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Senate

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.

OBSTRUCTIONISM 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 in earnest, I urge my Republican colleagues 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

how important it is to advance these important measures and prevent Iran from obtaining a nuclear weapon.

Republicans have also needlessly blocked progress on reauthorization of the Violence Against Women Act. This helps law enforcement effectively combat and prosecute domestic crimes against women. Although both Chambers have passed a version of this legislation, House Republicans have refused to go to conference with the Senate. Their excuse—a hypertechnical budget issue called a blue slip—isn't much of a figleaf to hide their blatant obstruction. The truth is that they are looking for any excuse to stall or kill this worthy legislation, but American women have not been fooled. If Republicans really want to give police the tools they need to prosecute domestic abusers, they will drop this facade. If Republicans really care about protecting women and families, they will abandon these hypertechnical objections and join us in conference.

There are differences between the House and Senate bills that could be worked out easily. American women and families are counting on our action. But in this Congress it seems the Republicans are more interested in inaction than action; they are more interested in blocking worthy legislation for partisan gain than in working together. Their infighting and partisan games have stopped reauthorization of the Violence Against Women Act, Iran sanctions, and the student loan fix—stopped them right in their tracks. These are just a few of their ways of stopping legislation, a few important measures they have stopped over the past few weeks. But the FDA bill, which will prevent drug shortages and make lifesaving medicines available more quickly, must not become another victim of this partisanship. I hope Republicans seize this opportunity to be cooperative rather than be combative.

Mr. President, would you announce the business of the day?

RESERVATION OF LEADER TIME

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

The motion to proceed is now pending.

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.

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 President, I ask unanimous consent that the order for the quorum call be rescinded.

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

ORDER OF PROCEDURE

Mr. REID. Mr. President, I ask unanimous consent that the cloture votes which were scheduled this afternoon on Watford be vitiated, all of the provisions of that order remain in effect.

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 devices. So for us life science is 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 around the world, often to countries that will never be able to afford an FDA.

We have worked very closely on a bipartisan basis to be able to create the legislative framework called PDUFA, the Pharmaceutical Drug User Fee Act, and there will be a lot of other UFAs, user fees, in this. As I said, we have worked together on a bipartisan basis to bring this legislation to the floor.

I note on the Senate floor at this moment is the ranking member of the Health, Education, Labor, and Pensions Committee, the Senator from Wyoming, Mr. ENZI, who has been a leader in fashioning legislation where we can continue the mission of what we want at FDA: safety and efficacy, moving drugs into clinical practice, regulations that are sensible, regulate but not strangulate the innovation economy or the potential for saving and improving lives. The bill before us is integral to achieving this shared goal.

This is not new legislation. PDUFA was enacted in 1992. At that time we were almost facing a crisis in our country. There was an unduly long wait for patients to have access to new medicines and technologies. For FDA, it often took 2 or 3 years to review a drug application. Materials were submitted manually in a very costly fashion. It cost manufacturers to the tune of almost $10 million a month.

So we decided to come together in the era when Bill Clinton said big government was over—not to make government to be bigger but for government to be smaller—and we came up with a public-private partnership called the PDUFA, the pharmaceutical user fee legislation. PDUFA supports drug review, so that those who make the products pay a fee to be able to have their drugs reviewed. They also expect their government to reduce the time it takes to move reviews expeditiously yet safely.

Let's be clear: This is a public-private partnership. For FDA, as it looks at its—remember, FDA has two jobs, which are food safety and then the safety of drugs and medical devices. More than 60 percent of funding for drugs and medical devices comes from industry fees—$712 million. The remainder comes from Federal appropriations—$473 million. So the private sector carries a big part of this responsibility. The kind of staffing, expertise, and modernization we have at FDA could not have happened without this public-private partnership. It has been a success.

More than 1,500 new medicines or technologies have been approved since 1992 for everything from the dread ''C'' words such as cancer or cardiovascular disease, to infectious disease, to the dread ''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 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 launched a listening tour in Maryland where I 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 where their government helped them and where their government hurt them, where should their government get out of the way, and where 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 of staff.

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 also in here MDUFA, the medical device act, and we do generic PDUFA. 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 others. If we don't reauthorize many other bills, they keep on going, but with the PDUFAs and the other user fee legislation, they actually will be sunsetted 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 will suffer. This isn't Senator BARB 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 patents 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, from the Ph.D. and the M.D. to 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. Think about the role of FDA. 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 to 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. I don't know what China is going to do, but I know we can stop ourselves if we don't pass legislation that promotes innovation in our country and private 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 S. 3187, 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 advocates, with stakeholders, 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 people 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 effective 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 are going to 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.

It 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 have started 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. Senators BLUMENTHAL, ROBERTS, CASEY, ALEXANDER, 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 other 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.

Chairman HARKIN 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 they expire this fall, the FDA will be forced to lay off 2,000 to 4,000 key employees. This will cause FDA's review of new drugs and devices to grind to a halt. This, in turn, will threaten biomedical industry jobs, patient access 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

will have to be chopped off because the money runs out when this bill expires, the previous bill expires, so it is critical that we get that done.

Another important thing with those 2,000 to 4,000 people who will have to be laid off at FDA is those are key technicians, scientists, informed people who have been working on this for a long time. If we lose this, they will still have jobs, it just will not be where we can get drugs on the market faster, devices on the market faster, generic drugs out faster, and all of the other things this bill covers.

So in conclusion, I would like to thank Chairman HARKIN and all the other members of the HELP Committee, FDA, industry, and many other groups for working with us on this important legislation.

I particularly want to point out the cooperation Senator HARKIN has provided, the leadership he has provided on the bill, and the way his staff members and mine 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 we can get this done expeditiously.

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.

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 this economic record when he is out on the campaign trail, and I can well understand why. It is not a very impressive record, especially if you are a taxpayer or a business owner.

Our national debt creeps closer to $16 trillion each day. It is now more than $5 trillion more than it was when the President took office. It now adds up to about $50,000 per person in the United States, and that is exclusive of interest payments. By way of contrast, the median yearly household income—in other words, all the people in the house—is less than $50,000. It is $49,445.

Unemployment recently dropped, but it did so for the simple reason that fewer people are searching for work.

The President's signature legislative items—the stimulus bill, ObamaCare, and Dodd-Frank—have not only been unhelpful in boosting growth, but they have left a trail of crushing debt, uncertainty, and new regulations in their wake. I want to make a few points about each of those bills because I think they paint a fair picture of the President's economic record.

First, let me talk about the stimulus. We have not forgotten about the stimulus, even though I suspect the President might like to—$1.2 trillion. It, obviously, failed to achieve the promised results. An Associated Press reporter wrote shortly before it was signed into law:

> They call it ''stimulus'' legislation, but the economic measures racing through Congress would devote tens of billions of dollars to causes that have little to do with jolting the country out of recession.

Of course, that is exactly what happened. It seemed more designed to shower taxpayer dollars on certain favored constituencies and pet interests than to actually jump-start the economy. Much of it was simply wasteful Washington spending. Many investors must have asked themselves why they should put their money to risk on new job-creating ventures when they have to compete with well-connected firms that can simply wring taxpayer-provided stimulus dollars out of Congress or the Obama administration.

A Washington Post poll released just last week showed that 48 percent of Americans have an unfavorable view of the stimulus—and this was, after all, the President's signature effort to spur the economy.

Indeed, as Jeffrey Anderson notes in a recent issue of the Weekly Standard magazine, the administration does seem to be downplaying the law. Not only has the stimulus failed to create robust growth, the costs have become more outrageous. He writes:

> It has now been five months since the Administration last put out a report card on [the stimulus.]. . . . the December report marked the sixth straight quarterly report showing that stimulus's cost per job is rising: In reports spanning January 2010 to December 2011, the stimulus's cost per job more than doubled, rising from $146,000 (in January 2010) to $317,000 (in December 2011). With each passing quarter, the stimulus has become an even worse deal for taxpayers.

So this is the administration's own report card on the stimulus, concluding in the last report, $317,000 per job. Think about that for a moment. To create each job, the taxpayers shell out $317,000.

Numbers like these remind me of a quip from writer Christopher Buckley. He said writing political satire these days can be difficult because it has to compete with reality—$317,000 for one job under the President's stimulus.

Well, second, ObamaCare. The $2.6 trillion bill is not aging very well. Since its passage, the act has imposed an estimated $14.9 billion in private sector burdens, approximately $7 billion in costs to the States, and 58.6 million annual paperwork hours, according to a weekly regulatory report.

The April Kaiser health tracking poll showed that more Americans have an unfavorable view of the law than favorable. It is 43 to 42 percent. More than half of Americans oppose its central provision, the so-called individual mandate. All told, the new taxes in ObamaCare would add up to $½ trillion over 10 years. Many of these taxes will coincide with the biggest tax increase in history—the one scheduled for the end of this year. So at the very time the income tax rates are scheduled to go up, the new taxes from ObamaCare will hit—$½ trillion worth of new taxes over the next 10 years.

