White House Counsel’s Office and the leadership of the Justice Department.

Watford also has strong support in the business community. The general counsels of leading American corporations, including Google, Mattel, Verizon, and CIRCOR, have also written in support of Mr. Watford. They say Watford “is exactly the kind of individual that any plaintiff or defendant—person, business, or government—would welcome deciding their case.”

In my view, Watford is truly both an excellent and distinguished choice for the Ninth Circuit. He is extremely bright. He is experienced at the trial and appellate level and in both civil and criminal cases. He is uniquely respected for his intellect and judgment, and he has broad support across the political spectrum and in the business community.

Maybe this is the reason cloture was vitiated. He is not fillibusterable. I hope people see the fine and keen intellect this man has for the law and that he should have a very large vote. If confirmed, he would be one of just two African-American active judges on the Ninth Circuit. The

Ninth Circuit, by far the busiest circuit in the Nation, urgently needs him to begin his service.

As I said the Ninth Circuit is a judicial emergency. This will fill one vacancy. So I urge my colleagues to vote at 5:30, in 15 minutes, for Mr. Watford’s nomination.

I yield the floor.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. GRASSLEY. Mr. President, today we are going to turn to a nomination that the Senator from California has just referred to, Paul Watford, to be circuit judge for the Ninth Circuit. I am disappointed that the majority leader has brought this nomination to the floor.

The reason I say that is there are at least 10 nominations on the Executive Calendar that might fall into the category of consensus nominees. Six nominees on the calendar had significant opposition. They clearly were not consensus nominees. Mr. Watford falls into this category of not being a consensus nominee.

I will oppose Mr. Watford’s nomination and ask my colleagues to oppose the nomination as well. My opposition to this nomination is based upon substantive concerns that I have regarding Mr. Watford’s views on both immigration and death penalty.

Mr. Watford partnered with the American Civil Liberties Union and the National Immigration Law Center in two cases to oppose Arizona’s 2010 immigration bill. In the first case, Friendly House, a class action lawsuit, Mr. Watford served as cocounsel for most of the plaintiffs, including the class action representative Friendly House.

The Friendly House complaint attacks the Arizona law on a variety of grounds. He argued the law violates the Supremacy clause; that it violates the Equal Protection clause by promoting racial profiling; that it violates the first amendment by chilling the speech of non-English speakers; that it violates the fourth amendment; and that it violates due process by inviting racial profiling and employing vague definitions of “public offense” and other statutory terms.

In the second case, United States v. Arizona, Mr. Watford served as cocounsel on an amicus brief filed by the National Immigration Law Center. This brief covers most of the arguments raised in the Friendly House complaint. But in addition, it asserts that Arizona “fails to account for the complexities and realities of Federal immigration law” because individuals lacking immigration registration documents are put at risk of “constant and repeated criminal prosecution.”

I do not believe an attorney should be held accountable for the legal positions he advocates on behalf of a client. Of course, there are some exceptions to that general rule; for instance, if the legal positions are far outside the mainstream of legal theory, are frivolous or indicate an unacceptable level of professional competence. However, in this case, Mr. Watford has not simply argued on behalf of a client, he adopted those legal theories as his own. On July 14, 2010, Mr. Watford gave a speech—analyzing the constitutionality of the Arizona law. His speech concentrated on “why S. 1070 is unconstitutional,” and he recapped many of the arguments he made in the Friendly House case.

Moreover, despite the fact that he discussed his views on immigration publicly, he nonetheless declined to answer many of my questions during his hearing before the Judiciary Committee. For instance, I asked about an article from Arizona statute prohibiting illegal aliens from soliciting work somehow violated the first amendment. The nominee responded that it would be inappropriate for him to comment on questions regarding law and policy. Whether the plaintiffs were entitled to constitutional protections other than those contained in the fifth, sixth and fourteenth amendments. Again, remember, he had already given a speech on this topic, so I was disappointed he did not share his views on these important topics.

With regard to the death penalty, Mr. Watford assisted in submitting an amicus brief to the Supreme Court in Baze v. Rees on behalf of a number of groups that opposed Kentucky’s three-drug lethal injection protocol.

In its plurality opinion, the Court rejected the arguments raised in the brief. Ultimately, Kentucky’s three-drug protocol was upheld on a 7-to-2 vote in the Supreme Court.

At the hearing we had for Mr. Watford, in following up questions, Mr. Watford gave the standard response that he would follow Supreme Court precedent regarding the death penalty. Yet it is very curious to me that he would go out of his way to provide his services to a case that would undermine the death penalty.

Furthermore, his concession that he would give consideration to foreign or international law in interpreting the meaning of the Cruel and Unusual Punishment clause makes me wonder how he would approach this issue. I have other concerns based on positions this nominee has taken in his legal advocacy, as well as some of his presentations.

I am generally willing to give the President’s nominees the benefit of the doubt when the nominee on the surface meets the requirements I have previously outlined. But I don’t think this nominee meets these requirements.

Furthermore, Republicans have to be accused of obstruction and delay when it comes to judicial nominations. This comes even as we have now confirmed 145 of this President’s district and circuit court nominees. That, of course, is during a period when we also confirmed two Justices to the Supreme Court. The last President who had two Supreme Court nominees had only 120
confirmations. So this argument of obstruction, of delay, and of unfairness doesn’t hold up.

I remind my colleagues on the other side of the aisle of the obstructionism, delay, and filibusters, which they perfected. The President nominate’s nominees to the ninth circuit provides some very important examples.

President Bush nominated nine individuals to the ninth circuit. Three of those nominations were filibustered. Two of those filibusters were successful. The nominations of Carolyn Kuhl and William Gerry Myers languished for years before being returned to the President. A fourth nominee, Randy Smith, waited over 14 months before finally being confirmed after his nomination was blocked and returned to the President. After being renominated, he was finally confirmed by a unanimous vote.

President Obama, on the other hand, has treated his nominees to the ninth circuit with a great deal of respect. Only one of those nominees was subject to a cloture vote. After that vote failed, the nominee withdrew. If confirmed, Mr. Watford will be the fourth nominee of President Obama to sit on the ninth circuit. Those four confirmations took an average of about 8 months from the date of nomination.

For all of President Obama’s circuit nominees, the average time for nomination to confirmation is about 242 days. For President Bush’s circuit nominees, the average wait for confirmation was 350 days. Given this history that I have spelled out, one might wonder then why President Bush and his nominees were treated differently and so much more unfairly than President Obama’s nominees.

Mr. Watford received his B.A. from the University of California, Berkeley in 1989 and his J.D. from the University of California, Los Angeles (UCLA) School of Law in 1992. Upon graduation, he clerked for Judge Alex Kozinski on the Ninth Circuit and then for Justice Ginsburg on the Supreme Court. In 1996, he began working as an associate in the Litigation Department at the Los Angeles law firm of Munger, Tolles & Olsen. From 1997-2000, Mr. Watford was an Assistant United States Attorney in the U.S. Attorney’s Office for the Central District of California. In Los Angeles, handling a variety of criminal litigation, such as immigration, narcotics, firearms trafficking, bank robbery, computer fraud, mail and wire fraud, and securities fraud.

In 2000, Mr. Watford returned to private practice as an associate in the appellate practice group at Sidney & Austin’s Los Angeles office. In 2001, he rejoined Munger, Tolles & Olsen as an associate, becoming a partner there in 2003. His practice focuses primarily on appellate litigation, specifically business and fraternal disputes. Mr. Watford has also taught a course on Judicial Opinion Writing at the University of Southern California’s Gould School of Law for three semesters (2007, 2008, and 2009).

The ABA Standing Committee on the Federal Judiciary unanimously rated him as Well Qualified for this position.

I yield the floor and suggest the adoption of the amendment.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

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

Mr. REID. Mr. President, I ask unanimous consent that the cloture vote on the motion to proceed to Calendar No. 400, S. 3187, the Food and Drug Administration Safety and Innovation Act, be vitiated; that at 2:15 tomorrow, Tuesday, May 22, the motion to proceed be agreed to, and that the Harkin-Enzi substitute amendment, which is at the desk, be agreed to, and the bill, as amended by the Harkin-Enzi substitute amendment, be considered original text for the purposes of further amendment, and that the majority leader be recognized at that time.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. REID. Mr. President, based on this, we will have a vote that should start in 5 minutes, which will be the only vote of the day.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

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

Mr. REID. Mr. President, I yield back all time and ask unanimous consent that the Harkin-Enzi substitute amendment, which is at the desk, be agreed to, and the bill, as amended by the Harkin-Enzi substitute amendment, be considered original text for the purposes of further amendment, and that the majority leader be recognized at that time.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. REID. Mr. President, based on this, we will have a vote that should start in 5 minutes, which will be the only vote of the day.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

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

Mr. REID. Mr. President, I yield back all time and ask unanimous consent that the vote start now.

The PRESIDING OFFICER. The bill clerk proceeded to call the roll.

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

The PRESIDING OFFICER. Is there a sufficient second?

There is a sufficient second.

The question is, will the Senate advise and consent to the nomination of Mr. P. Watford, of California, to be United States Circuit Judge for the Ninth Circuit.

The clerk will call the roll.

The bill clerk called the roll.

Mr. DURBIN. I announce that the Senator from Missouri (Mr. McCaskill) is necessarily absent.

Mr. KYL. The following Senators are necessarily absent: the Senator from South Carolina (Mr. DeMINT), the Senator from Nevada (Mr. Heller), the Senator from Illinois (Mr. Kirk), and the Senator from Louisiana (Mr. Vitter).

Further, if present and voting, the Senator from South Carolina (Mr. DeMINT) would have voted "nay."

The PRESIDING OFFICER. The nomination was confirmed.

The PRESIDING OFFICER. Under the previous order, the motions to reconsider are considered made and laid upon the table, and the President will be immediately notified of the Senate’s action.

LEGISLATIVE SESSION

The PRESIDING OFFICER. The Senate will resume legislative session.

The majority leader is recognized.

IRAN THREAT REDUCTION ACT OF 2011

Mr. REID. Madam President, I ask unanimous consent that the Foreign Relations Committee be discharged from further consideration of H.R. 1905, the Iran Threat Reduction Act, and that the Senate proceed to its consideration: that the Johnson of South Dakota-Shelby substitute amendment, which is at the desk and is the text of Calendar No. 320, S. 2101, the Iran Sanctions, Accountability, and Human Rights Act, as reported by the Banking Committee, be considered; that a Johnson of South Dakota-Shelby amendment, which is at the desk, be agreed to; that the substitute amendment, as amended, be agreed to; that the bill, as amended, be read a third time and the Senate proceed to a vote on passage of the bill, as amended.

The PRESIDING OFFICER. Is there objection to the consent request?
Mr. MCCAIN. Madam President, if I will not object, I would like to thank both leaders for their hard work in getting what I believe is one of the more important sense-of-the-Senate resolutions achieved here. It is very difficult. I think work must matter. The fact that this resolution points out that we need a comprehensive policy that includes economic sanctions, diplomacy in military planning, capabilities, and options; that this objective is consistent with the best judgments by experts in the State of the Union Address where he said, “Let there be no doubt: America is determined to prevent Iran from getting a nuclear weapon, and I will take no options off the table to achieve that goal”—I think this is an important resolution. I thank the majority leader. I also point out that the final part of it says that nothing in the act shall be construed as a declaration of war or an authorization of the use of force against Iran or Syria.

First of all, it is not an authorization. Second of all, I wonder if we ought to include Canada and maybe Brazil and other countries along with that. That decision comes in no way anything concerning Syria, but I guess we could probably throw it in. However, I will not ask for a unanimous consent to amend to add Canada, although the Canadians are very upset because they have no teams in the final NHHL Stanley Cup championship series.

Again, I thank both the Senate majority leader and the Republican leader for the work they did and also our friend Senator MENENDEZ, who was also an important factor in getting this done. I do not object.

The PRESIDING OFFICER. The Senator from South Carolina.

Mr. GRAHAM. Madam President, to the majority leader, well done. I think we are going to be able to voice vote a substitute amendment that states the policy of our country and our President very clearly.

To the Senator from New Jersey, Mr. MENENDEZ, great job on the sanctions. I hope the Senator understands why I wanted to put in all options. I hope the sanctions will work. This is a clear statement by the Senate backing up our President that when it comes to Iran and its nuclear capabilities, there will be more than sanctions on the table, and the Iranians need to know that.

I hope we can end this peacefully for Israel’s sake, for our sake, and for the world’s sake as we approach beefing up the sanctions with the Banking Committee, with Senator MENENDEZ’s and Senator KIRK’s leadership, and others, who have done a great job. If you are on the Banking Committee, you did a great job. I don’t even know who is on it.

The bottom line is I think the sanctions were really well drafted and will enhance the President’s hand, so to speak. We cannot leave this debate without making a very simple unequivocal statement that the goal is to get it right. And if sanctions can lead to getting it right, God bless. If the sanctions will not get us to where we want to go, everything is on the table, including the use of military force because this country—Republicans and Democrats—is not going to allow the Iranian regime to develop nuclear capability that will put the world into darkness.

To everybody who negotiated this outcome, thank you very much. I yield the floor.

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

The amendment (No. 2123) in the nature of a substitute was agreed to.

Mr. JOHNSON of South Dakota. Mr. President, to the majority leader, well done. I think we are going to be able to voice vote a substitute amendment that states the policy of our country and our President very clearly. To the Senator from New Jersey, Mr. MENENDEZ, great job on the sanctions. I hope the Senator understands why I wanted to put in all options. I hope the sanctions will work. This is a clear statement by the Senate backing up our President that when it comes to Iran and its nuclear capabilities, there will be more than sanctions on the table, and the Iranians need to know that.

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To everybody who negotiated this outcome, thank you very much. I yield the floor.

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

Mr. REID. Madam President, before we leave here this evening, I must mention the good work done by the Banking Committee, Senator JOHNSON of South Dakota, whose work has been stalwart in this issue. He and Senator SHELBY worked together. It has been very heart-warming.

I appreciate Senator MENENDEZ, who has been a loud voice in making sure we do something on this legislation about which he feels so strongly.

The most important thing for me is Iranians need to know we mean business, particularly with the next round of international negotiations taking place the day after tomorrow. I am glad we resolved our differences and everyone realizes how important it is to advance these measures to prevent Iran from obtaining a nuclear weapon. They should be aware that there is still more we can do. I am very happy with what we have done at this time.

The PRESIDING OFFICER. The Senator from South Dakota.

Mr. JOHNSON of South Dakota. Madam President. I rise to discuss today’s unanimous, bipartisan approval of the Senate Iran Sanctions, Accountability and Human Rights Act. With this action, we are adding additional tough, targeted sanctions against the Iranian Government, making it clear to the Iranian Government that they must stop their illicit pursuit of nuclear weapons or face increased pressure on their economy.

Madam President, I ask unanimous consent that a longer statement of mine on the bill plus a summary be included in the RECORD following my remarks.

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

Mr. JOHNSON. The bill the Senate adopted today passed the Banking Committee earlier this year by a unanimous bipartisan vote. Among its other provisions, this legislation will have important effects because it requires intensified targeting of Iran’s Revolutionary Guard Corps, sanctioning energy and uranium mining joint ventures with Iran, and mandating sanctions for those who supply Iran with technologies used to commit human abuses, including those used to impose an electronic curtain of censorship on Iran’s citizens. In addition, this legislation gives the President additional authority to sanction the Assad regime in Syria.

Today the Senate has shown that we can still act in a bipartisan way on important priorities. I thank every Member for supporting passage of this bill today. In particular, I thank all the work of the Banking Committee, Senator MENENDEZ, KIRK, SCHUMER, and BROWN. In addition, I thank Majority Leader REID for his determination to get this legislation through the Senate.

I look forward to working with my colleagues in the House to quickly come together on a final bill the President can sign soon. It is important that the Congress act swiftly so that we can continue to put pressure on the Iranian regime to end its illicit and illegal nuclear activity.

Again, I thank all my colleagues for their support on the Iran sanctions bill today.

EXHIBIT 1

TIGHTENING IRAN SANCTIONS

Mr. JOHNSON of South Dakota. Madam President, the prospect of a nuclear-armed Iran is the most pressing foreign policy challenge we face, and we must continue to do all we can to prevent Iran from obtaining a nuclear weapon. The administration is escalating the gravity of these issues, and the importance of an intensified, unified effort by the international community to further isolate Iran’s leaders and compel them to abandon their illicit nuclear activities. Iran’s willingness to sit down again with the P5 + 1 group—the five permanent members of the UN Security Council plus Germany—and begin to engage on the nuclear issues is a hopeful sign. But even after the first meeting, which both sides called “constructive,” it remains to be seen whether Iran will act in good faith and work towards progress on the central issues at the negotiating sessions planned for Baghdad
later this week, or whether these meetings will simply be another in a series of stalling actions to buy time to enrich additional uranium and further fortify their nuclear program.

As that process moves forward, today the full Senate is finally acting on an important bill to raise serious questions about our national security, to Israel and to our other allies in the Middle East and Europe. S. 2101, the Iran Sanctions Accountability and Halt Uranium Enrichment Act of 2012, was approved by a unanimous bipartisan vote in the Senate Banking Committee. I am pleased that, with the help of ranking member Senator Shelby and other Senate Banking Committee colleagues, we are presenting to the full Senate, as we did 2 years ago, this bipartisan bill to expand and tighten sanctions on Iran, along with a management summary that addresses several issues that required updating to take into account recent events, and clarifications or additions that my colleagues sought to expand the reach and effectiveness of the bill, including changes requested by Senator Menendez to an amendment he offered in committee, section 520, to narrow its application.

In pressing this bill forward we recognize that economic sanctions are not an end; they are a means of change. That end is to bring enough pressure to secure agreement from Iran’s leaders to fully, completely and verifiably abandon their illicit nuclear program. The President has made clear that his policy is not to contain Iran once it has a nuclear weapon: it is to prevent Iran from achieving that goal in the first place. He is deadset on that. At the same time, he is moving forward diplomatically, in consultation with our allies, to test Iran’s willingness to come clean on its nuclear program, and resolve the international community’s concerns on this front.

Let me describe where we have been on Iran sanctions, so that Senators may better understand where we’re going. This has been the subject of heated rhetoric on the Presidential campaign trail, so I want to describe clearly the longstanding bipartisan approach we in this Chamber have taken. Since 2002, when the Senate we sometimes cannot even agree to cross the street together, in today’s hyper-partisan environment bipartisan agreement on that that Iran sanctions have always worked in a bipartisan fashion; I hope that will continue.

In coordination with allies like the European Union, Japan, South Korea, Australia, Canada, and others, the Administration has taken its own steps to increase pressure on Iran’s petrochemical industry, oil and gas industry, and financial sector. We acted in the Senate 5 months ago on an amendment by Senators Menendez and Kirk to sanction the Central Bank and other entities that deal with Iranian banks involved in nefarious activities. Shortly thereafter, Europe announced it will ban oil imports from Iran, starting in July. This will further increase pressure on Iran’s economy and cut off other key sources of revenue for their nuclear program. Almost $50 billion in energy-related projects and other commercial projects have been canceled or postponed, and others will be.

Oil shipments have sharply declined due to sanctions. The Wall Street Journal recently reported that Iran’s crude oil exports were cut to its lowest level in over 20 years, due largely to the tightening squeeze of sanctions. And, in the last few months, about half of the tankers booked months ago to carry Iran’s crude oil elsewhere on its own account have not been able to find a buyer due to the sanctions. The minimal didn’t complete the voyages, according to brokers, company officials and shipping-tracking data. It is clear Iran is losing oil sales to key customers in Europe, Asia, and elsewhere, and is having some of its biggest customers demand steep discounts to buy its crude oil.

Iran’s oil revenues are approaching 40 percent of daily sales. Iran’s oil exports have the potential to fall another 300,000 to 500,000 barrels a day or more when Iran’s embargo takes effect in July, according to a report this week by Barclays. That is a huge impact. A senior IRGC official acknowledged the effectiveness of recent sanctions, saying: “The regime is at the height of isolation and in the midst of a technological, scientific and economic siege. We are not in a situation of imaginary threats and sanctions. Threats and sanctions against us are effectively being pursued.” These sanctions have had a powerful effect than many thought possible.

Iran is also isolated diplomatically. The international community is lined up against their nuclear program, with progressively tougher UN sanctions imposed on them. Their most important ally, Syria, is collapsing into civil war. They are, as President Obama said, “on the run.” Many believe the recent shift by Iran’s leaders on the nuclear issue is the result of that pain, and that the international community is holding the line. But while it is clear that existing sanctions are biting, they have not yet persuaded Iran’s leaders to drop their nuclear ambitions. We are in a critical time to lay the groundwork while there is still a chance to come clean on their nuclear program, suspend enrichment, and stop supporting terrorist activities around the globe. Or can they continue to face sustained multilateral economic and diplomatic pressure, and deepen their international isolation.

Just as then-Chairman Dodd and Ranking Member Shelby did in 2010, Senator Shelby and I have incorporated ideas from many of our Senate colleagues into one Committee report. The report was authored by Senator Menendez. Senator Menendez has been a leader on these issues, along with Senator Kirk, and I want to acknowledge their many contributions to this effort. The following are major refinements and ideas from legislation developed by Senators Lautenberg, Gillibrand, Schumer, Ky, Lieberman, Brown, and others. I will now touch on a few of the highlights of this bill and I will insert a more comprehensive and detailed summary into the record at the end of this session of Congress.

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The bill is all about. With these new sanctions, including those targeted at the IRGC, we are forcing Iran’s military and political leaders to make a choice: either end the suppression of their people, come clean on their nuclear program, suspend enrichment, and stop supporting terrorist activities around the globe, or they can continue to face sustained multilateral economic and diplomatic pressure, and deepen their international isolation.

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Sec. 201—Sanctions with respect to Energy Joint Ventures with Iran

Extends ISA sanctions to persons knowingly participating in petroleum resources development joint ventures established on or after January 1, 2002 anywhere in the world, unless such ventures are terminated within 180 days of enactment, in which Iran's government is a substantial partner or investor, or that could otherwise receive energy sector technology or know-how not previously available to its government.

Sec. 202—Expands Sanctions on Providers of Financial Services to Iran's Energy Sector

Requires imposition of ISA sanctions on persons who knowingly sell, lease, or provide to Iran goods, services, technology or support (including refinery construction or repair), that are predominant or essential for the transportation of refined petroleum products, that could directly and significantly contribute to its petroleum resources development, or otherwise support its programs in single transactions of $1 million or more or multiple transactions aggregating to $5 million or more in any 12-month period. Requires imposition of three ISA sanctions on persons who knowingly sell, lease, or provide to Iran goods, services, technology or support for its petrochemical sector in a single transaction of $5 million or more or multiple transactions aggregating to $10,000,000 or more in any 12-month period. In so doing, codifies the President's decision to extend US sanctions to petrochemicals.

Sec. 203—Sanctions with respect to Uranium Joint Ventures with Iran

Requires ISA sanctions to be imposed on persons who knowingly participate in joint ventures with Iran's government, Iranian firms, or persons acting for or on behalf of Iran's government in the mining, production or transportation of uranium anywhere in the world. Exempts such persons from sanctions if they or residing in the United States to submit a list, within 60 days of the date of enactment, of entities that provide financial communications services providers such as SWIFT apps are national security institutions to prevent the imposition of sanctions pursuant to IEEPA. Requires financial institutions to cease and desist from the provision of services to the Central Bank of Iran or financial institutions described in 104(c)(2)(ii)CISADA (i.e., institutions whose property is blocked in connection with Iran's WMD or its support for terrorism). Requires reporting by the Secretary of the Treasury within 90 days of enactment on the efforts of SWIFT to terminate its connection with the Central Bank of Iran and Iran's financial institutions designated for the imposition of sanctions. Sanctions also apply to entities providing shipping and insurance services to Iran, Iranian energy joint ventures worldwide, suppliers of Iran's petrochemical sector, and Iceland's nuclear program.

Sec. 204—Expansion of Sanctions Available for Violations of the Arms Export Control Act of 1976

Expands the current menu of sanctions, available to the President under the ISA, to authorize exclusion from the United States to submit a list, within 60 days of the date of enactment, of entities that provide financial communications services providers such as SWIFT apps are national security institutions to prevent the imposition of sanctions pursuant to IEEPA. Requires financial institutions to cease and desist from the provision of services to the Central Bank of Iran or financial institutions described in 104(c)(2)(ii)CISADA (i.e., institutions whose property is blocked in connection with Iran's WMD or its support for terrorism). Requires reporting by the Secretary of the Treasury within 90 days of enactment on the efforts of SWIFT to terminate its connection with the Central Bank of Iran and Iran's financial institutions designated for the imposition of sanctions. Sanctions also apply to entities providing shipping and insurance services to Iran, Iranian energy joint ventures worldwide, suppliers of Iran's petrochemical sector, and Iceland's nuclear program.

Sec. 205—Definitions

Defines “credible information” and “petrochemical product.” “Credible information” includes public announcements by persons that they are engaged in certain activities, including those made in a report to stockholders, and may include announcements made by the Government of Iran, and reports from the General Accountability Office (GAO), the Energy Information Administration, the Congressional Research Service, or other reputable governmental organizations. Defines “petrochemical product” consistent with Executive Order 13590.

Sec. 211—Sanctions for Shipping WMD or Terrorism-related Materials to or from Iran

Requires the blocking of assets of, and imposes other sanctions on, persons who knowingly provide ships, insurance or reinsurance to vessels providing transportation of goods that materially contribute to Iran's WMD program or its terrorism-related activities. The sanctions apply to parents of the persons involved if they knew or should have known of the sanctionable activity and to any of their subsidiaries that knowingly participated in the activity. Provides for Presidential national security interest waiver; requires a report to Congress regarding the use such waiver.

Sec. 212—Imposition of Sanctions on Subsidiaries and Agents of UN-sanctioned Persons

Amends CISADA to ensure that US financial sanctions imposed on UN-designated entities that are multinational in nature, including those made in a report to Congress, are imposed if they withdraw from such joint ventures after the date of enactment, of entities that provide financial communications services providers such as SWIFT apps are national security institutions to prevent the imposition of sanctions pursuant to IEEPA. Requires financial institutions to cease and desist from the provision of services to the Central Bank of Iran or financial institutions described in 104(c)(2)(ii)CISADA (i.e., institutions whose property is blocked in connection with Iran's WMD or its support for terrorism). Requires reporting by the Secretary of the Treasury within 90 days of enactment on the efforts of SWIFT to terminate its connection with the Central Bank of Iran and Iran's financial institutions designated for the imposition of sanctions. Sanctions also apply to entities providing shipping and insurance services to Iran, Iranian energy joint ventures worldwide, suppliers of Iran's petrochemical sector, and Iceland's nuclear program.

Sec. 213—Liability of US Companies for Violations by their Foreign Subsidiaries

Requires the imposition of civil penalties under the International Emergency Economic Powers Act (IEEPA) of up to twice the amount of the relevant transaction on US parent companies for the activities of their foreign subsidiaries which, if undertaken by a US person or in the United States, would violate US sanctions law. Subsidiaries are defined as those entities in which a US person has an interest or a majority of the seats on the board, or that a US person otherwise controls. Covers activities under the current US trade embargo. Applies regardless of whether the subsidiary was established to circumvent US sanctions.

Sec. 214—Securities and Exchange Commission Disclosures on Certain Activities in Iran

Amends the Securities and Exchange Act of 1934 to require issuers whose stock is tradable on US exchanges to disclose whether they or their affiliates have knowingly engaged in activities (i) in section 5 of the ISA (energy sector activity); (ii) in 104(c)(2) or (d)(1) of CISADA (related to foreign financial institutions who facilitate WMD/terrorism, money laundering, IRGC activity, and other violations) or (iii) in section 104(c)(1) (related to those who transfer weapons and other technologies to Iran likely to be used for human rights abuses); (iv) with persons whose designations are for WMD terrorism and; (v) persons in the governments of Iran. Provides for periodic public disclosure of such information, and conveyance of that information to the SEC to Congress and the President. Requires the President to initiate an investigation into the possible imposition of sanctions as specified, and to make a sanctions determination within 6 months.

Sec. 215—Immigration Restrictions on Senior Iranian Officials and their Family Members

Requires the identification of and denial of visa requests to senior officials, including the Supreme Leader, the President, members of the Assembly of Experts, senior members of the Intelligence Ministry of Iran, and members of the IRGC with the rank of brigadier general or higher that are involved in nuclear proliferation, support international terrorism or the commission of serious human rights abuses against citizens of Iran. Requires the President to report to Congress regarding the use such waiver.

Sec. 216—Sanctions with respect to the Provision of Certain Financial Communications Services to the Central Bank of Iran and Sanctioned Institutions

States the sense of Congress that the President should intensify current diplomatic efforts to ensure that global financial communications services providers such as SWIFT apps are national security institutions to prevent the imposition of sanctions pursuant to IEEPA. Requires financial institutions to cease and desist from the provision of services to the Central Bank of Iran or financial institutions described in 104(c)(2)(ii)CISADA (i.e., institutions whose property is blocked in connection with Iran's WMD or its support for terrorism). Requires reporting by the Secretary of the Treasury within 90 days of enactment on the efforts of SWIFT to terminate its connection with the Central Bank of Iran and Iran's financial institutions designated for the imposition of sanctions. Sanctions also apply to entities providing shipping and insurance services to Iran, Iranian energy joint ventures worldwide, suppliers of Iran's petrochemical sector, and Iceland's nuclear program.

Sec. 217—GAO Reports on Iran's Energy Sector

Mandates regular reports from GAO on financial transactions involving Iran, entities providing shipping and insurance services to Iran, Iranian energy joint ventures worldwide, suppliers of Iran's petrochemical sector, and Iceland's nuclear program.

Sec. 218—Expanded Reporting on Iran's Crude Oil and Refined Petroleum Products Sector

Amends section 110(b) of CISADA to require additional reporting on the volume of crude oil and refined petroleum products imported to and exported from Iran, the percentage of selling and transporting crude oil and refined petroleum products to countries with primary jurisdiction over those persons and the countries in which those products were refined, the sources of financing for such imports and the involvement of foreign persons in efforts to assist Iran in developing its oil and gas production capacity, import technology and facilities, and the capacity for conversion of existing Iranian refineries, converting existing chemical plants to petroleum refineries and maintaining, upgrading or expanding refineries or conversion new capacity.

Sec. 301—Sanctions on Iran Revolutionary Guard Corps Officials, Agents, and Affiliates

Requires the President to identify, and designate for sanctions those who are Iranian officials or agents of the IRGC within 90 days of enactment, and periodically thereafter; designation requires exclusion of such persons from the United States, and imposition of sanctions (related to WMD under IEEPA, including freezing their assets and otherwise isolating them financially). Also, outlines priorities for investigating certain foreign persons and transactions in assessing connections to the IRGC. Requires the President to report on designations and waivers.

Sec. 302—Sanctions on Foreign Persons Supporting IRGC

Subjects foreign persons to ISA sanctions if those persons knowingly provide material assistance to, or engage in any significant transactions with—of officials of the IRGC, its agents or affiliates. Requires imposition of similar sanctions against those persons who engage in significant transactions with IRGC-sanctioned persons, those acting for or on their behalf, or those owned or controlled by them. Provides for additional sanctions under IEEPA for those determined by the President to be engaged in significant transactions with IRGC-sanctioned persons.
Sec. 301—Rule of Construction
Clarifies that section 301 and 302 sanctions do not limit in any way the President’s authority to designate persons for sanction under IEEPA.

Sec. 311—Extension of US Procurement Ban to Foreign Persons who interact with IRGC
Requires certification by prospective US government contractors (for contract solicitations issued beginning 90 days from the date of enactment) that neither they nor their subsidiaries have engaged in significant economic transactions with designated IRGC officials, agents or affiliates.

Sec. 312—Sanctions Determinations on NIOC and NITC
Amends CISADA to require the Secretary of the Treasury to determine and notify Congress whether the National Iranian Oil Company and the National Iranian Tanker Company are agents or affiliates of the IRGC. If found to be IRGC entities, sanctions apply to transactions or relevant financial services for the purchase of petroleum or petroleum products from the NIOC or NITC only if the President determines that there exists a sufficient supply of petroleum from countries other than Iran to permit purchasers to significantly reduce their purchases from Iran. Provides for an exception to financial institutions of a country that has significantly reduced its purchases of Iranian petroleum or petroleum products within specified periods which track those provided for in section 1245 of the FY 2012 National Defense Authorization Act.

Sec. 401—Sanctions on Those Transferring to Iran Technologies for Human Rights Abuses
Imposes sanctions provided for in CISADA, including a visa ban and property blocking/asset freeze, on persons and firms which supply, sell, import or transfer to Iran, including weapons, rubber bullets, tear gas and other riot control equipment, and jamming, monitoring and surveillance equipment—which the President determines is likely to be used by Iranian officials to commit human rights abuses. Requires the President to maintain and update lists of such persons and firms, submit updated lists to Congress, and make the unclassified portion of those lists public. Requires the President to report on designations for sanctions and to prohibit certain economic transactions with designated persons and firms.

Sec. 402—Sanctions on Those Engaging in Censorship and Repression in Iran
Imposes sanctions as in section 401 against individuals and firms found to have engaged in censorship or curtailment of the rights of freedom of expression or assembly of Iran’s citizens.

Sec. 411—Expedited Processing of Human Rights Prisoners
 Declares that the United States should expand efforts to identify, assist, and protect prisoners of conscience in Iran to work to abolish Iranian human rights violations. Directs the Secretary of State to publicly call for the release of political prisoners, as appropriate.

Sec. 403 Interests in Financial Assets of Iran
Deems blocked assets of Iran severed from the US, and property interests of Iran in the United States, to include property held in book entry and related indirect forms, property held by securities clearing agencies and other intermediaries, and inchoate interests in funds transfers in the payment process through intermediary banks, regardless of federal or state law that might otherwise apply, if that property is an interest held for the benefit of Iran or if any intermediary holds the interest for the benefit of Iran and the status of the property is relevant to any attachment or proceedings in aid of execution, whenever issued, on judgments against Iran for damages for personal injury or death caused by torture, extrajudicial killing, aircraft sabotage, or hostage taking, or material support for such an act. Defines various terms used for purposes of the provisions of the act. Authorizes the Secretary of the Treasury, in any case in which a portion of blocked assets, “clearing corporation,” “financial asset,” “security,” and “securities Intermediary.”

Sec. 404—Report on Membership of Iran in International Organizations
Requires the Secretary of State to submit a report to Congress listing the international organizations of which Iran is a member and detailing the amount the US contributes to each such organization annually.

Sec. 405—Technical implementation; penalties
Provides the President with the necessary procedural tools to administer the provisions of this new law, drawing on relevant provisions of the IEEPA. Clarifies that the Administration can require recordkeeping of certain persons, and has subpoena and enforcement authority for certain specified provisions of the bill.

Sec. 406—Applicability to Authorized Intelligence Activities
Provides a general exemption for authorized intelligence activities of the U.S.

Sec. 403—Termination
Provides for termination of the Syria provisions if the President certifies that the Government of Syria is democratically elected, representative of the people of Syria, or a legitimate transitional government of Syria is in place. Certification required must stipulate that the government of Syria has refrained people accused of crimes under IEEPA on such persons. Requires periodic updating of the list, and public access via the websites of the Departments of State and Treasury.

Sec. 5—Waiver
Provides for presidential national security interest waiver for Syria provisions; requires a report to Congress on the reasons for the waiver.

Sec. 6—Termination
Provides for termination of the Syrian sanctions if the President certifies that the government of Syria has ceased development of chemical, biological, or nuclear weapons, and agreed to allow the UN and international observers to verify such claims. Provides for suspension of sanctions for 1 year if a transitional government in place, to provide time to develop the more detailed certification above.

I yield the floor.

The PRESIDING OFFICER. The Senator from New Jersey, Mr. MENENDEZ, Madam President, first let me thank the majority leader for his doggedness in making sure we could come to an agreement that sends a clear message to Iran before the P5+1 talks take place this week. His commitment made the difference.

I would also like to thank the chairman of the Banking Committee, Senator JOHNSON of South Dakota, who, in
an agenda that is incredibly full with all of the challenges the Banking Committee is taking up, made sure the whole effort on Iran sanctions had a priority in the committee and worked to get the strong, bipartisan, unanimous vote that came out of the committee that gives us the foundation to move forward today. So I thank both of them.

Today the Senate sends a clear message to Iran. The purpose for these P5+1 talks in Baghdad, and basically that message is: provide a real and verifiable plan for completely dismantling your nuclear weapons program or Washington will further tighten the economic noose. The Obama administration is moving forward with full implementation of the Menendez-Kirk Central Bank sanctions, and the U.S. Congress is ready with additional measures, such as sanctions on the National Iranian Oil Company and the National Iranian Energy Joint Ventures, that will further isolate the regime.

I think Iran’s Supreme Leader has a choice: Either come to Baghdad with a real plan to terminate Iran’s nuclear program, or we will make our own plan through sanctions and other necessary measures to ensure that Iran fails to achieve its nuclear ambitions.

And lest anyone think this is necessary, President Obama will make our plan through sanctions and other necessary measures to ensure that Iran fails to achieve its nuclear ambitions.

In case anyone has doubts as to the need for this legislation, the record is pretty clear. In recent weeks the International Atomic Energy Administration has been subject to Iranian delays and deception over access to the Parchin facility—a facility they claim has no connection to their nuclear program but which scientists believe contain a blast chamber used to test explosives that can trigger a nuclear blast.

Combine that information with Iran’s continued enrichment of uranium to 20 percent, development of new enrichment facilities, conducting of high explosives testing and detonator development to set off a nuclear charge, computer modeling of a core of a nuclear warhead, and the August 2011 IAEA report that revealed key components used to arm nuclear warheads was unaccounted for in Iran, and that Iran is working on an indigenously designed nuclear payload small enough to fit on Iran’s long-range Shahab-3 missile, a missile capable of reaching Israel, capable of reaching some of our allies in Europe which we are committed to NATO to defend, there is a pretty clear picture of why this is in the national interest and security of the United States and what is going on in Iran.

The bill is intended to give Iran a pretty clear picture in return of what America’s response to their posture would be. This includes sanctions on the national Iranian oil and tanker companies to terminate a work-around to the Central Bank sanctions; sanctions on satellite companies that provide services to Iran’s military; sanctions on Iran’s regime but fail to prevent jamming by Iran of transmissions by other users of the same satellite service company; sanctions on financial messaging service companies that provide services to Iran’s financial institutions; imposition of liability on parent companies for actions of foreign subsidiaries; and sanctions on energy joint ventures with Iran related to the development of petroleum resources. Those are just some.

This is perfect legislation to CISADA and I am so thrilled we are seeing it today.

Finally, I wish to also comment on one part of the bill to ensure there is no ambiguity about its intent. Section 503, as revised in the managers’ amendment, preempts any conflicting Federal or State law, but only as they pertain to the eligibility of Iranian leadership, Iranian leaders, and the government of Iran. Nothing in this legislation alters any other applicable law.

As one who authored these provisions, I wanted to be sure that there was understanding on the record that Iran, in addition to stopping its nuclear weapons program, which is in the national interest and security of the United States, should be able to avoid having its assets attached and seized and executed upon as they killed Americans and having been part of killing Americans abroad.

With that, I yield the floor.

The PRESIDING OFFICER. The Senator from New York.

ORDER OF PROCEDURE

Mr. SCHUMER. Madam President, I ask unanimous consent to speak for 2 minutes; immediately thereafter, the Senator from Ohio, Senator Brown, be permitted to speak for 5 minutes; and then the Senator from Kansas, Senator Moran, be permitted to speak for 5 minutes.

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

Mr. SCHUMER. I will be brief. First, I wish to thank our chairman, Senator Johnson of South Dakota, for being so steadfast in bringing this bill to the floor. I wish to thank our friend and colleague Senator Shelby, whom I thank as well. Senator Menendez has been a true leader on these issues and has been the lead sponsor of many of the pieces of legislation to tighten the economic sanctions to Iran to make sure Iran has no connection to their interests not to have nuclear weapons. That is the best thing for all of us, but, again, taking nothing off the table.

We have had a lot of divisions between Democrats and Republicans, but on the issue of making sure that Iran does not have a nuclear weapon, we are united. The threat, the specter of an Iranian nuclear weapon, will continue to be the central threat to our alliance and all of our interests. The Obama administration recognizes that, because we are going to continue to tighten and tighten and tighten restrictions so that Iran realizes that not just the United States but the entire world is against them.

The Iranians can’t talk about why shouldn’t it have it when everyone else does. With the kind of saber rattling and verbiage that comes out of that regime about what they might do to Israel or other countries, it shows they are not a mature enough nation to be possessing this God-awful power.

The point I wish to make here tonight is this is another step forward. We are further tightening the sanctions. We will continue to tighten them so that the answer for Iran, if they persist with moving forward on producing a nuclear weapon, is economic chaos for Iran and the rest of the world. Fortunately, for many of the Iranian people.

Let Iran beware. This is just another step. We will not stop. We are united as two parties, we are united as a Nation, and we are united as a family of nations to make sure we do everything we can to prevent Iran from becoming a nuclear power. That would represent a disaster to the nations of the world, and one we cannot tolerate. I yield the floor.

The PRESIDING OFFICER. The Senator from Ohio.

Mr. BROWN of Ohio. Madam President, I wish to reiterate and underscore the words of my colleague, the senior Senator from New York, step by step how important the tightening of the Iran sanctions are to Israel, to the United States of America, and to the stability of the world.

Allowing nuclear weapons in the hands of a country as unstable as Iran and which is hostile to so many of our values and which is hostile to most people in the world—not just the United States, not just Israel, not just the democratic world—how problematic this is for the entire world. That is why I am pleased with the work Chairman Johnson did, along with Ranking Member Shelby, Senator Menendez, Senator Graham, and others, so that this continues to send an important message to Iran that we will continue to increasingly tighten sanctions threatening to Iran and the stability of its economy, and helping Iran to understand that this will create difficulties for that regime in having any support left in the world. With the economic consequences that could happen as we tighten sanctions.

As Senator McCain said, we will take nothing off the table. We want a diplomatic solution with these sanctions. We want to make sure Iran realizes that their interests not to have nuclear weapons. That is the best thing for all of us, but, again, taking nothing off the table.
LEAD SMELTER SITES IN OHIO

Mr. BROWN of Ohio. Madam President, I rise to bring attention to a problem plaguing many aging communities in Ohio and throughout the industrial Midwest. We in this country have a rich manufacturing heritage, none richer than Ohio. We are the third leading manufacturing state in our country, trailing only in production, and trailing only States two and three times our size—Texas and California. We have built an infrastructure in this country that defined the landscape of the modern world.

At Ohio plants in places such as Middletown and Youngstown, Ohioans made steel beams that built America’s skyscrapers, railroads, and bridges. And at lead smelter sites from Cleveland to Cincinnati, OH, workers processed metal to shore up the economic foundation of 20th century America. But as revealed in a disturbing series of recent reports in USA TODAY, former lead smelter plants have left behind a terrible legacy: elevated lead levels in the soil and in the air and surrounding playgrounds and schools, especially in poorer areas of our cities. Many of these potentially contaminated places are in underresourced, aging areas where homes are not necessarily in good shape and where neighborhoods are plagued with many other problems as well.

Yesterday I met with Angelina and Ken Sheflon in Cleveland at a property that they believe is the site of an old lead smelter. What is even more troubling is that they didn’t even know this existed. They are parents of five. One of their sons was recently diagnosed with elevated blood lead levels. They fear for the other four children also. Parents such as them and thousands of Ohioans living in communities with aging and abandoned industrial sites are worried about the health and safety of their families.

A national newspaper report found that lead levels in soil near this smelter plant in Cleveland exceed 3,400 parts per million. The average lead level in U.S. soils is only 19 parts per million.

As a father and grandfather, I am particularly disturbed by these reports. We know that lead is not broken down when it lingers in the ground. It can enter our groundwater and children can absorb it on the baseball diamond or while making mud pies in the yard.

Real action from State and Federal Governments and local communities is needed to take action to clean up residual contamination.

Last week the CDC lowered by half the recommended allowable limit for lead exposure to young children, so we must ramp up our efforts to address the problem lingering in our soil. We need to prioritize testing our communities. Too many young lives are depending on our actions. Too many children in too many urban school districts suffer from behavior problems, suffer from intelligence problems, if you will, because they have had far too high lead levels in their blood which retard growth, restrict learning, and cause behavioral problems. It is a serious public health problem. It is the paint on the walls in these old homes, and it is the lead in the paint on the walls. It is the lead in the soil of the homes and neighborhoods and playgrounds. It does call for real action from State and Federal Governments and local communities.

I yield the floor.

The PRESIDING OFFICER. The Senator from Kansas.

HONORING THE LIFE OF BOB BETHELL

Mr. MORAN. Madam President, I woke up this morning in Kansas with some sad news. One of our State legislators, Bob Bethell, a 13-year member of the Kansas House of Representatives, died in a car wreck late last night. The Kansas legislature has had a difficult session and finally concluded, I believe after 100 days of the legislative session, this year’s work in Topeka, and one of our central Kansas legislators on the drive home from Topeka back to Alden, KS, was involved in a one-car accident, a fatality.

I rise tonight to pay respect to my friend and former colleague Bob Bethell, and express my respect and gratitude for his public service, and my care and concern. I do so in memory of, for his wife Lorene and his family and friends.

Bob Bethell was, I suppose you could call him, a great politician in the sense that his constituents loved and admired him. They respected him. They cared about him. He could be called a great politician because in Topeka he was someone whose voice was listened to. But nothing about Bob Bethell was a politician.

Bob Bethell was a person who was a Baptist minister in his small hometown. He loved God greatly. God was the focus of his life. He loved the people God created in his community and across Kansas. In fact, Bob became the administrator of a nursing home because of his care for senior citizens. It was that extension of his care for seniors that caused him to want to serve in the legislature. Bob wanted to extend that opportunity to make a difference in the lives of the people he cared for in his profession with public policy decisions that were important to them and their future and their families in Topeka, KS.