Finally, there is the Dodd-Frank financial regulatory reform bill. When it comes to financial regulatory reform, I think most Americans believe there should be two simple goals: preventing new crises from happening and making sure the taxpayers are not on the hook for Wall Street's mistakes.

Well, the Dodd-Frank bill did not achieve either goal. It is a complex web of regulations that institutionalized ''too big to fail'' and has served to increase uncertainty, increase moral hazard, and increase economic distortions, all the while adding 52.9 million paperwork hours since its passage.

So, as I said, President Obama does not seem to be running for reelection on this record of the stimulus package, ObamaCare, or Dodd-Frank regulatory reform. Instead, he is going to be sending—or maybe he has already sent it—to Congress a to-do list, things he would like for Congress to do, most of which are tax credits and other very short-term proposals that are not likely to have a big effect on jobs or growth because the business sector is not impressed with a one-time-only, short-term proposition. It wants to know that when it invests money, that investment is going to be for the long term. Apparently, he is going to campaign on this most recent list when he goes out to Iowa later this week.

Well, this happens to be Small Business Week, and one would think the President would turn to something that businesses have actually said they would like to do; that is, to prevent this tax tsunami coming at the end of this year—as I mentioned, the biggest tax increase in the history of the country, which automatically would take effect on January 1 of next year, unless Congress does something about it and the President can sign the legislation.

The NFIB, the National Federation of Independent Business, recently released a list of the top five uncertainties in the Tax Code that they say would harm small businesses. Let me just mention three of these uncertainties.

One is the pending increase in marginal tax rates, which will devastate the estimated 75 percent of small businesses that file as individuals. Every one of the five tax rates in the IRS Code will be increased as of January 1. Since most of the businesses now pay—especially small businesses—as individuals—so-called passthrough entities—these rate increases directly will impact small businesses.

Secondly, they are concerned about the death tax. That is going to ensnare 900 times more small business owners and 2,200 times more family farmers if the rate increases to 55 percent and the exemption falls to $1 million, as is scheduled to occur on January 1.

Third is the alternative minimum tax which will hit 27 million more

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 would 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.

Finally, I ask 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 PRESIDING 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. He says:

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 anemic 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 life 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 68.6 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 56.7 percent.

In other words, he is pointing out that not only would these higher tax rates hurt the small businesses and 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 such as Brazil, Russia, India, and China. How can American businesses compete in that situation?

Then, finally, Kudlow notes the effect of all of 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 all together. 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, businesses sitting on the sidelines because they cannot calculate what kind of return on investment they could get because of the potential for the huge tax increase that is going to occur on January 1, it is no wonder we cannot move forward with an economic recovery.

So I would just say to President Obama that providing long-term tax rate certainty would go a long way toward establishing a sound economy in this country, putting Americans back to work, and, ironically, establishing a better record on which the President could run. A year and a half ago, the President actually proposed—and I think Congress was very happy to go along with—a continuation of the existing tax rates because, as he said at the time, not to do so would be very damaging to the economy. I would submit it is equally damaging for that to happen at the end of this year.

So I would ask the President, help give the American people and American businesses the certainty they need to invest, to create jobs, to advance our economic growth, and create prosperity for our future.

EXHIBIT 1

[From National Review, May 17, 2012]

EXTEND THE BUSH TAX CUTS NOW

(By Larry Kudlow)

House Speaker John Boehner is playing a heroic role right now. In his efforts to prevent the Bush tax cuts from expiring, Boehner is aggressively taking on President Obama's leadership ineptitude on the economy. In essence, Boehner is pushing a Republican policy to wrap up a debt-limitation bill and extend the Bush tax cuts in one fell swoop before the election—and before all the last-minute, crisis-oriented, political machinations that would come in a lame-duck Congress, threatening another credit downgrade and leading to a business-hiring freeze and plunging stock market, all of which happened last year.

Tax-cut certainty is so vital right now because the anemic economic recovery may be moving towards deflation. That's the message of a gold price that has collapsed by near 20 percent, falling from around $1,900 an ounce to the mid-$1,500s. With a risk-averse economy at home, and with the Greek and European financial crises abroad, the demand for dollars seems to exceed the dollar supply printed by the Fed. This could be solved by more quantitative easing. But a better approach for a system already oversupplied with unused liquidity would be the extension of tax-rate growth incentives, not more monetary pump-priming.

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 anemic 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, taking the ''Buffett Rule'' into account). ''Equity capital is the life blood of investment and job creation for U.S. companies,'' they wrote. 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 56.7 percent.

And Speaker Boehner knows this. So he's begun a valiant fight 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 none.)

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 all together. 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 prairie fire of debt sweeping across Iowa and the nation,'' and he tied our newfound debt to the ''tepid recovery.''

But lower 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 tax-rate incentives 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-and-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 can make it plain to voters 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 hardheaded and stubborn.

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 standstill because the income coming into the Federal 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 Democrats have put over $2 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. I have been in meetings when they have said it. But not one has come to this floor to say: We are willing to put revenues on the table so we can match the cuts and move this country forward.

So I am a little tired of hearing them beat up on either President Obama or the Democrats when they are more to blame for the situation we are in. The American people are getting tired of it too because they can understand it is not 100 percent President Obama's fault. In fact, when he took office, the Titanic had already hit the iceberg because they had run right smack into it with the economic philosophies and policies they had. The ship was already sinking. But all they want to do is—either MITCH MCCONNELL or JON KYL, one day the Senator from Arizona or the Senator from Kentucky—every day come to the floor and talk about how it is the President's fault there is no way forward, there is no sure path forward, when they are the ones who have put boulders in the way every day.

So I hope the people can see through it. I came to the floor to talk about something else, but I am getting a little tired of hearing it myself. So I am sure everyone else is as well.

Again, Democrats have put $2 trillion of cuts before this body, and we have implemented some of them already. But we cannot run a government on 14 percent of the GDP. The average has been about 20 to 21 percent. So until they are willing to put some more revenues on the table, we are not going to get anywhere, and we are not going to be able to extend the tax cuts that cost people 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 yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. 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.

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 founded on the principle of trust. Users trust that their browsers are visiting real Web sites, not replicated ones. Internet commerce succeeds because people trust that their transactions are private and their financial information won't be shared with others. People trust the Internet because they believe their service providers work for them, 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 content that Americans consume must be at least as private as their library records, their video rentals, and book purchases in the brick-and-mortar world. Our law enforcement and intelligence agencies should not be free to monitor and catalog the speech of Americans just because it is online.

But the legislation passed by the other body, known as CISPA, would erode that trust. As an attempt to protect our networks from real cyber threats, CISPA is an example of what not to do. CISPA repeals important provisions of existing electronic surveillance laws that have been on the books for years, without instituting corresponding privacy, confidentiality, and civil liberty safeguards. It creates uncertainty in place of trust, it erodes statutory and constitutional civil rights protections, and it creates a surveillance regime in place of the targeted, nimble, cybersecurity program that is needed to truly protect our Nation.

Unfortunately, S. 2105, the bill before the Senate, shares some of these defects. Currently, Internet services and service providers have agreements with their customers that allow them to police and protect their networks and users. Rather than simply allowing these Internet companies to share information on users who violate their contracts and pose a security threat, the House and Senate proposals regrettably authorize a broad-based information-sharing regime that can operate with impunity. This would allow the personal data of individual Americans to be shared across a multitude of bureaucratic, military, and law enforcement agencies. This would take place regardless of the privacy agreements individual Americans have with their Internet service providers.

In fact, both the House and Senate bills subordinate all existing privacy rules and constitutional principles to the poorly defined interests of what is called cybersecurity.

These bills would allow law enforcement agencies to mine Internet users' personal data for evidence of acts entirely unrelated to cybersecurity. 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 in any cybersecurity program—not the privacy of individual Americans.

Congress could target this behavior with yet one more rule book and one more bureaucracy, creating a cybersecurity contractor 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. Shareholders and boards of 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 threat, they can and 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 every day 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 before the Senate and the 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 industrial complex that has an interest 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 the Congress seeks to promote and 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 is to 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.

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 it either 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.

Now the Congress is being 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.

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 tonight 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, with passage of this bill we will take 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 that can ensure 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 Senators HARKIN and ENZI deserve commendation for their work in 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 American citizens 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 of jobs 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—including 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. I think we are going to 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. We have had a situation which 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 this through 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 those 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. So 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 that can be used to streamline—without compromising safety in any way—the regulatory process so the approvals can be made.

Why is this important? Well, it is important not only to getting these products into the marketplace so they can be used to safely improve the health of American citizens, but this is a dynamic export industry where America has been the leading exporter of medical devices. I have heard from so many medical device manufacturers throughout Indiana that they are faced with the dilemma of having to potentially think about moving overseas simply because of the delays and the time lapse that exists for approval. They can manufacture these products overseas and get approval overseas and sell them on a worldwide basis much more quickly, but they do not want to do that. The United States is their home and they want to produce here, but they have to compete with their competitors across the waters that are subjected to fewer delays in implementing approvals.

To counter that, we simply want to use this medical device user fee in a way that will help the FDA's review process and eliminate these unnecessary delays, unpredictability, and inconsistency of past practices.