Again, I would say there is nothing political about Bob Bethell. He was respected and someone everybody enjoyed being around, but it wasn’t because he as a politician calculated what the right answer was or how to get along with people or one who took a poll to discover what the issues were that people supported; it was just that Bob Bethell, in his love of God, had a love of human beings, of citizens of Kansas. So we would see Bob Bethell with a smile on his face at every parade, at every community meeting.

I think sometimes in our lives, when we see an elected official, we may see someone walk across the street sometimes to avoid the political conversation. But, again, there was nothing political about Bob; he was somebody who cared about people and it showed. He enjoyed being around people; loved the conversation. He worked hard at being a constituent-service-oriented member in the Kansas House of Representatives. It is so sad for us to lose such a person.

I hope Lorene and her family and friends in Alden find comfort in the belief that God will care for Bob Bethell in the life hereafter. They believe that in their lives. They demonstrated that to the people across Kansas, and their focus was a love of others. Bob is a role model for all of us to make certain we focus on the things that matter—not the public opinion polls and not the calculation of how to get along with people, but the idea that we in public service are given an opportunity to make a great difference in the lives of others, and it ought to be that motivating factor, the one that Bob Bethell exhibited throughout his life, that we should exemplify.

So Robba and I—my wife and I—extend our greatest sympathies and care and concern to the people across Kansas, but especially to the family and the folks who knew Bob so well in his home district, the community of Rep. Bethell's Legislative District in Kansas. Our prayers and thoughts are extended to them, and we praise God for the life well lived of one of His servants, Bob Bethell.

I yield the floor.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. BROWN of Ohio. Madam President, I ask unanimous consent that the order for the quorum call be rescinded. The PRESIDING OFFICER. Without objection, it is so ordered.

MORNINg BUSINESS

Mr. BROWN of Ohio. Madam President, I ask unanimous consent that the Senate proceed to a period of morning business, with Senators permitted to speak therein for up to 10 minutes each.

The PRESIDING OFFICER. Without objection, it is so ordered.
RECOGNIZING THE LAS VEGAS METROPOLITAN POLICE DEPARTMENT

Mr. REID. Madam President, I rise today to recognize the Las Vegas Metropolitan Police Department’s Hispanic American Resource Team’s (H.A.R.T.) 10th Academy for their efforts to combat crimes against Hispanic-Americans, while building good will and trust between the city’s police department and the Hispanic community.

For more than a decade, H.A.R.T. has fulfilled and exceeded its mission, “to build positive community partnerships between the Hispanic community and the police through compassion and innovative thinking.” At its core, the H.A.R.T. program trains and places talented officers who are fluent in English and Spanish to work directly with Spanish-dominant community members. It is through language ability, cultural competence, and dedication that H.A.R.T. maintains public safety for the broader community regardless of language capability or immigration status.

A centerpiece of the educational services H.A.R.T. provides is the Hispanic Citizens Academy which offers an intensive 12-week training program in Spanish to non-English speaking community members to impart knowledge on how to navigate through routine law enforcement protocols, including knowing their legal rights and how to contact the police in case of an emergency. The Hispanic Citizens Academy helps strengthen the partnership between the Hispanic immigrant community and the Las Vegas Metropolitan Police Department. In fact, the National League of Cities recognized Las Vegas and the H.A.R.T. program as one of the top 17 U.S. police departments for good practices in a June 2011 report.


H.A.R.T. provides training and dedication law enforcement officers have demonstrated to the growing Hispanic population of my home State of Nevada. I ask my colleagues to please join me in congratulating the Las Vegas Metropolitan Police Department and its H.A.R.T initiative as they celebrate the 10th Hispanic Citizens Academy. I wish H.A.R.T. continued success in their future endeavors.

TRIBUTE TO JAMES CECIL

Mr. MCCONNELL. Madam President, today I wish to honor Mr. James Cecil, who is believed to be the last living member of the 729th Platoon of the 2nd Marine Division, known as the Lexington Platoon. Mr. Cecil and 69 other men from the central Kentucky area formed the Platoon in 1942, 8 months after the Japanese bombing of Pearl Harbor. These young men went on to fight in some of the costliest battles of the Pacific, including in Okinawa, Saipan, Tinian, and Guadalcanal.

The Lexington Platoon was honored on Thursday, May 17 at the Lexington Urban City Council meeting, with Mr. Cecil being present. Lexington Mayor Jim Gray proclaimed it James Cecil Day, and Councilman Jay McChord spoke about his interviews with Mr. Cecil while writing his 2010 book, A Veteran’s Legacy: Field Kit Journal.

James Cecil grew up on a tobacco farm, and chose to join the Marines when the United States entered the war rather than being drafted. He was part of a private ‘corporate’ fund raising effort and obtained his map of artillery positions, and received a Purple Heart for injuries suffered during the battle of Saipan in June 1944.

Although Mr. Cecil was recommended for officer candidate school in August 1945, he never got the chance to attend, as in the weeks following, the United States bombed Japan, thus ending World War II.

After his service, Mr. Cecil moved to Ohio and became the owner of a successful trucking company. He moved back to Lexington after the death of his wife, Janet, in 1988. Today, Mr. Cecil is in good health and still often reflects on his wartime experiences. He says that he feels “honored and proud that [he] served [his] country.”

I would like to ask at this time for my colleagues in the U.S. Senate to join me in recognizing Mr. James Cecil for his brave service to our Nation during World War II. There was recently an article published in the Lexington Herald-Leader highlighting Mr. Cecil’s valorous service and his platoon’s legacy. I ask unanimous consent that said article be printed in the RECORD.

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

Sole Surviving Marines’ Lexington Platoon Member To Be Honored
(By Tom Ehlen)

Eight months after the Japanese bombed Pearl Harbor, people gathered around the steps of the Fayette County Courthouse to honor James T. Cecil and 69 other local boys.

The recent graduates of Henry Clay, Lafayette and other central Kentucky high schools were forming the Lexington Platoon of the United States Marine Corps. Mayor T. Ward Havesly and other dignitaries spoke at the mass-induction ceremony. A young lady sang the Marine Hymn, and women and children wept, the Lexington Herald and Leader reported in late August 1942.

Platoon members left in buses that day for processing in Louisville and training in San Diego. From there, they joined some of the bloodiest battles of the Pacific Theater: Okinawa, Saipan, Tinian and Guadalcanal.

The Lexington Platoon will be honored again Thursday at the Urban County Council meeting. This time, Cecil, 88, will be the only platoon member present. “As best we can tell, I’m the only one left,” the former officer said.

Mayor Jim Gray will present a proclamation declaring James Cecil Day. Councilman Jay McChord will speak about how he met Cecil and Mitchell Alcorn while writing and illustrating his 2010 book, A Veteran’s Legacy: Field Kit Journal.

When the war came, he decided to join the Marines rather than wait to be drafted. After training, platoon members were scattered to various units of the 2nd Marine Division, although Cecil served alongside Alcorn and a few others from Lexington. “We were just like a big family,” he said.

As I talked with Cecil last week, he pulled out a small envelope. Inside was a portrait of a Japanese officer he killed, and money and a ration card he found in the officer’s pocket. That wasn’t all: The officer was carrying a map of artillery positions, a find that got Cecil promoted from private to corporal.

Cecil earned a Purple Heart for wounds suffered in the battle of Saipan on June 20, 1944. He survived several Japanese suicide attacks on his camps at night.

“The next morning you couldn’t walk without walking on a dead Marine or a dead Japanese,” he said.

At the battle of Okinawa, a Japanese suicide pilot hit the USS Hinsdale before Cecil’s unit could land on the beach. Cecil spent 45 minutes in the cold, searching for sharks, before a Navy destroyer rescued him.

“We had so many killed and wounded,” Cecil said. “Every battle, you just didn’t know who was going to be the last.”

Cecil’s only trip stateside came in August 1945, when he was recommended for officer candidate school. Before he could begin, though, U.S. forces dropped atomic bombs on Japan, and World War II ended.

After the war, Cecil had a successful career as the owner of an Ohio-based trucking company. He moved back to Lexington after Janet, his wife of 52 years, died in 1998. In his apartment, he proudly displays photos of his sons and grandchildren.

Cecil’s health is good, his mind sharp. He finds himself thinking a lot these days about his wartime experiences, including the occasional nightmare with Japanese soldiers “getting after me.”

“I just felt honored and proud that I served my country,” Cecil said. “Coming off a tobacco plantation, while into battle, that was a hell of a change. We were just a bunch of brave boys.”

ISHRA

Mr. JOHNSON of South Dakota. Madam President, earlier today the
Senate passed by Unanimous Consent S. 2101, the Iran Sanctions, Accountability, and Human Rights Acts of 2012 (ISHRA). The bill significantly increases pressure on Iran’s leaders and I thank my colleagues for their support of this important measure. As we begin negotiations with our counterparts in the House, I want to expand on my comments from my earlier statement. I do so in order to provide my colleagues some clarification regarding a few points in the bill.

First, section 201 of the Iran Sanctions, Accountability, and Human Rights Acts of 2012 will impose sanctions, for the first time, against entities involved in joint ventures to develop petroleum resources outside of Iran that are established on or after January 1, 2002. Those joint ventures which qualify are joint ventures which involve the Government of Iran as a substantial partner or investor, or through which Iran could receive technological knowledge or equipment not previously available to it that could contribute to its ability to develop domestic petroleum resources. Further, even if ancillary agreements to implement an existing pre-2002 joint venture are agreed to on or after January 1, 2002, sanctions are not authorized to be imposed against any third-party to that joint venture or against persons who provide goods, services, technology or information to such a joint venture, as a result of their participation in or dealings with such venture, by virtue of such ancillary agreements.

In addition, this legislation seeks to continue the long-standing tradition of ensuring that humanitarian trade, including agricultural commodities, food, medicine and medical products, is specifically exempted by Congress from sanctions that condition a trade be licensed by the Department of the Treasury’s Office of Foreign Assets Control, or OFAC. It is becoming more apparent that U.S. financial sanctions targeting Iran’s banking sector are causing increased concern among businesses and banks of our allies. The fear is that engaging in humanitarian trade in the current sanctions environment might lead to sanctions for legitimately licensed humanitarian trade.

However, it has not and has not been the intent of U.S. policy to harm the Iranian people by prohibiting humanitarian trade that is licensed by the U.S. Treasury Department. OFAC consists of many licenses, both general and specific, for this type of trade. The practical financing difficulties arising today between banks and those engaging in licensed humanitarian trade can and should be addressed by U.S. Government officials, who should do more to make it clear that no U.S. sanctions will be imposed against third-country banks that facilitate OFAC-licensed or exempted humanitarian trade. The Administration must make sure that U.S. Government officials are ready to engage and assist the local citizenry in issues that relate to their

CUBAN INDEPENDENCE DAY

Mr. NELSON of Florida. Madam President, today I wish to commemorate the 110th anniversary of Cuba’s independence. On May 20, 1902, after a series of rebellions against foreign rule, Cuba finally regained its freedom from the Spanish empire. I am honored to join with Cubans around the world in commemorating this day.

At the same time, we must remember that the island nation still remains under the tyrannical regime. We can never forget that the Castro regime continues to jail its political opponents, and it still holds an American hostage. Once again, I rise today to urge the Cuban regime in the strongest possible terms to immediately and unconditionally release Mr. Alan Gross.

Today, we reaffirm our solidarity with the people of Cuba. Now more than ever, the United States must continue policies that promote respect for the fundamental principles of political freedom, democracy, and human rights, in a manner consistent with the aspirations of the people of Cuba.

CITIZEN ENGAGEMENT BUILDING IN ETHIOPIA

Mr. BEGICH. Madam President, to mark the occasion of President Obama’s Camp David G8 Summit focusing, in part, on the problem of food security in Africa, I want to take this opportunity to address the necessity for the United States to help foster stable and democratic nations as partners as we build multilateral coalitions to tackle global issues like hunger and poverty.

Alaska is a long way from Africa, but the citizens of my State are committed to a stable and prosperous Africa. Many Alaskans contribute their time and resources toward this goal.

A year ago in Deauville, France, President Obama joined other leaders of the G8 in reaffirming that “democracy lays the best path to peace, stability, prosperity, shared growth and development.” As the events in North Africa and the Middle East have shown, supporting reliable autocrats who are helpful on matters of security and economics at the expense of human dignity, basic democratic rights, and access to economic opportunity is more perilous than ever to long-term U.S. national security interests.

It is for this reason that I make a few points about our reliable partner in the Horn of Africa. Ethiopia, a few weeks ago at the World Economic Forum, Ethiopian Prime Minister Meles Zenawi made hopeful remarks about the virtues of democratic society. I publically commit my continuing support for efforts to meld important principles a reality in Ethiopia. It is in the U.S. interest to match Ethiopia’s progress in economic development and poverty reduction with movement toward economic opportunity, social justice, and judicial independence.

Beginning in 1993, President Theodore Roosevelt and Ethiopian Emperor Menelik II launched a long and mutually beneficial history of working together on important geopolitical and economic strategic partnerships that last to this day. Our friend and partner, Ethiopia, has been a champion with the United States during many critical times for almost 110 years. When it invaded Ethiopia, we refused to recognize the conquest. When the United States asked for help during the Cold War, Haile Selassie was ready to help. When the regime of Mengistu Haile-Mariam fell, the United States came to Ethiopia’s side with help to prevent violence in Addis Ababa, by facilitating Mengistu’s departure. We gave this support for the mutual benefit and promise of democratization in Ethiopia.

Ethiopia’s macroeconomic successes of rapid growth rates and better than average performance in poverty reduction have been celebrated at this past week’s G8 Summit, and at the recent World Economic Forum. There Prime Minister Meles pondered aloud: What is the substantive political thing that creates such an environment [of fair economic opportunity for all citizens]? The one thing that creates such an environment is an engaged citizenry that is able to create an environment where corruption and loot cannot happen at the lower level, at the mid-level, at the higher level, and that goes beyond elections every four and five years.

On the microeconomic level, aside from the lack of progress on land reform, this is good news indeed, given recent complaints about poor state of economic opportunity for all of Ethiopia, and it is a sign that Ethiopia’s federal ministries are ready to engage and assist the local citizenry in issues that relate to their
economic interests. Many observers are pessimistic, but I prefer to think of the glass as half full, and ready to be filled to the brim.

The Prime Minister’s sentiments raise many issues, including: the nation’s commitment to an environment conducive to free speech and citizen participation; a commitment to building an informed and engaged citizenry as a key to inclusive, long term economic development; a call for the quick and unconditional release of journalists and political prisoners as a measure of good faith; and commitment to a diverse and multi-party election in 2015, free from federal government interference.

Hopeful as I am, I urge my Senate and House colleagues to re-commit to assistance we have offered the people of Ethiopia and their government in the past.

Let us help build a national consensus on the value of the following goals: an Ethiopia of robust democracy and institutions that represent the diversity of perspectives in Ethiopia; free and fair political processes drawing legitimacy from broad citizen participation; an independent judicial system as outlined in Ethiopia’s constitution; a press with institutional independence and legal protection to enable it to accommodate and a broad range of perspectives and ensure the free flow of information, ideas and opinions that are necessary in a democratic society, as outlined in Ethiopia’s constitution; an environment where each citizen can take advantage of Ethiopia’s economic success; and the security that comes with the assurance that universal rights are respected and protected.

Our international partnerships are stronger and more enduring when we share values of opportunity and freedom with our partners. A more democratic Ethiopia would represent a more stable and reliable partner for the United States and serve the long-term interests of peace and security in the Horn of Africa. A more democratic Ethiopia would ease the free flow of information, which would ease trade and ensure more informed investments. A more democratic Ethiopia would ensure that government policies are the result of broad national consultation with all segments of society.

Such are hallmarks of inclusive and sustainable economic growth, and they provide a return of robust stability and transparency to both American taxpayers and Ethiopian citizens. Let’s do what we can to help our fast and true friend, Ethiopia, extend opportunity and freedom to the majority of its citizenry.

CONGRATULATING THE SALVE REGINA UNIVERSITY MEN’S RUGBY TEAM

Mr. REED. Madam President, today I congratulate the Salve Regina University men’s rugby team for winning the 2012 National Small College Rugby Organization’s Division III National Championship on April 29, 2012, in Glendale, CO.

The Salve Regina Seahawks, ranked number one by the National Small College Rugby Organization, were undefeated in the season and went on to defeat Tufts University on November 13, 2011, in the New England Championship and then went on to defeat Molloy College on November 13, 2011, in the Northeast Region Championship.

Reestablished in 2007, the Salve Regina Seahawks men’s rugby team has appeared in the final four of the National Small College Rugby Organization’s Division III national tournament three times in the past five years. The Seahawks’ 21–15 victory over the California Maritime Academy Keelhaulers in the championship match was the first national championship victory for Salve Regina University in any sport.

I am especially pleased and proud to share that the members of the Salve Regina Seahawks men’s rugby team demonstrated great sportsmanship and represented both their school and the State of Rhode Island with distinction.

I would like to recognize the Seahawks head coach Michael Martin and his assistant U.S. Air Force Colonel Dan Lockert; team president Richard Casey; captains Paul Schacter and Jesse DiTullio; and members Andrew Balk, Jeffrey Bouley, Patrick Brown, Chris Buckman, Michael Burlingame, Brian Cronin, Christopher Dieselman, Matt Dougenik, Zachary Faella, Brian Goodridge, James Horn, Martin Kelliker, Alfred Knapp, John Kuchac, Shane Lange, Robert LaRiviere-Tougas, Stephen McEnery, Glen Miles, Zackary Moreau, Daniel Murphy, Troy Ochoa, Joshua Patterson, Nicholas Patti, Nicholas Pesce, Russell Petrucci, Jacob Piazza, Nicholas Pinto, Evan Raiff, Rylan Richard, Nathan Rose, Kyle Russell, Justin Ryel, Carlos Santos, David Seguin, Colby Sherman, Ryan Shillalis, Connor Taub, Grant Thiel, Quinn Turner, Patrick Wendt, and Joseph Zoeller.

I would also like to acknowledge the contributions of Salve Regina’s president Sister Jane Gerety, RSM, chancellor Sister M. Therese Antone, RSM, and athletic director Colin Sullivan. Once again, congratulations to the members of the Salve Regina Seahawks men’s rugby team on this outstanding achievement and well-deserved championship.

ADDITIONAL STATEMENTS

REMEMBERING EDWARD MALLOY

Mrs. GILLBRAND. Madam President, today I wish to mourn the passing of Edward J. Malloy, who dedicated his life as a champion for hard working men and women in New York State and throughout the country.

Mr. Malloy was a tireless advocate for workers’ rights, serving as president of the Building and Construction Trades Council of greater New York from 1992 to 2008 and as president of the New York State Building and Construction Trades Council from 1992 until his retirement earlier this year. Prior to his service in these capacities, Mr. Malloy served as a member of the Enterprise Association of Steamfitters Local Union 638, where he began as an apprentice, rose to journeyman and was a longtime member. He was also a veteran of the U.S. Army. Mr. Malloy was a driving force for private economic development and public infrastructure improvements throughout New York State. He was instrumental in promoting measures to contain construction costs and maximize employment opportunities for workers. His signature achievement in this regard was the advancement of project labor agreements for major public works projects, which are now widely used to deliver construction in a cost-efficient and timely manner.

Mr. Malloy was also a strong supporter of promoting opportunity and diversity in the construction industry’s workforce, helping launch programs to provide access to careers in the building trades for youth, veterans of the U.S. Armed Services, minorities and women. In particular, an organization that Mr. Malloy helped found has to date placed more than 1,300 youth, public housing residents and other city residents into unionized apprenticeships, 85 percent of whom are African American, Hispanic, Asian and other minorities. The results of these efforts are evident today, with the majority of union apprentices and workers in New York City’s construction industry being African American, Hispanic, Asian and other minorities.

Edward J. Malloy was respected by all who knew him as not only a tireless advocate for working men and women, but an advocate for our great city and State. His hard work allowed him to pass easily from union halls to business board rooms and the chambers of government.

This dedication and personality served members of organized labor well for decades as he worked to promote job creation, economic development and fairness. His contributions are immeasurable and we owe him an enormous debt of gratitude for them. We extend our heartfelt condolences to his family on behalf of an entire industry.

Mr. President, today, I ask all members of this esteemed body to join me in honoring Edward J. Malloy’s lifetime of commitment to improving the lives of working men and women from around the country.

CONGRATULATING THE UNIVERSITY OF TEXAS AT AUSTIN

Mrs. HUTCHISON. Madam President, today, I want to congratulate and acknowledge the University of Texas at Austin’s Department of History for creating an interactive website that offers...
a unique outlet for promoting information and enhancing understanding about U.S. and world history. This new site puts the expertise of the University of Texas world-renowned faculty at the service of the general citizenry, and provides a public forum for the discussion of historical and contemporary events.

The title of the website, www.notevenpast.org, “Not Even Past,” (NEP) derives its name from William Faulkner’s famous line that, “The past is never dead. It’s not even past.” It acknowledges the professional and ethical commitment to understanding history as a public conversation about the importance of the past for our actions, values, and beliefs in the present, and for the decisions we make today that will affect our lives tomorrow.

I would like to congratulate particularly the efforts of Professor Joan Neuberger, Chairman Alan Tully, the department faculty, and the input of graduate students for establishing this project in 2010.

NEP brings together a diverse group of historians in every major historical field by using modern technology as a vehicle to share their perspectives on topics related to Texas, the United States, and world history. The website allows people from around the world with an interest in history and historical events to take advantage of the University of Texas’ new resource. This unique and innovative website offers book and film recommendations, movie clips, podcasts, links to historical documents and artifacts, as well as as a fact-checker series and free virtual courses.

The development of NEP reinforces the reputation of the University of Texas Department of History. I believe this website is an invaluable resource of remarkable range and interest, and will advance the university’s goal of undertaking programs of civil, education, and social services.

Since NEP was launched in January 2011, the website has enabled hosting and sponsoring events devoted to the history curriculum, organization of a book club with award-winning professors and students of history, accumulation of an extensive library of podcasts, short articles and recommended movies related to all aspects of history, and even virtual history courses that are offered through the University of Texas. In June 2012, NEP will also begin posting university, high school, and middle school students’ history projects.

Congratulations to the University of Texas Department of History for creating this interactive website.

**TRIBUTE TO DR. LEWIS N. WALKER**

- Mr. LEVIN. Madam President, today I, along with my Senate colleague from Michigan, Senator STABENOW, recognize Dr. Lewis Walker, a dynamic and forward thinking leader who has been a driving force behind Lawrence Technological University’s growth and continued success. Dr. Walker retires in June after 18 years at Lawrence Tech, the last 6 as President and CEO.

Ensuring students acquire the skills necessary to meet the challenges of an ever-changing, global workplace has been a central tenet of Dr. Walker’s work at Lawrence Tech. Since joining Lawrence Tech in 1994, Dr. Walker has sought innovative ways to expand the university’s academic footprint. A hallmark of his tenure has been his commitment to broadening academic opportunities for students, pursuing international partnerships, and expanding the university’s technological infrastructure.

This work led to the creation of a number of certificate and degree programs at Lawrence Tech, from the associate to the doctoral level, and notably includes programs in robotics, defense and sustainability. Impressively, the diversity of academic programs the university offers has expanded from 60 to more than 100 and more than 40 “fast track” certificate programs have been created to help dislocated workers transition to new careers.

Dr. Walker also emphasized leadership, believing that “Our aim has been to imbue in our graduates the ability to have confidence in themselves.” This focus is truly perceptive. Seeking to integrate Lawrence Tech’s unique and innovative website offers book and film recommendations, movie clips, podcasts, links to historical documents and artifacts, as well as a fact-checker series and free virtual courses.

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MESSAGES FROM THE PRESIDENT

Messages from the President of the United States were communicated to the Senate by Mr. Pate, one of his secretaries.

**EXECUTIVE MESSAGES REFERRED**

As in executive session the Presiding Officer laid before the Senate messages from the President of the United States submitting sundry nominations which were referred to the appropriate committees. (The nominations received today are printed at the end of the Senate proceedings.)

**REPORT ON THE CONTINUATION OF THE NATIONAL EMERGENCY THAT WAS ORIGINALLY DECLARED IN EXECUTIVE ORDER 13303 OF MAY 22, 2003, RECEIVED DURING ADJOURNMENT OF THE SENATE ON MAY 18, 2012—PM 50**

The PRESIDING OFFICER laid before the Senate the following message from the President of the United States, together with an accompanying report, which was referred to the Committee on Banking, Housing, and Urban Affairs:

To the Congress of the United States:

Section 202(d) of the National Emergencies Act (50 U.S.C. 1722(d)) provides for the automatic termination of a national emergency unless, within 90 days prior to the anniversary date of its declaration, the President publishes in the Federal Register and transmits to the Congress a notice stating that the emergency is to continue in effect beyond the anniversary date. In accordance with this provision, I have sent the enclosed notice to the Federal Register for publication continuing the national emergency with respect to the stabilization of Iraq. This notice states that the national emergency with respect to the stabilization of Iraq declared in Executive Order 13303 of May 22, 2003, as modified in scope and relied upon for additional steps taken in Executive Order 13315 of August 29, 2003, Executive Order 13350 of July 29, 2004, Executive Order 13364 of November 29, 2004, and Executive Order 13438 of July 17, 2007, is to continue in effect beyond May 22, 2012.

This notice is to the orderly reconstruction of Iraq, the restoration and maintenance of peace and security in the country, and the development of political, administrative, and economic institutions in Iraq continue to pose an unusual and extraordinary threat to the national security and foreign policy of the United States. Accordingly, I have determined that it is necessary to continue the national emergency with respect to this threat and maintain in force the measures taken to deal with this threat.

Recognizing positive developments in Iraq, my Administration will continue to evaluate Iraq’s progress in resolving
outstanding debts and claims arising from actions of the previous regime, so that I may determine whether to further continue the prohibitions contained in Executive Order 13330 of May 22, 2003, as amended by Executive Order 13364 of November 29, 2004, on any account or property subject to sanctions, garnishment, or other judicial process with respect to the Development Fund for Iraq, the accounts, assets, and property held by the Central Bank of Iraq, and Iraqi petroleum-related contracts, which are in addition to the sovereign immunity accorded Iraq under otherwise applicable law.

BARACK OBAMA,


MESSAGE FROM THE HOUSE RECEIVED DURING ADJOURNMENT

Under the authority of the order of the Senate of January 5, 2011, the Secretary of the Senate, on May 18, 2012, during the adjournment of the Senate, received a message from the House of Representatives announcing that the Speaker has signed the following enrolled bills:

H.R. 272. An act to reauthorize the Export-Import Bank of the United States, and for other purposes.

H.R. 4045. An act to modify the Department of Defense Program Guidance relating to the award of Post-Deployment/Mobilization Respite Absence administrative absence days to members of the reserve components to exempt any member whose qualified mobilization commenced before October 1, 2010, and continued on or after that date, from the changes to the program guidance that took effect on that date.

Under the authority of the order of the Senate of January 5, 2011, the enrolled bills were signed on May 18, 2012, during the adjournment of the Senate, by the President pro tempore (Mr. INOUYE).

MESSAGE FROM THE HOUSE

At 2:04 p.m., a message from the House of Representatives, delivered by Mrs. Cole, one of its reading clerks, announced that the House has passed the following bills, in which it requests the concurrence of the Senate:


H.R. 5740. An act to extend the National Flood Insurance Program, and for other purposes.

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-6161. A communication from the Attorney-Advisor, U.S. Coast Guard, Department of Homeland Security, transmitting, pursuant to law, the report of a rule entitled “MARPOL Annex V Special Areas: Wider Caribbean Region” ((RIN1625–AB76) (Docket No. USCG–2012–0167)) received in the Office of the President of the Senate on May 9, 2012, to the Committee on Commerce, Science, and Transportation.

EC-6162. A communication from the Attorney-Advisor, U.S. Coast Guard, Department of Homeland Security, transmitting, pursuant to law, the report of a rule entitled “Changes to Vessel Identification System, Vessel Classification System, and Boating Accident Report Database” ((RIN1625–AB45) (Docket No. USCG–2003–14963)) received in the Office of the President of the Senate on May 9, 2012, to the Committee on Commerce, Science, and Transportation.

EC-6163. A communication from the Attorney-Advisor, U.S. Coast Guard, Department of Homeland Security, transmitting, pursuant to law, the report of a rule entitled “Sea-going Vessels—Correcting Amendment” ((RIN1625–AB57) (Docket No. USCG–2011–0365)) received in the Office of the President of the Senate on May 9, 2012, to the Committee on Commerce, Science, and Transportation.

EC-6164. A communication from the Attorney-Advisor, U.S. Coast Guard, Department of Homeland Security, transmitting, pursuant to law, the report of a rule entitled “Regulations; Zidell Waterfront Property, Willamette River, OR” ((RIN1625–AA11) (Docket No. USCG–2011–0254)) received in the Office of the President of the Senate on May 9, 2012, to the Committee on Commerce, Science, and Transportation.

EC-6165. A communication from the Attorney-Advisor, U.S. Coast Guard, Department of Homeland Security, transmitting, pursuant to law, the report of a rule entitled “Flood Insurance Program, and for other purposes.”

EC-6166. A communication from the Attorney-Advisor, U.S. Coast Guard, Department of Homeland Security, transmitting, pursuant to law, the report of a rule entitled “Innovation in Broadband Telecommunications (Public Notice 12008), Channel Sharing and Improvements to VHF” (ET Docket Nos. 10–235; FCC 12–45) received in the Office of the President of the Senate on May 8, 2012, to the Committee on Commerce, Science, and Transportation.

EC-6167. A communication from the Attorney-Advisor, U.S. Coast Guard, Department of Homeland Security, transmitting, pursuant to law, the report of a rule entitled “Anchorage Regulations; Subpart A—Special Anchorage Regulations, Newport Bay Harbor, CA” ((RIN1625–AA01) (Docket No. USCG–2012–0170)) received in the Office of the President of the Senate on May 9, 2012, to the Committee on Commerce, Science, and Transportation.

EC-6168. A communication from the Chief of Staff, Media Bureau, Federal Communications Commission, transmitting, pursuant to law, the report of a rule entitled “Standardized and Enhanced Disclosure Requirements for Television Broadcast Licensee Public Interest Obligations; Extension of the Filing Requirements For Children’s Television Programming Report” (MB Docket Nos. 00–188 and 00–41; FCC 12–44) received in the Office of the President of the Senate on May 8, 2012, to the Committee on Commerce, Science, and Transportation.

EC-6169. A communication from the Senior Program Analyst, Federal Aviation Administration, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled “Standard Numbering System, Roll-Royce plc Turbofan Engines” ((RIN2120–AA64) (Docket No. FAA–2010–0929)) received in the Office of the President of the Senate on May 8, 2012, to the Committee on Commerce, Science, and Transportation.

EC-6170. 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 Turbopfan Engines” ((RIN1625–AA49) (Docket No. FAA–2010–0969)) received in the Office of the President of the Senate on May 8, 2012, to the Committee on Commerce, Science, and Transportation.

EC-6171. A communication from the Acting Director, Office of Sustainable Fisheries, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled “Fisheries of the Northeastern United States; Atlantic Mackerel, Squid, and Butterfish Fisheries; Closure of the Trimester 1 Longfin Squid Fishery” (RIN0648–XB145) received in the Office of the President of the Senate on May 9, 2012, to the Committee on Commerce, Science, and Transportation.

EC-6172. A communication from the Acting Director, Office of Sustainable Fisheries, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled “Fisheries of the Exclusive Economic Zone of Alaska; Pacific Ocean National Marine Fisheries Using Trawl Gear in the Central Regulatory Area of the Gulf of Alaska” ((RIN0648–XB145) received in the Office of the President of the Senate on May 9, 2012, to the Committee on Commerce, Science, and Transportation.

EC-6173. A communication from the Acting Director, Office of Natural Resources, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled...
report for the Temporary Assistance for Needy Families Program; to the Committee on Health, Education, Labor, and Pensions.

EC–6201. A communication from the Chairman of the National Credit Union Administration, transmitting, pursuant to law, the Semi-Annual Report of the Inspector General for the period from October 1, 2011 through March 31, 2012; to the Committee on Homeland Security and Governmental Affairs.

EC–6202. A communication from the Chairman of the National Credit Union Administration, transmitting, pursuant to law, the Semi-Annual Report of the Inspector General for the period from October 1, 2011 through March 31, 2012; to the Committee on Homeland Security and Governmental Affairs.

EC–6203. A communication from the Deputy General Counsel, Office of Financial Assistance, Small Business Administration, transmitting, pursuant to law, the report of a rule entitled “Disaster Assistance Loan Program: Maximum Term for Disaster Loans to Small Businesses with Credit Available Elsewhere” (RIN2645–AG21); received in the Office of the President on May 17, 2012; to the Committee on Small Business and Entrepreneurship.

EC–6204. A communication from the Deputy General Counsel, Office of Size Standards, Small Business Administration, transmitting, pursuant to law, the report of a rule entitled “Small Business Size Standards: Transportation and Warehousing” (RIN2645–AG66); received in the Office of the President on May 17, 2012; to the Committee on Small Business and Entrepreneurship.

REPORTS OF COMMITTEES

The following reports of committees were submitted:

By Mr. LEVIN, from the Committee on Armed Services:

Special Report entitled “Inquiry into Counterfeit Electronic Parts in the Department of Defense Supply Chain” (Rept. No. 112–197).

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:

S. 3207. A bill to amend title 10, United States Code, to provide for relief in civil actions for violations of the protections on credit extended to members of the Armed Forces and their dependents; to the Committee on Armed Services.

By Mr. PORTMAN (for himself, Mr. UDALL of New Mexico, Ms. SNOWE, and Mr. WHITEHOUSE):

S. 3208. A bill to reauthorize the Multi-national Species Conservation Funds Semipostal Stamp, and for other purposes; to the Committee on Homeland Security and Governmental Affairs.

By Mr. TESTER:

S. 3209. A bill to provide for the settlement of the water rights claims of the Fort Belknap Indian Community, and for other purposes; to the Committee on Indian Affairs.

By Mr. BROWN of Massachusetts (for himself and Mr. RYAN):

S. 3210. A bill to amend title 38, United States Code, to modify the treatment under contracting goals and preferences of the Department of Veterans Affairs for small businesses owned by veterans of small businesses after the death of a disabled veteran owner, and for other purposes; to the Committee on Veterans Affairs.

By Mr. BENNET:

S. 3211. A bill to authorize the President to determine the appropriate export controls of satellites and related items based on the national security and foreign policy objectives of the United States, and for other purposes; to the Committee on Foreign Relations.

SUBMISSION OF CONCURRENT AND SENATE RESOLUTIONS

The following concurrent resolutions and Senate resolutions were read, referred, and referred as indicated:

By Mr. BLUMENTHAL (for himself, Mr. CASY, and Mr. CHAMBLISS):

S. Res. 468. A resolution expressing the sense of the Senate with respect to childhood stroke and recognizing May as “National Pediatric Stroke Awareness Month”; considered and agreed to.

By Ms. LANDRIEU (for herself, Ms. SNOWE, Mr. PYOR, Mr. LIEBERMAN, Mr. ENZI, Mr. KERRY, Mr. BROWN of Massachusetts, Ms. CANTWELL, Ms. AVETTRO, Mr. RUSC, Mr. CARR, Mrs. HAGAN, Mr. RUBIO, and Mr. MERKLEY):

S. Res. 469. A resolution honoring the entrepreneurial spirit of small business concerns in the United States during National Small Business Week, which begins on May 20, 2012; considered and agreed to.

ADDITIONAL COSPONSORS

S. 491. At the request of Mr. PYOR, the names of the Senator from Iowa (Mr. HARKIN) and the Senator from Minnesota (Mr. FRANKEN) were added as cosponsors of S. 491, a bill to amend title 38, United States Code, to recognize the service in the reserve components of the Armed Forces of certain persons by honoring them with status as veterans under law, and for other purposes.

S. 507. At the request of Mr. ROCKEFELLER, the name of the Senator from New York (Mrs. GILLIBRAND) was added as a cosponsor of S. 507, a bill to provide, for increased Federal oversight of prescription opioid treatment and assistance to States in reducing opioid abuse, diversion, and deaths.

S. 1507. At the request of Mr. HATCH, the name of the Senator from Nevada (Mr. HELLER) was added as a cosponsor of S. 1507, a bill to provide protections from workers with respect to their right to select or refrain from selecting representation by a labor organization.

S. 1551. At the request of Mr. KIRK, the name of the Senator from Wyoming (Mr. ENZI) was added as a cosponsor of S. 1551, a bill to establish a smart card pilot program under the Medicare program.

S. 1738. At the request of Mr. TOONEY, the name of the Senator from Maine (Ms. SNOWE) was added as a cosponsor of S. 1578, a bill to amend the Safe Drinking Water Act with respect to consumer confidence reports by community water systems.

S. 1796. At the request of Mr. LEAHY, the names of the Senator from Connecticut (Mr. BLUMENTHAL) was added as a cosponsor of S. 1696, a bill to improve the Public Safety Officers’ Benefits Program.

S. 1792. At the request of Mr. CASEY, the names of the Senator from New Jersey (Mr. LAUTENBERG) and the Senator from Michigan (Ms. STABENOW) were added as cosponsors of S. 1792, a bill to amend the Internal Revenue Code of 1986 to provide for the tax treatment of ABLE accounts established under State programs for the care of family members with disabilities, and for other purposes.

S. 1798. At the request of Mr. MENENDEZ, the name of the Senator from Montana (Mr. Tester) was added as a cosponsor of S. 1798, a bill to assist low-income individuals in obtaining recommended dental care.

S. 1861. At the request of Mr. DURBIN, the name of the Senator from Missouri (Mr. BLUNT) was added as a cosponsor of S. 1861, a bill to provide States with incentives to require elementary schools and secondary schools to maintain, and permit school personnel to administer, epinephrine at schools.

S. 1933. At the request of Mr. LIEBERMAN, the name of the Senator from New Jersey (Mr. MENENDEZ) was added as a cosponsor of S. 1933, a bill to provide benefits to domestic partners of Federal employees.

S. 1979. At the request of Mr. CONRAD, the name of the Senator from South Dakota (Mr. TRUNE) was added as a cosponsor of S. 1979, a bill to provide incentives to physicians to practice in rural and medically underserved communities and for other purposes.

S. 2071. At the request of Mr. SCHUMER, the name of the Senator from New Mexico (Mr. BINGAMAN) was added as a cosponsor of S. 2071, a bill to authorize the Secretary of Education to make demonstration grants to eligible local educational agencies for the purpose of reducing the student-to-school nurse ratio in public elementary schools and secondary schools.

S. 2066. At the request of Ms. MURKOWSKI, the name of the Senator from Ohio (Mr.
PORTMAN was added as a cosponsor of S. 2066, a bill to recognize the heritage of recreational fishing, hunting, and shooting on Federal public land and ensure continued opportunities for those activities.

S. 2116
At the request of Mr. CARPER, the names of the Senator from New York (Mrs. GILLIBRAND) and the Senator from Rhode Island (Mr. REED) were added as cosponsors of S. 2116, a bill to count revenues from military and veteran education programs toward the limit on Federal revenues that certain proprietary institutions of higher education are allowed to receive for purposes of section 487 of the Higher Education Act of 1965, and for other purposes.

S. 2138
At the request of Mr. VITTER, the name of the Senator from Louisiana (Ms. LANDRIEU) was added as a cosponsor of S. 2138, a bill to establish a pilot program to evaluate the cost-effectiveness and project delivery efficiency of non-Federal sponsors as the lead project developer for authorized civil works flood control and navigation construction projects of the Corps of Engineers.

S. 2165
At the request of Mrs. BOXER, the names of the Senator from Texas (Mr. CORNYN), the Senator from Virginia (Mr. WARNER) and the Senator from Montana (Mr. BAUCUS) were added as cosponsors of S. 2165, a bill to enhance strategic cooperation between the United States and Israel, and for other purposes.

S. 2220
At the request of Ms. AYOTTE, the name of the Senator from Alaska (Ms. MURKOWSKI) was added as a cosponsor of S. 2220, a bill to direct the American Battle Monuments Commission to provide for the ongoing maintenance of the Graycliff Cemetery in the Republic of the Philippines, and for other purposes.

S. 2371
At the request of Mr. RUBIO, the name of the Senator from Idaho (Mr. RISCH) was added as a cosponsor of S. 2371, a bill to amend the National Labor Relations Act to permit employers to pay higher wages to their employees.

S. 2374
At the request of Mr. BINGAMAN, the name of the Senator from Connecticut (Mr. BLUMENTHAL) was added as a cosponsor of S. 2374, a bill to amend the Helium Act to ensure the expedient and responsible draw-down of the Federal Helium Reserve in a manner that protects the interests of private industry, the scientific, medical, and industrial communities, commercial users, and Federal agencies, and for other purposes.

S. 3048
At the request of Mr. BROWN of Ohio, the name of the Senator from Rhode Is-land (Mr. WHITEHOUSE) was added as a cosponsor of S. 3048, a bill to provide for a safe, accountable, fair, and efficient banking system, and for other purposes.

S. 3118
At the request of Mrs. GILLIBRAND, the name of the Senator from New York (Mr. SCHUMER) was added as a cosponsor of S. 3118, a bill to increase the authorized number of Weapons of Mass Destruction Civil Support Teams.

S. 319
At the request of Mr. BEGICH, his name was added as a cosponsor of S. 3199, a bill to amend the Immigration and Nationality Act to stimulate international tourism to the United States and for other purposes.

S. RES. 435
At the request of Mr. CASEY, the names of the Senator from Oregon (Mr. MERKLEY) and the Senator from California (Mrs. BOXER) were added as cosponsors of S. Res. 435, a resolution calling for democratic change in Syria, and for other purposes.

AMENDMENT NO. 2197
At the request of Mr. MCCAIN, the names of the Senator from Minnesota (Mr. FRANKEN) and the Senator from Maine (Ms. SOWE) were added as cosponsors of amendment No. 2107 intended to be proposed to S. 3167, a bill to amend the Federal Food, Drug, and Cosmetic Act to extend and expand 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. 2198
At the request of Ms. MURKOWSKI, the names of the Senator from California (Mrs. FEINSTEIN) and the Senator from Oregon (Mr. WYDEN) were added as cosponsors of amendment No. 2108 intended to be proposed to S. 3167, 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. 2111
At the request of Mr. BINGAMAN, the name of the Senator from Ohio (Mr. BROWN) was added as a cosponsor of amendment No. 2111 intended to be 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 Mr. TESTER:
S. 3209. A bill to provide for the settlement of the water rights claims of the Fort Belknap Indian Community, and for other purposes.
Mr. TESTER. Mr. President, water is the foundation for life. That is true in every community, but especially in American Indian Country. Water plays a particularly important role in Native American life—past and present—in history, culture and religion. That is why I am proud to introduce the Gros Ventre and Assiniboine Tribes of the Fort Belknap Indian Community Water Rights Settlement Act of 2012.
Not every issue relating to this important compact is resolved. I very much appreciate the perspective of who say that changes are still needed. My goal in introducing this legislation is to get all interested parties to negotiate on the issues that must still be resolved. By introducing this bill today, the Ft. Belknap Indian community, surrounding counties and the State of Montana indicate to the United States that we are ready to negotiate in earnest. During that process, Montanans and I will work to gain support from the Department of the Interior, State of Montana, the Tribe, and local communities as we address individual concerns.
The current federal policy to determine Indian water rights is to negotiate, rather than litigate. Montana has had a similar policy since it created the Montana Reserved Water Rights Compact Commission in 1979. Both governments recognize that litigating every water right on Montana’s vast Indian reservations is cost prohibitive and time consuming. Negotiated settlements are cheaper. They are much faster than litigation. They allow individuals to participate in the outcome. They provide a greater degree of certainty to every involved. Folks working on this settlement and I intend this legislation to fulfill the spirit of those policies.
Since the Supreme Court’s 1908 decision in Winters, the United States has had a responsibility to provide water to the land it reserves for specific purposes, such as reservations, American Indian homelands. This legislation fulfills that responsibility. It will empower the Tribe to create jobs and stronger communities by improving critical infrastructure.
More importantly, it strikes the proper balance to achieve a fair, equitable, and final settlement of claims to water rights in the State of Montana between the State, the Tribe, and the United States for the benefit for the Tribe and allottees.
There is more work to do to ensure that all interested parties can support a final agreement. I understand that. However, hundreds of hours of deliberation over more than a decade have been put into shaping the terms of this Compact and Settlement. Although we have made good progress during that time, we still have a lot of work left. I look forward to working with my tribal, local, state and federal partners to get this done. It is the right thing to do for the United States, the Tribe and the State of Montana.
In 2001, as a member of the Montana legislature, I was happy to support
state ratification of the Fort Belknap Water Rights Compact. I look forward to assisting the parties in moving this Compact over the next hurdle—congressional authorization.

**SUBMITTED RESOLUTIONS**

**SENATE RESOLUTION 468—EX-Pressing the Sense of the Senate with Respect to Childhood Stroke and Recognizing May as “National Pediatric Stroke Awareness Month”**

Mr. BLUMENTHAL (for himself, Mr. CASEY, and Mr. CHAMBLISS) submitted the following resolution; which was considered and agreed to:

> S. Res. 468

Whereas a stroke, also known as a cerebrovascular accident, is an acute neurologic injury that occurs when the blood supply to a part of the brain is interrupted by a clot in the artery or a burst of the artery; 

Whereas stroke is a medical emergency that can cause permanent neurologic damage or even death if not promptly diagnosed and treated; 

Whereas stroke occurs in approximately 1 out of every 4,000 live births, and the risk of stroke from birth through age 18 is nearly 11 out of every 100,000 children per year; 

Whereas an individual can have a stroke before birth; 

Whereas stroke is among the top 10 causes of death for children in the United States; 

Whereas per cent and 40 percent of children who suffer a stroke die as a result; 

Whereas stroke recurrence in 20 percent of children who have experienced a stroke; 

Whereas the death rate for children who experience a stroke before the age of 1 year is the highest out of all age groups; 

Whereas the average time from onset of symptoms to diagnosis of stroke is 21 hours, putting many affected children outside the window of 3 hours for the most successful treatment; 

Whereas between 50 and 85 percent of infants and children who have a pediatric stroke will have serious, permanent neurologic disabilities, including paralysis, seizures, speech and vision problems, and attention, learning, and behavioral difficulties; 

Whereas those disabilities may require ongoing physical therapy and surgeries; 

Whereas the permanent health concerns and treatments resulting from strokes that occur during childhood and young adulthood have a considerable impact on children, families, and society; 

Whereas very little is known about the causes, treatment, and prevention of pediatric stroke; 

Whereas medical research is the only means by which the citizens of the United States can identify and develop effective treatment and prevention strategies for pediatric stroke; and 

Whereas early diagnosis and treatment of pediatric stroke greatly improves the chances that the affected child will recover and not experience a recurrence: Now, therefore, be it

Resolved, That the Senate—

(1) acknowledges May as “National Pediatric Stroke Awareness Month”;

(2) urges the people of the United States to support programs, services, and advocacy of organizations that work to enhance public awareness of childhood stroke; 

(3) supports the work of the National Institutes of Health in pursuit of medical progress on the matter of pediatric stroke; and 

(4) urges continued coordination and cooperation between government, researchers, families, and the public to improve treatments and prognosis for children who suffer strokes.

**SENATE RESOLUTION 469—Honoring the Entrepreneurial Spirit of Small Business Concerns in the United States During National Small Business Week, Which Begins on May 20, 2012**

Ms. LANDRIEU (for herself, Ms. SNOWE, Mr. PEYOR, Mr. LIEBERMAN, Mr. ENZI, Mr. KERRY, Mr. BROWN of Massachusetts, Ms. CANTWELL, Ms. AYOTTE, Mr. RISCH, Mr. CARDIN, Mrs. HAGAN, Mr. RUBIO, and Mr. MEHKKLEY) submitted the following resolution; which was considered and agreed to:

> WHEREAS, the approximately 27,500,000 small business concerns in the United States are the driving force behind the Nation’s economy, creating 2 out of every 3 new jobs and generating more than 50 percent of the Nation’s non-farm gross domestic product; 

> WHEREAS, small businesses are the driving force behind the economic recovery of the United States; 

> WHEREAS, small businesses represent 99.7 percent of employer firms in the United States; 

> WHEREAS, small business concerns are the Nation’s innovators, serving to advance technology and productivity; 

> WHEREAS, small business concerns represent 97.5 percent of sales of exported goods; 

> WHEREAS, Congress established the Small Business Administration in 1953 to aid, counsel, assist, and protect the interests of small business concerns in order to preserve and competitive enterprise, to ensure that a fair proportion of the total Federal Government purchases and subcontracts for property and services are placed with small business concerns, to ensure that a fair proportion of the total sales of government property are made to such small business concerns, and to maintain and strengthen the overall economy of the United States; 

> WHEREAS, the President has designated a “National Small Business Week” to recognize the contributions of small businesses to the economic well-being of the United States; 

> WHEREAS, in 2012, National Small Business Week will honor the estimated 27,200,000 small businesses in the United States; 

> WHEREAS, the Small Business Administration has helped small business concerns by providing access to critical lending opportunities, protecting small business concerns from excessive Federal regulatory enforcement, helping to ensure full and open competition for government contracts, and improving the economic environment in which small business concerns compete; 

> WHEREAS, for more than 50 years, the Small Business Administration has helped millions of entrepreneurs achieve the American dream by starting a small business, and has played a key role in fostering economic growth; and 

> WHEREAS, the President has designated the week beginning May 20, 2012 as “National Small Business Week”; Now, therefore, be it

Resolved, That the Senate—

(1) honors the entrepreneurial spirit of small business concerns in the United States during National Small Business Week, which begins on May 20, 2012; 

(2) applauds the efforts and achievements of the owners and employees of small business concerns, whose hard work and commitment to excellence have made such small business concerns a keystone of the economic vitality of the United States; 

(3) recognizes the work of the Small Business Administration and its resource partners in providing assistance to entrepreneurs and small business concerns; and 

(4) recognizes the importance of ensuring that:

A. Guaranteed loans, including microloans and microloan technical assistance, for start-up and growing small business concerns, and venture capital, are made available to all qualified small business concerns; 

B. The management assistance programs delivered by resource partners on behalf of the Small Business Administration, such as Small Business Development Centers, Women’s Business Centers, and the Service Corps of Retired Executives, are provided with the Federal resources necessary to provide invaluable counseling services to entrepreneurs in the United States; 

C. The Small Business Administration continues to provide timely and disaster assistance so that small businesses in areas struck by natural or manmade disasters can quickly return to business to keep local economies alive in the aftermath of such disasters; 

D. Affordable broadband Internet access is available to all people in the United States, particularly people in rural and underserved communities, so that small businesses can use the Internet to make their operations more globally competitive while boosting local economies; 

E. Regulatory relief is provided to small businesses through the reduction of duplicative or unnecessary regulatory requirements that increase costs for small businesses; and 

F. Leveling the playing field for contracting opportunities remains a primary focus, so that small businesses, particularly minority-owned small businesses, can compete for and win more of the $400,000,000,000 in contracts that the Federal Government enters into each year for goods and services.

**AMENDMENTS SUBMITTED AND PROPOSED**

SA 2113. Mr. INHOFE submitted an amendment intended to be proposed by him to the resolution S. Res. 466, calling for the release from prison of former Prime Minister of Ukraine Yulia Tymoshenko; which was referred to the Committee on Foreign Relations.

SA 2114. Mr. GRASSLEY (for himself and Mr. RANGEL) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, and to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table.

SA 2115. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2116. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2117. Mr. ROCKEFELLER submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.
SA 2118. Mr. ROCKEFELLER submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2119. Mr. ROCKEFELLER submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2120. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2121. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2122. Mr. HARKIN (for himself and Mr. ENZI) submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

SA 2123. Mr. REID (for Mr. JOHNSON of South Dakota (for himself and Mr. SHEELLEY)) proposed an amendment to the bill H.R. 1965, to strengthen Iran sanctions law for the purpose of compelling Iran to abandon its pursuit of nuclear weapons and other threatening activities, and for other purposes.

SA 2124. Mr. JOHNSON of South Dakota (for himself and Mr. SHEELLEY) proposed an amendment to amendment SA 2123 proposed by Mr. REID (for Mr. JOHNSON of South Dakota (for himself and Mr. SHEELLEY)) to the bill H.R. 1965, supra.

SA 2125. Mr. CARDIN submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table.

SA 2126. Mr. REED submitted an amendment intended to be proposed by him to the bill S. 3187, supra; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 2113. Mr. INHOFE submitted an amendment intended to be proposed by him to the resolution S. Res. 466, calling for the release from prison of former minister of the interior of Ukraine Yulia Tymoshenko; which was referred to the Committee on Foreign Relations; as follows:

In the preamble, strike the third and fourth whereas clauses and insert the following:

"Whereas, as a result of the electoral fraud by which Prime Minister Viktor Yanukovych was declared the winner of the 2004 presidential election, the citizens of Ukraine organized a series of protests, strikes, and sit-ins, which came to be known as "The Orange Revolution".

Whereas, as a result of the Orange Revolution, in concert with United States and international pressure, forced the Supreme Court of Ukraine to require an unprecedented second run-off election, which resulted in opposition leader Viktor Yushchenko defeating Mr. Yanukovych by a margin of 52 percent to 44 percent;"

SA 2114. Mr. GRASSLEY (for himself and Mr. WHITEHOUSE) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11. SUBPOENA AUTHORITY.

Section 702 (21 U.S.C. 372) is amended by adding at the end the following:

"(11) The Secretary may conduct investigations as the Secretary deems necessary—"(A) to carry out the authority of the Secretary under this Act or section 351 of the Public Health Service Act; or"(B) to determine whether any person has engaged or is about to engage in any act that constitutes or will constitute a violation of this Act or such section 351."(2) For the purpose of any investigation conducted under paragraph (1), the Secretary may administer oaths and affirmations, subpoena witnesses, compel the attendance of such witnesses, take evidence, and require the production of any books, papers, documents, or other materials that are relevant to the investigation.

"(3)(A) In case of contumacy or refusal to obey a subpoena issued under paragraph (2), the court district of the United States for the judicial district in which such investigation or proceeding is conducted, or in which the person on whom the subpoena is served resides or conducts business, may issue an order requiring such person to appear before the Secretary, testify, or produce books, papers, documents, or other materials that are relevant to the investigation. All process in any such case may be served in the judicial district in which such person resides or may be found.

"(B) Any failure to obey an order issued under subparagraph (A) may be punished by the court as contempt of court.""

SA 2115. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11. PROTECTIONS FOR THE COMMISSIONED CORPS OF THE PUBLIC HEALTH SERVICE AND THE NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION.

(a) COMMISSIONED CORPS OF THE PUBLIC HEALTH SERVICE ACT AND THE NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION.

"(1) REGISTRATION CONSIDERATION. Section 303(b) of the Controlled Substances Act (21 U.S.C. 832(b)) is amended by adding at the end the following:

"(2) The applicant's compliance with the training requirements described in subsection (g)(3) during any previous period in which the applicant has been subject to such training requirements.""

(b) REQUIREMENTS FOR PARTICIPATION IN OPIOID TREATMENT PROGRAMS.—Effective July 1, 2013, a physician practicing in an opioid treatment program (as defined in section (b) shall comply with the 16-hour training requirement of subparagraph (B) at least once during each 3-year period.

"(B) The training requirement of this subparagraph is that the practitioner has completed not less than 16 hours of training (through classroom situations, seminars at professional society meetings, online courses, electronic communications, or otherwise) with respect to—""(i) the treatment and management of opioid-dependent patients;""(ii) pain management treatment guidelines; and""(iii) early detection of opioid addiction, including through such methods as Screening, Brief Intervention, and Referral to Treatment (SBIRT),""that is provided by relevant professional societies, as determined by the Secretary,""(b) REQUIREMENTS FOR PARTICIPATION IN OPIOID TREATMENT PROGRAMS.—Effective July 1, 2013, a physician practicing in an opioid treatment program (as defined in section (b) shall comply with the requirements specified in section 303(g)(3) of the Controlled Substances Act (as added by subsection (a)) with respect to required minimum training at least once during each 3-year period.

(c) DEFINITION.—In this section, the term "opioid treatment program" has the meaning given such term in section 2 of title 42, Code of Federal Regulations (or any successor regulation).

(d) FUNDING.—The Drug Enforcement Administration shall fund the enforcement of the requirements specified in section 303(g)(3) of the Controlled Substances Act (as added by subsection (a)) through the use of a portion of the licensing fees paid by controlled substance prescribers under the Controlled Substances Act (21 U.S.C. 801 et seq.).
SA 2118. Mr. ROCKEFELLER submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 1141. SHORT TITLE; FINDINGS.

Section 3990 of the Public Health Service Act (42 U.S.C. 280g–3) is amended—

(a) SHORT TITLE.—This subtitle may be cited as the “Prescription Drug Abuse Prevention and Treatment Act of 2012”.

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

(1) Nonmedical use of prescription pain relievers is a matter of increasing public health concern. According to the Substance Abuse and Mental Health Services Administration, the proportion of all substance abuse treatment admissions aged 12 or older that reported any pain reliever abuse increased in percentage point from 2.2 to 9.8 between 1999 and 2008.

(2) In 2008, among the population of the United States aged 12 or older, nonmedical use of prescription pain relievers was the second most prevalent type of illicit drug use, after marijuana use.

(3) When used properly under medical supervision, prescription opiates enable individuals with chronic pain to lead productive lives. However, when taken without a physician’s oversight and direction, opiates can cause severe health effects resulting in dependence, abuse, and death.

(4) As with any controlled substance, there is a risk of abuse of methadone and other opioids.

(5) Methadone is an extensively tested, federally approved, and widely accepted method of treating addiction to prescription pain relievers or opiates.

(6) For more than 30 years, this synthetic prescription drug has been used for pain management and treatment for addiction to heroin, cocaine, and other opioid drugs.

(7) The efficacy and lower cost of methadone have resulted in its being prescribed for pain management.

(8) Prescription use of methadone has increased by nearly 700 percent from 1998 through 2006.

(9) According to the Centers for Disease Control and Prevention, the number of poisoning deaths involving methadone increased nearly 7-fold from almost 790 in 1999 to 5,200 in 2009. One major reason for the rapid increase among opioid analogues and other narcotics involved in poisoning deaths.

(10) The age-specific rates of methadone deaths among those aged 15 to 24 increased from 4 and 5 to 45 and 54 than for other age groups. However, the rate of methadone deaths in younger individuals (age 15 to 24) increased 11-fold from 1999 through 2009.

(11) Deaths from methadone and other opiates may actually be underreported. There is no comprehensive database of drug-related deaths in the United States.

(12) The lack of standardized reporting by Medical Examiners precludes a uniform definition of “cause of death” on death certificates.

(13) The Controlled Substances Act (21 U.S.C. 801 et seq.) requires that every person who dispenses or who proposes to dispense controlled narcotics, including methadone, whether for pain management or opioid treatment, obtain a registration from the Drug Enforcement Administration. Unfortunately, there is no condition of receiving the registration that these practitioners receive any education on the use of these controlled narcotics, including methadone.

(14) Current Federal oversight of methadone and other opioids is inadequate to address the growing number of opioid-related overdoses and deaths.

(15) Federal legislation is needed to avert opioid abuse, misuse, and death, without reducing patient access to needed care.
“(i)(1) An opioid treatment program that is registered under this section, and that closes for business on any weekday or weekend day, including a Federal or State holiday, shall comply with the requirements of this subsection.

“(2) The program shall make acceptable arrangements for the patient who is restricted, by Federal regulation or guideline, by the determination of the program medical director, from having a take-home dose of a controlled substance related to the treatment involved, to receive a dose of that substance under appropriate supervision during the closure.

“(3) The Administrator of the Substance Abuse and Mental Health Services Administration shall issue a notice that references regulation, or guidance promulgated under this subsection, or shall promulgate regulations on such acceptable arrangements.

SEC. 1146. ESTABLISHMENT OF THE CONTROLLED SUBSTANCES CLINICAL STANDARDS COMMISSION.

Part A of title V of the Public Health Service Act (42 U.S.C. 299a et seq.), as amended by section 1142, is further amended by adding at the end of the following:

“SEC. 506D. ESTABLISHMENT OF THE CONTROLLED SUBSTANCES CLINICAL STANDARDS COMMISSION.

“(a) In General.—The Secretary shall establish a Controlled Substances Clinical Standards Commission (referred to in this section as the ‘Commission’), to be composed of representatives from the Administration, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Pain Management Consortia of the National Institutes of Health, and other agencies that the Secretary may deem necessary, to develop:

“(i) appropriate and safe dosing guidelines for all forms of methadone, including recommendations for maximum daily doses of all forms as provided for in subsection (b)(1);

“(ii) benchmark guidelines for the reduction of methadone abuse, as provided for in subsection (b)(2);

“(iii) appropriate conversion factors for use by health care providers in transitioning patients from one opioid to another;

“(iv) specific guidelines for initiating pain management with methadone, that prescribing physicians or other clinicians shall comply with in order to meet Drug Enforcement Administration certification and re-certification requirements; and

“(v) consensus guidelines for pain management with prescription opioids.

“(b) GUIDELINES.—Not later than 3 years after the date of enactment of this section, the Commission established under subsection (a) shall publish in the Federal Register:

“(1) the initial benchmark guidelines for the reduction of methadone abuse to be used—

“(A) by opioid treatment programs in providing methadone therapy; and

“(B) by entities in the initial accreditation or certification, and the re-accreditation and re-certification, of such opioid treatment programs;

“(2) a model policy for dispensing methadone to be used by pharmacists that dispense methadone, which should include education and training guidelines for pharmacists;

“(3) the continuing education guidelines that all prescribers shall comply with in order to meet Drug Enforcement Administration certification and re-certification requirements, as set forth in section 330(c)(3) of the Controlled Substances Act (21 U.S.C. 823(g)(3)), which should include a minimum of 8 training hours at least every 3 years that include the integration of both addiction and pain management curricula; and

“(4) patient education guidelines for both opioid treatment and pain management, including recommendations for patient counseling prior to and during opioid addiction treatment or treatment for pain.

“(c) WEBSITE.—Not later than 180 days after the date of enactment of this section, the Commission shall consult with relevant professional organizations with expertise in the area of addiction, relevant professional organizations with expertise in the area of opioid treatment, pain management, pharmacy groups (including the National Association of Boards of Pharmacy), patient representatives, and any other organization that the Secretary determines is appropriate for purposes of this section.

“(d) METHADONE TOOLKIT.—Not later than 3 years after the date of enactment of this section, the Commission shall establish and operate a Commission website.

“(e) MORTALITY REPORT.—Not later than 1 year after the date of enactment of this section, the Commission shall publish in the Federal Register a mortality report to be used under paragraphs (1) and (2).

“(f) NATIONAL OPIOID DEATH REGISTRY.—

“(1) IN GENERAL.—Not later than July 1, 2012, the Secretary, acting through the Administrator, shall establish a model Opioid Treatment Program Mortality Report to be used for reporting opioid deaths.

“(2) REQUIREMENT OF STATES THAT RECEIVE FUNDING FOR THE CONTROLLED SUBSTANCE MONITORING PROGRAM.—As a condition for receiving funds under section 399O, each State shall require that any individual who signs a death certificate where an opioid drug is detected in the body of the deceased, or where such drug is otherwise associated with the death, report such death to the Administrator by submitting a Model Opioid Treatment Program Mortality Report described in paragraph (1) of this subsection. Such report shall be submitted to the Administrator on or before the later of—

“(A) 90 days after the date of signing the death certificate; or

“(B) as soon as practicable after the date on which the necessary postmortem and toxicology reports become available to such individual, as required by the Secretary.

“(3) DEVELOPMENT.—The Administrator, in consultation with State and local medical examiners, prescribing physicians, hospitals, and any other organization that the Administrator determines appropriate, shall develop a Model Opioid Treatment Program Mortality Report to be used under paragraphs (1) and (2).

“(g) APPROPRIATIONS.—There is authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2013 through 2017.”

SEC. 1147. PRESCRIPTION MONITORING PROGRAM.

Section 399O of the Public Health Service Act (42 U.S.C. 299o–3) is amended—

“(1) in subsection (a)(1), by inserting ‘‘(including prescribers of methadone)’’ after ‘‘dispensers’’;

“(2) in subsection (e), by adding at the end the following:

“(f) Subject to the requirements of section 543, the State shall, at the request of a Federal, State, or local officer whose duties include enforcing laws on controlled substances, provide to such officer information from the database relating to an individual who is the subject of an active drug-related investigation conducted by the officer’s employing government entity.’’; and

“(3) by striking subsection (n) and inserting the following:

“(n) APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $25,000,000 for each of fiscal years 2013 through 2017.”

SEC. 1148. MORTALITY REPORTING.

Part A of title V of the Public Health Service Act (42 U.S.C. 299a et seq.), as amended by section 1142, is further amended by adding at the end of the following:

“SEC. 506E. MORTALITY REPORTING.

“(a) MODEL OPIOID TREATMENT PROGRAM MORTALITY REPORT.—

“(1) IN GENERAL.—Not later than July 1, 2012, the Secretary, acting through the Administrator, shall require that a Model Opioid Treatment Program Mortality Report be completed and submitted to the Administrator for each individual who dies while receiving treatment in an opioid treatment program.

“(2) REQUIREMENT OF STATES THAT RECEIVE FUNDING FOR THE CONTROLLED SUBSTANCE MONITORING PROGRAM.—As a condition for receiving funds, each State shall require that any individual who signs a death certificate where an opioid drug is detected in the body of the deceased, or where such drug is otherwise associated with the death, report such death to the Administrator by submitting a Model Opioid Treatment Program Mortality Report described in paragraph (1) of this subsection. Such report shall be submitted to the Administrator on or before the later of—

“(A) 90 days after the date of signing the death certificate; or

“(B) as soon as practicable after the date on which the necessary postmortem and toxicology reports become available to such individual, as required by the Secretary.

“(3) DEVELOPMENT.—The Administrator, in consultation with State and local medical examiners, prescribing physicians, hospitals, and any other organization that the Administrator determines appropriate, shall develop a Model Opioid Treatment Program Mortality Report to be used under paragraphs (1) and (2).

“(4) NATIONAL OPIOID DEATH REGISTRY.—

“(1) IN GENERAL.—Not later than July 1, 2012, the Administrator shall establish and implement, through the National Center for Health Statistics, a National Opioid Death Registry (referred to in this subsection as the ‘Registry’) to track opioid-related deaths and information related to such deaths.

“(2) CONSULTATION.—In establishing the uniform reporting criteria for the Registry, the Administrator, in consultation with the Centers for Disease Control and Prevention shall consult with the Administrator, State and local medical examiners, prescribing physicians, hospitals, and any other organization that the Director determines is appropriate for purposes of this subsection.

“(3) APPROPRIATIONS.—There is authorized to be appropriated...
SA 2120. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11 _ PROTECTIONS FOR THE COMMISIONED CORPS OF THE PUBLIC HEALTH SERVICE ACT AND THE NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION.

(a) COMMISSIONED CORPS OF THE PUBLIC HEALTH SERVICE ACT.—Section 221(a) of the Public Health Service Act (42 U.S.C. 212a(a)) is amended by adding at the end the following:

'(18) Section 1034, Protected Communications; Prohibition of Retaliatory Personnel Actions.'.

(b) NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION.—Section 251 of the National Oceanic and Atmospheric Administration Commissioned Officer Corps Act of 2002 (33 U.S.C. 3071(a)) is amended by adding at the end the following:

'(17) Section 1034, Protected Communications; Prohibition of Retaliatory Personnel Actions.'.

(c) CONFORMING AMENDMENT.—Section 221(b) of the Public Health Service Act (42 U.S.C. 212a(b)) is amended by adding at the end the following: ‘For purposes of paragraph (18) of subsection (a), the term ‘Inspector General’ in section 1034 of such title 10 shall mean the Inspector General of the Department of Health and Human Services.’.

SA 2121. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11 _ PROTECTIONS FOR THE COMMISSIONED CORPS OF THE PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—Section 221(a) of the Public Health Service Act (42 U.S.C. 212a(a)) is amended by adding at the end the following:

'(18) Section 1034, Protected Communications; Prohibition of Retaliatory Personnel Actions.'.

(b) CONFORMING AMENDMENT.—Section 221(b) of the Public Health Service Act (42 U.S.C. 212a(b)) is amended by adding at the end the following: ‘For purposes of paragraph (18) of subsection (a), the term ‘Inspector General’ in section 1034 of such title 10 shall mean the Inspector General of the Department of Health and Human Services.’.

SA 2122. Mr. HARKIN (for himself and Mr. ENZI) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ‘‘Food and Drug Administration Safety and Innovation Act’’.

SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.

(a) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents; references in Act.

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

TITLE II—FEES RELATING TO DEVICES
Sec. 201. Short title; findings.
Sec. 203. Authority to assess and use device fees.
Sec. 204. Reauthorization; reporting requirements.
Sec. 205. Savings clause.
Sec. 206. Effective date.
Sec. 207. Sunset dates.
Sec. 208. Streamlined hiring authority to support activities related to the process for the review of device applications.

TITLE III—FEES RELATING TO GENERIC DRUGS
Sec. 301. Short title.
Sec. 302. Authority to assess and use human generic drug fees.
Sec. 303. Reauthorization; reporting requirements.
Sec. 304. Sunset dates.
Sec. 305. Effective date.
Sec. 306. Amendment with respect to misbranding.
Sec. 307. Streamlined hiring authority of the Food and Drug Administration to support activities related to human generic drugs.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS
Sec. 401. Short title; finding.
Sec. 402. Fees relating to biosimilar biological products.
Sec. 403. Reauthorization; reporting requirements.
Sec. 404. Sunset dates.
Sec. 405. Effective date.
Sec. 406. Savings clause.
Sec. 407. Conforming amendment.

TITLE V—PEDIATRIC DRUGS AND DEVICES
Sec. 501. Permanent.
Sec. 502. Written requests.
Sec. 503. Communication with Pediatric Review Committee.
Sec. 504. Access to data.
Sec. 505. Ensuring the completion of pediatric studies.
Sec. 506. Pediatric study plans.
Sec. 507. Reauthorizations.
Sec. 508. Report.
Sec. 509. Technical amendments.
Sec. 510. Relationship between pediatric labeling and new clinical investigation exclusivity.

TITLE VI—MEDICAL DEVICE REGULATORY IMPROVEMENTS
Sec. 601. Reclassification procedures.
Sec. 602. Condition of approval studies.
Sec. 603. Postmarket surveillance.
Sec. 101. Drug shortages.

Subtitle XI—OTHER PROVISIONS

Sec. 1134. Online pharmacy report to Congress.

Sec. 1132. Patient participation in medical research.

Sec. 1131. Drug development and testing.

Sec. 1124. Combating prescription drug abuse.

Sec. 1123. Electronic submission of applications.

Sec. 1122. Tanning bed labeling.

Sec. 1121. Information technology.

Sec. 1120. Reporting requirements.

Sec. 1119. Affordable medical product plan.

Sec. 1118. Applicability.

Sec. 1117. Regulations.

Sec. 1116. Accreditation of third-party auditors for drug establishments.

Sec. 1115. Standards for admission of imported drugs.

Sec. 1114. Notification.

Sec. 1113. Protection against intentional adulteration.

Sec. 1112. Extraterritorial jurisdiction.

Sec. 1111. Compliance with international agreements.

Subtitle B—Pharmaceutical Distribution Integrity

Sec. 724. Short title.

Sec. 723. Securing the pharmaceutical distribution supply chain.

TITLE VII—DRUG SUPPLY CHAIN

Subtitle A—Drug Supply Chain

Sec. 701. Registration of domestic drug establishments.

Sec. 702. Registration of foreign establishments.

Sec. 703. Identification of drug excipient information with product listing.

Sec. 704. Electronic system for registration and listing.

Sec. 705. Risk-based inspection frequency.

Sec. 706. Records for inspection.

Sec. 707. Failure to allow on-site inspection.

Sec. 708. Exchange of information.

Sec. 709. Enhancing the safety and quality of the drug supply.

Sec. 710. Accreditation of third-party auditors for drug establishments.

Sec. 711. Standards for admission of imported drugs.

Sec. 712. Notification.

Sec. 713. Protection against intentional adulteration.

Sec. 714. Extraterritorial criminal penalty for counterfeiting drug.

Sec. 715. Extraterritorial jurisdiction.

Sec. 716. Compliance with international agreements.

Sec. 717. Standards for importing orphan drugs.

Sec. 718. Notification.

Sec. 719. Protection against intentional adulteration.

Sec. 720. Protection against intentional adulteration.

Sec. 721. Short title.

Sec. 722. Securing the pharmaceutical distribution supply chain.

Sec. 723. Registration of domestic drug establishments.

Sec. 724. Registration of foreign establishments.

Sec. 725. Identification of drug excipient information with product listing.

Sec. 726. Electronic system for registration and listing.

Sec. 727. Risk-based inspection frequency.

Sec. 728. Records for inspection.

Sec. 729. Failure to allow on-site inspection.

Sec. 730. Exchange of information.

Sec. 731. Enhancing the safety and quality of the drug supply.

Sec. 732. Accreditation of third-party auditors for drug establishments.

Sec. 733. Standards for admission of imported drugs.

Sec. 734. Notification.

Sec. 735. Protection against intentional adulteration.

Sec. 736. Extraterritorial criminal penalty for counterfeiting drug.

Sec. 737. Extraterritorial jurisdiction.

Sec. 738. Compliance with international agreements.

Sec. 739. Standards for importing orphan drugs.

Sec. 740. Notification.

Sec. 741. Protection against intentional adulteration.

Sec. 742. Protection against intentional adulteration.

Sec. 743. Short title.

Sec. 744. Securing the pharmaceutical distribution supply chain.

Sec. 745. Registration of domestic drug establishments.

Sec. 746. Registration of foreign establishments.

Sec. 747. Identification of drug excipient information with product listing.

Sec. 748. Electronic system for registration and listing.

Sec. 749. Risk-based inspection frequency.

Sec. 750. Records for inspection.

Sec. 751. Failure to allow on-site inspection.

Sec. 752. Exchange of information.

Sec. 753. Enhancing the safety and quality of the drug supply.

Sec. 754. Accreditation of third-party auditors for drug establishments.

Sec. 755. Standards for admission of imported drugs.

Sec. 756. Notification.

Sec. 757. Protection against intentional adulteration.

Sec. 758. Extraterritorial criminal penalty for counterfeiting drug.

Sec. 759. Extraterritorial jurisdiction.

Sec. 760. Compliance with international agreements.

Sec. 761. Standards for importing orphan drugs.

Sec. 762. Notification.

Sec. 763. Protection against intentional adulteration.

Sec. 764. Protection against intentional adulteration.

Sec. 765. Short title.

Sec. 766. Securing the pharmaceutical distribution supply chain.

Sec. 767. Registration of domestic drug establishments.

Sec. 768. Registration of foreign establishments.

Sec. 769. Identification of drug excipient information with product listing.

Sec. 770. Electronic system for registration and listing.

Sec. 771. Risk-based inspection frequency.

Sec. 772. Records for inspection.

Sec. 773. Failure to allow on-site inspection.

Sec. 774. Exchange of information.

Sec. 775. Enhancing the safety and quality of the drug supply.

Sec. 776. Accreditation of third-party auditors for drug establishments.

Sec. 777. Standards for admission of imported drugs.

Sec. 778. Notification.

Sec. 779. Protection against intentional adulteration.

Sec. 780. Extraterritorial criminal penalty for counterfeiting drug.

Sec. 781. Extraterritorial jurisdiction.

Sec. 782. Compliance with international agreements.

Sec. 783. Standards for importing orphan drugs.

Sec. 784. Notification.

Sec. 785. Protection against intentional adulteration.

Sec. 786. Protection against intentional adulteration.
‘‘(B) WORKLOAD ADJUSTMENT.—Subject to subparagraph (C), the workload adjustment for fiscal year 2013 shall be—

(i) $652,709,000 plus the amount of the inflation adjustment calculated under subparagraph (A), multiplied by

(ii) the amount (if any) by which a percentage workload adjustment for fiscal year 2013, determined by the methodology described in section (c)(2)(A), would exceed the percentage workload adjustment (as so determined) for fiscal year 2012, if both such adjustments were calculated using the 5-year base period consisting of fiscal years 2003 through 2007.

(C) LIMITATION.—Under no circumstances shall the adjustment result in fee revenues for fiscal year 2013 that are less than the sum of the amount under paragraph (1)(A) and the amount under paragraph (1)(B).

(3) by striking subsection (c) and inserting the following:

‘‘(c) ADJUSTMENTS.—

‘‘(1) INFLATION ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by an amount equal to the sum of—

(A) one;

(B) the average annual percent change in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(b)(6)) for the first 3 years of the preceding 4 fiscal years; and

(C) the average annual percent change that the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data, multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(b)(6)) for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year under this paragraph shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this paragraph.

‘‘(2) WORKLOAD ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, after the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of human drug applications. With respect to such adjustment:

(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish under paragraph (1)(A), using the methodology described in this subparagraph), efficacy supplements, and manufacturing supplements submitted to the Secretary, and the change in the total number of the commercial investigational new drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish under paragraph (1)(A), using the methodology described in this subparagraph) for the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the sum of the amount under subsection (b)(1)(A) and the amount under subsection (b)(1)(B), as adjusted for inflation under paragraph (1).

‘‘(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2017, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1) and (2), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of fiscal year 2018. Before making such an adjustment, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2017. If the Secretary has carryover balances for such process in excess of 3 months of such operating reserves, the adjustment under this paragraph shall not be made.

‘‘(4) ADJUSTMENTS TO FEES.—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 adjustment fees under subsection (b), based on the revenue amounts established under subsection (b) and the adjustments provided under this paragraph.

‘‘(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs reasonably allocated for the process for the review of human drug applications.

(iv) by striking ‘‘fees authorized’’ and inserting ‘‘Subject to paragraph (2)(C), fees authorized’’; and

(v) in paragraph (2)(C), fees authorized’’;

(B) in paragraph (2)—

(i) in subparagraph (A)—

(I) in clause (i), by striking ‘‘shall be retained’’ and inserting ‘‘subject to subparagraph (C), shall be collected and available’’; and

(II) in clause (ii), by striking ‘‘shall only be collected and available’’ and inserting ‘‘shall be available’’;

and

(vi) by adding at the end the following new subparagraph:

‘‘(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year that begins after October 1, 2012, may be made by the Secretary in accordance with authority provided in title II of the Prescription Drug User Fee Amendments of 2012 (Public Law 112–57) and in the Senate a report concerning the progress of the Food and Drug Administration in meeting the goals identified in sections described in section 101(b) of the Prescription Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report under this subsection for a fiscal year shall include information on all previous cohorts for which the Secretary has not yet given a complete response on all human drug applications and supplements in the cohort.’’;

(2) in subsection (b), by striking ‘‘2008’’ and inserting ‘‘2009’’;

(3) in subsection (d), by striking ‘‘2012’’ each place it appears and inserting ‘‘2017’’.

SEC. 105. SUNSET DATES.

(a) AUTHORIZATION.—Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g; 379h) shall cease to be effective on October 1, 2017.


(c) TECHNICAL CLARIFICATIONS.—

(1) Effective September 30, 2007, section 509 of the Prescription Drug User Fee Amendments of 2002 (Public Law 107–188) is repealed.


SEC. 106. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later.

Notwithstanding the amendments made by this title, section 727 of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the date before the date of the enactment of this Act.
SEC. 202. DEFINITIONS.

Section 737 (21 U.S.C. 379l) is amended—

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

(2) in paragraph (10), by striking "October 2001" and inserting "October 2011"; and

(3) in paragraph (13), by striking "is required to register and all that follow through the end of paragraph (13) and inserting the following: "is registered (or is required to register) with the Secretary under section 510 because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device.

SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—Section 738(a) (21 U.S.C. 379j(a)) is amended—

(1) in paragraph (1), by striking "fiscal year 2008" and inserting "fiscal year 2015";

(2) in paragraph (2)(A)—

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

(i) by striking "subsections (d) and (e)" and inserting "subsections (d), (e), and (f)";

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

(B) in clause (viii), by striking "1.84" and inserting "2.64";

(3) DURATION.—The authority provided by this subsection terminates October 1, 2017.''

SEC. 204. APPLICATIONS AND SUPPLEMENTS.

(a) IN GENERAL.—Subject to subsections (c) and (d), the Secretary, in the Secretary's sole discretion, may authorize a waiver or reduction of fees under subsection (a) if the Secretary finds that such waiver or reduction is in the interest of public health.

SEC. 205. DURATION.—The authority provided by this subsection terminates October 1, 2017.''

(b) FEE WAIVER OR REDUCTION.—Section 738 (21 U.S.C. 379j) is amended to read as follows:

'(d) FEE WAIVER OR REDUCTION.—

'(1) FEE WAIVER OR REDUCTION.—

'(i) IN GENERAL.—The Secretary may, at the Secretary's sole discretion, grant a waiver or reduction of fees under subsection (a), if the Secretary finds that such waiver or reduction is in the interest of public health.

'(ii) LIMITATION.—The sum of all fee waivers or reductions granted by the Secretary in any fiscal year under paragraph (1) shall not exceed 2 percent of the total fee revenue amounts established for such year under subsection (c).

'(iii) DURATION.—The authority provided by this subsection terminates October 1, 2017.''

(c) CONDITIONS.—Section 738(h)(1)(A) (21 U.S.C. 379j(h)(1)(A)), as redesignated by subsection (d)(1), is amended—

'(4) CREDITING AND AVAILABILITY OF FEES.—

'(a) IN GENERAL.—The applicable inflation adjustment for a fiscal year shall be equal to 1.04, multiplied by the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All Items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by 0.60.

'(b) EFFECTIVE DATES.—

'(1) in paragraph (1), by striking "fiscal year 2002" and inserting "fiscal year 2003";

'(2) in paragraph (2), by striking "fiscal year 2003" and inserting "fiscal year 2008"; and

'(3) in paragraph (3)—

(A) in subparagraph (A)—

(i) by inserting "and subsection (f)" after "subsection (b)"; and

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

(B) in subparagraph (C), by striking "initial registration" and all that follows through "section 510." and inserting "later of—

'(i) the initial or annual registration (as applicable) of the establishment under section 510 or—

'(ii) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

(b) FEE AMOUNTS.—Section 738(h)(1)(B) (21 U.S.C. 379j(h)(1)(B)) is amended to read as follows:

'(b) FEE AMOUNTS.—

'(1) FEE WAIVER OR REDUCTION.—

'(A) IN GENERAL.—Subject to subsections (c), (d), (e), and (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:

Fiscal Year 2013 Fiscal Year 2014 Fiscal Year 2015 Fiscal Year 2016 Fiscal Year 2017

Table:

<table>
<thead>
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<th>Premarket Application</th>
<th>$248,000</th>
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<th>$258,019</th>
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<td>$3,200</td>
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<td>$3,872</td>
</tr>
</tbody>
</table>

'(c) INFLATION ADJUSTMENTS.—

'(1) ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—The applicable inflation adjustment for a fiscal year is—

'(I) the average annual percent change in the Consumer Price Index for all urban consumers (Washington, D.C.—Baltimore, Md.—Va.—W.Va.—Not Seasonally Adjusted; All Items; Annual Index) for the first 3 years of the preceding 4 years of available data, multiplied by 0.60; and

'(II) the average annual percent change in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All Items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by 0.40.

'(2) ADJUSTMENT TO BASE FEE AMOUNTS.—For each of fiscal years 2014 through 2017, the base fee amounts specified in subsection (b)(3) shall be adjusted as needed, on a uniform proportionate basis, to generate the total revenue amounts under subsection (b)(3), as adjusted for inflation under paragraph (3).

'(3) VOLUME-BASED ADJUSTMENTS TO ESTABLISHMENT REGISTRATION BASE FEES.—For each of fiscal years 2014 through 2017, after the base establishment fee amounts specified in subsection (b)(2) shall be adjusted under paragraph (2)(D), the base establishment registration fee amounts specified in such subsection shall be further adjusted, as the Secretary determines, in order for total fee collections for such fiscal year to generate the total revenue amounts, as adjusted under paragraph (2).'

'(d) FEE WAIVER OR REDUCTION.—

'(1) FEE WAIVER OR REDUCTION.—

'(i) IN GENERAL.—The Secretary may, at the Secretary's sole discretion, grant a waiver or reduction of fees under subsection (a), if the Secretary finds that such waiver or reduction is in the interest of public health.

'(ii) LIMITATION.—The sum of all fee waivers or reductions granted by the Secretary in any fiscal year under paragraph (1) shall not exceed 2 percent of the total fee revenue amounts established for such year under subsection (c).

'(iii) DURATION.—The authority provided by this subsection terminates October 1, 2017.'
“(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act;”;

(3) by amending paragraph (3) to read as follows:

“(3) AUTHORIZATIONS OF APPROPRIATIONS.—

For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for each fiscal year, as adjusted under subsection (c) and, for fiscal year 2017 only, further adjusted under paragraph (4),—

(A) by striking “fiscal years 2008, 2009, and 2010” and inserting “fiscal years 2013, 2014, and 2015”;

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

(C) by striking “June 30, 2011” and inserting “June 30, 2016”;

(D) by striking “the amount of fees specified in aggregate in” and inserting “the cumulative amount appropriated pursuant to”;

(E) by striking “aggregate amount in” before “excess shall be credited”; and

(F) by striking “fiscal year 2012” and inserting “fiscal year 2017”;

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

SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) REAUTHORIZATION.—Section 738A(b)(21 U.S.C. 739j–1(2)) is amended—

(1) in paragraph (1), by striking “2012” and inserting “2017”;

(2) in paragraph (2), by striking “2012” and inserting “2017”;

(b) REPORTS.—Section 738A(a) (21 U.S.C. 739j–1(a)) is amended—

(1) by striking “2008 through 2012” each place it appears and inserting “2013 through 2017”;

(2) by striking “section 201(c) of the Food and Drug Administration Amendments Act of 2002 (42 U.S.C. 282m)” and inserting “section 201(c) of the Medical Device User Fee Amendments of 2012”;

SEC. 205. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, the chapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to submissions described in section 738(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (as in effect as of such day) that are submitted on or after October 1, 2012, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required under such part for a fiscal year prior to fiscal year 2013.

SEC. 206. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for submissions described in section 738(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act received on or after October 1, 2012, regardless of the date of the enactment of this Act.

SEC. 207. SUNSET DATES.

(a) The titles—Sections 737 and 738 (21 U.S.C. 737; 739j–1) 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 201 of the Medical Device User Fee Amendments of 2007 (Title II of Public Law 110–85) is repealed.

SEC. 208. STREAMLINED HIRING AUTHORITY TO SUPPORT ACTIVITIES RELATED TO THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS.

Subchapter C (21 U.S.C. 371 et seq.) is amended by inserting after section 713 the following new section:

“SEC. 714. STREAMLINED HIRING AUTHORITY.

(a) IN GENERAL.—In addition to any other personnel authorized 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 are with respect to the activities under subsection (b), the goals referred to in section 738A(a)(1).

(d) TECHNICAL CLARIFICATION.—Effective September 7, 2007, section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) is repealed.

SEC. 209. AUTHORITY TO ASSOCIATE WITH HUMAN GENETIC DRUGS.

Subchapter C (21 U.S.C. 371 et seq.) is amended by adding, by adding at the end the following:

“PART 7—FEES RELATING TO GENERIC DRUGS

SEC. 744A. DEFINITIONS.

(For purposes of this part:

(1) The term ‘abbreviated new drug application’—

(A) means an application submitted under section 505(j), an abbreviated application submitted under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act) or an abbreviated new drug application submitted pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984; and

(B) does not include an application for a positron emission tomography drug.

(2) The term ‘active pharmaceutical ingredient’ means—

(A) a substance, or a mixture when the substance is unstable or cannot be transposed on its own, intended—

(i) to be used as a component of a drug; and

(ii) to furnish pharmacological activity or other direct effect in the diagnosis, care, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body;

(B) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture described in subparagraph (A).

(3) The term ‘adjustment factor’ means a factor applicable to a fiscal year that is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such index for October 2011.

(A) The term ‘affiliated business’ means an entity that has a relationship with a second business entity if, directly or indirectly—

(i) one business entity controls, or has power to control, the other business entity;

or

(ii) a third party controls, or has power to control, both of the business entities.

(B) The term ‘affiliated business’ means an entity whose only manufacturing or processing activities are one or more of the following: repackaging, relabeling, or testing.

(B) For purposes of subparagraph (A), separate buildings within close proximity are considered to be at one geographic location or address if the activities in them are—

(i) closely related to the same business enterprise;

(ii) under the supervision of the same local management; and

(iii) capable of being inspected by the Food and Drug Administration during a single inspection.

(C) If a business or other entity would meet the definition of a facility under this paragraph but for being under multiple management or ownership, the business or other entity is deemed to constitute multiple facilities, one per management entity, for purposes of this paragraph.

(5) The term ‘finished dosage form’ means—

(A) a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;

(B) a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or

(C) any combination of an active pharmaceutical ingredient with another component of a drug product for purposes of production of a drug product described in subparagraph (A) or (B).

(7) The term ‘generic drug submission’ means an application for an abbreviated new drug application, an amendment to an abbreviated new drug application, or a prior approval supplement to an abbreviated new drug application.

(8) The term ‘human genetic drug activities’ means the following activities of the Secretary associated with generic drugs and...
inspection of facilities associated with generic drugs.

(1) The activities necessary for the review of generic drug submissions, including review of active pharmaceutical ingredient drug master files referenced in such submissions; and

(2) The issuance of—

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

(ii) complete response letters which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

(c) The issuance of letters related to Type II active pharmaceutical drug master files which—

(i) set forth in detail the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies;

(ii) document that no deficiencies need to be addressed.

(d) Inspections related to generic drugs.

(e) Monitoring of research conducted in connection with the review of generic drug submissions and drug master files.

(f) Postmarket safety activities with respect to adverse-event data collection systems and information technology systems, including adverse event reports.

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

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

(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies) insofar as those activities relate to abbreviated new drug applications, and

(v) Carrying out section 505(k)(5)(6) (relating to adverse-event reports and postmarket safety activities).

(f) Postmarket safety activities with respect to the receipt of postmarket safety information on approved drugs, including adverse event reports.

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

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

(3) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies) insofar as those activities relate to abbreviated new drug applications, and

(v) Carrying out section 505(k)(5)(6) (relating to adverse-event reports and postmarket safety activities).

(g) Pharmaceutical science activities related to generic drugs.

(9) The term ‘postion emission tomography drug’ has the meaning given to the term ‘postion emission tomography drug’ in section 201(ii), except that paragraph (1)(B) of such section shall not apply.

(10) The term ‘prior approval supplement’ means a request to the Secretary to approve a change in the drug substance, drug product, production process, quality controls, equipment, or facilities covered by an approved abbreviated new drug application when that change has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

(11) The term ‘resources allocated for human generic drug activities’ means the expenses for—

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

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

(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 drug substance in support of approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.

SEC. 744B. AUTHORITY TO ASSesses AND USE HUMAN GENERIC DRUG FEES.

(a) TYPES OF FEES.—Beginning in fiscal year 2013, the Secretary may assess and collect fees in accordance with this section as follows:

(1) ONE-TIME BACKLOG FEE FOR APPROVED 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 FEES AMOUNT CALCULATION.—The amount of each one-time backlog fee shall be calculated by dividing $50,000,000 by the total number of abbreviated new drug applications pending on October 1, 2012, that have not received a tentative approval as of that date.