I do want to thank the FDA for paying significant attention to our device users by coming to Indiana and listening to them—a forum that I convened. There has been interaction back and forth, whether it is FDA traveling to Indiana or device manufacturers traveling here to Washington. I am pleased that this bill contains some items that are the result of all those negotiations and all those exchanges between the two.

Let me mention one last thing before closing, and that is the medical device tax, which is not part of this bill. To pay for the so-called affordable health care law, the administration included a 2.3-percent tax on medical devices, which will begin in 2013. That tax essentially was imposed on an industry that is paying its full share of taxes, contributing to the user fee, and yet it was slapped on as a way to pay for the costly health care bill. That has an enormous impact over a period of time on these device manufacturers and jeopardizes manufacturers' ability to remain based here in the United States rather than looking overseas.

There are a number of States in addition to Indiana—and my colleague from Minnesota is waiting to speak, and her State is also a major manufacturer 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 an opportunity to bring that 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 thank 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 places 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, things I heard 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, and we 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, then 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 for their son, who they had just found out 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 Canada, where the drug was readily 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 should never have happened, not in the United States of America, not 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. In fact, this 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 shouldn'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 a difference. We have pharmacists who are on the front line every day, and they came to us to get this bill introduced. We heard from emergency medical responders, who have told me that shortages have made it difficult to stock lifesaving drugs in their ambulances. I have listened to stories from parents whose children rely on drugs to help maintain their focus at school. I have seen firsthand how doctors and pharmacists have had to struggle to keep their patients alive as they look for these drugs.

These shortages have had significant impact on these patients' quality of life, oftentimes forcing them to pay hundreds more for expensive alternatives or risking their professional careers to adjust for their diseases and spending hours and days just trying to find a way to fill a prescription.

When we are dealing with so many costs and resource issues with health care, the last we want is for doctors and nurses and pharmacists to be wasting away hours trying to find drugs and then ultimately, in most cases, finding them, but this is no way to run a railroad. Across the country, hospitals, physicians, and pharmacists are confronting unprecedented shortages of these drugs.

So those are the stories, but here are the numbers.

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 overlapping 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 didn't work for their profits 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. When drugs are 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 drugs 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 BOB CASEY. We also have 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 that the 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 several 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 look in our own country, and if they can't find something in our own country they can look at safe locations overseas. 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.

I believe 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 what this bill does.

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 cytarabine 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 hospitals, 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 and in a bipartisan manner come up with a solution that would give the FDA more tools to prevent drug shortages and ensure patients such as Axel or Mary have the drugs they need when they need them. Recent announcements by the FDA have proven that early notification and cooperation with manufacturers have helped reduce the number of drug shortages by over half. There have been 42 newly scarce drugs so far this year, compared to 90 in the same period last year. That is progress.

While I applaud the FDA in their efforts to address this crisis, 42 drugs in shortage is still 42 too many for me. That is why it is so important to pass this provision and give the FDA the tools it needs to get the number down to zero.

I understand that early notification requirements may be a short-term solution to a long-term problem. That is why I will continue to work with my Senate colleagues to come up with a broad permanent solution, one that includes methods to address the root causes of drug shortages.

It has been a long road to get to this point. Nearly 2 years ago I began hearing about this drug shortage issue, and when I first talked about it some of the doctors said: Really? I haven't heard about it. Now, 2 years later, they have all heard about it. That is why we introduced the Preserving Access to Lifesaving Medication Act. That is why we came together to get an agreement in this legislation. That is why the President issued an Executive order that pushed for more voluntary notifications from manufacturers, and the FDA released an interim final rule that broadened the scope of the current notification requirement. That is why it is so important that we pass this legislation.

Patients such as Axel or Mary should not have to be burdened with the added stress and worry about whether they are going to have enough medication to get through their next treatment. They have enough on their minds. Let's get this done. It is a great example of people working across the aisle. When they heard something from their constituents, they were willing to listen and to put this bill together. Me, I would like to have gotten it done 2 years ago, but later is better than never. We can get it done this week.

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

The PRESIDING OFFICER. The clerk will call the roll.

The assistant bill clerk proceeded to call the roll.

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

The PRESIDING OFFICER (Mr. BLUMENTHAL). Without objection, it is so ordered.

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 on the floor this week. This bill is 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 set up working groups. Different Senators had different interests in different parts of the bill. 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.

This 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 personnel and get the equipment they need to more quickly review product applications. We need to reauthorize this bill to implement those agreements if we want to keep the FDA running at full steam, which is critical to preserving jobs at both the agency and in industry, and to ensuring that FDA has the resources to get safe medical products to patients quickly. Again, these agreements affect all of us by helping to maintain and create jobs in our home States. For example, in my own State of Iowa, these agreements will support our bioscience sector which is growing and is increasing employment in our State. Implementation of these agreements will continue to foster biomedical innovation and job growth throughout our country.

The bill before us reauthorizes the prescription drug user fee agreement, which is known in the nomenclature as PDUFA. The medical device user fee agreement is known as MDUFA. These will continue and improve the agency's ability to speed market access to both drugs and medical devices while ensuring patient safety.

We have a new part of the bill called the generic drug user fee agreement, which is expected to slash review times to 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. By having generic drugs available more rapidly than they have been in the past, it will mean taxpayers will save a significant amount of money in the future.

This bill 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 said, after months of negotiations 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 this 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 before they expire. If we don't, 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 years.

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, policymaking process that we have had for the last year. 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 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 keep pace with and adapt to 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 aspect, 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 in this bill. 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 Trust, Consumers Union, 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 Senators feel they want to bring that up, that is fine. That is the way the Senate should operate.

I hope nonrelevant 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 completing 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 whatever 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 industry itself.

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 of 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 Aids; Action CF; Advanced Medical Technology Association; AFL–CIO, Maryland and DC Chapter; AIDS Alliance for Children, Youth, and Families; AIDS Delaware; AIDS Foundation of Chicago; Alder Health; Alexion Pharmaceuticals; Allegheny Conference of Community Development; Alliance of AIDS Services—Carolina; Alzheimer's Association—Capital of Texas Chapter; Alzheimer's Association—Indiana Chapter; Alzheimer's Association; American Academy of Child and Adolescent Psychiatry; American Academy of Dermatology Association.

American Academy of Emergency Medicine; American Academy of Emergency Medicine Residential and Students Association; American Academy of Pediatric Dentistry; American Academy of Pediatrics; American Academy of Periodontology; American Association of Nurse Anesthetists; American Association of Oral and Maxillofacial Surgeons; American Association of Women Dentists; American Cancer Society Cancer Action Network, Colorado Chapter; American Cancer Society, Delaware Chapter; American Cancer Society, South-Atlantic Division; American College of Clinical Pharmacy; American College of Emergency Physicians; American College of Gastroenterology; American Council of the Blind; American Dental Association; American Foundation for the Blind; American Hospital Association; American Liver 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, Delaware Chapter; American Society for Gastrointestinal Endoscopy; American Society for Parenteral and Enteral Nutrition; American Society of Anesthesiologists; American Society of Clinical Oncology; American Society of Dentist Anesthesiologists; American Society of Health-System Pharmacists; American Society of Hematology; American Society of Pediatric Nephrology; American Thoracic Society; Amgen; Analtech; ARCA Biopharma; Arthritis Foundation; Association of Community Cancer Centers; Association of Medical School Pediatric Department Chairs; AstraZeneca Pharmaceuticals LP; Augmenta Biologicals.

Bayer Healthcare; BHGR Law; BIO; BioCrossroads; Biogen Idec; BioHouston; BioNJ;

BioOhio; BioRelix, Inc.; Biotech Vendor Services; Black Mental Health Alliance of Massachusetts; Bleeding Disorders Alliance Illinois; Blood Bank of Delmarva; Bloomington Chamber of Commerce; Boehringer Ingelheim Chemicals, Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Vetmedica, Inc.; Boehringer Ingelheim, Inc.; Bristol-Myers Squibb; Burlington Chamber of Commerce.

Cambridge Chamber of Commerce; CARA Therapeutics; Celgene Corporation; Central Connecticut Chambers of Commerce; Cerebral Palsy Association of Eastern Massachusetts; Chamber of Commerce of Eastern Connecticut; Child Neurology Society; Children's Defense Fund; Children's Hospital Association; Citizens Opposed to Additional Spending and Taxes (COAST); Cleveland Clinic; Coaches Against Multiple Myeloma; 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 (CBIA).

Connecticut Retail Merchants Association; Connecticut State Building and Construction Trades Council; Connecticut United for Research Excellence (CURE, CT's BIO); Consumers Union; Council of Pediatric Subspecialties; CT BEACON; Cubist; D'Souza and Associates; Delaware Academy of Medicine; Delaware AFL–CIO; Delaware Ecumenical Council on Children and Families; Delaware HIV Consortium; Delaware Technology Park; DelawareBIO; Denver Metro Chamber of Commerce; Des Moines Area Community College; Detroit Regional Chamber of Commerce; Develop Indy; Dun & Bradstreet.