(C) NOTICE.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the fee required by subparagraph (A).

(D) FEE DUE DATE.—The fee required by subparagraph (A) shall be due no later than 30 calendar days after the date of the publication of the notice specified in subparagraph (C).

(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 the date of publication of a Type II active pharmaceutical ingredient drug master file by the Secretary considers not to have been received shall be subject to a drug master file fee.

(B) ONE-TIME PAYMENT.—If a person has paid a Type II active pharmaceutical ingredient drug master file fee on or before the date of publication of a Type II active pharmaceutical ingredient drug master file is subsequently referenced in generic drug submissions.

(C) NOTICE.—

(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the fees under subparagraph (A) for fiscal year 2013.

(ii) FISCAL YEARS 2014 THROUGH 2017.—Not later than 60 days before the start of each 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.

(D) FEE DUE DATE.—

(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 fiscal years 2014 through 2017, the Secretary shall publish in the Federal Register the amount of the fees under subparagraphs (A) and (F) for such fiscal year.

(E) FEE DUE DATE.—

(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 such fiscal year.

(ii) FISCAL YEARS 2014 THROUGH 2017.—Not later than 60 days before the start of each fiscal years 2014 through 2017, the Secretary shall publish in the Federal Register the amount of the fees under subparagraphs (A) and (F) for such fiscal year.

(F) FEE DUE DATE.—

(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 fiscal years 2014 through 2017, the Secretary shall publish in the Federal Register the amount of the fees under subparagraphs (A) and (F) for such fiscal year.

(G) FEE DUE DATE.—

(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 fiscal years 2014 through 2017, the Secretary shall publish in the Federal Register the amount of the fees under subparagraphs (A) and (F) for such fiscal year.

(h) Type II active pharmaceutical ingredient drug master file fee has paid the fee required under subparagraph (A) within 20 calendar days after the applicable due date under subparagraph (E); and

(ii) the drug master file has not failed an inspection or completeness assessment conducted by the Secretary, in accordance with criteria to be published by the Secretary.

(iii) LIST.—The Secretary shall make publicly available on the Internet Site of the Food and Drug Administration a list of the drug master file numbers that correspond to drug master files that have successfully undergone an initial completeness assessment, in accordance with criteria to be published by the Secretary, and are available for reference.

(ii) FEE DUE DATE.—

(i) IN GENERAL.—Subject to clause (ii), a drug master file fee shall be due no later than the date on which the first generic drug submission is submitted that references the associated Type II active pharmaceutical ingredient drug master file.

(ii) LIMITATION.—No fee shall be due under subparagraph (A) for a fiscal year until the later of—

(i) 30 calendar days after publication of the notice provided for in clause (i); and

(ii) Fiscal year 2013.

(iii) 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.

(iv) 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 subparagraphs (A) and (F) for such fiscal year.

(v) FEE DUE DATE.—

(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 such fiscal year.

(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 subparagraphs (A) and (F) for such fiscal year.

(i) 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); and

(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 the submission of the appropriation or prior approval supplement for which the fees are due, 30 calendar days after the date that such an appropriation is enacted.

(v) FEE DUE DATE.—

(i) IN GENERAL.—Subject to clause (ii), a drug master file fee shall be due no later than the date on which the first generic drug submission is submitted that references the associated Type II active pharmaceutical ingredient drug master file.

(ii) LIMITATION.—No fee shall be due under subparagraph (A) for a fiscal year until the later of—

(i) 30 calendar days after publication of the notice provided for in clause (i); and

(ii) Fiscal year 2013.

(iii) 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.

(iv) 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 subparagraphs (A) and (F) for such fiscal year.
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May 21, 2012

‘‘(E) FEE FOR AN APPLICATION THE SECRETARY CONSIDERS NOT TO HAVE BEEN RECEIVED, OR THAT HAS BEEN WITHDRAWN.—An abbreviated new drug application or prior approval application the Secretary considers not to have been received, or that has been withdrawn, shall, upon resubmission of an application or a subsequent submission following the applicant’s withdrawal of the application, be subject to a full fee under subparagraph (A).’’

‘‘(F) FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

‘‘(A) IN GENERAL.—Facilities identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce a finished dosage form of a human generic drug or an active pharmaceutical ingredient contained in a human generic drug shall be subject to fees as follows:

‘‘(i) GENERIC DRUG FACILITY.—Each person that owns a facility which is identified or intended to be identified, in at least one generic drug submission that is pending or approved to produce one or more finished dosage forms of a human generic drug shall be assessed an annual fee for each such facility.

‘‘(ii) ACTIVE PHARMACEUTICAL INGREDIENT FACILITY.—Each person that owns a facility which produces, or which is pending review to produce, one or more active pharmaceutical ingredients identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce one or more finished dosage forms subject to clauses (i) or (ii) shall be subject to fees under such clauses for that facility.

‘‘(B) FEE DUE DATE.—

‘‘(i) FISCAL YEAR 2013.—For fiscal year 2013, the Secretary shall publish in the Federal Register a notice announcing the amount of the fee provided for in subparagraph (A) within the timeframe specified in subsection (d)(1)(B).

‘‘(ii) FISCAL YEARS 2014 THROUGH 2017.—With- in the timeframe specified in subsection (d)(1), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

‘‘(D) FEE DUE DATE.—

‘‘(i) FISCAL YEAR 2013.—For fiscal year 2013, the fees under subparagraph (A) shall be due on the later of

‘‘(i) not later than 45 days after the publication of the notice under subparagraph (B); or

‘‘(ii) if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of the publication of such notice, 30 days after the date that such an appropriations Act is enacted.

‘‘(ii) FISCAL YEARS 2014 THROUGH 2017.—For each of fiscal years 2014 through 2017, the fees under subparagraph (A) for such fiscal year shall be due on or before the end of the first business day on or after October 1 of each such year; or

‘‘(B) FEE REVENUE AMOUNTS.—

‘‘(1) IN GENERAL.—

‘‘(A) FISCAL YEAR 2013.—For fiscal year 2013, fees under subsection (a) shall be estimated to generate a total estimated revenue amount under subsection (a)(1) of $254,000,000.

‘‘(b) FEE REVENUE AMOUNTS.—

‘‘(1) IN GENERAL.—

‘‘(A) FISCAL YEAR 2013.—For fiscal year 2013, fees under subsection (a) shall be estimated to generate a total estimated revenue amount under subsection (a)(1) of $254,000,000.

‘‘(B) FISCAL YEARS 2014 THROUGH 2017.—For each of fiscal years 2014 through 2017, fees under subsection (a) shall be estimated to generate a total estimated revenue amount under subsection (a)(1) of $259,000,000, as adjusted pursuant to subsection (c).

‘‘(C) FISCAL YEAR 2018.—For fiscal year 2018, fees under subsection (a) shall be estimated to generate a total estimated revenue amount under subsection (a)(1) of $264,000,000, as adjusted pursuant to subsection (c).

‘‘(D) FISCAL YEARS 2019 THROUGH 2021.—For each of fiscal years 2019 through 2021, fees under subsection (a) shall be estimated to generate a total estimated revenue amount under subsection (a)(1) of $270,000,000, as adjusted pursuant to subsection (c).
‘(A) IN GENERAL.—Any person that owns or operates a site or organization described in subparagraph (B) shall submit to the Secretary information concerning the owner or operator, name, and address of the site or organization.

‘(B) SITES AND ORGANIZATIONS.—A site or organization is described in this subparagraph if it is identified in a generic drug submission and is—

‘(i) a site in which a bioanalytical study is conducted;

‘(ii) a clinical research organization;

‘(iii) a contract analytical testing site; or

‘(iv) a contract repackager site.

‘(C) NOTICE.—The Secretary may, by notice published in the Federal Register, specify the means and format for submission of the information under subparagraph (A) and may specify, as necessary for purposes of this section, any additional information to be submitted.

‘(D) INSPECTION AUTHORITY.—The Secretary, by a letter authorizing an inspection, a Type 704(a)(1) shall extend to all such sites and organizations.

‘(e) 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 or operates the drug application subject to that fee on an arrears list, such that no new abbreviated new drug application or supplement submitted on or after October 1 of that year, any affiliate of that person, will be received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

‘(2) DRUG MASTER FILE FEE.—

‘(A) Failure to pay the fee under subsection (a)(2) within 20 calendar days after the applicable due date under subparagraph (B) of a submission described in subsection (a)(2)(D)(ii)(I) shall result in the Type II active pharmaceutical ingredient drug master file not being deemed available for reference.

‘(B) Any generic drug submission submitted on or after October 1, 2012, that references a Type II active pharmaceutical ingredient drug master file that has not been deemed available for reference shall not be received within the meaning of section 505(j)(5)(A) unless the condition specified in clause (ii) is met.

‘(ii) The condition specified in this clause is that the fee established under subsection (a)(2) is paid or the facility is removed from all generic drug submissions that refer to the facility.

‘(f) NONRECEIVAL FOR NONPAYMENT.—

‘(1) NOTICE.—If an abbreviated new drug application or supplement to an abbreviated new drug application submitted on or after October 1, 2012, references a facility for which a facility fee has not been paid by the applicable date under subsection (a)(4)(C), the Secretary shall notify the sponsor of the new drug application submitted on or after October 1, 2012, that the newly submitted new drug application shall not be received within the meaning of section 505(j)(5)(A).

‘(2) LIMITATIONS.

‘(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2012, unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year involved.

 ‘(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year and if at a later date in such fiscal year the Secretary determines that fees should be assessed, the Secretary may accept and collect such fees, without any modification in the rate, for Type II active pharmaceutical ingredient drug master files, abbreviated new drug applications and prior approval supplements, and generic drug facilities and active pharmaceutical ingredient facilities that is assessed, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.
FEES.—

(1) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation in the amounts specified in this section.

(2) COLLECTIONS AND APPROPRIATIONS ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) subject to subparagraphs (C) and (D), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

(ii) shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of human generic drug activities (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activities), only if the Assistant Secretary allocates for such purpose an amount for such fiscal year (after fiscal year 2012) to defray the costs of human generic drug activities.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (a)(2) in any fiscal year if the Secretary allocates for such purpose an amount for such fiscal year (after fiscal year 2012) to defray the costs of human generic drug activities.

(C) FER COLLECTION DURING FIRST PROGRAM YEAR.—Until the end 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 beginning after fiscal year 2013, prior to the due date for such fees, may be accepted by the Secretary if the amount paid under this provision within the time period specified in subsection (g) shall be deemed not to have been substantially complete on the date of its submission solely because of failure to pay an applicable fee under the preceding sentence shall be deemed substantially complete and received within the meaning of subsection (h)(5)(B)(i)(II)(cc). An abbreviated new drug application that is not substantially complete on the date of its submission solely because of failure to pay an applicable fee under the preceding sentence shall be deemed substantially complete and received within the meaning of subsection (h)(5)(B)(i)(II)(cc).

SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 7 of subchapter C of chapter VII, as added by section 745C, is amended by inserting after section 744B the following:

"SEC. 744C. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives a report concerning the progress of the Food and Drug Administration's Internet Web site for human generic drug activities.

(b) FISCAL REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives a report concerning the progress of the Food and Drug Administration's Internet Web site for human generic drug activities.

(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(d) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations under subsection (b), the Secretary shall consult with the Congress with respect to the goals, and plans for meeting the goals, for human generic drug activities for the first 5 fiscal years after fiscal year 2013, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

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

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

(C) representatives of scientific and academic experts;

(D) health care professionals;

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

(F) the generic drug industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the generic drug industry, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

(D) publish the comments on the Food and Drug Administration's Internet Web site.

(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the generic drug industry, the Secretary shall—

(A) hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2);

(B) consult with representatives of the generic drug industry, the Secretary shall—

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

(B) publish such recommendations in the Federal Register;

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

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

(E) after consideration of such public views, transmit to Congress the recommendations developed under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the generic drug industry, the Secretary shall—

(A) publish a notice in the Federal Register, including specific suggestions for changes to the goals referred to in subsection (b), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(6) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—Before presenting to Congress the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall publicly available on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the generic drug industry.

(B) CONTENT.—The minutes described under subparagraph (A) shall include any substantive proposal made by any party to the negotiations as well as substantive changes, any controversial or differences of opinion during the negotiations and their resolution.

SEC. 304. SUNSET DATES.

Notes.—The amendments made by section 302 cease to be effective October 1, 2017.


(b) REPORTING REQUIREMENTS.—The amendments made by section 303 cease to be effective January 31, 2018.

SEC. 305. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this title, whichever is later, except that fees under section 302 shall be assessed for all human generic drug submissions after October 1, 2012, regardless of the date of enactment of this title.

SEC. 306. AMENDMENT WITH RESPECT TO MISBRANDING.

Section 502 (21 U.S.C. 352) is amended by adding at the end the following:

"(aa) 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 744H(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 "activities" and inserting "activities and-

"(1) activities";

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

and"; and

(C) by adding at the end the following:

"(2) activities under this Act related to human generic drug activities (as defined in section 744A.); and

(2) by amending subsection (c) to read as follows:

"(c) OBJECTIVES SPECIFIED.—The objectives specified in this subsection are—

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

(2) with respect to the activities under subsection (b)(2), the per diem fee approved for activities with respect to section 744A (regarding assessment and use of human generic drug fees), as set forth in the letters described in section 301(b) of the Generic User Fee Amendment of 2012."

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 401. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the "Biosimilar User Fee Act of 2012".

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 402. FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS.

Subchapter C of chapter VII (21 U.S.C. 379f et seq.) of the Federal Food, Drug, and Cosmetic Act, as added by title III of this Act, the following:

"PART 8—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 744G. DEFINITIONS.

For purposes of this part:

(1) the term 'adjustment factor' applicable to 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;

(B) a third party controls, or has power to control, both of the business entities.

(3) the term 'biosimilar biological product' means a product for which a biosimilar biological product application has been approved.

(4)(A) Subject to subparagraph (B), the term 'biosimilar biological product application' means an application for licensure of a biological product under section 351(k) of the Public Health Service Act.

(B) Such term does not include—

(i) a supplement to such an application;

(ii) an application filed under section 351(k) of the Public Health Service Act that cites as the reference biologic a blood product for topical application licensed before September 1, 1992, or a large volume parenteral drug product approved before such date;

(iii) an application filed under section 351(k) of the Public Health Service Act with respect to—

(D) 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 developmental plan, including a proposed design for, or data from, a study intended to support a biosimilar biological product application.

(6) The term 'biosimilar biological product development program' means the program under this part for expediting the process for the review of submissions in connection with biosimilar biological product development.

(7)(A) The term 'biosimilar biological product establishment' means a foreign or domestic place of business—

(i) that is at one general physical location consisting of one or more buildings, all of which are within five miles of each other; and

(ii) at which one or more biosimilar biological products are manufactured in final dosage form.

(B) The purposes of subparagraph (A)(i), the term 'manufactured' does not include packaging.

(8) The term 'biosimilar initial advisory meeting' means—

(A) 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

(9) The term 'costs of resources allocated for the process for the review of biosimilar biological product applications' means the costs in connection with the process for the review of biosimilar biological product applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers and employees and 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 to such biosimilar biological product applications.

(10) The term 'final dosage form' means, with respect to a biosimilar biological product, a finished dosage form which is approved for administration to a patient without subsequent further processing, such as lyophilized products before reconstitution.

(11) The term 'financial hold'—

(A) means an order issued by the Secretary to prohibit the sponsor of a clinical investigation from continuing the investigation if the Secretary determines that the investigation is intended to support a biosimilar biological product application and the sponsor has failed to pay any fee for the product required under subparagraph (A), (B), or (D) of section 744H(a)(1); and

(B) does not mean that any of the bases for a 'clinical hold' under section 505(i)(3) have been determined by the Secretary to exist concerning the investigation.

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

(13) The term 'process for the review of biosimilar biological product applications' means the following activities of the Secretary with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements to such biosimilar biological product applications:

(A) The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

(B) Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or which inform the sponsor of 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:

(ii) Collecting, developing, and reviewing safety information on biosimilar biological product applications or adverse-event reports.

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

(iv) Using improved analytical tools to assess potential safety problems, including access to external data bases.

(v) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(j)(2)(A) (relating to risk evaluation and mitigation strategies).

(vi) Carrying out section 505(k)(5) (relating to adverse-event reports and postmarket safety activities).

The term ‘supplement’ means a request to the Secretary to approve a change in a biosimilar biological product application.

The Secretary determines that the biosimilar biological product meets the standards for interchangeability.

SEC. 744I. 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 a biosimilar biological product development application on or before August 1 of the preceding fiscal year shall pay the initial biosimilar biological product development fee as required under subparagraph (C).

(ii) Meeting request.—The meeting request described in this clause is a request for a biosimilar biological product development meeting program.

(iii) Clinical protocol for IND.—A clinical protocol for an investigational new drug protocol described in this clause is a clinical protocol submitted with the provisions of section 505(i), including any regulations promulgated under section 505(i), (referred to in this section as ‘investigational new drug application’) describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for a product.

(iv) Due date.—The initial biosimilar biological product development fee shall be due by the earlier of the following:

(A) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

(B) The date of submission of an investigational new drug application that is equal to—

(1) the amount of the fee established for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued).

(2) The date of submission of an investigational new drug protocol described in subsection (i) (after the date on which such participation was discontinued) of an investigational new drug application that is equal to—

(A) a fee for a biosimilar biological product development program for the product (after the date on which such participation was discontinued) of—

(1) half of the amount of the fee established for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued).

(2) An amount equal to—

(A) the annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

(ii) No exception to investigational new drug applications.—Except in extraordinary circumstances, the Secretary shall not consider an investigational new drug application to have been received under section 505(i)(2) if—

(I) the Secretary determines that the investigational new drug application is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial annual biosimilar biological product development fee or the reactivation fee required under subparagraph (A) or (B), or a reactivation fee for the product as required under subparagraph (D).

(iii) Financial hold.—Notwithstanding section 505(i)(2), except in extraordinary circumstances, the Secretary shall prohibit the sponsor of a clinical investigation from continuing the investigation if—

(I) the Secretary determines that the investigational new drug application is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

(iv) No acceptance of biosimilar biological product applications or supplements.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), any biosimilar biological product application or supplement submitted by that person shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.

(v) Limits regarding biosimilar development program fees.—

(I) No refunds.—The Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or a reactivation fee paid under subparagraph (D).

(ii) No waivers, exemptions, or reductions.—The Secretary shall not grant a waiver, exemption, or any initial or annual biosimilar biological product development fee due or payable under subparagraph (A) or (B), or any reactivation fee due or payable under subparagraph (D), without first receiving an amount of fees owed by such person.

(vi) Biosimilar biological product application and supplement fees.—

(A) In general.—Each person that submits an application or supplement application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required, that is required to be collected under section 505(i)(2), except in extraordinary circumstances, shall be required to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting referring to the product for which fees are owed.

(ii) No receipt of investigational new drug applications.—Except in extraordinary circumstances, the Secretary shall not consider an investigational new drug application to have been received under section 505(i)(2) if—

(I) the Secretary determines that the investigational new drug application is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee or the reactivation fee required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

(iii) Financial hold.—Notwithstanding section 505(i)(2), except in extraordinary circumstances, the Secretary shall prohibit the sponsor of a clinical investigation from continuing the investigation if—

(I) the Secretary determines that the investigational new drug application is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

(iv) No acceptance of biosimilar biological product applications or supplements.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), any biosimilar biological product application or supplement submitted by that person shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.

(v) Limits regarding biosimilar development program fees.—

(I) No refunds.—The Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or a reactivation fee paid under subparagraph (D).

(ii) No waivers, exemptions, or reductions.—The Secretary shall not grant a waiver, exemption, or any initial or annual biosimilar biological product development fee due or payable under subparagraph (A) or (B), or any reactivation fee due or payable under subparagraph (D), without first receiving an amount of fees owed by such person.

(vi) Biosimilar biological product application and supplement fees.—

(A) In general.—Each person that submits an application or supplement application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required, that is required to be collected under section 505(i)(2), except in extraordinary circumstances, shall be required to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting referring to the product for which fees are owed.

(ii) No receipt of investigational new drug applications.—Except in extraordinary circumstances, the Secretary shall not consider an investigational new drug application to have been received under section 505(i)(2) if—

(I) the Secretary determines that the investigational new drug application is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee or the reactivation fee required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

(iii) Financial hold.—Notwithstanding section 505(i)(2), except in extraordinary circumstances, the Secretary shall prohibit the sponsor of a clinical investigation from continuing the investigation if—

(I) the Secretary determines that the investigational new drug application is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

(iv) No acceptance of biosimilar biological product applications or supplements.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), any biosimilar biological product application or supplement submitted by that person shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.
“(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 75 percent of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application.

(B) REDUCTION IN FEES.—Notwithstanding section 736(a)(1)(D) of the Food and Drug Administration Reorganization Act of 2012, any person who pays a fee under subparagraph (A), (B), (C), 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 establishment fee that may be assessed at the time when such biosimilar biological product application is submitted, by the cumulative amount of fees paid under subparagraphs (A), (B), (C), and (D) of paragraph (1) for that product.

(C) PAYMENT DUE DATE.—Any fee required by subparagraph (A) shall be due upon submission of the application or supplement for which such fee applies.

(D) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If a biosimilar biological product application or supplement was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn without a waiver for reasons other than the submission of a biosimilar biological product application or a supplement for the same product by the same person (or the person’s licensee or successor) shall not be subject to a fee under subparagraph (A).

(E) REFUND OF APPLICATION FEE IF APPLICATION REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under this paragraph for any application or supplement which was 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 is submitted by a person that paid the fee for such application or supplement, was accepted for filing, was not approved or was withdrawn without a waiver for reasons other than the submission of a biosimilar biological product application or a supplement for the same product by the same person (or the person’s licensee or successor) shall not be subject to a fee under subparagraph (A).

(G) FEES FOR APPLICATIONS SUBMITTED AFTER SUBMISSION OF A SIMILAR BIOLOGICAL PRODUCT.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a biosimilar biological product establishment fee has been assessed on the biosimilar biological product application—

(i) that did not manufacture the biosimilar biological product in the previous fiscal year; and

(ii) for which the full biosimilar biological product establishment fee has been assessed in the fiscal year at a time before manufacture of the biosimilar biological product was begun, the applicant shall not be assessed a share of the biosimilar biological product establishment fee for the fiscal year in which the manufacture of the product began.

(H) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—

(A) IN GENERAL.—Subject to paragraph (2), the Secretary shall, 60 days before the start of the fiscal year beginning on or after September 30, 2012, establish, for the next fiscal year, the fees under subsection (a), except as provided in subsection (c). If, after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section, the biosimilar biological product establishment fee shall be paid only once for each product for each fiscal year.

(B) DUE DATE.—The biosimilar biological product fee for a fiscal year shall be due on the later of—

(i) the first business day on or after Octo-

ber 1 of each such year; or

(ii) the first business day on or after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

(C) ONE FEE PER PRODUCT PER YEAR.—The biosimilar biological product establishment fee shall be paid only once for each product for each fiscal year.

(D) FEES SETTING AND AMOUNTS.—

(i) IN GENERAL.—Subject to paragraph (2), the Secretary shall, 60 days before the start of the fiscal year beginning on or after September 30, 2012, establish, for the next fiscal year, the fees under subsection (a). Except as provided in subsection (c), such fees shall be in the following amounts for each product—

(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The initial biosimilar biological product development fee shall be equal to 10 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A) for each fiscal year.

(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The annual biosimilar biological product development fee shall be equal to 10 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A) for each fiscal year.

(C) REACTIVATION FEE.—The reactivation fee shall be equal to 20 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A) for each fiscal year.

(D) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—The biosimilar biological product application fee under subsection (a)(2) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A) for that fiscal year.

(E) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—The biosimilar biological product establishment fee under subsection (a)(3) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug product for that fiscal year.

(F) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—The biosimilar biological product application 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.

(G) 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 estimated costs for the process for the review of biosimilar biological product applications.

(H) APPLICATION FEE WAIVER FOR SMALL BUSINESS.—

(i) WAIVER OF APPLICATION FEE.—The Secretary shall grant to a person who is named in a biosimilar biological product application a waiver of the fee assessed to that person under subsection (a)(2)(A) for the first biosimilar biological product application that a small business or entity that has fewer than 500 employees, in-the aggregate, has submitted to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

(i) the fee required for subsequent biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business; and

(ii) all subsequent biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business.

(ii) CONSIDERATIONS.—In determining whether to grant a waiver of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

(H) 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 own or control a drug product that is approved under a human drug application (as defined in section 735) or an approval letter for a human drug application (as defined in section 735) and introduced into interstate commerce.

(i) 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.

(j) CREDITING AND AVAILABILITY OF FEES.—

(i) IN GENERAL.—Subject to paragraph (2), fees collected under this section shall be credited to the appropriate appropriations Act for the sub-

section, the collection and obligation of fees for such fiscal year under this section.

(ii) the collection and obligation of fees for such fiscal year under this section.

(D) APPLICATION TO ESTABLISHMENT.—

(i) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—The biosimilar biological product establishment fee under section 736(a)(3) for a fiscal year shall be equal to the amount established for the establishment of the small business or entity that has fewer than 500 employees, in-the aggregate, that submitted the application for a human drug application described in section 736(a)(1)(A) for that fiscal year.

(i) IN GENERAL.—Subject to paragraph (2), fees collected under this section shall be credited to the appropriate appropriations Act for the subsection, the collection and obligation of fees for such fiscal year under this section.
in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year.

(B) FEE COLLECTION AND LIMITATION.—The fees authorized by this section shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of the process for the review of biosimilar biological product applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such review, only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) equal to the amount specified in appropriation Acts for such fiscal year), and each subsequent fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

(C) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2013, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013 may be collected and shall be credited to such account and remain available until expended.

(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2013), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(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 equal to the total amount of fees assessed for such fiscal year for which fees are paid under this section.

(1) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) when it is due, the Secretary shall treat such unpaid fees as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(2) WRITTEN REQUESTS FOR WAIVERS AND REFUNDS.—To qualify for consideration for a waiver under subsection (c), or for a refund of any fee collected in accordance with subsection (b), the Secretary shall require the applicant to submit such written request to the Secretary a written request for such waiver or refund not later than 30 days after such fee is due.

(1) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees engaged in the process of reviewing biosimilar biological product applications, be reduced to offset the number of officers, employers, and advisory committees engaged on the same subject.

(3) FINAL RESULTS.—Not later than September 30, 2016, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Science, Space, and Technology of the House of Representatives a report on the progress of the review of biosimilar biological product applications for the fiscal year.

(g) APPLICABILITY.—This section may consist of a study or studies required under section (d).

(h) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of reviewing biosimilar biological product applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

SEC. 403. RREAUTORIZATION; REPORTING REQUIREMENTS.

Part 8 of subchapter C of chapter VII, as added by section 402, is further amended by inserting after section 744H the following:

SEC. 744H. RREAUTORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this chapter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 402(b) of the Biologic User Fee Act of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting such goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response to all biosimilar biological product applications and supplements in the cohort.

(b) FISCAL REPORT.—Not later than 120 days after the end of fiscal year 2013 and each subsequent fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

(1) STUDY.—(i) IN GENERAL.—The Secretary shall conduct a study with an independent accounting or consulting firm to study the workload volume and full costs associated with the process for the review of biosimilar biological product applications for fiscal year 2013. The report shall be submitted to the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Science, Space, and Technology of the House of Representatives.

(b) RREAUTORIZATION.—

(i) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for the process for the review of biosimilar biological product applications for the first 5 fiscal years after fiscal year 2017, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

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

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

(C) scientific and academic experts;

(D) health care professionals;

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

(F) the regulated industry.

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

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

(B) publish such recommendations in the Federal Register;

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

(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than 30 days after the date of enactment of this title, the Secretary shall transmit to the Congress the recommendations described under paragraph (2), a summary of the views and comments received on the recommendations developed under paragraph (2), and any changes made to the recommendations in response to such views and comments.

SEC. 404. SUNSET DATES.

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

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

SEC. 405. EFFECTIVE DATE.

(a) IN GENERAL.—Except as provided under subsection (b), the amendments made by this title shall take effect on the later of—

(1) October 1, 2012; or

(2) the date of the enactment of this title.

(b) EXCEPTION.—Fees under part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as added by this title, shall continue to be assessed for all biosimilar biological product applications received on or after October 1, 2012, regardless of the date of the enactment of this title.

SEC. 406. CONFORMING AMENDMENT.

Section 735(1)(B) (21 U.S.C. 379g(1)(B)) is amended by striking “(or)” and inserting “(or)”.

TITLES V—PEDIATRIC DRUGS AND DEVICES

SEC. 501. PERMANENCE.

(a) PEDIATRIC STUDIES OF DRUGS.—Subsection (q) of section 505A (21 U.S.C. 355a) is amended—

(1) in the subsection heading, by striking “Sunset” and inserting “Permanence”;

(2) in paragraph (1), by striking “before October 1, 2012.”; and

(3) in paragraph (2), by striking “before October 1, 2012.”.

(b) RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.—Section 502B (21 U.S.C. 355c) is amended—

(1) by striking subsection (m); and

(2) by redesignating subsection (n) as subsection (m).

(c) WRITTEN REQUESTS.

(a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Subsection (h) of section 505A (21 U.S.C. 355a) is amended to read as follows:

(1) IN GENERAL.—Except as provided under subsection (h), fees authorized by this section may consist of a study or studies required under subsection (d).

(b) PUBLICATION OF RECOMMENDATIONS.—Exclusivity under this section shall only be granted for the completion of a study or studies that are subject of written request and for which reports are submitted and accepted in accordance with subsection (d)(3). Written requests under this section may consist of a study or studies required under subsection (d).

(c) WRITTEN REQUESTS.

(a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 351m(1) (21 U.S.C. 362m(1)) is amended by striking “(i), (k), (l), (p), and (q)” and inserting “(f), (h), (i), (j), (k), (l), (m), and (p)”.

SEC. 503. COMMUNICATION WITH PEDIATRIC REVIEW COMMITTEE.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this title as the “Secretary”) shall issue internal operating procedures that provide for the review by the internal review committee established under section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c). Such internal standard operating procedures shall be made publicly available.
SEC. 504. ACCESS TO DATA.

Not later than 3 years after the date of enactment of this Act, the Secretary shall make available to the public, including through posting on the Internet website of the Food and Drug Administration, the medical, statistical, and clinical pharmacy reviews of, and corresponding written requests issued to an applicant, sponsor, or holder of a pediatric data submission between January 4, 2002 and September 27, 2007 under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) for which the Secretary granted exclusivity and that resulted in a labeling change. The Secretary shall make public the information described in the preceding sentence in a manner consistent with the manner in which the Secretary releases information under section 505A(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355A(k)).

SEC. 505. ENSURING THE COMPLETION OF PEDIATRIC STUDIES.

(a) EXTENSION OF DEADLINE FOR DEFERRED STUDIES.—Section 505B (21 U.S.C. 355c) is amended—

(1) in subsection (a)(3)—

(A) by striking paragraph (B) as redesignated under subsection (c); and

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

``(B) DEFERRAL EXTENSION.—(1) DEFERRAL extension shall be granted only if both of the following occur:

(ii) the Secretary determines that the condition for deferral set forth in clause (I) of subparagraph (A)(ii) continues to be met; and

(ii) the applicant submits a new timeline for the deferred data submission under the agreed timeline in subsection (a)(I).

(2) In addition to deferral extensions granted under subparagraph (A), the Secretary shall—

(i) begin the assessment of the pediatric data submission within the timeframe specified by the applicant; and

(ii) complete the assessment within the timeframe specified by the applicant, if the Secretary determines that the condition for deferral set forth in clause (I) of subparagraph (A)(ii) continues to be met.

(3) The Secretary may grant deferral extensions on a case-by-case basis and may set different timelines for different pediatric data submissions.

(4) The Secretary shall—

(i) issue a written notice to the applicant at least 30 days before the expiration of the timeframe specified by the applicant; and

(ii) provide a review of the pediatric data submission at least 30 days before the expiration of the timeframe specified by the applicant.

(b) T RACKING OF EXTENSIONS; A NNUAL INFORM A TION.—Section 505B(f)(6)(D) (21 U.S.C. 355c(f)(6)(D)) is amended to read as follows:

``(D) SECRETAR IA L INFORM ATION.—The Secretary shall—

(i) collect and maintain information on the number of deferrals and deferral extensions granted under this section and, if granted, the reasons for each such deferral or deferral extension;

(ii) provide the applicant with a report of the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension;

(iii) provide the applicant with a report of the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension;

(iv) submit an annual report to Congress on the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension.

(c) EIGHTH EMPLOYEE OF THE WEEK.—The Secretar y shall—

(1) maintain a record of deferral extensions granted under this section and the reasons for each such deferral or deferral extension;

(2) provide the applicant with a written notice of the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension;

(3) provide the applicant with a written notice of the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension;

(4) submit an annual report to Congress on the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension.

(d) F IRM EXPENSES.—The Secretary shall—

(1) maintain a record of deferral extensions granted under this section and the reasons for each such deferral or deferral extension;

(2) provide the applicant with a written notice of the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension;

(3) provide the applicant with a written notice of the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension;

(4) submit an annual report to Congress on the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension.

(e) EIGHTH EMPLOYEE OF THE WEEK.—The Secretar y shall—

(1) maintain a record of deferral extensions granted under this section and the reasons for each such deferral or deferral extension;

(2) provide the applicant with a written notice of the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension;

(3) provide the applicant with a written notice of the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension;

(4) submit an annual report to Congress on the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension.

(f) EIGHTH EMPLOYEE OF THE WEEK.—The Secretar y shall—

(1) maintain a record of deferral extensions granted under this section and the reasons for each such deferral or deferral extension;

(2) provide the applicant with a written notice of the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension;

(3) provide the applicant with a written notice of the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension;

(4) submit an annual report to Congress on the number of deferrals and deferral extensions granted under this section and the reasons for each such deferral or deferral extension.
the same extent as such requirements apply to an initial pediatric study plan under paragraph (1). The requirements of paragraphs (3) and (4) shall apply to any agreement resulting from an amendment in the same manner and to the same extent as such requirements apply to an agreed initial pediatric study plan."

(6) **PEDIATRIC ADVISORY COMMITTEE.—**The Secretary shall consult the internal committee under section 505C on the review of the initial pediatric study plan, agreed initial pediatric plan, and to any significant amendments to such plans."

(7) **REQUIRED RULEMAKING.**—Not later than 1 year after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall promulgate proposed regulations and issue proposed guidance to implement the provisions of this subsection."

(b) **CONFORMING AMENDMENTS.**—Section 505B (21 U.S.C. 355c) is amended—

(1) by amending subclause (II) of subsection (a)(3)(A)(ii) to read as follows: "(II) a pediatric study plan as described in subsection (e);" and

(2) in subsection (f)—

(A) in the subsection heading, by striking "PEDIATRIC PLANS," and inserting "PEDIATRIC STUDY PLANS;",

(B) in paragraph (1), by striking "all pediatric study plans, agreed initial pediatric study plans," and inserting "prenatal, neonatal, and initial pediatric study plans,"; and

(C) in paragraph (4)—

(i) in the paragraph heading, by striking "PEDIATRIC PLANS," and inserting "PEDIATRIC STUDY PLANS;" and

(ii) by striking "prenatal, neonatal, and initial pediatric study plans, agreed initial pediatric study plans,; and"

(c) **EFFECTIVE DATES.**—

(1) **PEDIATRIC STUDY PLANS.—**Subsection (e) of section 505B of the Federal Food, Drug, and Cosmetic Act (other than paragraph (4) of such subsection), as amended by subsection (a), shall take effect 180 days after the date of enactment of this Act, without regard to whether the Secretary has promulgated final regulations under paragraph (4) of such subsection by such date.

(2) **CONFORMING AMENDMENTS.**—The amendments made by subsection (b) shall take effect 180 days after the date of enactment of this Act.

SEC. 507. REAUTHORIZATIONS.

(a) **PEDIATRIC ADVISORY COMMITTEE.**—Section 14(d) of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by striking "prenatal, neonatal, and initial pediatric study plans submitted and agreed to as identified in the marketing application under such section 505B;" and

(b) **PEDIATRIC SUBCOMMITTEE ON THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.**—Section 15(a)(3) of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by striking "prenatal, neonatal, and initial pediatric study plans submitted and agreed to as identified in the marketing application under such section 505B;" and


(d) **CONFORMING AMENDMENTS TO IMPROVE PEDIATRIC DEVICE AVAILABILITY.**—Section 305(e) of Pediatric Medical Device Safety and Improvement Act (Public Law 110–85; 42 U.S.C. 282 note) is amended by striking "$6,000,000 for each of fiscal years 2008 through 2012" and inserting "$3,500,000 for each of fiscal years 2017 through 2022;"

(e) **PROGRAM FOR PEDIATRIC STUDY OF DRUGS IN PHSA.**—Section 409I(e)(1) of the Public Health Service Act (42 U.S.C. 284m note) is amended by striking "to carry out this section" and all that follows through the end of paragraph (1) and inserting "to carry out this section $25,000,000 for each of fiscal years 2012 through 2017."

SEC. 508. REPORT.

(a) **IN GENERAL.**—Not later than October 31, 2016, and at the end of each subsequent 5-year period, the Secretary shall submit to Congress a report that evaluates the effectiveness of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) and section 491 of the Public Health Service Act (42 U.S.C. 284m) in ensuring that medicines used by children are tested in pediatric populations and properly labeled for use in children.

(b) **CONTENTS.**—The report under subsection (a) shall include—

(1) the number and importance of drugs and biological products for children for which studies have been requested or required (as of the date of such report) under 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) and section 409I of the Public Health Service Act (42 U.S.C. 284m), including—

(A) the number of labeling changes made to drugs and biological products pursuant to such sections since the date of enactment of this Act; and

(B) the importance of such drugs and biological products in the improvement of the health of children;

(2) the number of required studies under such section 505B that have not met the initial deadline provided under such section, including—

(A) the number of deferrals and deferral extensions granted and the reasons such extensions were granted; and

(B) the number of waivers and partial waivers granted; and

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

(3) the number of written requests issued, declined, and referred to the National Institutes of Health under such section 505A since the date of enactment of this Act (including the reasons for such declination), and a description and status of referrals made under subsection (n) of such section 505A;

(4) the reviews of pediatric study plans submitted and agreed to as identified in the marketing application under such section 505B;

(5) labeling changes recommended by the Pediatric Advisory Committee as a result of the review by such Committee of adverse events reports;

(6) the number current status of pediatric postmarketing requirements;

(7) the number and importance of drugs and biological products for children that are not being tested in pediatric populations, notwithstanding the existence of the programs under such sections 505A and 505B and section 491 of the Public Health Service Act; and

(8) the possible reasons for the lack of testing reported under paragraph (7);

(9) the number of drugs and biological products testing is being done (as of the date of the report) and for which a labeling change is required under the programs described in paragraph (7), including—

(A) the drug or biological product identified; and

(B) which labeling changes required the use of the dispute resolution process; and

(C) for labeling changes that required such dispute resolution process, a description of—

(i) the disputes;

(ii) the recommendations of the Pediatric Advisory Committee; and

(iii) the outcomes of such process; and

(D) an assessment of the effectiveness in improving information about pediatric uses of drugs and biological products;

(10)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonatal population (including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of these studies ethically acceptable); and

(B) the results of such efforts;

(11)(A) the number and importance of drugs and biological products for children with cancer that are being tested as a result of the programs described in paragraph (7); and

(B) any recommendations for modifications to such programs that would lead to new and better therapies for children with cancer, including a detailed rationale for each recommendation;

(12) an assessment of progress made in addressing the recommendations of any prior report issued by the Comptroller General, the Institute of Medicine, or the Secretary regarding the topics addressed in this section under this Act, including with respect to—

(A) improving public access to information from pediatric studies conducted under such sections 505A and 505B; and

(B) improving the timeliness of pediatric studies and pediatric study planning under such sections 505A and 505B;

(C) recommendations for modification to the programs that would improve pediatric drug research and increase pediatric labeling of drugs and biological products; and

(D) an assessment of the successes of and limitations to studying drugs for rare diseases under such sections 505A and 505B;

(c) **CONSULTATION ON RECOMMENDATIONS.**—At least 180 days before the report is due under subsection (a), and no sooner than 4 years after the date of enactment of this Act, the Secretary shall consult with representatives of patient groups, including pediatric patient groups, consumer groups, regulated industry, scientific and medical communities, academia, interested parties to obtain any recommendations or information relevant to the effectiveness of the programs described in subsection (b)(7), including suggestions for modifications to such programs.

SEC. 509. TECHNICAL AMENDMENTS.

(a) **PEDIATRIC STUDIES OF DRUGS IN FFDCA.**—Section 505A (21 U.S.C. 355a) is amended—

(1) in subsection (k)(2), by striking "subsection (f)(3)(F)" and inserting "subsection (f)(6)(F)";

(2) in subsection (n)—

(A) in the subsection heading, by striking "COMPLETED" and inserting "SUBMITTED"; and

(B) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking "have not been submitted" and inserting "have not been submitted by the date specified in the written request issued or if the applicant or holder does not agree to the request";

(ii) in subparagraph (A), in the first sentence, by inserting "or for which a period of exclusivity eligible for extension under subsection (b)(1) or (c)(1) of this section or under subsection (m)(2) or (m)(3) of section 505 of the Public Health Service Act has not ended" after "expired"; and
(II) by striking ‘‘Prior to’’ and all that follows through the period at the end; and
(III) in subparagraph (B), by striking ‘‘no listed patents or has 1 or more listed patents that have expired’’ and inserting ‘‘no unexpired listed patents and for which no unexpired periods of exclusivity eligible for extension under subsection (b)(1) or (c)(1) of this subchapter or under subsection (m)(2) or (m)(3) of section 351 of the Public Health Service Act apply,’’; and
(3) in subsection (o)(2), by amendment subparagraph (G) to read as follows:
‘‘(G) a statement of any appropriate pediatric contraindications, warnings, precautions, or other information that theSecretary considers necessary to assure safe use.’’;
(b) RUSHING INTENTIONAL PEDIATRIC USES FOR DRUGS AND BIOTECHNOLOGICAL PROJECTS IN FDAeca.—Section 503B (21 U.S.C. 355c) is amended—
(1) in subsection (a)—
(A) in paragraph (1)—
(i) in the matter preceding subparagraph (A), by inserting ‘‘for a drug’’ after ‘‘(or supplement to an application)’’;
(ii) in subparagraph (A), by striking ‘‘for a’’ and inserting ‘‘including, with respect to a drug, an application (or supplement to an application) for a’’;
(iii) in subparagraph (B), by striking ‘‘for a’’ and inserting ‘‘including, with respect to a drug, an application (or supplement to an application) for a’’;
(iv) in the matter following subparagraph (B), by inserting ‘‘(or supplement) after ‘‘application’’; and
(B) in paragraph (4)—
(i) in the first sentence, by inserting ‘‘partial’’ before ‘‘waiver is granted’’;
(ii) in the second sentence, by striking ‘‘either application of such a’’ and inserting ‘‘the labeling of such product’’; and
(B) in subsection (b)(1), in the matter preceding subparagraph (A), by striking ‘‘After providing notice and all that follows through ‘studies’, the’’ and inserting ‘‘The’’;
(3) in subsection (g)—
(A) in paragraph (1)(A), by inserting ‘‘that receives a priority review or 330 days after the date of the submission of an application or supplement that receives a standard review’’ after ‘‘after the date of the submission of the application or supplement’’; and
(B) by the deletion of subsection (g)(2) and inserting ‘‘the label of such product’’ and inserting ‘‘the labeling of such product’’; and
(B) in subsection (b)(1)—
(i) by striking ‘‘the label of the drug, an application (or supplement to an application) that contains’’ after ‘‘date of submission of’’; and
(ii) by inserting ‘‘, if the application (or supplement) receives a priority review, or not later than 330 days after the date of submission of an application (or supplement to an application) that contains a pediatric assessment under subsection (c), the application (or supplement) receives a standard review’’ after ‘‘under this section’’;
(c) INTERNAL REVIEW COMMITTEE.—The heading of section 490(c)(1)(C) of the Public Health Service Act (21 U.S.C. 335a(c)(1)(C)) is amended by inserting ‘‘and deferral extensions’’ after ‘‘clauses (iii) and (iv)’’.
(d) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—Section 503B (21 U.S.C. 355b) is amended—
(1) in the heading, by striking ‘‘section 503B’’ and inserting ‘‘section 505B’’;
(2) in paragraph (2), by striking ‘‘under section 505 of the Food, Drug, and Cosmetic Act’’;
(3) in paragraph (3) and (4) of subsection (c) and clauses (iii) and (iv) of section 505(c)(3)(E) of title 21, as so redesignated, 2 subparagraphs, as so redesignated, and inserting ‘‘the labeling of the product a determination that the product is not indicated for use in pediatric populations or subpopulations or information indicating that the results of an assessment were inconclusive or did not demonstrate that the product is safe or effective in pediatric populations or subpopulations’’;
(4) in paragraph (3)—
(A) in subparagraph (B), by inserting ‘‘that differ from adult formulations’’ before the semicolon at the end; and
(B) in subparagraph (C)—
(i) by striking ‘‘under section 505(j)’’ and inserting ‘‘under subsection (c) or (j) of section 505’’; and
(ii) by striking ‘‘under section 505(j)’’ and inserting ‘‘clauses (iii) and (iv) of section 505(c)(3)(E)’’ of title 21, as so redesignated, and inserting ‘‘exclusive under subsection (c) or (j) of section 505’’;
(5) in paragraph (4)—
(A) by striking ‘‘under section 505(j)’’ and inserting ‘‘under subsection (c) or (j) of section 505’’; and
(B) by inserting ‘‘clauses (iii) or (iv) of section 505(c)(3)(E) or’’ after ‘‘exclusive under subsection’’.
(e) PEDIATRIC RARE DISEASES.—Section 840(i)(2) (21 U.S.C. 360k(i)(2)) is amended—
(1) in the heading, by striking ‘‘section 840(i)(2)’’ and inserting ‘‘section 840(i)(2)(C)’’;
(2) in paragraph (2), by striking ‘‘under section 505(d)’’ and inserting ‘‘clauses (iii) and (iv) of section 505(c)(3)(E)’’; and
(3) in paragraph (3)—
(A) by striking ‘‘under section 505(j)’’ and inserting ‘‘under subsection (c) or (j) of section 505’’; and
(B) by inserting ‘‘clauses (iii) or (iv) of section 505(c)(3)(E) or’’ after ‘‘exclusive under subsection’’.
(f) TITLE VI—MEDICAL DEVICE REGULATORY IMPROVEMENTS
SEC. 601. RECLASSIFICATION PROCEDURES.
(a) CLASSIFICATION CHANGES.—
(1) IN GENERAL.—Section 513(a)(1) (21 U.S.C. 360d(a)(1)) is amended to read as follows:
‘‘(a)(1) Based on new information respecting a device, the Secretary may, upon the initiative of the Secretary or upon petition of an interested person, change the classification of such device, and revoke, on account of the change in classification, any regulation or requirement in effect under section 314 or 315 with respect to such device, and, by administrative order published in the Federal Register following publication of a proposed reclassification order in the Federal Register, a meeting of a device classification panel described in subsection (b), and consideration of comments to a public docket, notwithstanding subsection chapter II of this title and any other provision of this title and the Food, Drug, and Cosmetic Act. An order under this subsection changing the classification of a device from class
III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such device. "(b) A device reclassified as such class shall be regulated in the same manner such section 513(e)(1) applies to such Act with respect to such device in the previous calendar year under section 513(e)(1); and

(2) The number and type of devices reclassified as class II or class III in the previous calendar year under section 513(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) shall be deemed to include such regulation.