East End Group, LLC; Easter Seals 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 Pharmaceutical Association; GlaxoSmithKline; GlycoMimetrics; Grand Rapids Area Chamber of Commerce; Greater Boston Chamber of Commerce; Greater Des Moines Partnership; Greater New Haven Chamber of Commerce.

HealthHIV; HeathCare Institute of New Jersey (HINJ); Hematology/Oncology Pharmacy Association; Hep C Connection; Hon. Edd Houck, Former Virginia State Senator; Hospira; Hudson County Cancer Coalition; IBI Scientific; Illinois BIO; Illinois Biotechnology Industry Organization (iBIO); Illinois Chamber of Commerce Healthcare Council; Illinois Manufacturers' Association; Illinois Science and Technology Coalition; Incyte; Indiana Association of Cities and Towns; Indiana Health Industry Forum; Indiana Manufacturers Association; Indiana Medical Device Manufacturer's Council; Indiana State Chamber of Commerce; Infectious Diseases Society of America.

Innovation NJ; Institute for Safe Medication Practices; Institute For Systems Biology; Integrated Laboratory Services—Biotech; Iowa Academy of Family Physicians; Iowa Biotech Association; Iowa Nurses Association; Johns Hopkins Medicine; Johnson & Johnson; Joy's House; Junior Achievement of Central Maryland; Junior Achievement of Delaware; Junior Blind of America; Juvenile Diabetes Awareness Coalition; Juvenile Diabetes Research Foundation; Kalamazoo Chamber of Commerce; Kidney Cancer Association; Kolltan Pharmaceuticals, Inc.

Lancaster General Health; Legacy Community Health Services; 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—Illinois Chapter; Lupus Foundation of America DC/MD/VA Chapter; Lupus Foundation of America, Connecticut Chapter, Inc.; Lupus Foundation of America, DC/MD/VA Chapter; Lupus Foundation of New England; Lupus Foundation of Pennsylvania; Maetrics; March of Dimes; Maryland Chamber of Commerce; Maryland State Medical Society; Massachusetts Association of Mental Health; Massachusetts Biotechnology Council; Massachusetts Chamber of Commerce.

Mayors Committee on Life Sciences; MedCara Pharmaceuticals; Medical Device Manufacturers Association; Medical Imaging & Technology Alliance; Medical 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; Millennium, The Takeda Oncology Company; Morris County Chamber of Commerce; Mylan.

NAACP Columbus Chapter; NAMI Colorado; NAMI Indiana; NAMI NC; NAMI-IL; National Alliance 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, Central and Southeast Ohio Chapter; National Processing Solutions; National Research Center for Women & Families.

NC Autism Society; NC Bio NC Chamber; NC Psychological Association; Neurofibromatosis Mid-Atlantic; Neurofibromatosis of the Mid-Atlantic; Neurofibromatosis of the Mid-Atlantic; New Jersey Business and Industry Association (NJBIA); New Jersey Community Research Initiative; New Jersey Laborers' Union; New Jersey Life Science Vendors Alliance (NJLSVA); New Jersey State League of Municipalities; Newark Senior Center; NJ Healthcare Advocate Volunteer Effort (NJ Have); North Carolina Association for Biomedical Research; North Carolina Biotechnology; North Dakota Association of the Blind; North Hudson Community Action Corporation; North Texas Commission; Northwest Connecticut Chamber of Commerce.

Novo Nordisk Inc.; Nuclea Biotechnologies; NYU Langone Medical Center; Ohio Chamber of Commerce; Ohio Coalition of Concerned Black Citizens; Ohio Laborers' District Council; Ohio State Building and Construction Trades Council; One Southern Indiana; Ovarian Cancer National Alliance; PACT, Greater Philadelphia Alliance for Capital and Technologies; Parent Project Muscular Dystrophy (PPMD); Parkersburg Economic Development; Patient Advocates for Advanced Cancer Treatments; Pediatric Infectious Diseases Society; Pediatric Pharmacy Advocacy Group; Pennsylvania Bio; Pennsylvania Chamber of Business and Industry; Peoples Settlement Senior Center; Pew Charitable Trusts; Pfizer, Inc.; PhRMA; Pittsburgh Life Science Greenhouse.

Pittsburgh Technology Council; Pittsburgh Venture Capital Association; Plymouth/Terryville Chamber of Commerce; Premier healthcare alliance; Prevent Blindness America; Prevent Blindness Mid-Atlantic; Prevent Blindness Ohio; ProteoTech Inc; Psychiatric Society of Virginia; Respiratory Health Association of Metro Chicago; Rib-X Pharmaceuticals; Rio Grande Valley Diabetes Association; Rocky Mountain Stroke Center; Rush To Live Organization; Rx Partnership; San Antonio AIDS Foundation; Sanofi; Seattle BioMed; Sequella, Inc.; Sheet Metal Workers Local 40.

Society for Adolescent Health and Medicine; Society for Pediatric Research; Somerset County Business Partnership; South Jersey Geriatric Care, P.C.; South Jersey Senior Marketing Group; South Shore Chamber of Commerce; Southwest Michigan Pharmacists Association; Spanish American Merchants Association (SAMA); Stanford Hospital & Clinics; Supercritical Fluid Technologies; Susan G. Komen, Denver Metro Affiliate; Susan G. Komen for the Cure Advocacy Alliance; Takeda Pharmaceuticals U.S.A., Inc.; Targepeutics; Tech Council of Maryland; TECHQuest Pennsylvania; Teva Pharmaceuticals; Texas BioAlliance; Texas Health Care & Bioscience Institute.

The Arc of Connecticut; The Association for Corporate Health Risk Management; The Center for Health Care Services; Trinity Health—Novi, Michigan; Trust for America's Health; Union of Concerned Scientists; United Mitochondrial Disease Foundation; University City Science Center; University of Utah Health Care; University of Washington; Virginia Biotechnology Association; Virginia Chamber of Commerce; VisionServe Alliance; Visiting Angels; Washington Biotechnology & Biomedical Association.

Washington Global Health Alliance; Washington State Department of Commerce; Washington State University; Waterbury 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 PRESIDING OFFICER. 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, and 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 a series of standing 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 consequences, members agreed to a list of policy concepts. If it was not a consensus 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 was happening. 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 of each 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 product.

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. So for the 27th time, 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 promote a filibuster, but vote up or down, and I thank 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 litigator 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 they could give and they gave 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 such as 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.

Senate 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 say should apply to 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 very first judicial nomination, 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, Senator DICK 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 those nominees is the kind of brilliant 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 don't 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 the 1990s, 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 preliminary nose count, that he will be confirmed as a judge of the Ninth Circuit. 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 prosecutor. It is no surprise that he had support from conservatives as well as liberals. The shock I had was that for a while, his nomination was being held up and we couldn't get a vote.

Two former presidents of the Los Angeles 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 most 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 opponents), his nomination of Paul to the Ninth Circuit is a home-run and should receive bi-partisan support.

Henry Weissman, another former Federal Society chapter President, wrote 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 the law faithfully, objectively, and even-handedly.''

Conservative law professor Eugene Volokh of UCLA Law and creator of the conservative Volokh Conspiracy blog, expressed his strong support for Mr. Watford to the Committee, writing:

He has all the qualities that an appellate judge ought to have: intellectual brilliance, thoughtfulness, fairness, collegiality, an ability to deal civilly and productively with colleagues of all ideological stripes, and a deep capacity for hard work. . . . Paul is the sort of moderate Democratic nominee that moderates and conservatives, as well as liberals, should solidly support.

Conservative law professor Orin Kerr of George Washington University Law, a former special counsel to Senator CORNYN, called him ''extremely bright, a moderate, and very much a lawyer's lawyer,'' and concluded an online post saying, ''I hope he will be confirmed.''

In their letter of support, 32 of the clerks who served with him at the Supreme Court from the chamber of all the other Justices concluded: ''We are unanimous in our view that Paul possesses all the qualities of the most highly regarded jurists: powerful analytical abilities, a readiness to listen to and consider fairly all points of view, a calm temperament, and a prodigious work ethic.''

A number of corporate general counsels from leading U.S. corporations have written us urging confirmation:

Mr. Watford has represented a broad spectrum of clients, both in private industry as well as in the public sector. In doing so, he has demonstrated an understanding of the legal and economic challenges faced in both spheres, and an appreciation for the importance of fair, consistent application of the rules of law that govern business.

The assistant general counsel of Mattel joins in this support, writing: ''[I can] personally attest to his reputation for being remarkably intelligent, insightful and evenhanded. He is highly regarded within his firm, amongst his clients, and within the wider legal community for his exceptional skills as an appellate practitioner.''

Daniel Collins, an Associate Deputy Attorney General during the administration of President George W. Bush, described Paul Watford as ''incredibly intelligent and has solid integrity and great judgment.'' He concluded that this judicial nominee would not ''approach the job with any kind of agenda other than to do what is right and consistent with precedent as he understands it.''

I ask unanimous consent that copies of letters of support be printed in the RECORD at the conclusion of my statement.

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

(See exhibit 1.)

Mr. LEAHY. Paul Watford is far from an ideological, partisan selection. He shouldn't engender any serious objection; he is too good for that. He is the kind of nominee who, as my years here in the Senate demonstrate, normally receives unanimous support. It would usually not even require a roll call vote, because he has the qualifications, the judgment, and the ability. Maybe some were concerned that he was too well qualified or relatively young, and so some feared he might some day be nominated to a still higher court so they wanted to avoid voting on his nomination as they did when Elena Kagan was nominated to the D.C. Circuit by President Clinton, or when they delayed a vote as they did with Judge Sonia Sotomayor when she was nominated to the Second Circuit by President Clinton.

I strongly disagree with those who seek to nitpick this man's legal career. Since his service as a Federal prosecutor, he has worked at a highly respected Los Angeles law firm on a wide variety of matters. He has always represented his clients ethically and to the best of his legal ability.

The distinguished Presiding Officer, who has been an attorney general of his State, knows that lawyers are supposed to give their best counsel and their best effort to those whom they are representing. That is what lawyers are supposed to do. In my case, I defended criminals in private practice. I then prosecuted criminals as a prosecutor. In both cases, I knew what my role in the legal system was. As I said, that is what lawyers are supposed to do. Actually, that is what Republicans used to argue to defend the Federalist Society and corporate lawyers that were being nominated by a Republican President.

As Chief Justice Roberts noted during his confirmation hearing, lawyers represent clients. They do not stand in their client's shoes and they should not have their client's legal positions used against them.

Let's abandon the crude and inaccurate litmus tests being applied to President Obama's nominees. Let's stop the caricaturing. If not, no lawyer could ever be confirmed to the Federal bench. When we have a lawyer who has actually been active in his or her practice, of course they are going to represent some people others disagree with. Of course, they are going to represent 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 system break down if lawyers could only represent one side of an issue, or when a matter comes to court we can only hear from one side and not from the other? One of the most valued legal systems in the world would disintegrate.

As an attorney in private practice Paul Watford has advocated positions well within the mainstream of legal argument. There were only two cases on which he worked as a lawyer among 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 is affiliated represented groups challenging the controversial Arizona immigration law, and won a preliminary injunction against certain provisions for violating the Constitution. In his role as an attorney he was consulted by others working on the case to review and edit their preliminary injunction motion. That motion contains arguments based on Federal preemption, due process, and other constitutional rights that are well within the mainstream of legal advocacy and that were raised, as well, by the U.S. Department of Justice in its filings. That a Senator might disagree with the position he assisted in developing on behalf of his firm's clients in this case is hardly a reason to oppose his nomination. I did not oppose Chief Justice Roberts' nomination because he helped and advised the challenge resulting in Bush v. Gore. Paul Watford's legal work at Munger, Tolles was professional, principled and not out of the mainstream.

The other case on which critics have fastened as if to justify their opposition was his legal advocacy on behalf of clinical ethicists and critical care providers challenging a specific lethal injection protocol. He did not challenge the death penalty as unconstitutional. The legal challenge was to the manner in which it was being administered. In fact, in direct and express answers to questions from Senator GRASSLEY, the nominee wrote that he does not have any personal conviction or religious beliefs that would impact the way he would rule in a death penalty case and that he would have no difficulty ruling

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 record can be seen 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 disqualified for representing clients zealously. Go back in history. John Adams, one of the most revered Founders and later President of this country, wrote that his representation of the British soldiers in the controversial case regarding the Boston Massacre was ''one of the most gallant, generous, manly and disinterested actions of my whole life, and one of the best pieces of service I ever rendered my country.''

Did he agree with the British in holding the colonies subservient? Of course not. Did he agree with the efforts of us in this country to be free people—free from alliance with Great Britain? Of course he did. That is what he did when he helped and when he served as one of the Founders of this country and when he became President. But he also knew our whole system broke down if somebody within a court did not have adequate representation on both sides, and that is why he represented British soldiers in the case involving the Boston Massacre—not because he was supportive of what the British were doing and not because he wanted anything other than to have us as a free people, but because he wanted to make sure that in a free country, in a free United States of America, when someone goes before our courts, they are going to have representation on both sides, and that is the way it should be.

At his confirmation hearing to become the Chief Justice of the United States, John Roberts made the point:

[I]t's a tradition of the American Bar that goes back before the founding of the country that lawyers are not identified with the positions of their clients. The most famous example probably was John Adams, who represented the British soldiers charged in the Boston Massacre. He did that for a reason, because he wanted to show that the Revolution in which he was involved was not about overturning the rule of law, it was about vindicating the rule of law.

Our Founders thought that they were not being given their rights under the British system to which they were entitled, and by representing the British soldiers, he helped show that what they were about was defending the rule of law, not undermining it, and that principle, that you don't identify the lawyer with the particular views of the client, or the views that the lawyer advances on behalf of the client, is critical to the fair administration of justice.

That has always been our tradition. I hope it always will be our tradition, but I am concerned that some feel it should change. This litmus test that would disqualify nominees because as a lawyer they represented a side in a case on which we disagree is dangerous and wrong. Almost every nominee who has actually been a practicing attorney who has had more than one client in their life is going to fail such a test. They are going to be disqualified, because if they are practicing law, if they are doing what they are supposed to do, if they are making sure that someone is adequately represented in court no matter how unpopular that case may be, then of course they are going to take on some cases we might not like. The distinguished Presiding Officer was the chief prosecuting officer of his State. I was the chief prosecuting officer of my county. I prosecuted some people whom I wanted to go to jail for as long as possible. But the last thing I wanted was for them not to have a good and adequate lawyer on the other side. I wanted them to have the best of counsel on the other side, because that way, society is protected. That way, our court system is protected. That way, it meant that if any one of us came in and were innocent and were being charged, we would know there was an example of always having representation.

Republican obstruction of this nomination is particularly damaging given the dire need for judges on the Ninth Circuit. With three times the number of cases pending as the next busiest circuit and twice the caseload of the judges on other circuits, the Ninth Circuit cannot afford further delay filling its emergency vacancies. The 61 million people served by the Ninth Circuit are not served by this delay. I have been asked for months that the Senate expedite consideration of this nomination and that of Justice Hurwitz of Arizona to fill these judicial emergency vacancies.

The Chief Judge of the Ninth Circuit, Judge Alex Kozinski, a Reagan appointee, along with the members of the Judicial Council of the Ninth Circuit, wrote to the Senate months ago emphasizing the Ninth Circuit's ''desperate need for judges,'' urging the Senate to ''act on judicial nominees without delay,'' and concluding ''we fear that the public will suffer unless our vacancies are filled very promptly.'' The judicial emergency vacancies on the Ninth Circuit are harming litigants by creating unnecessary and costly delays. The Administrative Office of U.S. Courts reports that it takes nearly five months longer for the Ninth Circuit to issue an opinion after an appeal is filed, compared to all other circuits. The Ninth Circuit's backlog of pending cases far exceeds other Federal courts. As of September 2011, the Ninth Circuit had 14,041 cases pending before it, far more than any other circuit.

When Senate Republicans filibustered the nomination of Caitlin Halligan to the D.C. Circuit for positions she took while representing the State of New York, they contended that their underlying concern was that the caseload of the D.C. Circuit did not justify the appointment of another judge to that Circuit. I disagreed with their treatment of Caitlin Halligan, their shifting standards and their purported caseload argument. But if caseloads were really a concern, Senate Republicans would not have delayed action on this nomination to a judicial emergency vacancy on the overburdened Ninth Circuit for more than 3 months.

There is no justification for refusing to address the needs of the Ninth Circuit. A few years ago the Senate was forced to invoke cloture to overcome Republican filibusters of President Clinton's nominations of Richard Paez and Marsha Berzon to the Ninth Circuit. That obstruction is being repeated.

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 his 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 nomination 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 PALENCHAR & SCOTT LLP,
Chicago, IL, April 30, 2012.

Re Paul Watford.

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

Hon. PATRICK 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. One of us also spent a second year working with Paul during the year he spent as clerk to Justice Ginsburg at the United States Supreme Court.

During the crucible those intense years, we learned a lot about Paul's approach to legal issues, his attitudes about legal rules and precedents, and perhaps most importantly his demeanor when confronted with competing views of what the law is or should be. Paul is intelligent, thoughtful, balanced and fair. He is moderate, not extreme, in his 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 face of heated 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 (one registered Democrat, one registered Republican), to the personal qualities and temperament that make Paul not only qualified but uniquely well-suited to the position to which he has been nominated. We could go on (and on) with our praise for Paul, but the simple fact is that he will make an excellent judge.

We urge you to bring Paul's nomination to a vote, and to vote to confirm.

Very truly yours,

SEAN W. GALLAGHER,
MARK S. OUWELEEN.

MAY 15, 2012.

DEAR MAJORITY LEADER REID AND MINORITY LEADER MCCONNELL, We write in strong 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 1995 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 as a colleague. Based on what we saw then, 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. We encourage you to support his 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 his 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. In so doing, 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. Those of us who clerked with Paul for Justice Ginsburg know that she praised his work as exemplary and that she is a tough judge of legal talent.