(3) APPROVAL BY REJECTION PRIOR TO THE DATE OF ENACTMENT OF THIS ACT.—The amendments made by subsection (a)(2) of this Act shall have no effect on a regulation promulgated with respect to the classification of a device under section 513(e)(1) of the Food, Drug, and Cosmetic Act prior to the date of enactment of this Act.

(b) APPLICABILITY OF OTHER PROVISIONS.—In the case of a device reclassified under section 513(e)(1) of the Food, Drug, and Cosmetic Act (21 U.S.C. 360e(a)(1)) shall apply to such regulation promulgated under section 513(e) of such Act with respect to such device in the same manner such section 517(a)(1) applies to an administrative order issued with respect to a class II device after the date of enactment of this Act.

(2) A Proposed order required under section 513(e), (2) shall contain—

(i) the number and type of devices reclassified as class II or class III in the previous calendar year under section 513(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) of an application for premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e); and

(b) in subparagraph (b)—

(i) the number and type of devices reclassified as class II and class III devices reclassified as class II or class III in the previous calendar year under such section 513(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) and

(2) the number and type of devices reclassified as class II or class III in the previous calendar year under such section 513(e)(1) and

(3) the number and type of devices reclassified in the previous calendar year under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) of an application for postmarket surveillance.

SEC. 602. CONDITION OF APPROVAL STUDIES.


(1) the number and type of class I and class II devices reclassified as class II or class III in the previous calendar year under section 513(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) a); and

(b) by adding at the end the following:

"(II) An order approving an application for a device may require as a condition to such approval that the applicant conduct a postmarket study regarding the device."
(ii), and (v) of section 505(k)(3)(C) in order to expand the postmarket risk identification and analysis system established under such section to include and apply to devices.

(‘‘(B)’’) Under such section (ii) of clause (i) of section 505(k)(3)(C) shall not apply to devices.

(‘‘(C)’’) CLARIFICATION.—With respect to devices, the Secretary shall review for health-related electronic data provided under section 505(k)(3)(C)(i)(III)(bb) may include medical device utilization data, health insurance claims data, and procedure and device registries.

(‘‘(2)’’) DATA.—In expanding the system as described in paragraph (1)(A), the Secretary shall provide for the collection of device recall program data, including device recall data, medical device utilization data, health insurance claims data, and procedure and device registries.

(‘‘(3)’’) STAKEHOLDER INPUT.—To help ensure effective implementation of the system described in paragraph (1)(A), the Secretary shall engage outside stakeholders in development of the system through a public hearing, advisory committee meeting, public docket, or other like public measures, as appropriate.

(‘‘(4)’’) VOLUNTARY SURVEYS.—Chapter 35 of title 44, United States Code, shall not apply to the collection of voluntary information from device sponsors, manufacturers, or device surveymonitors, initiated by the Secretary for purposes of postmarket risk identification for devices.

SEC. 605. RECALLS.

(a) ASSESSMENT OF DEVICE RECALL INFORMATION.—

(1) IN GENERAL.—

(2) ASSESSMENT PROGRAM.—The Secretary of Health and Human Services (referred to in this section as the ‘‘Secretary’’) shall enhance the Food and Drug Administration’s recall program to routinely and systematically assess—

(i) information submitted to the Secretary pursuant to a device recall order under section 510(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(e)); and

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

(b) USE.—The Secretary shall use the assessment of information described under subparagraph (A) to identify strategies for mitigating health risks presented by defective or unsafe devices.

(2) DESIGNS.—The program under paragraph (1) shall—

(A) be based on a minimum, identified and trending in the numbers and types of device recalls;

(B) be of types of devices in each device class that are most frequently recalled;

(C) be of types of devices for which data are frequently collected; and

(D) be of any other information as the Secretary determines appropriate.

(b) AUDIT CHECK PROCEDURES.—

(1) THE SECRETARY.—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.

(2) ASSESSMENT CRITERIA.—The Secretary shall develop explicit criteria for assessing whether a person subject to a recall order under section 510(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(e)) or to a requirement under section 510(g) of such Act (21 U.S.C. 360(g)) has performed an effective recall or removal action under such section 510(g), respectively.

(d) TERMINATION OF RECALLS.—The Secretary, on the basis of the findings or determinations made by the Secretary under section 512 of this title, may terminate a device recall order under section 510(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 510(g) of such Act (21 U.S.C. 360(g)).

(c) CLINICAL HOLIDAYS ON INVESTIGATIONAL DEVICE EXEMPTIONS.

Section 520(g) (21 U.S.C. 360(g)) is amended by adding at the end the following:

(‘‘(B)’’) The Secretary may prohibit the sponsor of an investigation for conducting the investigation (referred to in this paragraph) if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(‘‘(D)’’) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is a determination that—

(i) the device involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the doctors and the information about the device, the design of the clinical investigation, the condition for which the device is to be investigated, and the health status of the involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish.

(c) VOLUNTARY SURVEYS.—

(1) AN INQUIRY.—The Secretary shall take such inquiry as is necessary to determine whether a person subject to a recall order under section 510(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(e)) and whether a person subject to a recall order under section 518 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)) may request the Secretary to make a determination described in subparagraph (A) if the Secretary determines that—

(A) it is appropriate to conduct a prospective device recall audit check to determine the effectiveness of a recall ordered under section 510(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(e)); and

(B) a device identified as defective or unsafe by the Secretary pursuant to a device recall order under section 510(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(e)) is the same device that was the subject of a previous device recall order under such section.

(d) AUDIT CHECK PROCEDURES.—

(1) IN GENERAL.—The Secretary shall take such inquiry as is necessary to determine whether the Secretary determines that—

(A) it is appropriate to conduct a prospective device recall audit check to determine the effectiveness of a recall ordered under section 510(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(e)); and

(B) a device identified as defective or unsafe by the Secretary pursuant to a device recall order under section 510(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(e)) is the same device that was the subject of a previous device recall order under such section.

(e) VOLUNTARY SURVEYS.—

(1) AN INQUIRY.—The Secretary shall take such inquiry as is necessary to determine whether the Secretary determines that—

(A) it is appropriate to conduct a prospective device recall audit check to determine the effectiveness of a recall ordered under section 510(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(e)); and

(B) a device identified as defective or unsafe by the Secretary pursuant to a device recall order under section 510(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(e)) is the same device that was the subject of a previous device recall order under such section.
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 that contains the Secretary’s determination that there is no legally marketed device upon which to base a substantial equivalence determination as that term is defined in subsection (a)(1), or the request for review under paragraph (B), the Secretary shall classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a). The Secretary may modify such annual distribution number when the Secretary grants such exemption.

(2) Submission of Request.—A person requesting a supervisory review under paragraph (1) shall submit such request to the Secretary not later than 30 days after such denial and shall indicate in the request whether such person seeks an in-person meeting or a teleconference review.

(3) Timeframe.—

(A) In general.—Except as provided in subparagraph (B), the Secretary shall schedule and conduct such review for all such requests, if so requested, not later than 30 days after such request is made. The Secretary shall issue a decision to the person requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a person who requests an in-person meeting or teleconference, 30 days after such meeting or teleconference.

(B) Exception.—Subparagraph (A) shall not apply in cases that involve consultation with experts outside of the Food and Drug Administration, or in cases in which the sponsor seeks to introduce evidence not already in the administrative record at the time the denial decision was made.

SEC. 611. GOOD GUIDANCE PRACTICES RELATING TO DEVICES.

Subparagraph (C) of section 760(h)(1) (21 U.S.C. 360k(h)(1)) is amended—

(1) by striking ‘‘(C) For guidance documents’’ and inserting ‘‘(C)(i) For guidance documents’’;

(2) by striking at the end the following:

‘‘(ii) With respect to devices, if a notice to industry guidance letter, a notice to industry advisory letter, or any similar notice sets forth initial interpretations of a regulatory advisory letter, or any similar notice, as amended by this Act.

The Secretary shall complete a study and submit to Congress a report on the effectiveness of the review pathway under section 515(f)(2)(A) of the Federal Food, Drug, and Cosmetic Act, as amended by this Act.

(c) Conforming Amendment.—Section 513(f)(1)(B) (21 U.S.C. 360c(f)(1)(B)) is amended by inserting ‘‘a request under paragraph (2) or’’ after ‘‘response to’’.

SEC. 613. HUMANITARIAN DEVICE EXEMPTIONS.

(a) In General.—Section 520(m) (21 U.S.C. 360m) is amended—

(1) by redesigning subparagraphs (B) and (C) as subparagraphs (C) and (D), respectively; and

(2) by amending subparagraph (A) to read as follows:

‘‘(A) In the case of a type of device that has not previously been classified under this Act, a person may do one of the following:

(i) Submit a report under section 515(k), and, if the device is classified into class III under paragraph (1), such person may request, not later than 30 days after receiving written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a). The Secretary may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

(ii) Submit a request for initial classification 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 (a)(1), or the request for review under paragraph (B), the Secretary shall classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a).

(iii) The Secretary shall classify the device under this subparagraph when the Secretary grants such exemption.

(b) APPLICABILITY TO EXISTING DEVICES.—A sponsor of a device for which an exemption was approved under paragraph (2) of section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m) before the date of enactment of this Act may seek a determination under this subsection.

(c) Report.—Not later than January 1, 2017, the Comptroller General of the United States shall submit to Congress a report that evaluates and describes—

(1) the effectiveness of the amendments made by subsection (a) in stimulating innovation with respect to medical devices, including any favorable or adverse impact on pediatric device development;

(2) the impact of such amendments on pediatric device approvals for devices that received a humanitarian use designation under section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m) prior to the date of enactment of this Act;

(3) the status of public and private insurance coverage of devices granted an exemption under paragraph (2) of such section 520(m) (as amended by subsection (a)) and costs to patients of such devices; and

(4) the impact that paragraph (4) of such section 520(m) has had on access to and insurance coverage of devices granted an exemption under paragraph (2) of such section 520(m); and

(5) the effect of the amendments made by subsection (a) on patients described in such section 520(m).

(c) Reauthorization of Third-Party Review and Inspections.

(a) Third-Party Review.—Section 523(c) (21 U.S.C. 360m(c)) is amended by striking ‘‘2012’’ and inserting ‘‘2017’’.

(b) Third-Party Inspections.—Section 704(i)(11) (21 U.S.C. 374(g)(11)) is amended by striking ‘‘2012’’ and inserting ‘‘2017’’.

(c) 510(k) Device Modifications.

The Secretary shall monitor potential unintended consequences that may result from the implementation of the Food
and Drug Administration guidance entitled "Guidance for Industry and FDA Staff—510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device." The Secretary of Health and Human Services shall withdraw such guidance promptly and ensure that, before any future guidance document on this issue is made final, affected stakeholders are provided with an opportunity to comment.

SEC. 616. HEALTH INFORMATION TECHNOLOGY.

(a) LIMITATION.—Notwithstanding any other law, the Secretary of Health and Human Services (referred to in this section as the ‘Secretary’) may issue final guidance on medical mobile applications only after the requirements under subsections (b) and (c) are met.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary, in consultation with the Commissioner of Food and Drugs, the National Coordinator for Health Information Technology, and the Chair of the Federal Communications Commission, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that contains a pro-

(c) REQUIREMENTS.—Notwithstanding any other law, the Secretary shall—

(1) within respect to drugs, the information described under paragraph (1); and

(2) with respect to devices, the information described under subsection (b)(2).

SEC. 702. REGISTRATION OF FOREIGN ESTABLISHMENTS.

(a) ENFORCEMENT OF REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 505(o) (21 U.S.C. 352(o)) is amended by striking ‘‘in any State’’.

(b) REGISTRATION OF FOREIGN DRUG ESTABLISHMENTS.—Section 510(i) (U.S.C. 360(i)) is amended—

(1) in paragraph (1)—

(A) by amending the matter preceding subparagraph (A) to read as follows: ‘‘Every person who owns or operates any establishment, and a point of contact e-mail address for each such drug importer;’’; and

(B) by adding at the end the following:

‘‘(2) the name and place of business of each such drug importer, the unique facility identifier of each such establishment, a point of contact e-mail address, and a point of contact for each such drug importer.’’.

SEC. 704. ELECTRONIC SYSTEM FOR REGISTRATION AND LISTING.

Section 510(p) (21 U.S.C. 360(p)) is amend-

(1) by striking ‘‘(p) Registrations and listings’’ and inserting the following:

‘‘(1) ELECTRONIC REGISTRATION AND LISTING.—

‘‘(1) IN GENERAL.—Registration and listing’’; and

(2) by adding at the end the following:

‘‘(2) ELECTRONIC DATABASE.—Not later than 2 years after the Secretary specifies a unique facility identifier system under subsections (b) and (i), the Secretary shall maintain an electronic database, which shall not be subject to inspection under subsection (f), populated with the information submitted as described under paragraph (1), or combination of such fields; and

‘‘(A) enables personnel of the Food and Drug Administration to search the database by any field of information submitted in a registration under paragraph (1), or combination of such fields; and

‘‘(B) uses the unique facility identifier system to link with other relevant databases within the Food and Drug Administration, including the database for submission of information under section 801(r).

‘‘(3) RISK-BASED INFORMATION AND COORDINATION.—The Secretary shall ensure the accuracy and coordination of relevant Food and Drug Administration databases in order to identify and inform risk-based inspections under section 510(h).

SEC. 705. RISK-BASED INSPECTION FREQUENCY.

(a) IN GENERAL.—Every establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 704.

(b) INSPECTIONS.—

(1) IN GENERAL.—Every establishment which is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs classified in paragraph (1), in any State, that is engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices classified in class II or III shall be inspected by one or more officers or employees duly designated by the Secretary, or such officers and employees accredited to conduct inspections under section 704(g), at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter.

(c) RISK-BASED SCHEDULE FOR DRUGS.—The Secretary, acting through officers or employees duly designated by the Secretary, shall inspect establishments described in paragraph (1) that are engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs (referred to in this subsection as ‘‘drug establishments’’) in accordance with a risk-based schedule established by the Secretary.

(3) RISK FACTORS.—In establishing the risk-based schedule under paragraph (3), the Secretary shall inspect establishments according to the known safety risks of such establishments, which shall be based on the following factors:

(A) The compliance history of the establishment;

(B) The record, history, and nature of recalls linked to the establishment.
"(C) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment.

"(D) The certifications described under subsection (c) and any other certifications required by the Secretary for the establishment.

"(E) Whether the establishment has been inspected in the preceding 4-year period.

"(F) Any other criteria deemed necessary and appropriate in the judgment of the Secretary for purposes of allocating inspection resources.

"(5) EFFECT OF STATUS.—In determining the risk associated with an establishment for purposes of establishing a risk-based schedule under paragraph (3), the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed at such establishment are drugs described in section 503(b).

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

"(A)(i) the number of domestic and foreign establishments registered pursuant to this section in the previous fiscal year; and

"(ii) the number of such domestic establishments and the number of such foreign establishments that the Secretary inspected in the previous fiscal year;

"(B) with respect to establishments that manufacture, prepare, propagate, compound, or process an active ingredient of a drug, a finished drug product, or an excipient of a drug, the number of each such type of establishment; and

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

"(7) PUBLIC AVAILABILITY OF ANNUAL REPORT.—Not later than 1 year after the date on which the report required under paragraph (6) is available to the public on the Internet Web site of the Food and Drug Administration, the Secretary shall make such report public.

SEC. 709. AUTHORITY TO ENTER INTO MEMORANDUM OF UNDERSTANDING FOR PURPOSES OF INFORMATION EXCHANGE.—The Secretary may enter into written agreements regarding the exchange of information referenced in section 301(c) subject to the following criteria:

"(1) CERTIFICATION.—The Secretary may only enter into written agreements under this subsection with foreign governments that the Secretary determined, in consultation with the authority and demonstrated ability to protect trade secret information from disclosure. Responsibility for this certification shall not be delegated to an employee other than the Commissioner.

"(2) WRITTEN AGREEMENT.—The written agreement under this subsection shall include a commitment by the foreign government to protect information exchanged under this subsection from disclosure unless and until the sponsor gives written permission for disclosure. The agreement also shall make a declaration of a public health emergency pursuant to section 319 of the Public Health Service Act that is relevant to the information.

"(3) INFORMATION EXCHANGE.—The Secretary may provide to a foreign government that has been certified under paragraph (1) and that has executed a written agreement under paragraph (2) information referenced in section 301(c) in the following circumstances:

"(A) Information concerning the inspection of a facility may be provided if—

"(i) the Secretary reasonably believes, or that the written agreement described in paragraph (2) provides, that the foreign government has authority to otherwise obtain such information; and

"(ii) the written agreement executed under paragraph (2) limits the recipient's use of the information to the recipient's civil regulatory purposes.

"(B) Information not described in subparagraph (A) may be provided as part of an investigation, or to alert the foreign government to the potential need for an investigation, if the Secretary has reasonable grounds to believe that the information has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

"(4) EFFECT OF SUBSECTION.—Nothing in this subsection affects the ability of the Secretary to enter into any written agreement authorized by other provisions of law to share confidential information.

SEC. 708. EXCHANGE OF INFORMATION.

Section 708 (21 U.S.C. 379) is amended—

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

(a) CONTRACTORS.—The Secretary; and

(2) by adding at the end the following:

"(a) ABILITY TO PROTECT CONFIDENTIAL INFORMATION.—The Secretary shall not be required to disclose under section 552 of title 5, United States Code, or any other provision of law, any information relating to drugs obtained from a Federal, State or local government agency, or from a foreign government agency, if the agency has requested that the information be kept confidential, except pursuant to an order of a court of the United States. For purposes of section 552 of title 5, United States Code, this subsection shall be considered a statute described in section 552(b)(3)(B).

(3) AUTHORITY TO ENTER INTO MEMORANDUM OF UNDERSTANDING FOR PURPOSES OF INFORMATION EXCHANGE.—The Secretary may enter into written agreements regarding the exchange of information referenced in section 301(c) subject to the following criteria:

"(1) CERTIFICATION.—The Secretary may only enter into written agreements under this subsection with foreign governments that the Secretary determined, in consultation with the authority and demonstrated ability to protect trade secret information from disclosure. Responsibility for this certification shall not be delegated to an employee other than the Commissioner.

"(2) WRITTEN AGREEMENT.—The written agreement under this subsection shall include a commitment by the foreign government to protect information exchanged under this subsection from disclosure unless and until the sponsor gives written permission for disclosure. The agreement also shall make a declaration of a public health emergency pursuant to section 319 of the Public Health Service Act that is relevant to the information.

"(3) INFORMATION EXCHANGE.—The Secretary may provide to a foreign government that has been certified under paragraph (1) and that has executed a written agreement under paragraph (2) information referenced in section 301(c) in the following circumstances:

"(A) Information concerning the inspection of a facility may be provided if—

"(i) the Secretary reasonably believes, or that the written agreement described in paragraph (2) provides, that the foreign government has authority to otherwise obtain such information; and

"(ii) the written agreement executed under paragraph (2) limits the recipient's use of the information to the recipient's civil regulatory purposes.

"(B) Information not described in subparagraph (A) may be provided as part of an investigation, or to alert the foreign government to the potential need for an investigation, if the Secretary has reasonable grounds to believe that the information has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

"(4) EFFECT OF SUBSECTION.—Nothing in this subsection affects the ability of the Secretary to enter into any written agreement authorized by other provisions of law to share confidential information.

SEC. 707. FAILURE TO ALLOW FOREIGN INSPECTIONS OF THE DRUG SUPPLY.

Section 809 (21 U.S.C. 381(a)) is amended by adding at the end the following:

"(A) PREVENTION.—The Secretary shall not authorize the Commissioner to conduct an inspection of a foreign government as a third-party auditor at the request of the Secretary unless the Secretary determines that the foreign government is capable of conducting inspections in accordance with the regulations prescribed by the Secretary.

"(B) NOTICE.—At least 30 days before the date of any inspection conducted under paragraph (A), the Secretary shall provide written notice to the foreign government of its obligation to permit inspections.

"(C) AUTHORITY TO ENTER INTO MEMORANDUM OF UNDERSTANDING FOR PURPOSES OF INFORMATION EXCHANGE.—The Secretary may enter into written agreements regarding the exchange of information referenced in section 301(c) subject to the following criteria:

"(1) CERTIFICATION.—The Secretary may only enter into written agreements under this subsection with foreign governments that the Secretary determined, in consultation with the authority and demonstrated ability to protect trade secret information from disclosure. Responsibility for this certification shall not be delegated to an employee other than the Commissioner.

"(2) WRITTEN AGREEMENT.—The written agreement under this subsection shall include a commitment by the foreign government to protect information exchanged under this subsection from disclosure unless and until the sponsor gives written permission for disclosure. The agreement also shall make a declaration of a public health emergency pursuant to section 319 of the Public Health Service Act that is relevant to the information.

"(3) INFORMATION EXCHANGE.—The Secretary may provide to a foreign government that has been certified under paragraph (1) and that has executed a written agreement under paragraph (2) information referenced in section 301(c) in the following circumstances:

"(A) Information concerning the inspection of a facility may be provided if—

"(i) the Secretary reasonably believes, or that the written agreement described in paragraph (2) provides, that the foreign government has authority to otherwise obtain such information; and

"(ii) the written agreement executed under paragraph (2) limits the recipient's use of the information to the recipient's civil regulatory purposes.

"(B) Information not described in subparagraph (A) may be provided as part of an investigation, or to alert the foreign government to the potential need for an investigation, if the Secretary has reasonable grounds to believe that the information has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

"(4) EFFECT OF SUBSECTION.—Nothing in this subsection affects the ability of the Secretary to enter into any written agreement authorized by other provisions of law to share confidential information.

SEC. 706. ENHANCING THE SAFETY AND QUALITY OF THE DRUG SUPPLY.

Section 501 (21 U.S.C. 351) is amended by adding at the end the following:

"(2) EFFECT OF SUBSECTION.—Nothing in this subsection affects the ability of the Secretary to enter into any written agreement authorized by other provisions of law to share confidential information.

SEC. 705. ACCREDITATION OF THIRD-PARTY AUDITORS FOR DRUG ESTABLISHMENTS.

(a) IN GENERAL.—Chapter VIII (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

"(a) DEFINITIONS.—In this section:

"(1) ACCREDITATION BODY.—The term 'accreditation body' means an authority that performs accreditation of third-party auditors.

"(2) ACCREDITED THIRD-PARTY AUDITOR.—The term 'accredited third-party auditor' means a third-party auditor (which may be an individual) accredited by an accreditation body to conduct drug safety and quality audits.

"(3) AUDIT AGENT.—The term 'audit agent' means an individual who is an employee or agent of an accredited third-party auditor and, although not individually accredited, is qualified to conduct drug safety and quality audits on behalf of an accredited third-party auditor.

"(4) CONSULTATIVE AUDIT.—The term 'consultative audit' means an audit of a finished drug product or for internal purposes only to determine whether an establishment is in compliance with the provisions of this Act and applicable industry practices, or any other such service.

"(5) DRUG SAFETY AND QUALITY AUDIT.—The term 'drug safety and quality audit' means an audit of an eligible entity to certify that the eligible entity meets the requirements of this Act applicable to drugs, including the requirements of section 501 with respect to drugs; and

"(6) ELIGIBLE ENTITY.—The term 'eligible entity' means an entity, including a foreign drug establishment registered under section 510(c), in the drug supply chain that chooses to be audited by an accredited third-party auditor or the audit agent of such accredited third-party auditor.

"(7) THIRD-PARTY AUDITOR.—The term 'third-party auditor' means a foreign government, agency of a foreign government or any other third party (which may be a group of individuals) determined appropriate in accordance with the criteria described in subsection (c)(1), that is eligible to be considered for accreditation to conduct drug safety and quality audits.

"(b) ACCREDITATION SYSTEM.—

"(1) RECOGNITION OF ACCREDITATION BODIES.—In general.—Not later than 2 years after date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall establish a system for the recognition of accreditation bodies that accredit third-party auditors to conduct drug safety and quality audits.

"(2) DIRECT ACCREDITATION.—

"(i) AUTHORITY.—The Secretary shall establish a system for the recognition of accreditation bodies that accredit third-party auditors to conduct drug safety and quality audits.

"(ii) CERTAIN DIRECT ACCREDITATIONS.—Notwithstanding the provisions of clause (i), the Secretary may directly accredit any foreign government or any agent of a foreign government as a third-party auditor at the request of the Secretary.

"(b) IN GENERAL.—If, by the date that is 2 years after the date of establishment of the system described in paragraph (A), the Secretary has not identified and recognized an accreditation body to meet the requirements of this section, the Secretary may directly accredit third-party auditors.
‘(2) NOTIFICATION.—Each accreditation body recognized by the Secretary shall submit to the Secretary—

(A) a list of all accredited third-party auditors; such body shall review the name, contact information, and scope and duration of accreditation for each such auditor; and

(B) updates lists as needed to ensure the list held by the Secretary is accurate.

‘(3) REVOCATION OF RECOGNITION AS AN ACCREDITATION BODY.—The Secretary shall promptly revoke, after the opportunity for an informal hearing, the recognition of any accredited third-party auditor found, to not be in compliance with the requirements of this section.

‘(4) REINSTATEMENT.—The Secretary shall establish procedures to reinstate recognition of an accreditation body if the Secretary determines, based on evidence presented by such accreditation body, that revocation was inappropriate or that the body meets the requirements for recognition under this section.

‘(5) MODEL ACCREDITATION STANDARDS.—

‘(A) IN GENERAL.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall develop model requirements for recognition of drug safety and quality audit results, reports, and certifications, and each recognized accreditation body shall ensure that third-party auditors and audit agents of such auditors meet such standards in order to qualify such third-party auditors as accredited third-party auditors under this section.

‘(B) CONTENT.—The standards developed under subparagraph (A) may—

(i) include a description of required standards relating to the training of auditors, competency, management responsibilities, quality control, and conflict of interest requirements of accredited third-party auditors; and

(ii) set forth procedures for the periodic renewal of the accreditation of accredited third-party auditors.

‘(C) REQUIREMENT TO PROVIDE RESULTS AND REPORTS TO THE SECRETARY.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the third-party auditor or audit agent of such body) shall provide the Secretary, upon request, the results of any drug safety and quality audits, and certifications, and each recognized accreditation body shall ensure that third-party auditors and audit agents of such auditors comply with all requirements of this section.

‘(6) D ISCLOSURE.—The Secretary may require the third-party auditor to be accredited by such body; and

(B) in the case of a third-party auditor accredited by a recognized accreditation body for which recognition as an accreditation body is revoked under subsection (b)(3), revoked, if the Secretary determines that there is good cause for the revocation of accreditation.

‘(4) REACCREDITATION.—The Secretary shall establish procedures to reinstate the accreditation of accredited third-party auditors for which accreditation has been revoked under paragraph (3).

‘(5) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICE.—

‘(A) IN GENERAL.—An accredited third-party auditor shall issue a drug certification described in subparagraph (A) only after conducting a drug safety and quality audit and determining that the audit agent is in compliance with the provisions of section 501.

‘(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), revoked, if the Secretary determines that there is good cause for the revocation of accreditation.

‘(4) REACCREDITATION.—The Secretary shall establish procedures to reinstate the accreditation of accredited third-party auditors for which accreditation has been revoked under paragraph (3).

‘(A) if the Secretary determines, based on evidence presented, that—

(i) the third-party auditor satisfies the requirements of this section; and

(ii) adequate grounds for revocation no longer exist; and

(B) in the case of a third-party auditor accredited by an accreditation body for which recognition as an accreditation body is revoked under subsection (b)(3), revoked, if the Secretary determines that there is good cause for the revocation of accreditation.

‘(5) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICE.—

‘(A) IN GENERAL.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) may not accredit a third-party auditor unless such third-party auditor agrees to issue a written and, as appropriate, electronic, document or certification, as the Secretary may require, that the party meets such standards in order to qualify such third-party auditor under section 704.

‘(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), revoked, if the Secretary determines that there is good cause for the revocation of accreditation.

‘(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), revoked, if the Secretary determines that there is good cause for the revocation of accreditation.

‘(5) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICE.—

‘(A) IN GENERAL.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) shall perform such reviews and audits of the training and qualifications of the 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 requiring third-party auditors accredited by such entity to establish compliance with the provisions of section 501.

‘(ii) adequate grounds for revocation no longer exist; and

‘(5) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICE.—

‘(A) IN GENERAL.—An accredited third-party auditor shall issue a drug certification described in subparagraph (A) only after conducting a drug safety and quality audit and determining that the audit agent is in compliance with the provisions of section 501.

‘(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), revoked, if the Secretary determines that there is good cause for the revocation of accreditation.

‘(5) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICE.—

‘(A) IN GENERAL.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) shall perform such reviews and audits of the training and qualifications of the 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 requiring third-party auditors accredited by such entity to establish compliance with the provisions of section 501.

‘(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), revoked, if the Secretary determines that there is good cause for the revocation of accreditation.

‘(5) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICE.—

‘(A) IN GENERAL.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) shall perform such reviews and audits of the training and qualifications of the 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 requiring third-party auditors accredited by such entity to establish compliance with the provisions of section 501.

‘(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), revoked, if the Secretary determines that there is good cause for the revocation of accreditation.

‘(5) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICE.—

‘(A) IN GENERAL.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) shall perform such reviews and audits of the training and qualifications of the 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 requiring third-party auditors accredited by such entity to establish compliance with the provisions of section 501.

‘(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), revoked, if the Secretary determines that there is good cause for the revocation of accreditation.

‘(5) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICE.—

‘(A) IN GENERAL.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) shall perform such reviews and audits of the training and qualifications of the 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 requiring third-party auditors accredited by such entity to establish compliance with the provisions of section 501.

‘(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), revoked, if the Secretary determines that there is good cause for the revocation of accreditation.

‘(5) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICE.—

‘(A) IN GENERAL.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) shall perform such reviews and audits of the training and qualifications of the 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 requiring third-party auditors accredited by such entity to establish compliance with the provisions of section 501.

‘(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), revoked, if the Secretary determines that there is good cause for the revocation of accreditation.
“(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 an eligible entity to be certified 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 auditor.—An accredited third-party auditor shall—

“(i) keep audited, or controlled by any person that owns or operates an eligible entity to be certified by such auditor;

“(ii) in carrying out drug safety and quality audits of eligible entities under this section, have procedures to ensure against the use of any officer or employee of such auditor that has a financial conflict of interest regarding an eligible entity to be certified by such auditor; and

“(iii) annually make available to the Secretary disclosures of the extent to which such body and the officers and employees of such body have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

“(C) 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

“(A) issue a notice of proposed rulemaking that includes the proposed regulations; and

“(B) a structure to decrease the potential for conflicts of interest, including timing and public disclosure, for fees paid by eligible entities to accredited third-party auditors; and

“(C) appropriate limits on financial affiliations between an accredited third-party auditor or audit agents of such auditor and any person that owns or operates an eligible entity to be audited by such auditor, as described in subparagraphs (A) and (B).

“(4) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2).”.

(b) REPORT ON ACCREDITED THIRD-PARTY AUDITORS.—Not later than January 20, 2017, the Comptroller General of the United States shall submit to Congress a report that describes the following, with respect to the period beginning on the date of implementation of section 809 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) and ending on the date described in subsection (a) of such Act (as amended by section 705).

(1) The extent to which drug safety and quality audits performed by accredited third-party auditors under such section 809 are being used by the Secretary of Health and Human Services (referred to in this subsection as the “Secretary”) in establishing or applying the risk-based inspection schedules under section 510(k) of such Act.

(2) The extent to which drug safety and quality audits completed by accredited third-party auditors in such an amount necessary to establish and administer the recognition and accreditation program under this section. The Secretary may require accredited third-party auditors to conduct a drug safety and quality audit for the Food and Drug Administration for the work performed to carry out this section. The Secretary shall not generate surplus revenue from such fees.

(3) Whether the Secretary has been able to access drug safety and quality audit reports completed by accredited third-party auditors under such section 809.

(4) Whether accredited third-party auditors accredited under such section 809 have adhered to the terms and other interest provisions set forth in such section.

(5) The extent to which the Secretary has audited recognized accreditation bodies or accredited third-party auditors to ensure compliance with the requirements of such section 809.

(6) The number of waivers under subsection (c)(7)(B) of such section 809 issued during the most recent 12-month period and the official justification by the Secretary for each determination that there was insufficient access to an accredited third-party auditor.

(7) The number of times a manufacturer has used the same accredited third-party auditor for 2 or more consecutive drug safety and quality audits under such section 809.

(8) Recommendations to Congress regarding the accreditation program under such section 809, including whether Congress should continue, modify, or terminate the program.

SEC. 711. STANDARDS FOR ADMISSION OF IMPORTED DRUGS.

Section 801 (21 U.S.C. 381) is amended—

(1) in subsection (o), by striking “drug or”;

and

(2) by adding at the end the following:

“(v) The Secretary may require, as a condition of granting admission to a drug or drug product to the United States, that the importer electronically submit information demonstrating that the drug complies with applicable requirements of this Act.

“(2) The information described under paragraph (i) may include—

“(A) information demonstrating the regulatory status of the drug, such as the new drug application, abbreviated new drug application, investigational new drug application, or new master file number;

“(B) facility information, such as proof of registration and the unique facility identifier;

“(C) indication of compliance with current good manufacturing practice, testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations; and

“(D) any other information deemed necessary and appropriate by the Secretary to assess compliance of the article being offered for import;

“(3) Information requirements referred to in paragraph (2)(C) may, at the discretion of the Secretary, be satisfied—

“(A) by certifications from accredited third parties, as described under section 809;

“(B) through representation by a foreign government, if such inspection is conducted using standards and practices as determined appropriate by the Secretary; or

“(C) other appropriate documentation or evidence as described below.

“(4)(A) Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this subsection. Such requirements shall be appropriate for the type of inspection as well as for import into the United States for use in preclinical research or in a clinical investigation or as an investigational new drug exemption under section 505(i).

“(B) In promulgating the regulations implementing this subsection, the Secretary shall—

“(i) issue a notice of proposed rulemaking that includes the proposed regulation;
“(ii) provide a period of not less than 60 days for comments on the proposed regulation; and
“(iii) publish the final regulation not less than 30 days before the effective date of the regulation.
“(C) Notwithstanding any other provision of law, the Secretary shall promulgate regulations under this subsection only as described in subparagraph (B).”.

SEC. 712. NOTIFICATION.
(a) Prohibited Acts.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:
““(aaa) The failure to notify the Secretary in violation of section 586.”.
(b) Notification.—(1) IN GENERAL.—Chapter E of chapter V (21 U.S.C. 356bb et seq.) is amended by adding at the end the following:
“SEC. 586. NOTIFICATION.
“(a) Notification to Secretary.—With respect to a drug, the Secretary may require notification to the Secretary by a covered person if the covered person knows—
“(1) of a substantial loss or theft of such drug; or
“(2) that such drug—
“(A) is being counterfeited; and
“(B) is a counterfeit product in commerce in the United States; or
“(ii) is offered for import into the United States.
“(b) MANNER OF NOTIFICATION.—Notification under this section may be made in a reasonable time, in such reasonable manner, and by such reasonable means as the Secretary may require by regulation or specify in guidance.
“(c) DEFINITION.—In this section, the term ‘covered person’ means—
“(1) a person who is required to register under section 510 with respect to an establishment engaged in the manufacture, pre- paration, packing, labeling, or compounding, or processing of a drug; or
“(2) a person engaged in the wholesale distribution (as defined in section 503(e)(3)(B)) of a drug.”.

(2) APPLICABILITY.—Notifications under section 568 of the Federal Food, Drug, and Cosmetic Act (as added by paragraph (1)) apply to losses, thefts, or counterfeiting, as described in subsection (a) of such section 568, that occur on or after the date of enactment of this Act.

SEC. 713. PREVENTION AGAINST INTENTIONAL ADULTERATION.
Section 303(b) (21 U.S.C. 333(b)) is amended by adding at the end the following:
“(7) Subsection (a)(2), any person that knowingly and intentionally adulterates a drug such that the drug is adulterated under subsection (a)(1), (b), (c), or (d) of section 501 and has a reasonable probability of causing serious adverse health consequences or death to humans or animals shall be imprisoned for not more than 20 years or fined not more than $1,000,000, or both.”.

SEC. 714. ENHANCED CRIMINAL PENALTY FOR COUNTERFEITING DRUGS.
(a) FFDCA.—Section 303(b) (21 U.S.C. 333(b)), as amended by section 713, is further amended by adding at the end the following:
“(7) Subsection (a)(2), any person that knowingly and intentionally violates section 301(1) shall be imprisoned for not more than 20 years or fined not more than $4,000,000 or both.”.
(b) TITLE III.—Subsection 232(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:
“(C) COUNTERFEIT DRUGS.—
““(2) Counterfeit drugs.—

SEC. 715. EXTRATERRITORIAL JURISDICTION.
Chapter III (21 U.S.C. 331 et seq.) is amended by adding at the end the following:
“SEC. 581. DEFINITIONS.
“(a) In this subchapter:
“(1) DATA CARRIER.—The term ‘data carrier’ means a machine-readablegraphic that is intended to be affixed to, or imprinted upon, an individual saleable unit and a homogenous case of product. The data carrier shall comply with a form and format developed by a widely recognized international standards development organization to ensure interoperability among distribution chain participants.
“(2) INDIVIDUAL SALEABLE UNIT.—The term ‘individual saleable unit’ means the smallest container of product put into interstate commerce by the manufacturer that is intended by the manufacturer for individual sale to a pharmacy or other dispenser of such product.
“(3) PRODUCT.—The term ‘product’ means a finished drug subject to section 508(b)(1).
“(4) PRODUCT TRACING.—The term ‘product tracing’ means—
“(A) identifying the immediate previous source of a product at the lot level when a manufacturer ships a product at the lot level, without regard to the change in ownership involving the wholesale distributor; and
“(B) identifying the immediate previous source of a product at the lot level when a manufacturer ships a product at the lot level, except as otherwise described in this subchapter.
“(5) RxTEC.—The term ‘RxTEC’ means a data carrier that includes the standardized identifier, the lot number, the expiration date, and the expiration date of a product. The standard data carrier RxTEC shall be a 2D data matrix barcode affixed to each individual saleable unit of a product and a linear or 2D data matrix barcode on a homogenous case of product. Such information shall be both machine readable and human readable.
“(6) RxTEC product.—The term ‘RxTEC product’ means a product that, based on credible evidence—
“(A) is potentially counterfeit, diverted, or stolen;
“(B) is reasonably likely to be intentionally adulterated such that the product would result in serious adverse health consequences or death to humans or animals;
“(C) appears otherwise unfit for distribution such that the product would result in serious adverse health consequence or death to humans or animals;
“(7) VERIFICATION.—The term ‘verification’ means the process of determining whether a product has the standardized numerical identifier or any other method such as through purchase records or invoices.

SEC. 582. ADVERSE EVENTS.
“(a) In General.—Sections 355 and 356 of title 21, United States Code, are amended by adding at the end the following:
“Subchapter B—Pharmaceutical Distribution Integrity

SEC. 721. SHORT TITLE.
This subtitle may be referred to as the “Securing Pharmaceutical Distribution Integrity Act of 2012” or the “Securing Pharmaceutical Distribution Integrity Act of 2012.”
information pursuant to subparagraphs (C)
and in a reasonable manner—
(A) maintain change of ownership and transac-
tion information, including RxTEC data that associate unit and lot level data for each individual saleable unit of product and homogenous case introduced in inter-
state commerce; and
(B) maintain change of ownership and transac-
tion information, including RxTEC data, that associate unit and lot level data for each individual saleable unit of product and homogenous case introduced in inter-
state commerce; and
(C) maintain, where a change of ownership
has occurred between non-affiliated enti-
ties or, in the case of a return from the im-
mediate previous source, change of owner-
ship and transaction information relating to a product, including—
(i) RxTEC data;
(ii) the business name and address of the im-
mmediate previous source, if applicable, and the immediate subsequent recipient of the product;
(iii) the proprietary or established name or names of the product;
(iv) the National Drug Code number of the product;
(v) container size;
(vi) number of containers;
(vii) the lot number or numbers of the product; and
(viii) the date of the transaction;
(D) provide the following change of owner-
ship and transaction information to the im-
mmediate subsequent recipient of such product—
(i) the proprietary or established name or names of the product;
(ii) the National Drug Code number of the product;
(iii) container size;
(iv) number of containers;
(v) the lot number or numbers of the product; and
(vi) a signed statement that the manu-
facturer did not knowingly and intentionally
counterfeit such product; and
(E) upon request by the Secretary, other appro-
priate, which—
(i) RxTEC data by lot; and
(ii) change of ownership and transaction infor-
mation pursuant to subparagraph (C) or
any guidance the Secretary issues re-
making necessary by the Secretary or such
other Federal or State official to investigate
a suspect product, provide in a reasonable
time and in a reasonable manner—
(xi) RxTEC data by lot; and
(xii) change of ownership and transaction infor-
mation pursuant to subparagraphs (C) and
(D) necessary to identify the immediate
previous source or immediate subsequent re-
cipient of such product, as applicable.
(2) VERIFICATION REQUIREMENTS.—A manu-
facturer, not later than 4 1⁄2 years after the
date of enactment of the Securing Pharma-
cutical Distribution Integrity Act of 2012 and in accord-
ance with this section, shall—
(A) utilize RxTEC data at the lot level, as
part of ongoing activities to significantly
minimize or prevent the incidences of sus-
p ect product in the pharmaceutical distribu-
tion supply chain, as applicable and appro-
 priate, which—
(i) may include—
(A) apply RxTEC to the individual sale-
able units and the homogenous case of all
product intended to be introduced into inter-
state commerce;
(B) maintain change of ownership and transac-
tion information, including RxTEC data, that associate unit and lot level data for each individual saleable unit of product and homogenous case of product intro-
duced in interstate commerce, including
RxTEC data received for such products and
for which a repackager applies a new RxTEC;
(C) receive only products encoded with
RxTEC data from a licensed or registered
manufacturer, not later than 4 1⁄2 years after the
date of enactment of the Securing Pharma-
cutical Distribution Integrity Act of 2012 and in accord-
ance with this section, shall—
(1) PRODUCT TRACING.—A repackager, not later than 5 years after the date of
enactment of the Securing Pharmaceutical Dis-
tribution Integrity Act of 2012 and in accordance
with this section, shall—
(A) maintain change of ownership and transac-
tion information, including RxTEC data, that associate unit and lot level data for each individual saleable unit of product and homogenous case of product intro-
duced in interstate commerce, including
RxTEC data received for such products and
for which a repackager applies a new RxTEC;
(B) receive only products encoded with
RxTEC data from a licensed or registered
manufacturer or wholesaler;
(C) maintain, where a change of owner-
ship has occurred between non-affiliated enti-
ties or, in the case of a return from the im-
mmediate previous source of the product,
(i) RxTEC data; and
(ii) the business name and address of the im-
mmediate previous source and the imme-
diate subsequent recipient of the product;
``(B) conduct unit level verification upon
the request of a licensed or registered manu-
ufacturer, wholesale distributor, dispenser, or
the Secretary, regarding such product;

``(C) WHOLESALE DISTRIBUTOR REQUIRE-
MENTS.—

``(1) PRODUCT TRACING REQUIREMENTS.—A
wholesale distributor engaged in wholesale dis-
tribution, not later than 60 days after the date of
enactment of the Pharmaceutical Distribution
Integrity Act of 2012 and in accordance with this
section, shall—

``(i) promptly notify the Secretary and im-
pacted trading partners, as applicable and
appropriate; and

``(ii) take steps to remove such product from
the pharmaceutical distribution supply chain;

``(B) REDISTRIBUTION.—Any product subject
to a notification under this subsection may not
be redistributed as a saleable product un-
less the Secretary or manufacturer as applicable,
determines such product may reenter the
pharmaceutical distribution supply chain.

``(C) CONFIDENTIAL DATA.—A wholesale dis-
tributor may confidentially maintain RxTCE data
for a direct trading partner and provide access to
such information to such trading partner in lieu of
data transmission, if mutually agreed upon by such trading partners.