After leaving the Court, Paul has had a distinguished legal career in public service and private practice. At the United States Attorney's Office in Los Angeles, Paul was a standout lawyer in the criminal division and appeared regularly before the Ninth Circuit. For many years, Paul has been a partner at Munger, Tolles & Olson, where he helps lead that firm's appellate practice and has represented a wide range of commercial clients in important and complex appellate matters. Paul has been a lawyer representative to the Ninth Circuit Judicial Conference, and has achieved distinction in the profession. Given his experience as a law clerk, as a federal prosecutor, and as a lawyer in private practice, Paul has an ideal background for the position of a Circuit Judge.

The group below is composed of individuals with very different political viewpoints and represents clerks from the chambers of every Justice on the Supreme Court during the OT95 term. We are unanimous in our view that Paul possesses all the qualities characteristic of the most highly regarded jurists: powerful analytical abilities, a readiness to listen to and consider fairly all points of view, a calm temperament, and a prodigious work ethic. We respectfully request that the Senate bring Paul's nomination to a vote and confirm him to the Ninth Circuit.

Sincerely,

Julia Ambrose, David Barron, Stuart Benjamin, Yochai Benkler, Steve Chanenson, Nancy Combs, Jeff Dobbins, Charlie Duggan, Ward Farnsworth, Lisa Beattie Frelinghuysen, Shawn Fagan, Sean Gallagher, Heather Gerken, Craig Goldblatt, Mark Harris, Julie Katzman, Joseph Kearney, Steve Kinnaird, Kelly Klaus, Laurie Allen Mullig, Eileen Mullen, Kate Moore, Jennifer Newstead, Gretchen Rubin, Kevin Russell, Maria Simon, Simon Steel, Ted Ullyot, Phil 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 MCCONNELL, CHAIRMAN LEAHY, AND RANKING MEMBER GRASSLEY: We write in support of the nomination of Paul J. Watford to the United States Court of Appeals for the Ninth Circuit. Like Mr. Watford, we have all clerked for the Honorable Alex Kozinski of the U.S. Court of Appeals for the Ninth Circuit, and we wish to echo the strong support that Chief Judge Kozinski has given to Mr. Watford.

All of us believe that Mr. Watford has the ability and character to be an excellent federal appellate judge. Mr. Watford has a stellar reputation in the legal community. He is known not only for his intelligence, but also for his collegiality and even temperament. For those of us who know Mr. Watford personally, his graciousness, sincerity and brilliance are immediately apparent.

Mr. Watford's legal career confirms that he has the experience, skills and demeanor well-suited for the bench. He clerked for two distinguished jurists, then-Judge Kozinski on the U.S. Court of Appeals for the Ninth Circuit and Justice Ruth Bader Ginsburg on the Supreme Court of the United States. He served in the Department of Justice as an Assistant United States Attorney in the Central District of California. Mr. Watford is currently a partner in the Los Angeles office of Munger, Tolles, & Olson LLP, a well-respected law firm. He also has taught a course on judicial writing for prospective law clerks at USC's Gould School of Law. In his experiences in public service and private practice, Mr. Watford has gained the respect and admiration of his peers. At every stage of his career, he has demonstrated a strong work ethic, a judicious temperament, unquestionable 1 integrity, a collaborative and respectful manner, and a deeply thoughtful approach to each and every issue that has crossed his desk.

As a close family of Kozinski clerks, we share Chief Judge Kozinski's strong faith in Mr. Watford's abilities. We believe he has the necessary qualifications and characteristics to make an exemplary federal appellate judge. Based on his record and personality, we have no doubt that Mr. Watford would approach each case with an open mind and make thoughtful judgments based on the law. Accordingly, we recommend him for this position without hesitation or reservation.

Sincerely,

Jerry L. Anderson, Drake University Law School, Judge Alex Kozinski (1986–1987); Fred A. Bernstein, Judge Alex Kozinski (1996–1997); James Burnham, Judge Alex Kozinski (2009–2010); Steven A. Engel, Dechert LLP, Judge Alex Kozinski (2000–2001); Justice Anthony M. Kennedy (OT 2001); Kristin A. Feeley, Judge Alex Kozinski (2009–2010); Stuart Banner, UCLA School of Law, Judge Alex Kozinski (1988–1989); Justice Sandra Day O'Connor (OT 1991); William A. Burck, Quinn Emanuel Urquhart & Sullivan LLP, Judge Alex Kozinski (1998–1999); Justice Anthony M. Kennedy (OT 1999); Jacqueline Gerson Cooper, Judge Alex Kozinski (1990–1991); Justice Anthony M. Kennedy (OT 1991); Susan E. Engel, Kirkland & Ellis LLP, Judge Alex Kozinski (2000–2001); Justice Antonin Scalia (OT 2001); Victor Fleischer, Professor of Law, University of Colorado, Judge Alex Kozinski (1997–1998).

Troy Foster, Wilson Sonsini Goodrich & Rosati, Judge Alex Kozinski (1999–2000); Sean W. Gallagher, Judge Alex Kozinski (1994–1995), Justice Sandra Day O'Connor (OT 1995); Stephanie Grace, Latham & Watkins LLP, Judge Alex Kozinski (2010–2011); Robert K. Hur, Judge Alex Kozinski (2001–2002), Chief Justice William H. Rehnquist (OT 2002); T. Haller Jackson IV, Tulane University School of Public Health & Tropical Medicine, Judge Alex Kozinski (2009–2010); Theane Evangelis Kapur, Gibson, Dunn & Crutcher LLP, Judge Alex Kozinski (2003–2004), Justice Sandra Day O'Connor (OT 2004); Scott Keller, Judge Alex Kozinski (2007–2008), Justice Anthony M. Kennedy (OT 2009); John P. Franz, Judge Alex Kozinski (1996–1997); Daniel L. Geyser, Gibson, Dunn & Crutcher LLP, Judge Alex Kozinski (2002–2003); Leslie Hakala, Judge Alex Kozinski (1997–1998), Justice Sandra Day O'Connor (OT 1999); Eitan Hoenig, Wachtell, Lipton, Rosen & Katz, Judge Alex Kozinski (2010–2011); Robert E. Johnson, Judge Alex Kozinski (2009–2010); Kevin M. Kelly, Gendler & Kelly, Judge Alex Kozinski (1989–1990), Justice Sandra Day O'Connor (OT 1990); Michael S. Knoll, Theodore K. Warner Professor, Law School Professor of Real Estate, Wharton School Co-Director, Center for Tax Law, and Policy University of Pennsylvania; Judge Alex Kozinski (1986).

Tara Kole, Gang, Tyre, Ramer & Brown, Judge Alex Kozinski, (2003–2004), Justice Antonin Scalia (OT 2004); Chi Steve Kwok, Judge Alex Kozinski (2002–2003), Justice Anthony M. Kennedy (OT 2003); C.J. Mahoney, Judge Alex Kozinski (2006–2007), Justice Anthony M. Kennedy (OT 2007); Chris Newman, George Mason University School of Law, Judge Alex Kozinski (1999–2000); Christopher R.J. Pace, Weil Gotshal & Manges LLP, Judge Alex Kozinski (1991–1992), Justice Anthony M. Kennedy (OT 1992); Mark A. Perry, Gibson, Dunn & Crutcher LLP, Judge Alex Kozinski (1991–1992), Justice Sandra Day

O'Connor (OT 1993); David A. Schwarz, Irell & Manella LLP, Judge Alex Kozinski, (1988–1989); Kathryn H. Ku, Munger, Tolles & Olson LLP, Judge Alex Kozinski (2003–2004); Joshua Lipshultz, Gibson, Dunn & Crutcher LLP, Judge Alex Kozinski (2005–2006), Justice Antonin Scalia (OT 2006); Laura Nelson, Judge Alex Kozinski (1985–1986); Mark Ouweleen, Bartlitt Beck Herman Palenchar & Scott LLP, Judge Alex Kozinski (1994–1995); Eugene Paige, Keker & Van Nest LLP, Judge Alex Kozinski (1998–1999); Justice Anthony M. Kennedy (OT 2000); Kathryn Haun Rodriguez, Judge Alex Kozinksi (2000–2001), Justice Anthony M. Kennedy (OT 2004); K. John Shaffer, Stutman, Treister & Glatt PC, Judge Alex Kozinski (1989–1990), Justice Anthony M. Kennedy (OT 1990).

Steven M. Shepard, Judge Alex Kozinski (2007–2008), Justice Anthony M. Kennedy (OT 2008); Elina Tetelbaum, Wachtell, Lipton, Rosen & Katz, Judge Alex Kozinski (2010–2011); Alexander ''Sasha'' Volokh, Assistant Professor, Emory Law School, Judge Alex Kozinski (2004–2005); Justice Sandra Day O'Connor and Justice Samuel Alito (OT 2005); Christopher J. Walker, Assistant Professor of Law, The Ohio State University, Judge Alex Kozinski (2006–2007), Justice Anthony M. Kennedy (OT 2008); Harry Susman, Judge Alex Kozinski (1996–1997); Justice Anthony M. Kennedy (OT 1997); Mary Ann Todd, Munger, Tolles & Olson LLP, Judge Alex Kozinski (1993–1994); Eugene Volokh, Gary T. Schwartz Professor of Law, UCLA School of Law, Judge Alex Kozinski (1992–1993), Justice Sandra Day O'Connor (OT 1993).