``(D) Use of RxTEC.—A wholesale dis-
tributor, manufacturer, or repackager as applicable,
determines such product may reenter the
pharmaceutical distribution supply chain.

``(E) CONFIDENTIAL DATA.—A wholesale dis-
tributor may maintain RxTEC data from a licen-
sed or registered manufacturer, wholesaler, or repackager;

``(F) FOR INVESTIGATION PURPOSES ONLY, AND
for investigation purposes only, and
for recalled product; and

``(G) maintain, in wholesale distribution
where a change of ownership has occurred
between non-affiliated entities, change of
ownership and transaction information, in-
cluding—

``(i) RxTCE data by lot;

``(ii) the business name and address of the
immediate previous source and the im-
mediate subsequent recipient of the product;

``(iii) the proprietary or established name or
numbers of the product; and

``(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) for the following change of own-
ership and transaction information to the im-
mediate 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 whole-
leisure—

``(I) is licensed or registered;

``(II) received the product from a registered
or licensed manufacturer, repackager, or
wholesale distributor, as applicable;

``(III) received a signed statement from the
immediate subsequent recipient of such product
that such trading partner did not
knowingly and intentionally adulterate or

knowingly and intentionally counterfeit
such product; and

``(IV) did not knowingly and intentionally
adulterate or knowingly and intentionally
counterfeit such product; and

``(D) upon request by the Secretary, other
manufacturers as applicable, determine the
product does not have the standardized nu-
merical identifier or lot number, consistent
with this section, and expiration date assigned by the
Secretary, or such other Federal or State official, to inves-
tigate a suspect product, provide in a reason-
able time and in a reasonable manner—

``(i) RxTCE data from a manufacturer,
repackager, or wholesaler in consultation with
the pharmaceutical distribution supply chain,
as applicable and appropriate; and

``(ii) the history and severity of incidences
of counterfeit, diversion, and theft of such product;

``(iii) the point in the pharmaceutical dis-
tribution supply chain where counterfeit, di-
version, and theft has occurred or is most
likely to occur; and

``(iv) the likelihood that such activities
will reduce the risk of product entering
the pharmaceutical distribution supply chain;

``(v) whether the product could mitigate
or prevent a drug shortage as defined in sec-
tion 506C; and

``(vi) any guidance the Secretary issues re-
garding high-risk scenarios that could
increase the risk of suspect product entering
the pharmaceutical distribution supply chain;

``(C) conduct lot-level verification in the
event of a recall, including upon the request
of a licensed or registered manufacturer, re-
packager, or wholesaler, upon request by the Secretary, and
for recalled product; and

``(D) upon the determination that a particu-
lar product has a high potential risk with respect to
pharmaceutical distribution supply chain se-
curity,

``(I) upon the request of a trade-
ning partner or the Secretary,

``(ii) conduct unit level verification of a
suspect product or recall;

``(iv) conduct unit level verification of a
suspect product;

``(v) upon the request of a licensed or reg-
istered manufacturer, wholesaler, or
the Secretary, regarding such product;

``(vi) upon the determination that a pro-
duct is a suspect product;

``(B) LIMITATION.—Nothing in this para-
graph shall require a wholesale distributor to
verify product at the unit level except as
required under subsections (ii) and (iii) of sub-
paragraph (A).
wholesaler as applicable, determines such
Secretary, and manufacturer, repackager, or
less the dispenser, in consultation with the
not be redistributed as a saleable product un-
to a notification under this paragraph may

ance with this section.

technologies or business systems for compli-

tion; and

the unit level; or

retary determines that such requirements

uarters, as applicable and

unfit for distribution, shall—

a suspect product or a product otherwise

hality available and appropriate;

orms for the interoperable ex-

velop standards for the interoperable ex-

officials, manufacturers, repackagers, whole-

availability and appro-}
(III) the increase in resistance rates in humans; and

(IV) the morbidity and mortality in humans; and

(b) The Secretary shall consult with experts in infectious diseases and antibiotic resistance, including the Centers for Disease Control and Prevention, the Food and Drug Administration, medical professionals, and the clinical research community.

(3) Review.—Every 5 years, or more often as needed, the Secretary shall review, provide recommendations to, and publish the list of qualifying pathogens under subparagraph (A) and shall by regulation revise the list as necessary, in accordance with subsection (e).

(d) Qualified Infectious Disease Product.—The term "qualified infectious disease product" means an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by—

(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

(2) qualifying pathogens listed by the Secretary under subsection (f).

(f) Application.—Section 505E of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to a drug that is first approved under section 505(b) of such Act (21 U.S.C. 355(c)) on or after the date of the enactment of this Act.

SEC. 802. PRIORITY REVIEW.

(a) Amendment.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 524 the following:

"SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.

If the Secretary designates a drug under section 524 of this title as a qualified infectious disease product, then the Secretary shall give priority review to any application submitted for approval for such drug under section 505(b) of such Act (21 U.S.C. 355(b)) on or after the date of the enactment of this Act.

SEC. 803. FAST TRACK PROGRESS.

Section 506(a)(1) (21 U.S.C. 356(a)(1)), as amended by section 901(b), is amended by inserting "the Secretary"

(b) Application.—Section 524A of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to an application that is submitted under section 505(b) of such Act (21 U.S.C. 355(b)) on or after the date of the enactment of this Act.

SEC. 804. FAST TRACK PRODUCT.

Section 506(a)(1) (21 U.S.C. 356(a)(1)), as amended by section 901(b), is amended by inserting "the Secretary"

(b) Application.—Section 524A of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to an application that is submitted under section 505(b) of such Act (21 U.S.C. 355(b)) on or after the date of the enactment of this Act.

SEC. 805. CLINICAL TRIALS.

(a) Review and Revision of Guidance Documents.—

(1) In General.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall review and, as appropriate, revise not fewer than 3 guidance documents per year, which shall include—

(A) reviewing the guidance documents of the Food and Drug Administration for the conduct of clinical trials with respect to antibacterial and antifungal drugs; and

(B) as appropriate, revising such guidance documents to reflect developments in scientific and technological and to ensure clarity regarding the procedures and requirements for approval of antibacterial and antifungal drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 et seq.).

(2) Issues for Review.—At a minimum, the review under paragraph (1) shall address the appropriate, revise not fewer than 3 guidance documents per year, which shall include—

(A) reviewing the guidance documents for non-inferiority trials.

(B) reviewing the guidance documents for superiority trials.

(C) the steps the Secretary will take to ensure regulatory certainty and predictability with respect to qualified infectious disease products.

(3) Rule of Construction.—Except to the extent to which the Secretary makes revisions to documents described in this section, the term "qualified infectious disease product" shall be construed to have the same meaning as the term "qualified infectious disease product" as defined in section 505E of such Act.

(b) Recommendations for Investigations.—

(1) Request.—The sponsor of a drug intended to be designated as a qualified infectious disease product may request that the Secretary provide written recommendations for nonclinical and clinical investigations by which the Secretary believes may be necessary to support the drug before such drug may be approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in treating, detecting, preventing, or curing the disease for which the drug is designated.

(2) Time.—The Secretary shall provide the written recommendation for the clinical investigation within 60 days after the date of receipt of the request.

(c) DRUGS.—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); and

(2) the number and type of qualified infectious disease products for which a clinical trial has been or is planned to be conducted.

(d) MEASURES.—Not later than 3 years after the date of enactment of this Act, the Secretary shall submit to the Congress a report on—

(1) the progress made toward the priorities identified under subsection (a); and

(2) the number and type of qualified infectious disease products for which a clinical trial has been or is planned to be conducted.
Life-threatening diseases or conditions.

(4) the number of such qualified infectious disease products and that have been approved or licensed on or after the date of enactment of this Act.

(5) the number of calendar days it took for the approval or licensure of the qualified infectious disease products approved or licensed on or after the date of enactment of this Act.

(c) QUALIFIED INFECTIOUS DISEASE PRODUCT.—For purposes of this section, the term ‘qualified infectious disease product’ has the meaning given such term in section 505(e)(2) of the Federal Food, Drug, and Cosmetic Act, as added by section 801.

TITLE IX—DRUG APPROVAL AND PATIENT ACCESS

SEC. 901. ENHANCEMENT OF ACCELERATED PATIENT ACCESS TO NEW MEDICAL TREATMENTS.

(a) FINDINGS: SENSE OF CONGRESS.—(1) FINDINGS.—Congress finds as follows: (A) The Food and Drug Administration (referred to in this section as the ‘FDA’) serves a critical role in helping to ensure that new medicines are safe and effective.

(B) Medical innovation is a critical component of the Nation’s strategy to address serious and life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs.

(C) As a result of these remarkable scientific and medical advances, the FDA should be encouraged to implement more broadly effective processes for the expedited development and review of important new medicines.

(D) Patients benefit from expedited access to safe and effective innovative therapies to treat unmet medical needs for serious or life-threatening diseases or conditions, including those for rare diseases or conditions, using a broad range of surrogate or clinical endpoints and modern scientific tools earlier in the drug development cycle when appropriate.

(E) For these reasons, the statutory authority in effect on the day before the date of enactment of this Act governing expedited approval of drugs for serious or life-threatening diseases or conditions should be amended in order to enhance the authority of the FDA to consider appropriate scientific data, evidence, and evidence submitted in an application is reasonably likely to predict clinical benefit, on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. The approval described in the preceding sentence is referred to in this section as ‘accelerated approval’.

(B) EVIDENCE.—The evidence to support that an endpoint is reasonably likely to predict clinical benefit under subparagraph (A) may include—

(i) a surrogate endpoint that is reasonably likely to predict clinical benefit, on a clinical endpoint that can be measured earlier than 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’.

(ii) a surrogate endpoint that is reasonably likely to predict clinical benefit, on a clinical endpoint that can be measured earlier than 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’.

(iii) a surrogate endpoint that is reasonably likely to predict clinical benefit, on a clinical endpoint that can be measured earlier than 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’.

(iv) a surrogate endpoint that is reasonably likely to predict clinical benefit, on a clinical endpoint that can be measured earlier than 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’.

(ii) a surrogate endpoint that is reasonably likely to predict clinical benefit, on a clinical endpoint that can be measured earlier than 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’.

(iii) a surrogate endpoint that is reasonably likely to predict clinical benefit, on a clinical endpoint that can be measured earlier than 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’.

(iv) a surrogate endpoint that is reasonably likely to predict clinical benefit, on a clinical endpoint that can be measured earlier than 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) LIMITATION.—Approval of a product under this subsection may be subject to 1 or more of both of the following:

(A) That the sponsor conduct appropriate post-approval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

(B) That the sponsor submit copies of all promotional materials related to the product to the Secretary either before or at the time of approval and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the material.

(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

(A) the sponsor fails to conduct any required post-approval study of the drug with due diligence;

(B) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

(C) other evidence demonstrates that the product is not safe or effective under the conditions of use; or

(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

(4) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—The Secretary shall—

(A) provide a schedule for submission of information necessary to make the application complete; and

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

(5) EXCEPTION.—An 18-month time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) on or after the date on which the application is complete.

(6) AWARENESS EFFORTS.—The Secretary shall—

(A) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to accelerated approval and fast track products; and

(B) establish a program to encourage the development of surrogate and clinical endpoints, using appropriate scientific methods and tools that can assist the Secretary in determining whether the evidence submitted in an application is reasonably likely to predict clinical benefit for serious or life-threatening conditions for which significant unmet medical needs exist.

(7) CONSTRUCTION.—The amendments made by the Food and Drug Administration Safety and Innovation Act to this section are intended to encourage the Secretary to utilize the flexibility and flexibility of the Food and Drug Administration to expedite the assessment of products under accelerated approval for treatments for patients with serious or life-threatening diseases or conditions and unmet medical needs.
of evidence under subsection (c) or (d) of section 505 (including the substantial evidence standard in section 505(d) of this Act or under section 535(a) of the Public Health Service Act). To the extent such evidence applies to the review and approval of products under this section, including whether a product is safe and effective. Nothing in this section shall apply to products for which the Secretary to rely on evidence that does not come from adequate and well-controlled investigations for the purpose of determining whether the drug is reasonably likely to predict clinical benefit as described in section (b)(1)(B)."

(c) GUIDANCE; AMENDED REGULATIONS.—

(1) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall issue draft guidance to implement the amendments made by this section. In developing such guidance, the Secretary shall specifically consider issues arising under the accelerated approval and fast track processes under section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), for drugs designated for a rare disease or condition under section 522 of such Act (21 U.S.C. 360bb) and shall also consider any unique issues associated with very rare diseases.

(2) FINAL GUIDANCE.—Not later than 1 year after the issuance of draft guidance under paragraph (1), and after an opportunity for public comment, the Secretary shall issue final guidance.

(3) CONFORMING CHANGES.—The Secretary shall issue, as necessary, conforming amendments to the applicable regulations under title II of the Food, Drug, and Cosmetic Act, as amended by subsection (b), to make concurrent with, or at any time after, the submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

(3) DESIGNATION.—

(A) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a breakthrough therapy and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

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

(ii) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the non-clinical and clinical data necessary for approval is scientifically defensible;

(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

(iv) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor;

(v) taking steps to ensure that the design of the clinical development and regulatory review programs to evaluate the Food and Drug Administration's application of the processes described in section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), and the impact of such processes on the development and timely availability of innovative treatments for patients suffering from serious or life-threatening conditions. Such an investigation shall include consultation with regulated industries, patient advocacy and disease research foundations, and relevant academic medical centers.

SEC. 902. BREAKTHROUGH THERAPIES.

(a) IN GENERAL.—Section 506 (21 U.S.C. 356), as amended by section 901, is further amended—

(1) by redesignating subsections (a) through (c) as subsections (b) through (d), respectively;

(2) in redesignating subsection (d) as subsection (f);

(3) by inserting before subsection (b), as so redesignated, the following:

"(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH THERAPY.—

"(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of such drug if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. (In this section, such a drug is referred to as a 'breakthrough therapy.')

"(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a breakthrough therapy. A request for the designation may be made concurrently with, or at any time after, the submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

"(3) DESIGNATION.—

(A) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a breakthrough therapy and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

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

(ii) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the non-clinical and clinical data necessary for approval is scientifically defensible;

(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

(iv) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor;

(v) taking steps to ensure that the design of the clinical development and regulatory review programs to evaluate the Food and Drug Administration's application of the processes described in section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), and the impact of such processes on the development and timely availability of innovative treatments for patients suffering from serious or life-threatening conditions. Such an investigation shall include consultation with regulated industries, patient advocacy and disease research foundations, and relevant academic medical centers.

(b) GUIDANCE; AMENDED REGULATIONS.—

(1) IN GENERAL.—

(A) GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Secretary shall issue final guidance with respect to breakthrough therapies, as set forth in section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356a), as amended by section 901.

(B) AMENDED REGULATIONS.—

(i) IN GENERAL.—If the Secretary determines that it is necessary to amend the regulations under title 21, Code of Federal Regulations in order to implement the amendments made by this section to section 506(a) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall amend such regulations not later than 2 years after the date of enactment of this Act.

(ii) PROCEDURE.—In amending regulations under clause (i), the Secretary shall—

(I) issue a notice of proposed rulemaking that includes the proposed regulation;

(II) provide a period of not less than 60 days for comments on the proposed regulation; and

(III) publish the final regulation not less than 30 days before the effective date of the regulation.

(iii) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing the amendments made by this section only as described in clause (ii).

(2) REQUIREMENTS.—Guidance issued under this section shall—

(A) specify the process and criteria by which the Secretary makes a designation under section 506(a)(3) of the Federal Food, Drug, and Cosmetic Act; and

(B) specify the actions the Secretary shall take to expedite the development and review of a breakthrough therapy pursuant to such designation under such section 506(a)(3), including updating good review management practices to reflect breakthrough therapies.

(c) INDEPENDENT REVIEW.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States, in consultation with appropriate experts, shall assess the manner by which the Food and Drug Administration has applied the processes described in section 506(a) of the Federal Food, Drug, and Cosmetic Act, as amended by this section, and the impact on the processes described in section 506 and the timely availability of innovative treatments for patients affected by serious or life-threatening conditions. Such assessment shall be made publicly available upon completion.

(d) CONFORMING AMENDMENTS.—Section 506B(e) (21 U.S.C. 356b) is amended by striking "section 506(b)(2)(A)" each place such term appears and inserting "section 506(c)(2)(A)"

SEC. 903. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

(a) IN GENERAL.—For the purpose of promoting the efficiency of and informing the review by the Food and Drug Administration of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, the following shall apply:

(1) CONSULTATION WITH STAKEHOLDERS.—Consistent with sections X.C and IX.E.4 of the PDUSA Reauthorization Performance and Accountability Reports for Fiscal Years 2011 to 2013 (referred to in this section as the "Secretary") shall issue draft guidance on implementing the requirements with respect to breakthrough therapies, as set forth in section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356a), as amended by section 901.
Drug User Fee Amendments of 2012, the Secretary shall ensure that opportunities exist, at a time the Secretary determines appropriate, for consultations with stakeholders on the establishment of working group. (2) CONSULTATION WITH EXTERNAL EXPERTS.—The Secretary shall develop and maintain a list of external experts who, because of their specific 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 with such external experts on issues related to the review of new drugs and biological products for rare diseases and drugs and biological products for blindness. (3) TOPICS FOR CONSULTATION.—Topics for consultation pursuant to this section may include—

(a) rare diseases;
(b) the severity of rare diseases;
(c) the unmet medical need associated with rare diseases;
(d) the willingness and ability of individuals with a rare disease to participate in clinical trials;
(e) assessment of the benefits and risks of therapies to treat rare diseases;
(f) the general design of clinical trials for rare disease populations and subpopulations; and
(g) demographics and the clinical description of patient populations.

(4) CLASSIFICATION AS SPECIAL GOVERNMENT EMPLOYEES.—The external experts who are consulted under this section may be considered special government employees, as defined under section 202 of title 18, United States Code.

(e) PROTECTION OF PROPRIETARY INFORMATION.—Nothing in this section shall be construed to alter the protections offered by laws, policies, or regulations governing the disclosure of confidential commercial or trade secret information, and any other information considered confidential. (f) 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; and
(2) the term ‘prescription drug container’ means a pharmacy that receives prescriptions and dispenses prescription drugs through an Internet website or by mail.

(2) REQUIREMENTS.—

(a) ESTABLISHMENT OF WORKING GROUP.—

The Architectural and Accessible Communities and Blind Consumers. (b) REQUIREMENTS.—

The Architectural and Accessible Communities and Blind Consumers.

SEC. 901. ACCESSIBILITY OF INFORMATION ON PRESCRIPTION DRUG CONTAINER LABELS BY VISUALLY-IMPAIRED AND BLIND CONSUMERS.

(a) ESTABLISHMENT OF WORKING GROUP.—

(1) IN GENERAL.—The Architectural and Transportation Barriers Compliance Board (referred to in this section as the “Access Board”) shall convene a stakeholder working group (referred to in this section as the “working group”) to develop best practices for prescription drug container labels for individuals who are blind or visually impaired.

(b) MEMBERS.—The working group shall be comprised of representatives of national organizations representing blind and visually-impaired individuals, national organizations representing the elderly, and industry groups representing retail, mail order, and independent community pharmacies, as well as any other stakeholders the Secretary determines appropriate. (c) PROTECTION OF PROPRIETARY INFORMATION.—The working group shall ensure that opportunities exist, at a time the Secretary determines appropriate, for consultations with stakeholders on the design of clinical trials; and

(A) the use of—
(ii) auditory means, such as—
(III) radio frequency identification tags;
(iii) enhanced visual means, such as—

(D) classifying as special government employees, as defined under section 202 of title 18, United States Code.

(f) PROTECTION OF PROPRIETARY INFORMATION.—Nothing in this section shall be construed to alter the protections offered by laws, policies or regulations governing the disclosure of confidential commercial or trade secret information, and any other information considered confidential. (g) OTHER CONSIDERATIONS.—Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals as authorized prior to the date of enactment of this section.

(2) OTHER CONSIDERATION.—Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals as authorized prior to the date of enactment of this section.

(g) NO RIGHT OR OBLIGATION.—Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder. Nothing in this section shall be construed to alter the requirements of the Federal Register or the requirements for public comment set forth in the Federal Register.

(2) REQUIREMENTS.—

(a) IN GENERAL.—The Secretary shall implement a structured r
deficiencies, 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.

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

(A) the use of—
(i) Braille;
(ii) auditory means, such as—

(E) ELEMENTS.—The study conducted under subsection (a) shall model at least 3 separate segments on the medical technologies market as candidates targets for the 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.

(b) REQUIREMENTS.—

(1) IN GENERAL.—The study conducted under subsection (a) shall model at least 3 separate segments on the medical technologies market as candidates targets for the medical innovation inducement prize design issues, including the challenges presented in the implementation of prizes for end products, open source dividend prizes, and prizes for upstream research.

(2) MARKET SEGMENTS.—The segments on the medical technologies market that shall be considered under paragraph (1) include—

(A) all pharmaceutical and biologic drugs and vaccines;
(B) drugs and vaccines used solely for the treatment of HIV/AIDS; and
(C) antibiotics.

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

(1) Whether a system of large innovation inducement prizes could work as a replacement for the existing product monopoly

such as—

(A) the use of—
(ii) auditory means, such as—

(iii) enhanced visual means, such as—

(i) ‘talking bottles’ that provide audible container label information;
(II) digital voice recorders attached to the prescription drug container;

(b) REQUIREMENTS.—

(1) IN GENERAL.—The study conducted under subsection (a) shall model at least 3 separate segments on the medical technologies market as candidates targets for the medical innovation inducement prize design issues, including the challenges presented in the implementation of prizes for end products, open source dividend prizes, and prizes for upstream research.

(2) MARKET SEGMENTS.—The segments on the medical technologies market that shall be considered under paragraph (1) include—

(A) all pharmaceutical and biologic drugs and vaccines;
(B) drugs and vaccines used solely for the treatment of HIV/AIDS; and
(C) antibiotics.

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

(1) Whether a system of large innovation inducement prizes could work as a replacement for the existing product monopoly

such as—

(A) the use of—
(ii) auditory means, such as—

(iii) enhanced visual means, such as—

(i) ‘talking bottles’ that provide audible container label information;
(II) digital voice recorders attached to the prescription drug container;

(b) REQUIREMENTS.—

(1) IN GENERAL.—The study conducted under subsection (a) shall model at least 3 separate segments on the medical technologies market as candidates targets for the 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) How large the innovation prize funds would have to be in order to induce at least as much research and development investment in innovation as is induced under the current system of time-limited market exclusivity, as in effect on the date of enactment of this Act.

(3) Whether a system of large innovation inducement prizes would expand access to new products and improve health outcomes.

(4) Whether a system of large innovation inducement prizes would expand access to new products and improve health outcomes.

(5) Whether a system of large innovation inducement prizes would expand access to new products and improve health outcomes.

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

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

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

SEC. 506C. DISCONTINUANCE OR INTERRUPTION OF DRUG AND BIOTECHNOLOGY DEVELOPMENT, MANUFACTURING, OR FIELD TESTING ACTIVITIES OR DEFERRAL OF REGISTRATION.

(a) In general.—Section 506C of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended by striking “2008 through 2012” and inserting “2013 through 2017.”

(b) Human clinical testing.—Section 5(b)(1)(A)(ii) of the Orphan Drug Act (21 U.S.C. 360ee(b)(1)(A)(ii)) is amended by striking “after the date such drug is designated under section 526 of such Act and”.

(c) Expiration date.—Section 1001 of the Orphan Drug Act (21 U.S.C. 356c) is amended to read as follows:

“SEC. 1001. DRUG SHORTAGES.

“(a) In general.—Not later than 1 year after the date of enactment of this Act, the Secretary, through the Commissioner of Food and Drugs, shall publish on the Internet website of the Food and Drug Administration a report, consisting of the recommendations of the Food and Drug Administration pertaining to the protection of sponsors’ confidential commercial information as of the date of enactment of this Act and 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 readily available to the public in a timely manner by means of the product labeling or the Food and Drug Administration’s website.

“(b) Action plan.—In general.—Not later than 1 year after the publication of the report described in subsection (a), the Secretary, through the Commissioner, shall publish an action plan on the Internet website of the Food and Drug Administration and provide such publication to Congress.

“(c) Definitions.—In this section:

“(1) Commissioner.—The Commissioner of Food and Drugs.

“(2) Drug.—The term “drug” has the meaning given in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)).

“(3) “Biological product” means the term “biological product” as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

“(4) “Product” means any drug or biological product;

“(5) “Regulatory action” means an action that could precipitate a drug shortage or prevent such shortage.

“(i) 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.

“(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 the Secretary should alert about potential or actual drug shortages, how the communication should occur, and what types of information should be shared; and

“(iv) Plans for considering the impact of drug shortages on research and clinical trials.

“(5) Consultation.—In carrying out this section, the Task Force shall ensure consultation with the appropriate offices within the Food and Drug Administration, including the Office of the Commissioner, the Center for Drug Evaluation and Research, the Office of Laboratory Services, and employees within the Department of Health and Human Services with expertise regarding drug shortages. The Secretary shall ensure that government stakeholders and experts as appropriate.

“(6) Timings.—Not later than 1 year after the date of enactment of this Act, the Secretary shall—

“(A) publish the strategic plan described in this subsection; and

“(B) submit such plan to Congress.

“(7) Definitions.—In this section:

“(1) Drug shortage.—The term “drug shortage” means a drug shortage that could lead to a meaningful disruption in the supply of that drug in the United States.

“(2) Drug.—The term “drug” means a drug described in subsection (a), the Secretary may—

“(A) expedite the review of a supplement to a new drug application submitted under section 505(j) of the Orphan Drug Act (21 U.S.C. 355(j)), or a supplement to such an application submitted under section 505(k) that could help mitigate or prevent such shortage.

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

“(8) Coordination.—

“(A) Task force and strategic plan.—The strategic plan described in clause (i) shall include—

“(I) plans for enhanced interagency and interstate 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 the Secretary should alert about potential or actual drug shortages, how the communication should occur, and what types of information should be shared; and

“(IV) plans for considering the impact of drug shortages on research and clinical trials.

“(B) Consultation.—In carrying out this section, the Task Force shall ensure consultation with the appropriate offices within the Food and Drug Administration, including the Office of the Commissioner, the Center for Drug Evaluation and Research, the Office of Laboratory Services, and employees within the Department of Health and Human Services with expertise regarding drug shortages. The Secretary shall ensure that government stakeholders and experts as appropriate.

“(c) Expedited inspections and re-inspections.—If, based on notifications described in subsection (a) or any other relevant information, the Secretary concludes that there is, or is likely to be, a drug shortage of a drug described in subsection (a), the Secretary may—

“(1) expedite the review of a supplement to a new drug application submitted under section 505(j) of the Orphan Drug Act (21 U.S.C. 355(j)), or a supplement to such an application submitted under section 505(k) that could help mitigate or prevent such shortage.

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

“(d) Coordination.—

“(1) Task force and strategic plan.—The strategic plan described in this section shall include—

“(A) plans for enhanced interagency and interstate coordination, communication, and decisionmaking;

“(B) 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;

“(C) plans for effective communication with outside stakeholders, including the Secretary should alert about potential or actual drug shortages, how the communication should occur, and what types of information should be shared; and

“(D) plans for considering the impact of drug shortages on research and clinical trials.

“(2) Consultation.—In carrying out this section, the Task Force shall ensure consultation with the appropriate offices within the Food and Drug Administration, including the Office of the Commissioner, the Center for Drug Evaluation and Research, the Office of Laboratory Services, and employees within the Department of Health and Human Services with expertise regarding drug shortages. The Secretary shall ensure that government stakeholders and experts as appropriate.

“(e) Exemption.—The Secretary shall ensure that, prior to any enforcement action...
or issuance of a warning letter that the Secretary determines could reasonably be anticipated to lead to a meaningful disruption in the supply in the United States of a drug described in subsection (a), then the Secretary shall evaluate the risks associated with the impact of such shortage upon patients and those risks associated with the violation involved before taking action or issuing such letter, unless there is imminent risk of serious adverse health consequences or death to humans.

(3) Action.—If the Secretary determines, after the communication described in paragraph (1), that the drug or drug shortage identified in the communication could cause, or exacerbate, a shortage of the drug.

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

(5) Internal review.—

(i) the number of applications for which the Secretary issued a notification under subsection (a) in each calendar year.

(ii) the number of applications for which the Secretary reviewed the drug or drug shortage notified under subsection (a).

(6) Records kept by the Secretary in connection with the drug shortages described in subparagraph (B).

(7) Annual report.—The Secretary shall submit a report to the Senate and the Committee on Energy and Commerce of the House of Representatives, the Appropriations Committee of the Senate, and the Committee on Appropriations of the House of Representatives for each fiscal year that includes the following:

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

(B) The number of drug shortages that occurred in each calendar year and a list of drug names, drug types, and classes that were the subject of such shortages.

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

(D) The number of applications for which the Secretary reviewed the drug or drug shortage identified in the communication could cause, or exacerbate, a shortage of the drug.

(8) Notification requirement.—

(1) the term 'drug'—

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

(B) does not include biological products (as defined in section 351 of the Public Health Service Act), unless otherwise provided by the Secretary in the regulations promulgated under subsection (b); and

(C) the term 'shortage', with respect to a drug, means a period of time when the demand or projected demand for the drug within the United States exceeds the supply.

(9) Definitions.—For purposes of this section—

(1) the term 'drug shortage'—

(A) means a change in production that is more than negligible and impacts the ability of the manufacturer to fill orders or meet inventory needs; and

(B) does not include changes 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 the permanent discontinuation of the drug, to drug manufacturers, operators of distribution centers, and下游 entities.

(3) REGULATION.—The Secretary shall implement this section, the Secretary shall submit a report to the Senate and the Committee on Energy and Commerce of the House of Representatives implementing this section, the Secretary shall adopt a final regulation implementing this section.

(4) RESTRICTIONS.—Notwithstanding any provision of Federal law, in implementing this section, the Secretary shall promulgate regulations as described in paragraph (3).''.

(b) Effect of Notification.—The submission of a notification to the Secretary of Health and Human Services (referred to in this section as the 'Secretary') for purposes of complying with the requirement in section 506C(a) of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)) shall not be construed—

(1) as an admission that any product that is the subject of such notification violates any provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or

(2) as evidence of an intention to promote or market the product for an indication or use for which the product has not been approved by the Secretary.

(c) Internal Review.—Not later than 2 years after the date of enactment of this Act, the Secretary shall—

(1) analyze and review the regulations promulgated under the Federal Drug, Food, 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 such Act related to manufacturing of drugs, to identify any regulations, guidelines, policies, or practices that cause, exacerbate, prevent, or mitigate drug shortages as defined in section 506C of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)); and

(2) determine how regulations, guidelines, policies, or practices identified under paragraph (1) should be modified, streamlined, expanded, or discontinued in order to reduce or prevent such drug shortages, taking into consideration the effect of any changes on the public health.

(d) Study on Market Factors Contributing to Drug Shortages and Stockpiling.—

(1) In general.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States, in consultation with the Secretary, shall submit to the Committee on Health and Human Services Office of the Inspector General, the Attorney General, and Chairman of the Federal Trade Commission, a report reviewing any findings that drug shortages (as defined in paragraph (1)) have led market participants to stockpile affected drugs or sell them at significantly increased prices, the impact of such activities on the public health, 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 short supply and the number of manufacturers producing such drugs; and

(ii) the pricing structure, including Federal reimbursements, for such drugs before the shortage was in effect, and the potential cost, revenue received by each such manufacturer of such drugs;

SEC. 2. TRENDS ANALYSIS.—The Secretary is authorized to retain a third party to conduct a study, if the Secretary believes such a study would help clarify the causes, trends, or solutions relating to the drug shortages 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), but did not evaluate the risks associated with the impact of such shortage upon patients and those risks associated with the violation involved before taking action or issuing such letter, unless there is imminent risk of serious adverse health consequences or death to humans.

(3) Annual summary.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report summarizing, with respect to the 1-year period preceding such report, the information described in paragraph (1). Such report shall not include information that is exempt from disclosure under subsection (a) of section 522 of title 5, United States Code, by reason of subsection (b)(4) of such section.

(4) Definitions.—For purposes of this section—

(1) the term 'drug'—

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

(B) does not include biological products (as defined in section 351 of the Public Health Service Act), unless otherwise provided by the Secretary in the regulations promulgated under subsection (b);

(2) the term 'shortage', with respect to a drug, means a period of time when the demand or projected demand for the drug within the United States exceeds the supply.

(3) the term 'meaningful disruption'—

(A) means a change in production that is reasonably likely to lead to a reduction in the supply of a drug by a manufacturer that is more than negligible and impacts the ability of the manufacturer to fill orders or meet inventory needs; and

(B) does not include changes 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.

(5) Distribution.—To the maximum extent practicable, the Secretary may distribute information on drug shortages and the permanent discontinuation of the drug, to drug manufacturers, operators of distribution centers, and downstream entities.

(6) Regulations.—The Secretary shall adopt a final regulation implementing this section, the Secretary shall submit a report to the Senate and the Committee on Energy and Commerce of the House of Representatives implementing this section, the Secretary shall adopt a final regulation implementing this section.
(iii) pricing structure and revenue, to the extent possible, for the same drugs when sold under the conditions described in paragraph (1); and

(iv) the impact of contracting practices by market participants (including manufacturers, distributors, group purchasing organizations, and providers) on competition, access to drugs, and pricing of drugs;

(C) whether the activities described in paragraph (1) are consistent with applicable law; and

(D) recommendations to Congress on what, if any, additional reporting or enforcement actions are necessary.

(3) TRADE SECRET AND CONFIDENTIAL INFORMATION.—Notwithstanding this subsection alters or amends section 1905 of title 18, United States Code, or section 522(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 transporting repackaged drugs among hospitals within a common health system during a drug shortage as identified by the Secretary.

TITLE XI—OTHER PROVISIONS

Subtitle A—Reauthorizations

SEC. 1101. REAUTHORIZATION OF PROVISION RELATING TO EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

(a) In General.—Section 505(u)(4) (21 U.S.C. 355(u)(4)) is amended by striking "2012" and inserting "2017".


SEC. 1102. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

Section 566(f) (21 U.S.C. 360bbb-3(f)) is amended by striking "2012" and inserting "2017".

Subtitle B—Medical Gas Product Regulation

SEC. 1111. REGULATION OF MEDICAL GAS PRODUCTS.

(a) Regulation.—Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter G—Medical Gas Products"

"SEC. 575. REGULATIONS OF MEDICAL GAS PRODUCTS.

"(a) Certification of Designated Medical Gas Products.—

"(1) Submission.—

"(A) In General.—Beginning on the date of enactment of this section, any person may file with the Secretary a request for a certification of a designated medical gas product.

"(B) Content.—A request under subparagraph (A) shall contain—

"(i) a description of the medical gas product;

"(ii) the name and address of the sponsor;

"(iii) the name and address of the facility or facilities where the gas product is or will be manufactured;

"(iv) any other information deemed appropriate by the Secretary to determine whether the medical gas product is a designated medical gas product.

"(2) Grant of Certification.—A certification described under paragraph (1)(A) shall be determined to have been granted unless, not later than 60 days after the filing of a request under paragraph (1), the Secretary finds that—

"(A) the medical gas product subject to the certification is not a designated medical gas product;

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

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

"(3) Effect of Certification.—

"(A) IN GENERAL.—Beginning on 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 the necessary advice of the Food and Drug Administration (referred to in this Act as the "FDA") and the necessary advice of the Federal Bureau of Investigation, the Drug Enforcement Administration, and the Food and Drug Administration, and the necessary advice of the Secretary of the Treasury, the Secretary shall issue guidance that clarifies the policy of the Food and Drug Administration regarding hospital pharmacies repackaging and safely transporting repackaged drugs among hospitals within a common health system during a drug shortage as identified by the Secretary.

"(B) Certification of Medical Gas Products.—The Secretary may revoke the grant of a certification under this section if the Secretary determines that the request for certification contains any material omission or falsification.

"(4) Withdrawal, Suspension, or Revocation.—

"(A) In General.—Nothing in this subchapter limits the authority of the Secretary to withdraw or suspend approval of a drug, including a designated medical gas product deemed under this section to have in effect an approved application, under section 505 or section 512.

"(B) Revocation.—The Secretary may revoke the grant of a certification under this section if the Secretary determines that the request for certification contains any material omission or falsification.

"(b) Prescription Requirement.—

"(1) In General.—A designated medical gas product shall be subject to section 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) or the use in question is authorized pursuant to another provision of this Act relating to use of medical products in emergencies.

"(2) Exception for Oxygen.—

"(A) In General.—Notwithstanding paragraph (1), oxygen may be provided without a prescription for the following uses:

"(i) The use in the event of depressurization or other environmental oxygen deficiency.

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

"(B) Labeling.—For oxygen provided pursuant to subparagraph (A), the requirements established in section 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.

"(c) Inapplicability of Drug Fees to Designated Medical Gas Products.—A designated medical gas product deemed under this section to have in effect an approved application shall not be assessed fees under section 738(a) on the basis of such deemed approval.

SECT. 1112. REGULATIONS.

(a) Review of Regulations.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall, after obtaining input from medical gas product manufacturers, and any other interested members of the public, submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representa-
tives regarding any changes to the Federal rules, regulations, and orders that have been promulgated in title 21, Code of Federal Regulations that the Secretary determines to be necessary.
(b) AMENDED REGULATIONS.—If the Secretary determines that changes to Federal law or regulations are necessary under subsection (b) in order to ensure that Federal regulations implementing such changes do not later than 4 years after the date of enactment of this Act.

SEC. 111A. ABILITY.

Nothing in this subtitle or the amendments made by this subtitle shall apply to—

(1) a drug that is covered by an application under section 505(c), 512, 512(n), or 512(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 356b) approved prior to May 1, 2012; or

(2) any of the drugs listed in subparagraphs (A) through (G) of section 753(c) of such Act (as added by section 1111), or any mixture of any such drugs, for an indication that—

(A) is not included in, or is different from, those specified in subclauses (I) through (VII) of section 576(a)(3)(i) of such Act (as added by section 1111); and

(B) is approved on or after May 1, 2012, pursuant to an application submitted under section 505 or 512 of such Act.

Subtitle C—Miscellaneous Provisions

SEC. 1121. ADVISORY COMMITTEE CONFLICTS OF INTEREST.

Section 712 (21 U.S.C. 379d-1) is amended—

(1) in subsection (b)—

(A) by striking paragraph (2); and

(B) by redesignating paragraph (3) as paragraph (2); and

(ii) subparagraph (A), by redesignating clauses (i) through (iii) as subparagraphs (A) through (C), respectively, and moving such subparagraphs as so redesignated, 2 ems to the left;

(ii) subparagraph (B), by redesignating clauses (i) through (iii) as subparagraphs (A) through (C), respectively, and moving such subparagraphs as so redesignated, 2 ems to the left;

(iii) subparagraph (A), by so redesignating, 2 ems to the left;

(2) by amending subsection (c)(2)(C) to read—

(3) by adding at the end the following:

``'SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.

Subchapter D of chapter VII (21 U.S.C. 379k et seq.) is redesignated by inserting after section 745 the following:

SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.

(a) Drugs and Biologics.—

(i) IN GENERAL.—Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for public comment under subsection (b), (i), (j), or (k) of section 505 of this Act or subsection (a) or (k) of section 515 of the Public Health Service Act shall be submitted in an electronic format as specified by the Secretary in such guidance.

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

(A) provide a timeframe for establishment by the Secretary of further standards for electronic submission as required by such paragraph; and

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

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

(4) DEVICES.—

(i) IN GENERAL.—Beginning no earlier than 24 months after the issuance of a final guidance implementing this paragraph, pre-submissions and submissions for devices under section 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), and 564 of this Act or section 351 of the Public Health Service Act, and any supplements to such submissions, shall include an electronic copy of such pre-submissions or submissions.

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

(A) provide standards for the electronic copy required under such paragraph; and

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

SEC. 1122. GUIDANCE DOCUMENT REGARDING PRODUCT PROMOTION USING THE INTERNET.

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance that describes Food and Drug Administration policy regarding the promotion, using the Internet (including social media), of medical products that are regulated by such Administration.

SEC. 1123. ELECTRONIC SUBMISSION OF APPLICATIONS.

Not later than 2 years after the date of enactment of this Act, the Secretary shall issue guidance that describes how the Secretary reviews the financial interests and involvement of advisory committee members (as so defined and included in paragraph 573(c)(3)(i)), including those specified in subclauses (I) through (IV) of section 576(a)(3) of such Act (as added by section 1111), as it relates to collection of information relevant to adverse events, patient safety, and patient outcomes, to create a centralized data clearinghouse and early warning tool.

Not later than 6 months after the date of enactment of this Act, the Secretary shall conduct a study and report on prescription drug abuse. Such report shall evaluate trends in prescription drug abuse, assess opportunities to inform and educate the public, patients, and health care providers on issues related to prescription drug abuse and misuse, and identify potential barriers, if any, to prescription drug monitoring program participation and implementation.

SEC. 1125. TANNING BED LABELING.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall determine whether to amend the warning label requirements for sunlamp products to include special requirements to more clearly and effectively convey the risks that such products pose for the development of irreversible damage to the eyes and skin, including skin cancer.

SEC. 1126. OPTIMIZING GLOBAL CLINICAL TRIALS.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall determine whether to amend the warning label requirements for sunlamp products to include special requirements to more clearly and effectively convey the risks that such products pose for the development of irreversible damage to the eyes and skin, including skin cancer.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance that describes Food and Drug Administration policy regarding the promotion, using the Internet (including social media), of medical products that are regulated by such Administration.

Not later than 2 years after the date of enactment of this Act, the Secretary shall issue guidance that describes how the Secretary reviews the financial interests and involvement of advisory committee members (as so defined and included in paragraph 573(c)(3)(i)), including those specified in subclauses (I) through (IV) of section 576(a)(3) of such Act (as added by section 1111), as it relates to collection of information relevant to adverse events, patient safety, and patient outcomes, to create a centralized data clearinghouse and early warning tool.

Not later than 2 years after the date of enactment of this Act, the Secretary shall issue guidance that describes how the Secretary reviews the financial interests and involvement of advisory committee members (as so defined and included in paragraph 573(c)(3)(i)), including those specified in subclauses (I) through (IV) of section 576(a)(3) of such Act (as added by section 1111), as it relates to collection of information relevant to adverse events, patient safety, and patient outcomes, to create a centralized data clearinghouse and early warning tool.
“(B) facilitate the use of foreign data; and
“(C) minimize the need to conduct duplicative clinical studies, preclinical studies, or non-clinical studies.

(b) MEDICAL PRODUCT.—In this section, the term ‘medical product’ means a drug, as defined in subsection (g) of section 201, a device, as defined in subsection (h) of such section, or a biological product, as defined in section 351(i) of the Public Health Service Act.

(c) SAVINGS CLAUSE.—Nothing in this section shall alter the criteria for evaluating the safety or effectiveness of a medical product under this Act.

SEC. 1128. INFORMATION TECHNOLOGY.
(a) IN GENERAL.—In determining whether to approve, license, or clear a drug or device pursuant to an application submitted under this chapter, the Secretary shall accept data from clinical investigations conducted outside of the United States, including the European Union, if the applicant demonstrates that such data is adequate for the purpose of verifying the safety and effectiveness of the drug or device in the United States.

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 verifying the safety and effectiveness of the drug or device in the United States, the Secretary shall provide written notice to the sponsor of the application of such finding and include the rationale for such finding and include the rationale for such finding and include the rationale for such finding.

SEC. 1127. ADVANCING REGULATORY SCIENCE TO PROMOTE PUBLIC HEALTH INNOVATION.
(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ‘‘Secretary’’) shall develop a strategy and implementation plan for advancing regulatory science for medical products in order to promote the public health and advance innovation in regulatory decisionmaking.

(b) REQUIREMENTS.—The strategy and implementation plan developed under subsection (a) shall be consistent with the user fee performance goals in the Prescription Drug User Fee Agreement commitment letter, the Medical Device User Fee Agreement commitment letter, and the Biosimilar User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 20, 2012, and the Medical Device User Fee Agreement commitment letter transmitted by the Secretary to Congress on April 20, 2012, and shall—

(1) identify a clear vision of the fundamental role of efficient, consistent, and predictable, science-based decisions throughout regulatory decisionmaking of the Food and Drug Administration regarding medical products and allocation of resources towards such regulatory science priorities;

(2) identify the regulatory science priorities of the Food and Drug Administration directly related to fulfilling the mission of the agency with respect to decisionmaking concerning medical products and allocation of resources towards such regulatory science priorities;

(3) identify regulatory and scientific gaps that impede the timely development and review of, and regulatory certainty with respect to, the licensure, clearance, or approval of medical products, including with respect to companion products and new technologies, and facilitating the timely introduction and adoption of new technologies, and methodologies in a safe and effective manner;

(4) identify clear, measurable metrics by which progress on the priorities identified under paragraph (2) and gaps identified under paragraph (3) will be measured by the Food and Drug Administration, including metrics specific to the integration and adoption of advances in regulatory science described in paragraph (5) and improving medical product decisionmaking in a predictable and science-based manner; and

(5) set forth how the Food and Drug Administration will ensure that advances in regulatory science for medical products are adopted, as appropriate, on an ongoing basis and in an manner integrated across centers, divisions, and branches of the Food and Drug Administration, including through—

(A) development, updating, and consistent application of guidance documents that support medical product decisionmaking; and

(B) the adoption of the tools, methods, and processes under section 566 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–5).

(c) ANNUAL PERFORMANCE REPORTS.—As part of the annual performance reports submitted to Congress under sections 705(b), 738(b), 739(b), 743(b), and 744(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376), the Secretary shall annually report on the progress made with respect to—

(1) advancing the regulatory science priorities identified under paragraph (2) of such section and resolving the gaps identified under paragraph (3) of such subsection, including reporting on specific metrics identified under paragraph (4) of such subsection;

(2) the integration and adoption of advances in regulatory science as set forth in paragraph (5) of such subsection; and

(3) the progress made in advancing the regulatory science goals outlined in the Prescription Drug User Fee Agreement commitment letter, the Generic Drug User Fee Agreement commitment letter, and the Biosimilar User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 13, 2012, and the Medical Device User Fee Agreement transmitted by the Secretary to Congress on April 20, 2012.

(d) INDEPENDENT ASSESSMENT.—Not later than January 1, 2016, the Comptroller General of the United States shall submit to Congress a report—

(1) detailing the progress made by the Food and Drug Administration in meeting the priorities and addressing the gaps identified in subsection (b), including any outstanding gaps; and

(2) containing recommendations, as appropriate, on how regulatory science initiatives for medical products can be strengthened and improved to promote the public health and advance innovation in regulatory decisionmaking.

(e) MEDICAL PRODUCT.—In this section, the term ‘medical product’ means a drug, as defined in subsection (g) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), a device, as defined in subsection (h) of such section, or a biological product, as defined in section 351(i) of the Public Health Service Act.

SEC. 1129. 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 the development and adoption of a comprehensive information technology strategic plan to align the information technology systems modernization projects with the strategic goals of the Food and Drug Administration, including results-oriented goals, strategies, milestones, performance measures; and

(B) efforts to finalize and approve a comprehensive inventory of the information technology systems of the Food and Drug Administration and a strategic plan for describing each system, such as costs, system function or purpose, and status information, and incorporate use of the system portfolios into the information technology management process of the Food and Drug Administration;

(b) The ways in which the Food and Drug Administration uses, updates, and maintains the information architecture described in paragraph (A) to guide and coordinate the modernization projects and activities of the Food and Drug Administration, including the interdependencies among projects and activities; and

(d) the extent to which the Food and Drug Administration has fulfilled or is implementing recommendations of the Government Accountability Office with respect to the Food and Drug Administration and information technology; and

(2) develop—

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

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

GAO REPORT.—Not later than January 1, 2016, the Comptroller General of the United States shall issue a report regarding the strategic plan described in subsection (a)(1)(A) and related actions carried out by the Food and Drug Administration. Such report shall assess the progress the Food and Drug Administration has made on—

(1) the development and implementation of a comprehensive information technology strategic plan, including the results-oriented goals, strategies, milestones, and performance measures identified in subsection (a)(1)(A); and

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

(3) the extent to which the Food and Drug Administration has fulfilled recommendations of the Government Accountability Office with respect to such agency and information technology.

SEC. 1128. REPORTING REQUIREMENTS.
(a) Section 2 of 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.

(1) each fiscal year for which fees are collected under paragraphs (2) through (5) of subsection (a) of section 712(a) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall—

(A) report to the Senate and the Committee on Energy and Natural Resources of the Senate and the Committee on Appropriations of the House of Representatives a report concerning, for all applications for approval of a new drug under section 505(b) of this Act or a new biological product under section 351 of the Public Health Service Act filed in the previous fiscal year—
“(1) the number of such applications that met the goals identified for purposes of part 2 of subchapter C in the letters from the Secretary of Health and Human Services to the Chairmen of the Committee on Energy and Commerce of the House of Representatives as set forth in the Congressional Record; and

“(2) the percentage of such applications that were approved; and

“(3) the percentage of such applications that were withdrawn; and

“(4) the percentage of such applications that were subject to a refuse-to-file action; and

“(5) the number of calendar days spent by the sponsor responding to a complete response letter; and

“(6) the average total time to decision by the Secretary for all applications for approval of a new drug under section 505(b)(2) of this Act or a new biological product under section 351(k) of the Public Health Service Act, including the number of calendar days spent during the review by the Food and Drug Administration and the number of calendar days spent by the sponsor responding to a complete response letter.”

“(A) the number of applications for approval filed under section 351(k) of the Public Health Service Act; and

“(B) the percentage of applications described in paragraph (A) that were approved by the Secretary.

“(2) ADDITIONAL INFORMATION.—As part of the performance report described in paragraph (1), the Secretary shall include an explanation of how the Food and Drug Administration is managing the biological product review program to ensure that the user fees collected under part 2 are not used to review an application under section 351(k) of the Public Health Service Act,”.

**SEC. 1130. STRATEGIC INTEGRATED MANAGEMENT PLAN.**

“(a) STRATEGIC INTEGRATED MANAGEMENT PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ”Secretary“) shall submit to Congress a strategic integrated management plan for the Center for Drug Evaluation and Research and, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health. Such strategic management plan shall—

“(1) identify institutional goals and priorities for the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health; and

“(2) describe the actions the Secretary will take to recruit, retain, train, and continue to develop the workforce at the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health to fulfill the public health mission of the Population and Productivity Protection.

“(3) identify results-oriented, outcome-based measures that the Secretary will use to measure the progress of achieving the strategic goals identified under paragraph (1) and the effectiveness of the actions identified under paragraph (2), including metrics to ensure that managers and reviewers of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health are familiar with the protocol and applicable requirements related to Investigational New Drug Applications or informed consent.

“(4) assess the extent to which performance information is collected, analyzed, and acted on by managers; and

“(5) make recommendations, as appropriate, regarding the development of a comprehensive strategy and related actions of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health could be improved to fulfill the public health mission of the Food and Drug Administration in an efficient and effective manner as possible.

**SEC. 1131. DRUG DEVELOPMENT AND TESTING.**

“(a) IN GENERAL.—Section 505-1 (21 U.S.C. 355-1) is amended by adding at the end the following:

“(k) DRUG DEVELOPMENT AND TESTING.—

“(1) IN GENERAL.—Notwithstanding any other provision of law, if a drug is a covered drug, no elements to ensure safe use shall prohibit, or be construed or applied to prohibit, supply of such drug to any eligible drug developer for a written notice authorizing the supply of a covered drug for purposes of testing as described in paragraph (1), and the Secretary shall issue a written notice to such eligible drug developer and the holder of an application for a covered drug authorizing the supply of such drug to such eligible drug developer for purposes of testing as described in paragraph (2).

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

“(B) in the event the eligible drug developer is conducting bioequivalence or other clinical testing, the eligible drug developer has submitted, and the Secretary has approved, a protocol and applicable requirements related to such testing, including any applicable requirements related to Investigational New Drug Applications or informed consent.

“(2) ADDITIONAL ELEMENT.—The Secretary shall require as an element of each risk evaluation and mitigation strategy with respect to such use approved by the Secretary that the holder of an application for a covered drug shall not restrict the resale of the covered drug to an eligible drug developer for purposes of testing as described in paragraph (2) unless, at any time, the Secretary provides written notice to the holder of the application directly that the resale of such drug for patients, national security concerns related to access to such drug, or such other reason as the Secretary may specify.

“(a) IN GENERAL.—Beginning with fiscal year 2014, not later than 120 days after the end of such fiscal year for which fees are collected under part 8 of subchapter C, the Secretary shall prepare and submit to the Committee on Health Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning—
(1) Section 505-1(c)(2) (21 U.S.C. 355-1(c)(2)) is amended by striking "(e) and (f)" and inserting "(e), (f), and (k)(3)".

(2) Section 505(y) (21 U.S.C. 355(y)) is amended by striking "and subsection (b)(2)", (e) or (f) of section 505-1" and inserting "(d), (e), (f), or (k)(3) of section 505-1".

SEC. 1132. PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSIONS.

Subchapter E of chapter V (21 U.S.C. 360bb et seq.) as amended by section 1126, is further amended by adding at the end the following:

"SEC. 509C. PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSIONS.

"(a) In General.—The Secretary shall develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions, including by—

"(1) fostering participation of a patient representative who may serve as a special government employee in appropriate agency meetings with medical product sponsors and investigators; and

"(2) exploring means to provide for identification of advocates who not have any, or have minimal, financial interests in the medical products industry.

"(b) Financial Interest.—In this section, the term "financial interest" means a financial interest under section 208(a) of title 18, United States Code.

SEC. 1133. NANOTECHNOLOGY REGULATORY SCIENCE PROGRAM.

(a) In General.—Chapter X (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 1013. NANOTECHNOLOGY REGULATORY SCIENCE PROGRAM.

"(a) In General.—Not later than 180 days after the date of enactment of this Act, the Secretary shall establish within the Food and Drug Administration a Nanotechnology Regulatory Science Program (referred to in this section as the 'program') to enhance scientific understanding of novel properties of nanomaterials and on specific nanomaterials that might contribute to toxicity; facilitate the identification of generalized principles and characteristics regarding the behavior of classes of nanomaterials with biological systems; and on Energy and Commerce of the House of Representatives a report that describes any nanomaterials imported products regulated under this Act; and national consensus standards activities; and

"(8) encouraging the Food and Drug Administration to participate in international and national consensus standards activities pertaining to nanomaterials and nanotechnology.

"(9) carrying out other activities that the Secretary determines are necessary and consistent with the purposes described in paragraphs (1) through (8).

"(c) Program Administration.—

"(1) Designated individual.—In carrying out the program under this section, the Secretary, acting through the Commissioner of Food and Drugs, may designate an appropriately qualified individual who shall supervise the planning, management, and coordination of the program.

"(2) Duties.—The duties of the individual designated under paragraph (1) may include—

"(A) developing a detailed strategic plan for achieving specific short- and long-term technical goals for the program;

"(B) coordinating and reviewing the strategic plan with activities by the Food and Drug Administration and other departments and agencies participating in the National Nanotechnology Initiative;

"(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 the adequacy of the proposed funding levels for the program, including an assessment of the adequacy of such funding levels to support program activities; and

"(3) a review of the coordination of activities under the program with other departments and agencies participating in the National Nanotechnology Initiative.

"(e) Effect of Section.—Nothing in this section shall affect the authority of the Secretary under any other provision of this Act or any other statutes administered by the Food and Drug Administration.

"(b) Effective Date; Sunset.—The Nanotechnology Regulatory Science Program authorized under section 1013 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later. Such Program shall cease to be effective October 1, 2017.

SEC. 1134. ONLINE PHARMACY REPORT TO CONGRESS.

Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes any Internet Web sites that violate Federal or State law, including—
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 regarding the expansion of multilateral sanctions regime and implementation of sanctions.

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 sector of Iran.

Sec. 203. Imposition of sanctions with respect to joint ventures with the Government of Iran relating to mining, production, or transportation of uranium.

Sec. 204. Expansion of sanctions available under the Iran Sanctions Act of 1996.

Sec. 205. Expansion of definitions under the Iran Sanctions Act of 1996.

Subtitle B—Additional Measures Relating to Sanctions Against Iran

Sec. 211. Imposition of sanctions with respect to the provision of vessels or shipping services to transport certain goods related to proliferation or terrorism activities to Iran.

Sec. 212. Imposition of sanctions with respect to subsidiaries and agents of persons sanctioned by United Nations or 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 financial communications services to the Central Bank of Iran and sanctioned Iranian financial institutions.


 Sec. 218. Reporting on the importation to and exportation from Iran of crude oil and refined petroleum products.

TITLE III—SANCTIONS WITH RESPECT TO IRAN’S REVOLUTIONARY GUARD CORPS

Subtitle A—Identification of, and Sanctions With Respect to, Officials, Agents, Affiliates, and Supporters of Iran’s Revolutionary Guard Corps and Other Sanctioned Persons

Sec. 301. Identification of, and imposition of sanctions with respect to, officials, agents, and affiliates of Iran’s Revolutionary Guard Corps.

Sec. 302. Identification of, and imposition of sanctions with respect to, persons that support or conduct certain transactions with Iran’s Revolutionary Guard Corps or other sanctioned persons.

Sec. 303. Rule of construction.

Subtitle B—Additional Measures Relating to Iran’s Revolutionary Guard Corps

Sec. 311. Expansion of procurement prohibitions to foreign persons that engage in certain transactions with Iran’s Revolutionary Guard Corps.

Sec. 312. Determinations of whether the National Iranian Oil Company and the National Iranian Tanker Company, and their agents or affiliates, are subject to Iran’s Revolutionary Guard Corps.

TITLE IV—MEASURES RELATING TO HUMAN RIGHTS ABUSES IN SYRIA

Subtitle A—Expanding Iran Sanctions Act of 1996

Sec. 401. Imposition of sanctions with respect to persons who engage in censorship or other related activities against citizens of Iran.

Sec. 402. Imposition of sanctions with respect to persons who engage in activities related to human rights abuses in Iran.

Sec. 413. Sense of Congress on political prisoners.

TITLE V—MISCELLANEOUS

Sec. 501. Exclusion of citizens of Iran seeking to invest in the nuclear and energy sectors of Iran.

Sec. 502. Technical correction.

Sec. 503. Interests in financial assets of Iran.

Sec. 504. Report on membership of Iran in international organizations.

TITLE VI—GENERAL PROVISIONS

Sec. 601. Expiration of certain sanctions with respect to persons who engage in activities related to human rights abuses in Iran.

Sec. 602. Technical correction.

Sec. 603. Applicability to certain intelligence activities.

Sec. 604. Territorial applicability.

TITLE VII—SANCTIONS WITH RESPECT TO HUMAN RIGHTS ABUSES IN SYRIA

Sec. 701. Short title.

Sec. 702. Imposition of sanctions with respect to certain persons who are responsible for or complicit in human rights abuses committed against citizens of Syria or their family members.

Sec. 703. Imposition of sanctions with respect to the transfer of goods or technologies to Syria that are likely to be used to commit human rights abuses.
 SEC. 101. POLICY OF THE UNITED STATES WITH RESPECT TO DEVELOPMENT OF NUCLEAR WEAPONS CAPABILITIES BY IRAN.

It shall be the policy of the United States—
(1) to prevent the Government of Iran from—
(A) acquiring or developing nuclear weapons;
(B) developing its advanced conventional weapons and ballistic missile capabilities; and
(C) continuing its support for terrorist organizations and other activities aimed at undermining and destabilizing its neighbors and other countries; and
(2) to fully implement all multilateral and bilateral sanctions against Iran, as part of larger multilateral and bilateral diplomatic efforts, in order to compel the Government of Iran—
(A) to abandon efforts to acquire a nuclear weapons capability and other threatening activities can be effectively achieved through—
(1) the prompt expansion, vigorous implementation, and intensification of enforcement of the current sanctions regime with respect to Iran; and
(2) full and vigorous implementation of all sanctions enacted into law, including sanctions imposed by this Act or amendments made by this Act.

SEC. 102. SENSE OF CONGRESS ON EXPANSION OF MULTILATERAL SANCTIONS REGIME AND IMPLEMENTATION OF DIMINISHING THE THREAT POSED BY THE PURSUIT OF NUCLEAR WEAPONS CAPABILITY.

It is the sense of Congress that the goal of compelling Iran to abandon efforts to acquire a nuclear weapons capability and other threatening activities can be effectively achieved through—
(1) the prompt expansion, vigorous implementation, and intensification of enforcement of the current multilateral sanctions regime with respect to Iran; and
(2) full and vigorous implementation of all sanctions enacted into law, including sanctions imposed by this Act or amendments made by this Act.

SEC. 103. DIPLOMATIC EFFORTS TO EXPAND MULTILATERAL SANCTIONS REGIME.

(a) MULTILATERAL NEGOTIATIONS.—In order 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 current 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; and
(iii) support by the Government of Iran for terrorist organizations, including Hamas and Hezbollah; and
(B) a requirement that each member country of the United Nations prohibit the Islamic Republic of Iran Shipping Lines from landing at seaports, and cargo flights of Iran Air from landing at airports, in that country because of the role of those organizations in proliferation and illegal arms sales;
(2) expanding the range of sanctions imposed with respect to Iran by allies of the United States;
(3) expanding efforts to limit the development of petroleum resources and the importation of refined petroleum products by Iran;
(4) developing additional initiatives to—
(A) increase the production of crude oil in countries other than Iran; and
(B) assist countries that purchase or otherwise obtain crude oil or petroleum products from Iran to reduce their dependence on crude oil and petroleum products from Iran; and
(5) eliminating the revenue generated by the Government of Iran from the sale of petrochemical products produced in Iran to other countries.

(b) REPORTS TO CONGRESS.—Not later than 180 days after the date of the enactment of this Act, and every 180 days thereafter, the President shall submit to the appropriate congressional committees a report on the extent to which diplomatic efforts described in subsection (a) have been successful that includes—
(1) an identification of the countries that have agreed to impose additional sanctions or 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; and
(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 which the imposition by any country of any sanction with respect to Iran is inconsistent with the obligations of that country as a member of the World Trade Organization or under the General Agreement on Tariffs and Trade, done at Geneva October 30, 1947.

SEC. 104. SENSE OF CONGRESS REGARDING THE IMPOSITION OF SANCTIONS WITH RESPECT TO IRAN.

It is the sense of Congress that all efforts should be made by the President to maximize the effects of existing sanctions with respect to Iran and that the United States should take all necessary measures to preserve robust information-sharing activities.

TITLE II—EXPANSION OF SANCTIONS RELATING TO THE ENERGY SECTOR OF IRAN AND PROLIFERATION OF WEAPONS OF MASS DESTRUCTION BY IRAN

Subtitle A—Expansion of Iran Sanctions Act of 1996

SEC. 201. IMPOSITION OF SANCTIONS WITH RESPECT TO JOINT VENTURES WITH THE GOVERNMENT OF IRAN RELATING TO DEVELOPING PETROLEUM RESOURCES.

Section 5(a) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) is amended—
(1) in the subsection heading, by striking “WITH RESPECT TO” and inserting “TO THE ENERGY SECTOR OF IRAN” and “WITH RESPECT TO” and all that follows thereto; and
(2) by adding at the end the following:
“(A) JOINT VENTURES RELATING TO DEVELOPING PETROLEUM RESOURCES.—
“(A) In general.—Except as provided in subparagraph (B) and subsection (i), the President shall impose the sanctions described in section 5(a) with respect to a person if the President determines that the person knowingly participates, on or after January 1, 2002, in 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.
“(B) EFFECTS.—Subparagraph (A) shall not apply with respect to participation in a joint venture established before January 1, 2002, and before the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012 in a joint venture with respect to the development of petroleum resources outside of Iran if—
“(i) the joint venture is established on or before January 1, 2002; and
“(ii) the Government of Iran is a substantial partner or investor in the joint venture; or
“(B) Effect of Prohibition.—The Government of Iran—
“(A) shall not impose the sanctions described in section 5(a) with respect to a person if the President determines that the person knowingly participates, on or after January 1, 2002, in 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.
“(B) Effect of Prohibition.—Subparagraph (A) shall not apply with respect to participation in a joint venture established before 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 term that participation prior to the date that is 180 days after such date of enactment.”.
Section 5(a) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note), as amended by section 201, is further amended by adding at the end the following:

(5) SUPPORT FOR THE DEVELOPMENT OF PETROCHEMICAL SECTORS AND REFINED PETROLEUM PRODUCTS IN IRAN.—

“(A) IN GENERAL.—Except as provided in subsection (f), the President shall impose 3 or more of the sanctions described in section 6(a) with respect to a person if the President determines that the person knowingly, on or after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, serves, leases, or provides to Iran goods, services, technology, or support described in subparagraph (B)—

(i) any of which has a fair market value of $1,000,000 or more; or

(ii) that, during a 12-month period, have an aggregate fair market value of $5,000,000 or more.

“(B) GOODS, SERVICES, TECHNOLOGY, OR SUPPORT DESCRIBED.—Goods, services, technology, or support described in this subparagraph are goods, services, technology, or support that could directly and significantly contribute to the maintenance or enhancement of Iran’s—

(i) ability to develop petroleum resources located in Iran; or

(ii) domestic production of refined petroleum products, including any direct and significant assistance with respect to the construction, modernization, or repair of petroleum refineries or directly associated infrastructure, including port facilities, railroads, or roads, if the predominant use of those facilities, railroads, or roads is for the transportation of petroleum products.

“(6) DEVELOPMENT AND PURCHASE OF PETROCHEMICAL PRODUCTS FROM IRAN.—

(A) IN GENERAL.—Except as provided in subsection (f), the President shall impose 3 or more of the sanctions described in section 6(a) with respect to a person if the President determines that the person knowingly, on or after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, sells, leases, or provides to Iran chemicals, or equipment, for the production of—

(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.’’.

Section 5(b) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) is amended—

(1) in paragraph (1)—

(A) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and moving such clauses, as so redesignated, 2 ems to the left;

(B) by striking “a person has, on or after” and inserting the following: “a person has—

(A) on or after—

(C) by striking paragraph (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, Accountability, and Human Rights Act of 2012, in a joint venture—

(i) with—

(I) the Government of Iran; or

(II) an entity involved 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 and in control of, the Government of Iran or an entity described in clause (ii); and

(ii) that involves any activity relating to the mining, production, or transportation of uranium;’’; and

(2) by adding at the end the following:

“(3) APPLICABILITY OF SANCTIONS WITH RESPECT TO JOINT VENTURES RELATING TO THE MINING, PRODUCTION, OR TRANSPORTATION OF URANIUM.—

(A) IN GENERAL.—Paragraph (1)(B) shall apply with respect to participation, on or after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, in—

(i) a joint venture established on or after such date of enactment; and

(ii) except as provided in subparagraph (B), a joint venture established before such date of enactment that—

(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 that participation no 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) in paragraph (1)—

(A) by redesignating paragraph (9) as paragraph (11); and

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

“(9) EXCLUSION OF CORPORATE OFFICERS.—The President may direct the Secretary of State to deny a visa to, and the Secretary of Homeland Security to exclude from the United States any alien that the President determines is a corporate officer or principal of, or a shareholder with a controlling interest in, a sanctioned person.

(10) SANCTIONED PRINCIPAL EXECUTIVE OFFICERS.—The President may impose on the principal executive officer or officers of any sanctioned person, or on persons performing similar functions for 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:

“(20) PETROCHEMICAL PRODUCT.—The term ‘petrochemical product’ includes any arroyo derivative of such a gas, including ethylene, propylene, butadiene, benzene, toluene, xylenes, ammonia, methanol, and urea.’’.

(b) PERSONS SPECIFIED.—The persons specified in subsection (b) of section 6 of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) are—

(A) a successor entity to the person referred to in paragraph (1);

(B) owns or controls the person referred to in paragraph (1), if the person that owns or controls the person referred to in paragraph (1) had actual knowledge or should have known that the person referred to in paragraph (1) provided the vessel, insurance or reinsurance, or other shipping service, or

(C) is owned or controlled by, or under common ownership or control with, the person referred to in paragraph (1), if the person owned or controlled by, or under common ownership or control with (as the case may be), the person referred to in paragraph (1)
knowingly engaged in the provision of the vessel, insurance or reinsurance, or other shipping service.

(c) Waiver.—The President may waive the requirement to impose sanctions with respect to a person under subsection (a) on or after the date that is 30 days after the President—

(i) determines that such a waiver is in the national security interests of the United States; and

(ii) submits to the appropriate congressional committees a report that contains the reasons for that determination.

(d) Rule of Construction.—Nothing in this section shall be construed to limit the authority of the President to designate persons for the imposition of sanctions pursuant to Executive Order 13322 (70 Fed. Reg. 38567; relating to the blocking of property of weapons of mass destruction proliferators and their supporters) or Executive Order 13224 (66 Fed. Reg. 40970; relating to blocking property and prohibiting transactions with persons who commit, threaten to commit, or support terrorism), or otherwise pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).

(e) Authority.—Nothing in this section shall be construed to limit the authority of the President to—

(i) maintain or establish economic sanctions against any person;

(ii) impose economic sanctions against any person;

(iii) maintain or establish economic sanctions against any financial intermediary;

(iv) initiate an investigation into the possible imposition of sanctions under the Iran Sanctions Act of 1996 (Public Law 104-172; 50 U.S.C. 1761 note), section 104 or 105A of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, an Executive Order specified in clause (i) or (ii) of paragraph (a)(D), or any other provision of law relating to the imposition of sanctions with respect to Iran, as applicable; and

(f) Penalties.—Any person who violates any provision of this section shall be subject to such criminal or civil penalty as the President may determine.
IMPOSITION OF SANCTIONS WITH RESPECT TO IRAN'S REVOLUTIONARY GUARD CORPS

Subtitle A—Identification of, and Sanctions With Respect To, Officials, Agents, Affiliates, and Supporters of Iran's Revolutionary Guard Corps and Other Sanctioned Persons

SEC. 301. IDENTIFICATION OF, AND SANCTIONS WITH RESPECT TO, OFFICIALS, AGENTS, AFFILIATES, AND SUPPORTERS OF IRAN'S REVOLUTIONARY GUARD CORPS

(a) In General.—Not later than 90 days after the date of the enactment of this Act, and as appropriate thereafter, the President shall—

(1) identify foreign persons that are officials, agents, or affiliates of Iran's Revolutionary Guard Corps; and

(2) for each foreign person identified under paragraph (1) that is not already designated for the imposition of sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) with respect to Iran, block and prohibit all transactions in property or interests in property of that person, and as appropriate thereafter, give the President authority to block and prohibit all transactions in property or interests in property of the President, any member of the Revolutionary Guard Corps, and any person acting on behalf of, or as an agent for, the Revolutionary Guard Corps.

(b) Priority for Investigation.—In identifying foreign persons pursuant to subsection (a)(1), the President shall give priority to—

(1) officials of the Revolutionary Guard Corps; and

(2) officials, agents, or affiliates of the Revolutionary Guard Corps that have engaged in or attempted to engage in activities described in subsection (c).

(c) Sensitive Transactions and Activities Described.—A sensitive transaction or activity described in this subsection is a transaction or activity concerning or involving—

(1) trade or sales in crude oil, refined petroleum products, or other goods or services described in subsection (b); and

(2) transactions involving financial institutions designated for the imposition of sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) with respect to Iran or its Revolutionary Guard Corps.

(d) Designation Authorization.—Not later than 90 days after the date of the enactment of this Act, and as appropriate thereafter, the President may issue a determination prohibiting all transactions in property or interests in property of a person designated pursuant to subsection (a) in respect of which there is reason to believe that the person is engaged in a sensitive transaction or activity described in subsection (c).
nuclear, chemical, biological, or advanced conventional weapons, including ballistic missiles;

(3) a transaction relating to the manufacture, procurement, or sale of goods, services, and technology relating to Iran's energy sector, including a transaction relating to the development of the energy resources of Iran, the extraction relating to the transportation, 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 (52 U.S.C. 8515(c))).

(d) EXCLUSION FROM UNITED STATES.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary of State shall deny a visa to, and the Secretary of Homeland Security shall exclude from the United States, any alien who, on or after the date of the enactment of this Act, is a foreign person designated pursuant to subsection (a) or (b) or section 219 of the Iran Sanctions Act of 1996, as amended by this Act, or who is a foreign person subject to any modification or suspension of sanctions under this Act.

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to remove any sanction of the United States in force with respect to Iran’s Revolutionary Guard Corps or any of its officials, agents, or affiliates, the property and interests in property of which are blocked pursuant to the Iran Sanctions Act of 1996, as amended by this Act.

SEC. 302. IDENTIFICATION OF, AND IMPOSITION OF SANCTIONS ON, PERSONS THAT SUPPORT OR CONDUCT CERTAIN TRANSACTIONS WITH IRAN’S REVOLUTIONARY GUARD CORPS OR OTHER SANCTIONED PERSONS.

(a) IDENTIFICATION.—

(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, and every 180 days thereafter, the President shall submit to the appropriate congressional committees a report identifying foreign persons that the President determines, on or after the date of the enactment of this Act, knowingly:

(A) physically assist, sponsor, or provide financial, material, or technological support for, or goods or services in support of, Iran’s Revolutionary Guard Corps or any of its officials, agents, or affiliates the property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.); and

(B) engage in a significant transaction or transactions with Iran’s Revolutionary Guard Corps or any such official, agent, or affiliate.

(2) FORM OF REPORT.—A report submitted under paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

(3) METHOD OF IDENTIFICATION.—

(A) IN GENERAL.—The President shall, in making any identification, consider whether the foreign person

(i) has materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services in support of, Iran’s nuclear, chemical, biological, or advanced conventional weapons, including ballistic missiles;

(ii) has engaged in a transaction or transactions described in subsection (a)(1) to the same extent that such provisions apply with respect to the imposition of sanctions under section 5(a) of the Iran Sanctions Act of 1996, as amended by this Act; or

(iii) has engaged in a transaction or transactions described in subsection (a)(1) to the same extent that such provisions apply with respect to the imposition of sanctions under section 5(a) of the Iran Sanctions Act of 1996, as amended by this Act.

(B) SALES OR SERVICES.—Nothing in this section shall be construed to—

(i) impose any liability on the United States government; and

(ii) require the United States government to take any action to prevent the recurrence of any activity described in section 5(a) of the Iran Sanctions Act of 1996, as amended by this Act.

(c) REPORT REQUIREMENTS.—

(1) IN GENERAL.—The President shall submit a report to the appropriate congressional committees in the unclassified form but may contain a classified annex.

(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

(A) impose any liability on the United States government; and

(B) require the United States government to take any action to prevent the recurrence of any activity described in section 5(a) of the Iran Sanctions Act of 1996, as amended by this Act.

(d) APPLICATION OF PROVISIONS OF IRAN SANCTIONS ACT OF 1996.—The following provisions of the Iran Sanctions Act of 1996, as amended by this Act, apply with respect to the imposition under subsection (b)(1) of sanctions relating to activities described in subsection (a)(1) to the same extent that such provisions apply with respect to the imposition of sanctions under section 5(a) of the Iran Sanctions Act of 1996, as amended by this Act:

(1) Subsections (c) and (e) of section 4.

(2) Subsections (c), (d), and (f) of section 5.

(3) Section 6.

(4) Section 7.

(5) Section 8.

(6) Section 9.

(7) Section 12.

(8) Subsection (b) of section 13.

SEC. 303. RULE OF CONSTRUCTION.

Nothing in this subtitle shall be construed to remove any sanction of the President to designate foreign persons for the imposition of sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).

Subtitle B—Additional Measures Relating to Iran’s Revolutionary Guard Corps

SEC. 311. EXPANSION OF PROCUREMENT PROHIBITION TO FOREIGN PERSONS THAT ENGAGE IN CERTAIN TRANSACTIONS WITH IRAN’S REVOLUTIONARY GUARD CORPS.

(a) IN GENERAL.—Section 6(b)(1) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) is amended—

(1) by striking ‘‘Not later than 90 days’’ and inserting the following:

‘‘(A) EXECUTIVE AGENCY.—The term ‘executive agency’ has the meaning given that term in section 133 of title 41, United States Code.

(2) by striking subsection (b) (1)(A) and inserting the following:

‘‘(A) EXECUTIVE AGENCY.—The term ‘executive agency’ has the meaning given that term in section 133 of title 41, United States Code.

(b) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) Section 6(b) of the Iran Sanctions Act of 1996, as amended by subsection (a), is further amended—

(A) in paragraph (1)(A), as redesignated, by striking ‘‘issued pursuant to section 25 of the Office of Federal Procurement Policy Act (41 U.S.C. 421);’’

(B) in paragraph (2)—

(i) in subparagraph (A), by striking ‘‘the revision’’ and inserting ‘‘the applicable revision’’; and

(ii) in subparagraph (B), by striking ‘‘the revision’’ and inserting ‘‘the applicable revision’’; and

(c) Definitions.—In this subsection:

(A) EXECUTIVE AGENCY.—The term ‘executive agency’ has the meaning given that term in section 133 of title 41, United States Code.

(2) No later than 90 days after the date of the enactment of this Act, the President shall submit to the appropriate congressional committees a report identifying certain transactions with Iran’s Revolutionary Guard Corps or any of its officials, agents, or affiliates the property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).
"(B) FEDERAL ACQUISITION REGULATION.—The term ‘Federal Acquisition Regulation’ means the regulation issued pursuant to section 103(a)(1) of title 41, United States Code.

(D) in paragraph (7)—

(i) by striking ‘‘The revisions to the Federal Acquisition Regulation required under paragraph (1)’’; and

(ii) by adding at the end the following:

‘‘(B) CERTIFICATIONS RELATING TO TRANSACTIONS WITH IRAN’S REVOLUTIONARY GUARD CORPS.—The Federal Acquisition Regulation required under paragraph (1)(B) shall apply with respect to contracts for which solicitations are issued on or after the date that is 90 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012.’’.

SEC. 312. DETERMINATIONS OF WHETHER THE NATIONAL IRANIAN OIL COMPANY AND THE NATIONAL IRANIAN TANKER COMPANY ARE AGENTS OR AFFILIATES OF IRAN’S REVOLUTIONARY GUARD CORPS.

(a) IN GENERAL.—Section 104(c) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)) is amended by adding at the end the following:

‘‘(4) DETERMINATIONS REGARDING NIOC AND NTTC.—

‘‘(A) DETERMINATIONS.—For purposes of paragraph (2)(E)(i), the Secretary of the Treasury shall, not later than 60 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012—

‘‘(i) determine whether the NIOC or the NTTC is an agent or affiliate of Iran’s Revolutionary Guard Corps; and

‘‘(ii) submit to the appropriate congressional committees a report on the determinations made under clause (i), together with the reasons for those determinations.

‘‘(B) FORM OF REPORT.—A report submitted under subparagraph (i) shall clearly state the reasons for the determinations and include a classified annex.

‘‘(C) APPLICABILITY WITH RESPECT TO PETROLEUM PRODUCTS.—

‘‘(i) APPLICATION OF SANCTIONS.—Except as provided in clause (ii), the regulations prescribed under paragraph (1) shall apply to a transaction for the purchase of petroleum or petroleum products from, or to financial services relating to such a transaction for, the NIOC or the NTTC on or after the date that is 90 days after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2012 (Public Law 112–81) only if the President has determined, pursuant to section 1245(d)(4)(B) of that Act, that there is a sufficient supply of petroleum and petroleum products produced in countries other than Iran to permit purchasers of petroleum or petroleum products from or to financial services relating to such a transaction for, the NIOC or the NTTC not to be affected by the regulations prescribed under paragraph (1) so as to reduce significantly in volume their purchases from Iran.

(ii) EXCEPTION FOR CERTAIN COUNTRIES.—The regulations prescribed under paragraph (1) shall not apply to a transaction for the purchase of petroleum or petroleum products from, or to financial services relating to such a transaction for, the NIOC or the NTTC if the President determines and reports to Congress, not later than 90 days after the date on which the President makes the determination required by section 1245(j) of the National Defense Authorization Act for Fiscal Year 2012, and every 180 days thereafter, that the country with primary jurisdiction over the foreign financial institution has significantly reduced its volume of crude oil purchases from Iran during the period beginning on the date on which the President submitted the last report with respect to the country under this clause.

‘‘(D) DEFINITIONS.—In this paragraph:

‘‘(i) NIOC.—The term ‘NIOC’ means the National Iranian Oil Company.

‘‘(ii) NTTC.—The term ‘NTTC’ means the National Iranian Tanker Company.

SEC. 105A. IMPOSITION OF SANCTIONS WITH RESPECT TO THE TRANSFER OF GOODS OR TECHNOLOGIES TO IRAN THAT ARE LIKELY TO BE USED TO COMMIT HUMAN RIGHTS ABUSES.

(a) IN GENERAL.—The President shall impose sanctions in accordance with subsection (c) with respect to a person on the list required by subsection (b).

(b) LIST.—

‘‘(1) LIST.—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 an updated list to those committees that the President determines have knowingly engaged in an activity described in paragraph (2) on or after such date.

‘‘(2) ACTIVITY DESCRIBED.—

‘‘(A) IN GENERAL.—A person engages in an activity described in this paragraph if the person—

‘‘(i) transfers, or facilitates the transfer of, goods or technologies described in subparagraph (C) to Iran;

‘‘(ii) provides services with respect to goods or technologies described in subparagraph (C) after such goods or technologies are transferred to Iran;

‘‘(B) TRANSFERS TO CONTRACTS AND OTHER AGREEMENTS.—A person engages in an activity described in subparagraph (A) without regard to whether the activity is carried out pursuant to a contract or other agreement entered into before, on, or after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012.

‘‘(C) GOODS OR TECHNOLOGIES DESCRIBED.—Goods or technologies described in this subparagraph are goods or technologies that the President determines are likely to be used by the Government of Iran or any of its agencies or instrumentalities to commit serious human rights abuses against the people of Iran, including—

‘‘(i) firearms or ammunition (as those terms are defined in section 921 of title 18, United States Code), rubber bullets, police batons, pepper or chemical sprays, stun grenades, electroshock weapons, tear gas, water cannons, or surveillance technology; or

‘‘(ii) advanced technology (as defined in section 106(c)).

‘‘(3) SPECIAL RULE TO ALLOW FOR TERMINATION OF SANCTIONABLE ACTIVITY.—The President shall not be required to include a person on the list required by paragraph (1) if the President certifies in writing to the appropriate congressional committees that—

‘‘(A) the person is not a principal, or has taken significant verifiable steps toward stopping, the activity described in paragraph (2) for which the President determines have knowingly engaged in such activity described in paragraph (2) in the future.

‘‘(4) UPDATES OF LIST.—The President shall submit to the appropriate congressional committees an updated list under paragraph (1)—

‘‘(A) each time the President is required to submit an updated list to those committees under section 105(b)(2).

‘‘(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 shall contain a classified annex.

‘‘(B) PUBLIC AVAILABILITY.—The unclassified portion of the list required by paragraph (1) shall be made available to the public and posted on the websites of the Department of the Treasury and the Department of State.

‘‘(C) APPLICATION OF SANCTIONS.—

‘‘(i) IN GENERAL.—Subject to paragraph (2), the President shall impose sanctions described in section 105(c) with respect to a person on the list required by subsection (b).

‘‘(ii) TRANSFERS TO IRAN’S REVOLUTIONARY GUARD CORPS.—In the case of a person on the list required by subsection (b) for transferring, or facilitating the transfer of, goods or technologies described in subsection (b)(2)(C) to Iran’s Revolutionary Guard Corps, or providing services with respect to such goods or technologies after such goods or technologies are transferred to Iran’s Revolutionary Guard Corps, the President shall—

‘‘(A) impose sanctions described in section 105(c) with respect to the person; and

‘‘(B) impose such other sanctions from among the sanctions described in section 6(a) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) as the President determines appropriate.

‘‘(D) CLERICAL AMENDMENT.—The table of contents for the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 is amended by inserting after the item relating to section 105 the following:

‘‘Sec. 105A. Imposition of sanctions with respect to the transfer of goods or technologies described in section 105(c) with respect to citizens of Iraq that are likely to be used to commit human rights abuses.’’.  

SEC. 402. 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 amended by inserting after section 105 the following:

‘‘(b) LIST.—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 an updated list to those committees that have known engaged in activities described in subsection (a) on or after such date.

‘‘(b) 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 to commit serious human rights abuses against the people of Iran, including—

‘‘(i) telecommunications equipment and services (as defined in section 106(c));

‘‘(ii) goods or technologies that are likely to be used to commit human rights abuses; or

‘‘(iii) items on the list required by section 105(c) with respect to citizens of Iraq that are likely to be used to commit human rights abuses.’’.
with respect to cada person on the list re- quired by subsection (b).

"(b) LIST OF PERSONS WHO ENGAGE IN CEN- sorship.—

"(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 sub- mit to the appropriate congressional committees a list of persons on the list that the President in- structs that the President has determined have engaged in censorship or other activities that prohibit, limit, or penalize the exercise of freedom of expression or assembly by citizens of Iran.

"(2) APPLICABILITY.—Paragraph (1) applies with respect to censorship or other activities described in that paragraph that are—

"(A) commenced on or after the date of the enactment of the Iran Sanctions, Account- ability, and Human Rights Act of 2012; or

"(B) commenced before such date of enact- ment, if such activities continue on or after such date of enactment.

"(3) UPDATES OF LIST.—The President shall submit to the appropriate congressional committees an updated list under paragraph (1) on each of the following dates:

"(A) each time the President is required to submit an updated list to those committees under section 106(b)(2)(A); and

"(B) as new information becomes available.

"(4) FORM OF REPORT; PUBLIC AVAIL- ABILITY.—

"(A) FORM.—The list required by paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

"(B) PUBLIC AVAILABILITY.—The unclassi- fied 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) CERITICAL AMENDMENT.—The table of contents for the Comprehensive Iran Sanctions, Accountability, and Human Rights Act of 2010, as amended by section 401, is further amended by inserting after the item relating to section 105A the following:

"Sec. 105B. Imposition of sanctions with re- spect to persons who engage in censorship or other related activities against citizens of Iran.

"(c) CONFORMING AMENDMENTS.—Section 401(b)(1) of the Comprehensive Iran Sanctions, Accountability, and Human Rights Act of 2010, as amended by section 401, is further amended by inserting "105A(a), or 105B(a)" after "105A"; and

"(2) by inserting "105A(a), or 105B(a)" after "105B(b)."

Subtitle B—Additional Measures to Promote Human Rights in Iran

SEC. 411. EXPEDITED CONSIDERATION OF RE- QUESTS FOR AUTHORIZATION OF CERTAIN M AINTHEIXS, HUMANI TARIAN, AND DEMOCRACY-RELATED ACTIVITIES WITH RESPECT TO IRAN.

(a) REQUIREMENTS.—The Office of Foreign Assets Control, in consultation with the De- partment of State, shall establish an expedi- tected process for the consideration of complete requests to authorize to engage in human rights-, humanitarian-, or democracy-related activities relating to Iran that are submitted by—

"(1) entities receiving funds from the De- partment of State to engage in the proposed activity;

"(2) the Broadcasting Board of Governors; and

"(3) other appropriate agencies of the United States Government.

(b) PROCEDURES.—Requests for authoriza- tion under paragraph (a) shall be submitted to the Office of Foreign Assets Control in conformance with the agency’s regulations, including section 501.801 of title 31, Code of Federal Regulations (commonly known as the Reporting, Procedures and Penalties Regulations). Applicants must fully disclose the purpose for which they request authorization to engage in the proposed activity, and describe the activities to be undertaken. Li- cense applications involving the exportation or reexportation of goods, technology, or software in violation of an official Commodity Classification issued by the Department of Commerce, Bureau of In- dustry and Security, as part of the license application process.

(c) FOREIGN POLICY REVIEW.—The Depart- ment of State shall complete a foreign policy review of a request for authorization under subsection (a) not later than 30 days after the request is referred to the Department by the Office of Foreign Assets Control.

(d) LICENSE DETERMINATION.—License de- terminations for complete requests for au- thorization under subsection (a) shall be made not later than 90 days after receipt by the Office of Foreign Assets Control, with the following exceptions:

"(1) Any requests involving the exportation or reexportation to Iran of goods, tech- nology, or software on the Commerce Control List maintained pursuant to part 774 of the Export Administration Regulations shall be processed in the manner consistent with the Iran-Iraq Arms Non-Proliferation Act of 1992 (title XVI of Public Law 102–489) and other applicable provisions of law.

"(2) Any other requests presenting novel or extraordinary circumstances.

"(e) REGULATIONS.—The Secretary of the Treasury may prescribe such regulations as are appropriate to carry out this section.

SEC. 412. COMPREHENSIVE STRATEGY TO PRO- MOTEM INTERNET FREEDOM AND AC- CESSION TO INFORMATION IN IRAN.

Not later than 90 days after the date of the enactment of this Act, the President shall submit to the appropriate congressional committees a strategy de- veloped in consultation with the Department of State, the Department of the Treasury, and other Federal agencies, as appropriate, to—

"(1) assist the people of Iran to produce, ac- cess, and share information freely and safely via the Internet, including in Farsi and re- gional languages;

"(2) support the development of counter- censorship technologies that enable the cit- izens of Iran to undertake Internet activities without interference from the Government of Iran;

"(3) increase the capabilities and avail- ability of secure communications through connective technology among human rights and democracy activists in Iran;

"(4) provide resources for digital safety training for media and academic and civil so- ciety organizations in Iran;

"(5) provide access to substantially Inter- net content in local languages in Iran;

"(6) increase emergency resources for the most vulnerable human rights advocates seeking to organize, disseminate information, and support human rights in Iran;

"(7) expand surrogate radio, television, live stream, and social network communications in the Persian language. "Voice of America’s Persian News Network and Radio Free Eu- rope/Radio Liberty’s Radio Farda, to provide hourly live news update programming and breaking news coverage 24 hours a day and 7 days a week;

"(8) expand activities to safely assist and train human rights, civil society, and democ- racy activists in Iran to operate effectively and securely;

"(9) identify and utilize all available re- sources to overcome attempts by the Gov- ernment of Iran to deny access to social media and international satellite broadcasting signals; and

"(10) expand worldwide United States em- bassy and consulate programming for and outreach to Iranian dissident communities.

SEC. 413. SENSE OF CONGRESS ON POLITICAL PRISONERS.

It is the sense of Congress that—

"(1) the Secretary of State should support efforts to research and identify prisoners of conscience and cases of human rights abuses in Iran;

"(2) the United States Government should—

"(A) offer refugee status or political asylum in the United States to political prisoners in Iran if requested and consistent with the laws and national security interests of the United States; and

"(B) offer to assist, through the United Na- tions High Commissioner for Refugees, with the relocation of such political prisoners to other countries if requested, as appropriate and with appropriate consideration for United States national security interests; and

"(3) the Secretary of State should publicly call for the release of Iranian dissidents by name and raise awareness with respect to in- dividual cases of Iranian dissidents and pris- oners of conscience, as appropriate and if re- quested by the dissidents or prisoners them- selves or their families.

TITLE V—MISCELLANEOUS

SEC. 501. EXCLUSION OF CITIZENS OF IRAN SEEK-ING EDUCATION RELATING TO THE NUCLEAR AND ENERGY SECTORS OF IRAN.

(a) IN GENERAL.—The Secretary of State shall deny a visa to, and the Secretary of Homeland Security shall exclude from the United States, any alien who is a citizen of Iran that the Secretary of State determines seeks to enter the United States to partici- pate in coursework at an institution of higher education (as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001)) to prepare the technical or scientific workforce in the energy sector of Iran or in nuclear science or nuclear engineering or a related field in Iran.