THE GENERAL COUNSELS OF
FOUR LARGE BUSINESSES,
February 1, 2012.

Re Nomination of Paul J. Watford as Circuit Judge of the U.S. Court of Appeals for the Ninth Circuit.

Hon. PATRICK J. LEAHY,
Chairman, U.S. Senate, Committee on the Judiciary, Washington, DC.
Hon. CHUCK GRASSLEY,
Ranking Member, U.S. Senate, Committee on the Judiciary, Washington, DC.

DEAR CHAIRMAN LEAHY AND RANKING MEMBER GRASSLEY: We write to express our support for the nomination of Paul J. Watford to the U.S. Court of Appeals for the Ninth Circuit, and urge that the Committee promptly and favorably act to send his nomination to the floor for confirmation. We are General Counsels of a broad spectrum of American businesses. Everything we know about Mr. Watford, both from the direct contact some of us have had to others who have only seen his work, indicates that he would be a superb addition to the bench.

For the last 11 years of private practice at one of the nation's premier law firms, Mr. Watford has represented a broad spectrum of clients, both in private industry as well as in the public sector. In doing so, he has demonstrated an understanding of the legal and economic challenges faced in both spheres, and an appreciation for the importance of fair, consistent application of the rules of law that govern business. The jobs, goods and services that constitute our economy require exactly that objective and impartial approach to deciding the important legal principles that come before a court such as the Ninth Circuit. We have every confidence that Mr. Watford has the right experience, intellect and character for such an important role in the judiciary.

It also is noteworthy that Mr. Watford's experiences prior to joining private practice demonstrate the same even-handed perspective. He served as a law clerk on the Ninth Circuit and on the Supreme Court to jurists who are known to come at issues from very different places and often end at very different conclusions. Working closely with such diverse intellects is emblematic of Mr. Watford's own capabilities and temperament, and his legal talents are reflective of their skills as well. He is a superb writer, a keen intellect, a strong oral advocate, and someone with a genuine appreciation for the real interests on all sides. He is exactly the kind of individual that any plaintiff or defendant—person, business or government—would welcome deciding their case, and would trust would do so fairly.

We urge the Committee to swiftly and favorably act on Mr. Watford's nomination.

Respectfully,

Alan J. Glass, Vice President, General Counsel & Secretary, CIRCOR International, Inc.; Randal S. Milch, Executive Vice President and General Counsel, Verizon Communications Inc.; Bob Normile, Executive Vice President and Chief Legal Officer, Mattel, Inc.; Kent Walker, Senior Vice President and General Counsel, Google, Inc.

MATTEL, INC.,
El Segundo, CA, January 31, 2012.

Hon. PATRICK J. LEAHY,
Chairman, Senate Judiciary Committee, 224 Dirksen Senate Office Building, Washington, DC.
Hon. CHARLES E. GRASSLEY,
Ranking Member, Senate Judiciary Committee, 224 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 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: UCLA Law Review Editor, clerk to Judge Alex Kozinski of the Ninth Circuit, clerk to Justice Ruth Bader Ginsburg of the U.S. Supreme Court, Assistant U.S. Attorney in Los Angeles, and currently, a partner at the esteemed firm of Munger, Tolles & Olson. Paul has had significant, substantive involvement in bar association activities; most notably, he served as the Chair of the ABA Litigation Section's Appellate Practice Committee, and on the ABA's Amicus Curiae Committee. In addition, Paul shares his talent and time with the broader community, serving on the board of a non-profit legal services provider for low income clients and teaching upper-division legal writing at USC. Certainly, Paul's resume is testament to his stellar qualifications and his dedication to the law.

Paul has assisted Mattel with several appellate matters. His analysis, reasoning and writing is of the highest caliber. His performance as a ''judge'' on a moot court panel, however, is what stands out most in my mind. His questions went right to the core issues, his follow-up questioning was quick and insightful, and his discussion of legal nuances and distinctions came easily and naturally. As always, his demeanor was thoughtful, attentive and respectful. Paul has all the hallmarks of an excellent jurist, and I highly endorse his appointment to the Ninth Circuit.

Sincerely,

JILL E. THOMAS.

Mrs. BOXER. I rise today to support Paul Watford, a California nominee for the Ninth Circuit Court of Appeals whose nomination is before us today.

Mr. Watford has been nominated for a seat that is designated as a judicial emergency, which means that it is critical we move swiftly to confirm him.

I was pleased when President Obama nominated Mr. Watford to serve on the U.S. Ninth Circuit Court of Appeals. He has a wide breadth of experience, ranging from public service to the private sector, and he will make an excellent addition to the federal bench.

Let me say a few words about his background.

Mr. Watford was born in Garden Grove, CA. He is a graduate of the University of California at Berkeley, and received his law degree from the University of California at Los Angeles, where he graduated with honors and was an editor of the UCLA Law Review.

Following law school, he clerked for Judge Alex Kozinski on the Ninth Circuit Court of Appeals, then clerked for Justice Ruth Bader Ginsburg on the United States Supreme Court.

From 1997 through 2000, Mr. Watford served as a federal prosecutor in the United States Attorney's Office for the Central District of California, where he handled a variety of criminal trial and appellate matters for the office, including major fraud investigations.

After his tenure as a prosecutor, Mr. Watford entered private practice—first with Sidley & Austin, then with his current law firm, Munger Tolles, where he is a partner specializing in appellate casework and complex commercial litigation.

In addition to his record as a lawyer, Mr. Watford has served in bar associations and professional committees. He has served as Co-Chair of the American Bar Association's Appellate Practice Committee, and he is a member of the Central District Court'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 as 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

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.)

Mrs. BOXER. 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.

EXHIBIT 1

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

HON. PATRICK J. LEAHY,
Chairman, U.S. Senate, Committee on the Judiciary, 473 Russell Senate Office Building, Washington, DC.

HON. MITCH MCCONNELL,
Republican Leader, U.S. Senate, 317 Russell Senate Office Building, Washington, DC.

HON. CHUCK GRASSLEY,
Ranking Member, U.S. Senate, Committee on the Judiciary, 135 Hart 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 can unreservedly 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 of having observed how he approaches 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 I 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 applicable case law. 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 proper limits 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 differ on certain jurisprudential issues, I have always been impressed by the even-handed and measured approach he brings to bear in analyzing legal problems. I feel confident that, on the bench, he would do his level best to fairly reach the correct answer under the law as be 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 gravitated to 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 reactions 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 Mohamad v. Jeppesen DataPlan Inc., in which he and 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'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 Watford has the talent, fairness, and integrity to be an excellent jurist, and I am pleased to support his confirmation.

Sincerely,

DANIEL P. COLLINS.

HORVITZ & LEVY LLP,
Encino, CA, January 26, 2012.

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 am also 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), his nomination of Paul to the Ninth Circuit is a home-run and should receive bi-partisan support. As an appellate lawyer, I care deeply about our nation's appellate courts and see on a daily basis the important role they play in our society. For appellate courts to effectively serve the public, it is vitally important that brilliant, collegial, and fair-minded men and women serve as appellate judges. Paul Watford is such a person.

Paul graduated with honors from UCLA Law School and then served as a law clerk to two extremely distinguished judges (one Republican and one Democrat), Alex Kozinski and Ruth Bader Ginsberg. Paul then served the public admirably as an assistant United States Attorney. Since 2000, Paul has been an extremely distinguished appellate lawyer in private practice where he has handled many complex and sophisticated appeals. Throughout his career, Paul has shown himself to possess excellent legal analysis and judgment. Indeed, there are few lawyers in California (or elsewhere) who are better prepared for the intellectual challenges of becoming an appellate judge.

Most lawyers who have achieved as much as Paul tend to be unpleasant egomaniacs. Not Paul. He is humble, polite and a good listener. I have no doubt that he will have collegial relations with the other judges on the Ninth Circuit. I also have no doubt that Paul will be fair-minded and will carefully apply the relevant legal precedent to each case he decides. Through his clerking experience, and his public and private practice, Paul has always demonstrated high integrity and ethics.

In short, everyone who knows Paul (whether they are conservative or liberal, or somewhere in between) recognizes that he possesses the qualities that are most needed in an appellate judge. Given the urgent need to fill vacancies in the Ninth Circuit, I would strongly urge the Senate to swiftly confirm Paul.

Very truly yours,

JEREMY B. ROSEN.

UNIVERSITY OF CALIFORNIA,
SCHOOL OF LAW,
Los Angeles, CA, January 30, 2012.

Hon. PATRICK J. LEAHY,
Chairman, Senate Judiciary Committee, Washington, DC.