(b) APPLICABILITY.—Subsection (a) applies with respect to visa applications filed on or after the date of the enactment of this Act.

SEC. 502. TECHNICAL CORRECTION.

(a) IN GENERAL.—Section 1012(d)(2) of the National Defense Authorization Act for Fiscal Year 2012 (Public Law 112-81) is amended—

"(1) in the paragraph heading, by inserting "AGRICULTURAL COMMODITIES," after "SALES OF";

"(2) in the text, by inserting "agricultural commodities," after "sales of";

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect as if included in the National Defense Authoriza- tion Act for Fiscal Year 2012 (Public Law 112-81).

SEC. 503. INTERESTS IN FINANCIAL ASSETS OF IRAN.

(a) INTERESTS IN BLOCKED ASSETS.—Not- withstanding any other provision of law, and preempting any inconsistent provision of State law, the property interest of Iran in a blocked asset shall include an interest in property of any nature whatsoever, direct or indirect, including any direct or indirect in- terest in securities or other financial assets immobilized or in any other manner held in book entry form and credited to a securities account in the United States and the proceeds thereof, or in any funds transfers held in a United States financial account. The property interest of Iran in securities or other financial assets immobilized or in any other manner held in book entry form and credited to a securities account in the United States and the proceeds thereof shall be deemed to exist at every tier of securities
intermediary necessary to hold an interest in any such securities or other financial assets. The property interest of Iran in a funds transfer shall exist at any intermediary bank necessary to complete such funds transfer.

(b) PROPERTY IN THE UNITED STATES OF IRAN.—Notwithstanding any other provision of law, and preempting any inconsistent provision of State law, the property, including any interest in the property, of Iran shall be deemed to be property in the United States of Iran if—

(1) that property is an interest, held directly or indirectly for the benefit of Iran or for the benefit of any other securities intermediary that directly or indirectly holds the interest for the benefit of Iran, in securities or other financial assets that are represented by certificated securities or other physical form and are immobilized, customized, or held for safekeeping or any other reason in the United States; or

(2) that property is an interest in securities or other financial assets held in book entry form or otherwise, and credited to a securities account in the United States by any intermediary directly or indirectly for the benefit of Iran, in securities or other financial assets held in book entry form or otherwise, and credited to a securities account in the United States by any intermediary necessary to hold an interest described in paragraphs (1) and (2) of subsection (a) of this section.

(c) DETERMINATION OF WHETHER SECURITIES OR OTHER ASSETS ARE HELD OR CREDITED TO IN ANY SUCH SECURITIES OR OTHER FINANCIAL ASSETS.—The term "property," in its capacity as a securities intermediary necessary to hold an interest for the benefit of Iran, in securities or other financial assets held in book entry form or otherwise, and credited to a securities account in the United States by any intermediary necessary to hold an interest described in paragraphs (1) and (2) of subsection (a) of this section.

(d) COMMERCIAL ACTIVITY IN THE UNITED STATES.—Notwithstanding any other provision of law, the ownership by Iran, or its central bank or monetary authority, of any property, including the interest in property described in paragraphs (1) and (2) of subsection (b), or any other interest in property, shall be deemed to be commercial activity in the United States and that property, including any other property, shall be deemed not to be held for the central bank’s or monetary authority’s own account.

(e) APPLICABILITY.—This section applies to all transactions in aid of execution issued or obtained before, on, or after the date of the enactment of this Act with respect to judgments entered against the United States Government for final payment of damages for personal injury or death caused by an act of torture, extrajudicial killing, aircraft sabotage, or hostage-taking, or that violates, attempts to violate, conspires to violate, or causes a violation of a provision specified in paragraph (2) of this subsection, or an order or regulation prescribed pursuant to such a provision, to the extent that such penalties apply to a person that commits an unlawful act described in section 206(a) of that Act.

(f) PROVISIONS SPECIFIED.—The provisions specified in this paragraph are the following:

(A) Sections 211 and 216, subtitle A of title III, and title VII of this Act.

(B) Sections 105A and 105B of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, as added by subtitle A of title IV of this Act.

SEC. 602. AUTHORITY TO CERTAIN INTELLEC-

TIGENCY ACTIVITIES.

Nothing in this Act or the amendments made by this Act shall apply to the authorized intelligence activities of the United States.

SEC. 603. TERMINATION.

The provisions of sections 211, 213, 216, 217, and 501, title I, and subtitle A of title III shall terminate on the date that is 30 days after the date on which the President makes a certification described in section 401(a) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8551(a)).

TITLES VII—SANCTIONS WITH RESPECT TO HUMAN RIGHTS ABUSES IN SYRIA

SEC. 701. SHORT TITLE.

This title may be cited as the "Syria Human Rights Accountability Act of 2012."

SEC. 702. IMPOSITION OF SANCTIONS WITH RESPECT TO CERTAIN PERSONS WHO ARE RESPONSIBLE FOR OR COMPLICIT IN HUMAN RIGHTS ABUSES COMMITTED AGAINST CITIZENS OF SYRIA OR THEIR FAMILY MEMBERS.

(a) IN GENERAL.—The President shall impose sanctions described in subsection (c) with respect to each person on the list required by paragraph (1).

(b) LIST OF PERSONS WHO ARE RESPONSIBLE FOR OR COMPLICIT IN CERTAIN HUMAN RIGHTS ABUSES COMMITTED AGAINST CITIZENS OF SYRIA OR THEIR FAMILY MEMBERS.

(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 an updated list under paragraph (1) that violates, attempts to violate, conspires to violate, or causes a violation of a provision specified in paragraph (2) of this subsection, or an order or regulation prescribed pursuant to such a provision, to the extent that such penalties apply to a person that commits an unlawful act described in section 206(a) of that Act.

(B) PUBLIC AVAILABILITY.—The unclassified portion of the list required by paragraph (1) shall be made available to the public and posted on the websites of the Department of the Treasury and the Department of State.

(C) DETERMINATION OF WHETHER SECURITIES OR OTHER ASSETS ARE HELD OR CREDITED TO IN ANY SUCH SECURITIES OR OTHER FINANCIAL ASSETS.—In preparing the list required by paragraph (1), the President shall consider contributions of information from other foreign countries and nongovernmental organizations, including organizations in Syria, that
monitor the human rights abuses of the Government of Syria.

(c) SANCTIONS DESCRIBED.—The sanctions described in this subsection are sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.), including blocking of property and restrictions on financial transactions and the exportation and importation of property, subject to such regulations as the President may prescribe.

SEC. 703. IMPROVEMENT OF SANCTIONS WITH RESPECT TO THE TRANSFER OF GOODS OR TECHNOLOGIES TO SYRIA THAT ARE LIKELY TO BE USED TO COMMIT HUMAN RIGHTS ABUSES.

(a) IN GENERAL.—The President shall impose sanctions described in section 702(c) with respect to—

(1) each person on the list required by subsection (b); and

(2) any person that—

(A) is a successor entity to a person on the list;

(B) owns or controls a person on the list, if the person that owns or controls the person on the list had actual knowledge or should have known that the person on the list engaged in the activity described in subsection (b)(2) for which the person was included in the list;

(C) is owned or controlled by, or under common ownership or control with, the person on the list, if the person owned or controlled; or, under common ownership or control with (as the case may be), the person on the list knowingly engaged in the activity described in subsection (b)(2) for which the person was included in the list;

(b) LIST.—

(I) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the President shall submit to the appropriate congressional committees a list of persons that the President determines have knowingly engaged in an activity described in paragraph (2) on or after such date of enactment.

(II) APPLICABILITY TO CONTRACTS AND OTHER AGREEMENTS.—A person engages in an activity described in this subsection if—

(A) the person transfers, facilitates the transfer of, goods or technologies described in subparagraph (C) to Syria; or

(B) provides services with respect to goods or technologies described in subparagraph (C) and any of the goods or technologies are transferred to Syria.

(c) APPLICABILITY TO CONTRACTS AND OTHER AGREEMENTS.—A person engages in an activity described in paragraph (2) if the person is engaged in an activity described in paragraph (2) on or after such date of enactment.

SEC. 704. IMPOSITION OF SANCTIONS WITH RESPECT TO PERSONS WHO ENGAGE IN CENSORSHIP OR OTHER FORMS OF RESTRICTION OF THE FREE FLOW OF INFORMATION 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 OR OTHER FORMS OF RESTRICTION OF THE FREE FLOW OF INFORMATION IN SYRIA.

(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the President shall submit to the appropriate congressional committees a list of persons that the President determines have engaged in censorship, or activities relating to censorship, in a manner that prohibits, limits, or penalizes the legitimate exercise of freedom of expression by citizens of Syria.

(2) UPDATES OF LIST.—The President shall submit to the appropriate congressional committees an updated list under paragraph (1)—

(A) not later than 270 days after the date of the enactment of this Act and every 180 days thereafter; and

(B) as new information becomes available.

(c) FORM OF REPORT; PUBLIC AVAILABILITY.—

(1) FORM.—The list required by paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

(2) 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.

(d) 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.

SEC. 705. WAIVER.

The President may waive the requirement to include a person on a list required by section 703 or 704 or to impose sanctions pursuant to any such section if the President—

(1) determines that such a waiver is in the national security interests of the United States; and

(2) submits to the appropriate congressional committees a report on the reasons for that determination.

SEC. 706. TERMINATION.

(a) IN GENERAL.—The provisions of this title and any sanctions imposed pursuant to this title shall terminate on the date on which the President submits to the appropriate congressional committees—

(1) the certification described in subsection (b); and

(2) a certification that—

(A) the Government of Syria is democratically elected and representative of the people of Syria; or

(B) a legitimate transitional government of Syria is in place.

(b) CERTIFICATION DESCRIBED.—A certification described in this subsection is a certification by the President that the Government of Syria—

(1) has unconditionally released all political prisoners;

(2) has ceased its practices of violence, unlawful detention, torture, and abuse of citizens of Syria engaged in peaceful political activity;

(3) has ceased its practice of procuring sensitive technologies described in paragraph (2) to disrupt, monitor, or otherwise restrict the right of citizens of Syria to freedom of expression, association, or assembly;

(4) has ceased providing support for foreign terrorist organizations and no longer allows such organizations, including Hamas, to operate in territory under the control of the Government of Syria; and

(5) has ceased the development and deployment of medium- and long-range surface-to-surface ballistic missiles.

(6) is not pursuing or engaged in the research, development, acquisition, production, transfer, or deployment of biological, chemical, or nuclear weapons, and has provided credible assurances that it will not engage in such activities in the future; and

(7) has agreed to allow the United Nations and other international observers to verify that the Government of Syria is not engaging in such activities and to assess the credibility of the assurances provided by that Government.

(c) SUSPENSION OF SANCTIONS AFTWER 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.

SA 2124. Mr. REID (for Mr. JOHNSON of South Dakota (for himself and Mr. SHEPHERD)) proposed an amendment to amendment SA 2123 proposed by Mr. REID (for Mr. JOHNSON of South Dakota (for himself and Mr. SHEPHERD)) to the bill H.R. 1905, to strengthen Iran sanctions laws for the purpose of compelling Iran to abandon its pursuit of nuclear weapons and other threatening activities, and for other purposes; as follows:

Beginning on page 7, strike line 18, and all that follows through page 8, line 8, and insert the following:
It is the sense of Congress that the goal of comprehensive efforts to isolate and squeeze Iran to acquire a nuclear weapons capability and other threatening activities can be effectively achieved through a comprehensive policy that includes economic sanctions, diplomacy, and military planning, capabilities and options, and that this objective is consistent with the one stated by President Barack Obama in the 2012 State of the Union Address: “Let there be no doubt: America is determined to prevent Iran from getting a nuclear weapon, and I will take no options off the table to achieve that goal”.

Among these economic sanctions are:

1. prompt enforcement of the current multilateral sanctions regime with respect to Iran;
2. full, timely, and vigorous implementation of all sanctions enacted into law, including sanctions imposed or expanded by this Act or amendments made by this Act, through—
   (A) intensified monitoring by the President and his designees, including the Secretary of the Treasury and the Secretary of State, along with senior officials in the intelligence community; and
   (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;
3. 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
4. expansion of cooperation with international sanctions enforcement efforts; and
5. 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—
      (i) 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 efforts to correct any gaps in the existing sanctions regime with respect to Iran or violations of the human rights of the people of Iran;
      (ii) 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
      (iii) urgent and ongoing evaluation of Iran’s energy, national security, financial, and telecommunications sectors, to gauge the effects, and possible defects in, particular sanctions and the need for prompt efforts to correct any gaps in the existing sanctions regime with respect to Iran.

On page 30, line 12, insert “that includes doing so by serving as an intermediary financial institution with access to such messaging services.”

(2) the European Union is to be commended for strengthening the multilateral sanctions regime against Iran by deciding that specialized financial messaging services may not be provided to the Central Bank of Iran and other sanctioned Iranian financial institutions by persons subject to the jurisdiction of the European Union; and
3. the loss of access by sanctioned Iranian financial institutions to specialized financial messaging services to be maintained.

(b) REPORTS REQUIRED.—

(1) In General.—Not later than 60 days after the enactment of this Act, and every 90 days thereafter, the Secretary of the Treasury shall submit to the appropriate congressional committees a report that contains—
   (A) a list of all persons that the Secretary has identified that directly provide specialized financial messaging services to, or enable or facilitate direct or indirect access to such messaging services for, the Central Bank of Iran or a financial institution described in section 104(c)(2)(E)(ii) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)), the President may impose sanctions pursuant to that section or the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.), with respect to a person;
   (B) a detailed assessment of the status of efforts by the Secretary to end the direct provision of such messaging services to, and the enabling or facilitation of direct or indirect access to such messaging services for, the Central Bank of Iran or a financial institution described in section 104(c)(2)(E)(ii) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(E)(ii)); and
   (C) the differences between those groups of financial institutions do not adversely affect the national interest of the United States; and
   (D) 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 each Iranian financial institution identified under such governing foreign law for purposes of that sanctions regime.

On page 58, between lines 6 and 7, insert the following:

SEC. 401. FINDINGS.

Congress makes the following findings:

(1) The Government of Iran continues to violate systematically the basic human rights of citizens of Iran, including by cutting off their access to information and technology, suppressing their freedom of expression, and punishing severely, and sometimes brutally, their attempts to exercise political rights.

(2) In a March 20, 2012, speech celebrating Nowruz, the Iranian President Barack Obama described censorship of the Internet and monitoring of computers and
cell phones by the Government of Iran as depriving the people of Iran of ‘‘the information they want [and] stopping the free flow of information and ideas into the country’’. The concern is that—in recent weeks, Internet restrictions have become so severe that Iranians cannot communicate freely with their loved ones within Iran, or beyond that, that an electronic curtain has fallen around Iran.’’. (3) At a time when growing numbers of Iranians turn to the Internet as a source for news and political debate, the response of the Government of Iran has combined increasingly pervasive jamming and filtering of the Internet, blocking of email, social networking websites, and interception of Internet, telephonic, and mail communications. (4) The March 2012 Report of the United Nations Human Rights Council Special Rapporteur on Iran details the Government of Iran’s widespread human rights abuses and censorship, its chronic disregard of due process, and its equally chronic harassment, abuse, and intimidation of the people of Iran. (5) There has been no independent investigation into the months of violence that followed the fraudulent 2009 presidential election, violence that included the beatings of scores of Tehran University students by security forces using weapons, such as chains, batons, and electric prods, and the subsequent imprisonment of many students, some of whom died in captivity. (6) The Government of Iran has failed to cooperate with human rights investigations by the Special Rapporteur, and its failure to cooperate in those and similar investigations has been criticized in reports of the United Nations Secretary-General, General Assembly, and Human Rights Council, even as human rights abuses continue. SEC. 402. SENSE OF CONGRESS. It is the sense of Congress that— (1) the Government of Iran, especially Iran’s Revolutionary Guard Corps, continues to engage in serious, systematic, and ongoing violations of human rights and the rise in the level of such violations after the 2009 presidential elections has not abated; (2) the Government of Iran is engaging in a systematic effort to prevent news entertainment, and opinions from reaching media, including the facilitation or support of intentional frequency manipulation by the Government of Iran that would jam or restrict an international signal to prohibit intentional frequency manipulation by the Government of Iran that would jam or restrict an international signal or the failure to prohibit intentional frequency manipulation by the Government of Iran that would jam or restrict an international signal by the Government of Iran, including the failure to prohibit elite services to the Government of Iran or any entity owned or controlled by the Government of Iran; (3) the Government of Iran is engaging in a systematic effort to prevent news entertainment, and opinions from reaching media, including the facilitation or support of intentional frequency manipulation by the Government of Iran that would jam or restrict an international signal; and (4) the March 2012 Report of the United Nations Human Rights Council Special Rapporteur on Iran details the Government of Iran’s widespread human rights abuses and censorship, its chronic disregard of due process, and its equally chronic harassment, abuse, and intimidation of the people of Iran. SEC. 403. INTERESTS IN CERTAIN FINANCIAL ASSETS OF IRAN. (a) INTERESTS IN BLOCKED ASSETS.—Notwithstanding any other provision of law, including the provision of law relating to sovereign immunity, and preempting any inconsistent provision of State law, a financial asset that is— (1) property in the United States of a foreign sovereign intermediary doing business in the United States, (2) a blocked asset (whether or not subsequently unblocked) that is property described in subsection (b), and (3) equal in value to a financial asset of Iran, including an asset of the central bank or monetary authority of that Government, that such foreign securities intermediary or a related intermediary holds abroad, shall be available for all attachments and other proceedings in aid of execution, with respect to judgments entered against Iran for damages for personal injury or death caused by an act of torture, extrajudicial killing, aircraft sabotage, or hostage-taking, or the provision of material support or resources for such an act. (b) PROPERTY DESCRIBED.—Property described in this subsection is property that is— (A) property seized or frozen by the United States Government; or (B) does not include property that— (i) is subject to a license issued by the United States, and for which the Secretary of the Treasury has been specifically required by a provision of law other than the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) or the United Nations Participation Act of 1945 (22 U.S.C. 287 et seq.); or (ii) is property subject to the Vienna Convention on Diplomatic Relations or the Vienna Convention on Consular Relations, or that enjoys equivalent privileges and immunities under the laws of the United States; and (c) R ULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the exceptions to the application of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that are specifically required by a provision of law other than the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) or the United Nations Participation Act of 1945 (22 U.S.C. 287 et seq.).
this section as the “Secretary”), acting through the Commissioner of Food and Drugs, shall review and modify, as necessary, the Food and Drug Administration’s communication plan to inform and educate health care providers, patients, and payors on the benefits and risks of medical products, with particular focus on underrepresented subpopulations and racial subgroups.

(b) CONTENT.—The communication plan described under subsection (a) shall take into account—

(A) the goals and principles set forth in the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities issued by the Department of Health and Human Services;

(B) the nature of the medical product; and

(C) health and disease information available from other agencies within such Department, as well as any new means of communicating health and safety benefits and risks related to medical products;

(2) taking into account the nature of the medical product, shall address the best strategy for communicating safety alerts, labeled indications for the medical products, changes to the label or labeling of medical products (including black box warnings, health care provider and safety benefit and risks), particular actions to be taken by healthcare professionals and patients, any information identifying particular subpopulation(s), and any other relevant information as determined appropriate to enhance communication, including varied means of electronic communication; and

(3) shall include a process for implementation of any improvements or other modifications determined to be necessary.

(c) ISSUANCE AND POSTING OF COMMUNICATION PLAN.—

(1) COMMUNICATION PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall issue the communication plan described under this section.

(2) POSTING OF COMMUNICATION PLAN ON THE OFFICE OF MINORITY HEALTH WEBSITE.—The Secretary, acting through the Commissioner of Food and Drugs, shall publicly post the communication plan on the Internet website of the Office of Minority Health of the Food and Drug Administration, and provide links to any other appropriate webpage, and seek public comment on the communication plan.

SA 2126. Mr. REED submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 111. COMPLIANCE DATE FOR RULE RELATING TO SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE.

In accordance with the final rule issued by the Commissioner of Food and Drug entitled “Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Delay of Compliance Dates” (71 Fed. Reg. 52501 (May 11, 2012)), a product subject to the final rule issued by the Commissioner entitled “Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Delay of Compliance Dates” (71 Fed. Reg. 2591 (January 17, 2011)), shall comply with such rule not later than—

(1) December 17, 2013, for products subject to such rule with annual sales of less than $25,000 and

(2) December 17, 2012, for all other products subject to such rule.

NOTICE OF HEARING

COMMITTEE ON INDIAN AFFAIRS

Mr. AKAKA. Mr. President, I would like to announce that the Committee on Indian Affairs will meet on May 24, 2012, in room SD-628 of the Dirksen Senate Office Building, at 2:15 p.m., to conduct a hearing entitled “Programs and Services for Native Veterans.”

Those wishing additional information may contact the Indian Affairs Committee at (202) 224–2251.

AUTHORITY FOR COMMITTEES TO MEET

SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, THE FEDERAL WORKFORCE, AND THE DISTRICT OF COLUMBIA

Mr. LANDRIEU. Mr. President, I ask unanimous consent that the Committee on Homeland Security and Governmental Affairs’ Subcommittee on Oversight of Government Management, the Federal Workforce, and the District of Columbia be authorized to meet during the session of the Senate on May 21, 2012, at 2:30 p.m. to conduct a hearing entitled, “A National Security Crisis: Foreign Language Capabilities in the Federal Government.”

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

PRIVILEGES OF THE FLOOR

Mr. HARKIN. Mr. President, I ask unanimous consent that William McConagha and Kathleen Wise be granted the privilege of the floor for the duration of consideration of S. 3187, the Food and Drug Administration Safety and Innovation Act.

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

NATIONAL PEDIATRIC STROKE AWARENESS MONTH

Mr. BROWN of Ohio. Madam President, I ask unanimous consent that the Senate proceed to the consideration of S. Res. 468, which was submitted earlier today by Senator BLUMENTHAL.

The PRESIDING OFFICER. The clerk will report the resolution by title.

The legislative clerk read as follows:

A resolution (S. Res. 468) expressing the sense of the Senate with respect to childhood pedestrian stroke greatly improves the outcome between government, researchers, and advocates of organizations that work to enhance public awareness of childhood stroke.

Whereas between 50 and 85 percent of infants and children who have a pediatric stroke will have serious, permanent neurological disabilities, including paralysis, seizures, speech and vision problems, and attention, learning, and behavioral difficulties;

Whereas those disabilities may require ongoing physical therapy and surgeries;

Whereas the permanent health concerns and treatments resulting from strokes that occur during childhood and young adulthood can have considerable impact on children, families, and society;

Whereas very little is known about the cause, treatment, and prevention of pediatric stroke;

Whereas medical research is the only means by which the citizens of the United States can identify and develop effective treatment and prevention strategies for pediatric stroke; and

Whereas early diagnosis and treatment of pediatric stroke greatly improves the chances that the affected child will recover and not experience a recurrence: Now, therefore, be it

Resolved, That the Senate—

(1) acknowledges May as “National Pediatric Stroke Awareness Month”; which urges the people of the United States to support the efforts, programs, services, and advocacy of organizations that work to enhance public awareness of childhood stroke;

(3) supports the work of the National Institutes of Health in pursuit of medical progress on the matter of pediatric stroke; and

(4) urges continued coordination and cooperation between government, researchers, and the public to improve treatments and prostheses for children who suffer strokes.
Mr. BROWN of Ohio. Madam President, I ask unanimous consent that the Senate proceed to the consideration of S. Res. 469, submitted earlier today.

The PRESIDING OFFICER. The clerk will report the resolution by title.

The legislative clerk read as follows:

A resolution (S. Res. 469) honoring the entrepreneurial spirit of small business concerns that we have observed on Small Business Week, which begins on May 20, 2012.

There being no objection, the Senate proceeded to consider the resolution.

Ms. LANDRIEU. We have submitted a resolution, because it is Small Business Week, on behalf of myself and Senator SNOWE, Senator PRYOR, Senator LIEBERMAN, Senator ENZI, Senator KERRY, Senator BROWN, Senator CANTWELL, Senator BURTON, Senator CARDIN, and Senator HAGAN, a very good representation of our Small Business Committee and others that submitted a resolution this week, again, as we have done every year since 1953. We have done so every year since 1953.

As we have done every year since 1953, when communism was reigning in the Soviet Union, and the Arab world was in darkness, I mean the market was in the United States.

But that is no longer the case, as these countries and areas have emerged and created markets and opportunities of their own.

So one thing we learned is that the ecosystem needs to be stronger by helping small businesses to export. They do not have the back office or the expertise of 10 accountants and a Chinese specialist and a South American specialist. But we can, by being smart, help. Through the Commerce Department, the Small Business Administration, or maybe even through some of our research and development arms of some of our departments, we can be the back office for small businesses.

We are excited about what is happening there. So access to capital, access to global markets, access to counseling, mentoring, technical assistance and education. I have had so many small businesses come before our committee and say: You know, Senator, getting your business off the ground was the first step. But if so-and-so had not shown up in my office from the Score Chapter or if I could not have reached out to my local university or my small business center there, I would never have been able to make it because they told me what to do to save me from making a fatal mistake and got me on my way or helped me to rethink my market during the recession.

How one lady put it before our committee, they helped her market her business so now it is growing faster than ever. I think also access to strategic partnerships is important. No man is an island. We do not accomplish anything by ourselves in the world. That is true of individuals, that is true of small businesses. So we asked ourselves: Who are the partners, strategic partners for small businesses? Cities are doing some creative things.

Madam President, you were a county executive. You know the things you did as a county executive. Your reputation is well known in that regard.

States can be strategic partners to their small businesses. We explored those opportunities. Access to government contracting—you know, the Federal Government, state governments, and local governments are some of the biggest spenders and biggest businesses—if they were businesses, which they are not; they are differences—but if we were a business, the Federal Government would be the largest business in the world. It buys more goods and services than others. We do not have to do all of that just with the big businesses such as ExxonMobil. We can contract with small businesses. It takes a little more time, takes a little more energy, takes a little bit different approach, but we must certainly buy some of the things we need from the small business right down the street.

So we are shaping policies to do that. Senator CARDIN from Maryland has been particularly aggressive when it them at our universities, to where thirsty and women-owned businesses, which make up a significant and growing area. It is very exciting as more women enter not just the workforce but decide they want their flexibility. They want to be their own bosses. They want to establish businesses that allow them to also raise children at home, to be there when their kids need them. So they find that small businesses operating out of their homes are the answer to that dilemma. We want to give them access to government contracting when, of course, they are capable and provide the right price.

One of the big-ans is that we looked at is access to human capital. I think you probably heard, Madam President, many of our businesses saying: Why is it that we are bringing in some of the smartest people in the world, educating them, they are getting master's degrees and Ph.D.s in engineering, math, and science, and then we send them back to the country they came from so they can create businesses to compete against us? Why don't we extend visas to these master's and Ph.D. candidates?

That is a good question, and we have bills to answer that. We also want to develop a skilled workforce in America. Access to human capital is what small businesses need to grow and to expand.

Finally, we need access to flexible regulation and smart tax policy. We are never going to live in a world where we are going to pay taxes. It is just the nature of what we have to do to keep our government running and operating, with a government that serves the people—by the people, for the people.

But our taxes should not be too high. Our regulatory regime should not be either too light or too onerous. It should be just right. But it is hard to get that just-right approach. We are working at it every day. Senator Snowe has been working on regulatory reform. Senator WARNER has been working very hard on regulatory reform—and other Members of this body.
The bottom line is that this is Small Business Week. We want to honor the small businesses that are helping us put this recession in the rearview mirror. I want to ask the leadership to pass this resolution—a very straightforward, noncontroversial resolution by both Democrats and Republicans, recognizing this is Small Business Week.

I also wanted to bring to the attention of the body the conclusion, basically, of the three roundtables we held and thank the Members who attended. We had good attendance, and we gleaned some excellent ideas about the brackets I have outlined today, and have been in the process of filing over the last week, and throughout this week, individual bills that reflect what we have learned in these roundtables. We have taken those ideas and turned them into legislation.

I am happy to say there is not going to be a big price tag on this legislation. It is not just throwing money at the problem, but we do need additional resources. It is sharpening things, reforming some of our strategies, laws, rules, and regulations on the books, and granting competitive grants, some of these strategic partnerships with counties, cities, and States. I look forward to seeing how this body responds to some of the new pieces of legislation we put out. I was working with colleagues through this week and the month of May, through the summer, and into the election, to keep focused on the No. 1 issue on the minds of the American people, which is jobs, economic hope, and economic opportunity for themselves and their families. Tom Friedman has been saying all over the world that when kids graduate from college, it is not a job they are looking for. They may not be able to find the job they are looking for. They need to create the job that they want. They need to build a business, build a better mousetrap, think about a different way of delivering a product or a service or think about a business that is selling to a domestic market and taking it global. With technology and opportunities, many young people are doing just that.

In conclusion, I had the wonderful opportunity on Friday to be involved and took the opportunity Saturday morning to stop in at the Cambridge Innovation Center in Massachusetts, which is the grandaddy of all small business incubators. It is across the street from MIT, Microsoft, and Google. There were some young and exciting college students in the building. You could either rent a cubicle that looked like a kindergarten, with your name on it to get in the building or you could rent a space such as a bullpen where you could work or rent your own cubicle or private office; and thousands, literally, of young people were moving into that building—especially young, even retired executives who decided, I have always wanted to try out my idea, so let’s see if I can get my business started. Even on a Saturday—and it was very quiet—I could feel the energy in that building, even though it was virtually empty.

I have walked through incubators in New Orleans, and I hope the occupant of the chair did, and helped to create the environment. The Presidential administration is going to take, a strategic partnership between government and the private sector, letting the private sector do what they do best, but letting government do what it does best. That was a perfect example of what I saw. That is in terms of taking research dollars that are spent at MIT, moving them out to the universities, and then on to these ideas, where they are literally being tested and commercialized to get out into the hands of Americans today and opportunity for the United States and the world.

I am happy to be chair of the Small Business Committee. For small business and entrepreneurial growth, it is National Small Business Week. I thank all the groups helping us to celebrate this week and, most important, I thank the entrepreneurs who literally risk everything to create their dreams and bring economic prosperity not just to themselves and their family business but to a Nation that relies on them every day. We want to make that burden lighter. I want to help them in every way we can in our committee in Washington, and throughout our States, counties, and cities, and be the partner they can rely on to get the job done.

Madam President, I don’t see anyone else on the floor. I urge my colleagues to adopt our resolution. I thank all of us who are speaking today and this week on Small Business Week.

Mr. BROWN of Ohio. Madam President, it is my understanding we are ready to act on this resolution.

The PRESIDING OFFICER. If there is no further debate, the question is on agreeing to the resolution. The resolution (S. Res. 469) was agreed to.

Mr. BROWN of Ohio. Madam President, I now ask that we act on the preamble.

The PRESIDING OFFICER. If there is no further debate, the question is on agreeing to the preamble.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

Whereas the approximately 27,500,000 small business concerns, and the small business community, are the key part of the economic vitality of the United States; and

(1) honores the entrepreneurial spirit of small business concerns in the United States during National Small Business Week, which begins on May 20, 2012, and applauds the efforts and achievements of the owners and employees of small business concerns, whose hard work and commitment to excellence have made such small business concerns a key part of the economic vitality of the United States; and

(2) recognizes the work of the Small Business Administration and its resource partners in providing assistance to entrepreneurs and small business concerns; and

(3) the Small Business Administration, such as Small Business Development Centers, Women’s Business Centers, and the Service Corps of Retired Executives, are provided with the Federal resources necessary to provide invaluable counseling services to entrepreneurs and small business concerns in the United States; and

(4) the Small Business Administration continues its role to provide fast disaster assistance so that small businesses in areas struck by natural or manmade disasters can quickly return to business to keep local economies alive in the aftermath of such disasters;

(5) recognizes that small businesses need the Internet to make its operations more globally competitive while boosting local economies;

(6) regulatory relief is provided to small businesses through the reduction of duplicative or unnecessary regulatory requirements that increase the cost of doing business, and

(7) level the playing field for contracting opportunities remains a primary concern for government contractors. That the Senate—
focus, so that small businesses, particularly minority-owned small businesses, can compete for and win more of the $400,000,000,000 in contracts that the Federal Government enters into each year for goods and services.

Mr. BROWN of Ohio. Madam President, I ask unanimous consent that the motions to reconsider be laid upon the table, and any statements related to the resolution be printed in the RECORD.

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

APPPOINTMENTS

The PRESIDING OFFICER. The Chair, on behalf of the Republican Leader, pursuant to Public Law 96–114, as amended, appoints the following individuals to the Congressional Award Board:

Michael Schmid of Wyoming,
Cheryl D. Maddox of Kentucky, and
Charmaine Yoest of Virginia.

ORDERS FOR TUESDAY, MAY 22, 2012

Mr. BROWN of Ohio. Madam President, I ask unanimous consent that when the Senate completes its business today, it adjourn until 10 am on Tuesday, May 22, that following the prayer and pledge, the Journal of proceedings be approved to date, the morning hour be deemed expired, the time for the two leaders be reserved for their use later in the day, and that the majority leader be recognized; that the first hour following the remarks of the majority leader and Republican leader be equally divided and controlled between the two sides, with the majority controlling the first half and the Republicans controlling the second half; further, that the Senate recess from 12:30 until 2:15 p.m. to allow for the weekly caucus meetings.

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

PROGRAM

Mr. BROWN of Ohio. Madam President, it is the majority leader’s intention to resume the motion to proceed to Calendar No. 400, S. 3187, the Food and Drug Administration user fees legislation, when the Senate convenes tomorrow. At 2:15 the Senate will begin consideration of the bill. Senators will be notified when votes are scheduled.

ADJOURNMENT UNTIL 10 A.M. TOMORROW

Mr. BROWN of Ohio. Madam President, if there is no further business to come before the Senate, I ask unanimous consent that it adjourn under the previous order.

There being no objection, the Senate, at 6:53 p.m., adjourned until Tuesday, May 22, 2012, at 10 a.m.

CONFIRMATION

Executive nomination confirmed by the Senate May 21, 2012:

THE JUDICIARY

PAUL J. WATFORD, OF CALIFORNIA, TO BE UNITED STATES CIRCUIT JUDGE FOR THE NINTH CIRCUIT.

There being no objection, the Senate, at 6:53 p.m., adjourned until Tuesday, May 22, 2012, at 10 a.m.

NOMINATIONS

Executive nominations received by the Senate:

THE JUDICIARY

THOMAS M. INUKEN, OF ILLINOIS, TO BE UNITED STATES DISTRICT JUDGE FOR THE NORTHERN DISTRICT OF ILLINOIS, VICE WAYNE R. ANDERSEN, RETIRED.

NATIONAL INSTITUTE OF BUILDING SCIENCES

JOSEPH BYRNE DONOVAN, OF VIRGINIA, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE NATIONAL INSTITUTE OF BUILDING SCIENCES FOR A TERM EXPIRING SEPTEMBER 7, 2013, VICE LANE CARSON, RESIGNED.

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

BRUCE R. SHERER, OF CALIFORNIA, TO BE A MEMBER OF THE NATIONAL COUNCIL ON THE HUMANITIES FOR A TERM EXPIRING JANUARY 26, 2018, VICE KENNETH R. WEINSTEIN, TERM EXPIRED.

IN THE ARMY

THE FOLLOWING NAMED OFFICER FOR APPOINTMENT IN THE UNITED STATES ARMY TO THE GRADE INDICATED WHILE ASSIGNED TO A POSITION OF IMPORTANCE AND RESPONSIBILITY UNDER TITLE 10, U.S.C., SECTION 601:

To be lieutenant general

MAJ. GEN. WILLIAM B. GARRETT III
### SENATE COMMITTEE MEETINGS

Title IV of Senate Resolution 4, agreed to by the Senate on February 4, 1977, calls for establishment of a system for a computerized schedule of all meetings and hearings of Senate committees, subcommittees, joint committees, and committees of conference. This title requires all such committees to notify the Office of the Senate Daily Digest—designated by the Rules Committee—of the time, place, and purpose of the meetings, when scheduled, and any cancellations or changes in the meetings as they occur.

As an additional procedure along with the computerization of this information, the Office of the Senate Daily Digest will prepare this information for the Congressionally authorized £.digest will prepare this information for the Congressionally authorized

Meetings scheduled for Tuesday, May 22, 2012 may be found in the Daily Digest of today’s RECORD.

### MEETINGS SCHEDULED

#### MAY 23

<table>
<thead>
<tr>
<th>Time</th>
<th>Committee</th>
<th>Location</th>
</tr>
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<tbody>
<tr>
<td>9:30 a.m.</td>
<td>Armed Services Strategic Forces Subcommittee</td>
<td>2203, Rayburn Building</td>
</tr>
<tr>
<td>10 a.m.</td>
<td>Judiciary Administrative Oversight and the Courts Subcommittee</td>
<td>2203, Rayburn Building</td>
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<tr>
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<td>Appropriations Department of Defense Subcommittee</td>
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<td>10 a.m.</td>
<td>Finance</td>
<td>2203, Rayburn Building</td>
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<tr>
<td>10 a.m.</td>
<td>Foreign Relations</td>
<td>2203, Rayburn Building</td>
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<td>Veterans Affairs</td>
<td>2203, Rayburn Building</td>
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<td>10:30 a.m.</td>
<td>Homeland Security and Governmental Affairs</td>
<td>2203, Rayburn Building</td>
</tr>
<tr>
<td>2 p.m.</td>
<td>Banking, Housing, and Urban Affairs Security and International Trade and Finance Subcommittee</td>
<td>2203, Rayburn Building</td>
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<td>2:30 p.m.</td>
<td>Armed Services Closed business meeting to markup the proposed National Defense Authorization Act for fiscal year 2013.</td>
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<td>Judiciary Business meeting to consider S. 2076, to improve security at State and local courthouses, S. 2370, to amend title 11, United States Code, to make bankruptcy organization more efficient for small business debtors, the nominations of Robert E. Bacharach, of Oklahoma, to be United States Circuit Judge for the Tenth Circuit, Paul William Grimm, to be United States District Judge for the District of Maryland, John E. Dowell, to be United States District Judge for the Northern District of Oklahoma, Mark E. Walker, to be United States District Judge for the Northern District of Florida, Brian J. Davis, of Florida, to be United States District Judge for the Middle District of Florida, and Charles Thomas Massarone, of Kentucky, to be a Commissioner of the United States Parole Commission.</td>
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#### JUNE 7

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<tbody>
<tr>
<td>2:15 p.m.</td>
<td>Indian Affairs To hold an oversight hearing to examine programs and services for native veterans.</td>
<td>2203, Rayburn Building</td>
</tr>
<tr>
<td>10 a.m.</td>
<td>Health, Education, Labor, and Pensions</td>
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#### POSTPONEMENTS

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*This “bullet” symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor. Matter set in this typeface indicates words inserted or appended, rather than spoken, by a Member of the House on the floor.*
Daily Digest

Senate

Chamber Action

Routine Proceedings, pages S3295–S3388

Measures Introduced: Five bills and two resolutions were introduced, as follows: S. 3207–3211, and S. Res. 468–469.

Measures Reported:

Special Report entitled “Inquiry into Counterfeit Electronic Parts in the Department of Defense Supply Chain”. (S. Rept. No. 112–167)

Measures Passed:

Iran Threat Reduction Act: Committee on Foreign Relations was discharged from further consideration of H.R. 1905, to strengthen Iran sanctions laws for the purpose of compelling Iran to abandon its pursuit of nuclear weapons and other threatening activities, and the bill was then passed, after agreeing to the following amendments proposed thereto:

Reid (for Johnson (SD)/Shelby) Amendment No. 2124 (to the language proposed by Amendment No. 2123), to improve the bill.

Reid (for Johnson (SD)/Shelby) Amendment No. 2123, in the nature of a substitute.

National Pediatric Stroke Awareness Month: Senate agreed to S. Res. 468, expressing the sense of the Senate with respect to childhood stroke and recognizing May as “National Pediatric Stroke Awareness Month”.


Measures Considered:

FDA User Fee—Agreement: Senate resumed consideration of the motion to proceed to consideration of 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.

A unanimous-consent agreement was reached providing that the motion to invoke cloture on the motion to proceed to consideration of the bill, be withdrawn; that at 2:15 p.m., Tuesday, May 22, 2012, the motion to proceed be agreed to; that a Harkin-Enzi substitute amendment, which is at the desk, be agreed to; and the bill, as amended, by the Harkin-Enzi substitute be considered original text for the purposes of further amendment; and that the Majority Leader be recognized.

Appointments:

Congressional Award Board: The Chair, on behalf of the Republican Leader, pursuant to Public Law 96–114, as amended, appointed the following individuals to the Congressional Award Board: Michael Schmid of Wyoming, Cheryl D. Maddox of Kentucky, and Charmaine Yoest of Virginia.

Message from the President: Senate received the following message from the President of the United States:

Transmitting, pursuant to law, a report on the continuation of the national emergency that was originally declared in Executive Order 13303 of May 22, 2003, received during adjournment of the Senate on May 18, 2012; which was referred to the Committee on Banking, Housing, and Urban Affairs. (PM–50)

Nomination Confirmed: Senate confirmed the following nomination:

By 61 yeas to 34 nays (Vote No. EX. 104), Paul J. Watford, of California, to be United States Circuit Judge for the Ninth Circuit.

A unanimous-consent agreement was reached providing that the motion to invoke cloture on the nomination, be withdrawn.

Nominations Received: Senate received the following nominations:

Thomas M. Durkin, of Illinois, to be United States District Judge for the Northern District of Illinois.
Joseph Byrne Donovan, of Virginia, to be a Member of the Board of Directors of the National Institute of Building Sciences for a term expiring September 7, 2013.

Bruce R. Sievers, of California, to be a Member of the National Council on the Humanities for a term expiring January 26, 2018.

1 Army nomination in the rank of general.

Committee Meetings

FOREIGN LANGUAGE CAPABILITIES IN THE FEDERAL GOVERNMENT

Committee on Homeland Security and Governmental Affairs: Subcommittee on Oversight of Government Management, the Federal Workforce, and the District of Columbia concluded a hearing to examine national security, focusing on foreign language capabilities in the Federal government, after receiving testimony from Eduardo Ochoa, Assistant Secretary of Education for Postsecondary Education; Linda Thomas-Greenfield, Director General of the Foreign Service and Director of Human Resources, Department of State; Laura J. Junor, Assistant Secretary for Readiness, Glenn Nordin, Principal Foreign Language and Area Advisor, Office of the Under Secretary for Intelligence, and Major Gregory Mitchell, G–3/5/7 Training Directorate, United States Army, all of the Department of Defense; Tracey North, Deputy Assistant Director, Intelligence Operations Branch, Directorate of Intelligence, Federal Bureau of Investigation, Department of Justice; Andrew Lawless, Dig-IT Globalization Consulting, Andover, Massachusetts; Allan E. Goodman, Institute of International Education, and Dan E. Davidson, American Councils for International Education, both of Washington, D.C.; and Paula Patrick, Fairfax County Public Schools, Shauna Kaplan, Michelle Dressner, and Jeffrey Wood, all of Fairfax, Virginia.

House of Representatives

Chamber Action

The House was not in session today. The House is scheduled to meet at 10 a.m. on Tuesday, May 22, 2012 in pro forma session.

Committee Meetings

No hearings were held.

Joint Meetings

No joint committee meetings were held.

Committee Meetings for Tuesday, May 22, 2012

Committee on Appropriations: business meeting to mark up proposed budget estimates for fiscal year 2013 for Military Construction and Veterans Affairs, and Related Agencies and Department of Homeland Security, 10:30 a.m., SD–106.

Subcommittee on State, Foreign Operations, and Related Programs, business meeting to mark up proposed budget estimates for fiscal year 2013 for Department of State, Foreign Operations, and Related Programs, 2:30 p.m., SD–138.

Committee on Armed Services: Subcommittee on SeaPower, closed business meeting to mark up those provisions which fall under the subcommittee’s jurisdiction of the

Subcommittee on Readiness and Management Support, business meeting to mark up those provisions which fall under the subcommittee’s jurisdiction of the proposed National Defense Authorization Act for fiscal year 2013, 11 a.m., SD–G50.

Subcommittee on Emerging Threats and Capabilities, closed business meeting to mark up those provisions which fall under the subcommittee’s jurisdiction of the proposed National Defense Authorization Act for fiscal year 2013, 2 p.m., SR–232A.

Subcommittee on Airland, closed business meeting to mark up those provisions which fall under the subcommittee’s jurisdiction of the proposed National Defense Authorization Act for fiscal year 2013, 3:30 p.m., SR–232A.

Subcommittee on Personnel, closed business meeting to mark up those provisions which fall under the subcommittee’s jurisdiction of the proposed National Defense Authorization Act for fiscal year 2013, 5 p.m., SR–232A.

Committee on Banking, Housing, and Urban Affairs: to hold hearings to examine implementing derivatives reform, focusing on reducing systemic risk and improving market oversight, 10 a.m., SD–538.

Committee on Energy and Natural Resources: to hold hearings to examine the report produced by the American Energy Innovation Council titled “Catalyzing American Ingenuity: The Role of Government in Energy Innovation” and related issues, 10 a.m., SD–366.

Select Committee on Intelligence: closed business meeting to mark up expiring provisions of the “FISA Amendment Act”, 2:30 p.m., SH–219.

House

No hearings are scheduled.
Next Meeting of the SENATE
10 a.m., Tuesday, May 22

Senate Chamber
Program for Tuesday: The Majority Leader will be recognized. The Majority Leader intends to continue consideration of the motion to proceed to consideration of S. 3187, FDA User Fee, and at 2:15 p.m. the motion to proceed will be agreed to.

(Senate will recess from 12:30 p.m. until 2:15 p.m. for their respective party conferences.)

Next Meeting of the HOUSE OF REPRESENTATIVES
10 a.m., Tuesday, May 22

House Chamber
Program for Tuesday: The House will meet in pro forma session at 10 a.m.