Hon. CHARLES E. GRASSLEY,
Ranking Member, Senate Judiciary Committee, Washington, DC.

DEAR CHAIRMAN LEAHY AND SENATOR GRASSLEY: I am writing this to express my strong support for the nomination of Paul Watford to the United States Court of Appeals for the Ninth Circuit. I have long been extremely impressed by Paul, since I first met him almost 20 years ago, when my then-boss Judge Alex Kozinski (now Chief Judge) was interviewing him as a law clerk.

As you know, Paul had a stellar academic career, graduating very near the top of his class at UCLA School of Law and then clerking for Judge Kozinski and Justice Ruth Bader Ginsburg. He has also earned tremendous respect as a practicing lawyer, both as a federal prosecutor and an appellate lawyer. He has all the qualities that an appellate judge ought to have: intellectual brilliance, thoughtfulness, fairness, collegiality, an ability to deal civilly and productively with colleagues of all ideological stripes, and a deep capacity for hard work. If confirmed, he'll make a superb judge.

Let me turn then to the question of ideology. In the overwhelming majority of cases that an appellate judge faces, the judge's legal philosophy is entirely or almost entirely irrelevant: The cases are either straightforward applications of clear and well-settled law, or, even if less than clear, involve highly technical legal questions that relate little to high-level philosophical debates. For those questions Paul's intellect, care, and legal craftsmanship will yield results that both liberals and conservatives should applaud.

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 inevitable: Law is not mathematics. Some legal questions are unsettled and not answered by statutory or constitutional text, or binding precedent. And in the absence of a clear and obvious legal answer, different judges reach different results based partly on their philosophies. Paul is a moderate liberal; I am a moderate libertarianish conservative; I therefore expect that, if he is confirmed, there would be some future decisions of his with which I will disagree.

Yet our 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 rules that he is obligated to follow? 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 Democratic nominee that moderates and conservatives, as well as liberals, should solidly support.

Sincerely,

EUGENE VOLOKH.

HENRY WEISSMANN,
Los Angeles, CA, May 3, 2012.

Re Nomination of Paul Watford.

Hon. HARRY REID,
Majority Leader, U.S. Senate, Hart Senate Office Building, Washington, DC.
Hon. PATRICK J. LEAHY,
Chairman, U.S. Senate, Committee on the Judiciary, Russell Senate Office Building, Washington, DC.
Hon. MITCH MCCONNELL,
Republican Leader, U.S. Senate, Russell Senate Office Building, Washington, DC.
Hon. CHUCK GRASSLEY,
Ranking Member, U.S. Senate, Committee on the Judiciary, Hart Senate Office Building, Washington, DC.

DEAR SENATORS REID, MCCONNELL, LEAHY AND GRASSLEY: I write in support of the nomination of Paul Watford to the United States Court of Appeals for the Ninth Circuit.

I am a partner of Mr. Watford's at Munger, Tolles & Olson LLP. Prior to joining Munger, Tolles, I had the honor of serving as a law clerk to Justice Antonin Scalia of the Supreme Court and Judge James L. Buckley of the United States Court of Appeals for the D.C. Circuit. I am also a past President of the Los Angeles Chapter of the Federalist Society and serve on the Executive Committee of its national Telecommunications Practice Group. Although I do not agree with President Obama on many issues, I completely agree with his nomination of Mr. Watford.

I have had the pleasure of working with Mr. Watford for over a decade in a variety of appellate matters involving large corporate clients. He is brilliant, developing effective arguments on matters of first impression. He is efficient, producing top-quality work product quickly. He is respectful of his colleagues, his opponents, and the courts. Above all, he is a careful lawyer, applying precedent and common sense in a way that leads to moderate arguments. I have never seen any hint of politics in Mr. Watford's lawyering.

Mr. Watford is highly regarded not only within our firm, but also in the legal community at large. Lawyers from private practice, his former colleagues in the U.S. Attorney's office, clients, academics, and many others—including those from a wide range of political perspectives—hold Mr. Watford in the highest esteem.

I have every confidence that, as a judge, Mr. Watford would apply the law faithfully, objectively, and even-handedly. Mr. Watford would be an outstanding addition to the Ninth Circuit, and I support his nomination enthusiastically.

Sincerely,

HENRY WEISSMANN.

Mr. LEAHY. Mr. President, I ask unanimous consent that following the vote on the Watford nomination, the motion to reconsider be considered made and laid upon the table, with no intervening action or debate, that no further motions be in order to the nomination; that any statements related to the nomination be printed in the RECORD; that the President be immediately notified of the Senate's action, and that the Senate then resume legislative session.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. LEAHY. Mr. President, I suggest the absence of a quorum, but I ask unanimous consent that the time between now and the vote at 5:30 be evenly divided.

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

The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

FDA REAUTHORIZATION

Mr. COONS. Mr. President, I rise today in strong support of the bipartisan legislation to which the Senate will move to reauthorize the Food and Drug Administration user fees and critical programs to ensure Americans have access to safe and effective medications.

Most of us do not think about the FDA on a regular basis. In fact, we rarely think about where our medicines come from, the scientists who invented them, the investments required to develop them, and the innovative, cutting-edge new treatments that are essential to keeping Americans healthy and safe or the regulators who make sure these pharmaceuticals, devices, and treatments work as they are supposed to. But when the moment comes that we face a health crisis and our doctors prescribe us essential medication, we want those pharmaceuticals available right away, and we want them to work as promised.

One example of the many constituents who have contacted me about PDUFA is Virginia from Newark, DE, who recently sent a letter to my office. She volunteers with the National Brain Tumor Society and is concerned that without reauthorization of this legislation, safe and effective brain tumor therapies will be slower to be developed and made available to patients who need them. She wrote:

> It has been too long since any new therapies have become available for brain tumor patients that significantly extend survival. Anyone can be diagnosed with a brain tumor, and they are the second leading cause of cancer death in children under twenty.

I say to the Presiding Officer, I am sure, like me, in your office, as a Senator from Connecticut, you regularly are visited by folks from around the country or around your State who are deeply concerned about continuing medical progress, discovery and development of the lifesaving treatments Americans have developed over the last two decades. It is my hope that the Senate will continue to clear the way. That is why we need this legislation.

This reauthorization helps take care of innovation and safety so consumers and patients do not have to worry. It permanently authorizes programs that have helped make medicines safer for millions of children. It upgrades the FDA's tools to police the global supply chain and helps reduce the risk of drug shortages of the kind we saw recently, which Senator KLOBUCHAR just spoke to earlier this afternoon, when supplies of critical cancer medications ran low.

This is a matter of great urgency. The current FDA authorization will expire in a few short months. If we allow that to happen, we put at risk patient access to new medications as well as America's ongoing global leadership in biomedical innovation.

Worst of all, failing to reauthorize would cost us thousands of jobs, and more pink slips is not what we need as our economic recovery gains strength. If new drug and medical device user fee agreements are not authorized before the current ones expire, the FDA must lay off nearly 2,000 employees. Because that does not happen overnight, layoff notices would start going out as early as July. The good news is we are moving forward with a timely reauthorization to save those jobs, save America's leading role in innovation, and ensure that the FDA continues to make progress.

This is an all-too-rare display of bipartisanship across both Chambers. This legislation was unanimously approved by the House committee and found strong bipartisan support in the HELP Committee here in the Senate, ably led by Chairman HARKIN and Ranking Member ENZI.

There is a reason Members of the House and Senate of both parties are in such strong support of this reauthorization.

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 faith, my hope, that we will see more and more narrowly targeted drugs created specifically 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 country or 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 stay 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 bad for 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 strengthen and streamline the review timeline for new 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 put 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 every 5 years since is what 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 since it was first enacted. It has 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 medications to treat rare and widely experienced diseases.

In closing, the FDA is the oldest comprehensive consumer protection agency in the Federal Government. Its relevance has not decreased with age; in fact, quite the opposite. As 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 with the Presiding Officer 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 the 21st century, 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. But before I do, I think Members might want to consider the fact that the Ninth Circuit is by far the busiest U.S. circuit in the Nation. It has over 1,400 appeals pending per three-judge panel. That is the most of any circuit. It is over two times the average of other circuits combined.

The Judicial Conference of the United States has declared each Ninth Circuit vacancy a ''judicial emergency.'' So today we are, in fact, filling one of the seats which is a judicial emergency. The candidate is Paul Watford, a Ninth Circuit nominee with stellar credentials and support across the political spectrum. I am delighted that cloture was vitiated so the vote will be directly on his nomination, and it is anticipated that he will be confirmed without controversy.

Mr. Watford earned his bachelor's degree from the University of California Berkeley in 1989 and his law degree from UCLA in 1994 where he was editor of the UCLA Law Review and graduated Order of the Coif. After finishing law school, Mr. Watford clerked for Ninth Circuit Judge Alex Kozinski, an appointee of President Reagan's. He then clerked for Justice Ruth Bader Ginsburg on the U.S. Supreme Court.

Following his two clerkships, he spent a year in private practice at the prestigious firm of Munger, Tolles, and Olson and then moved into public service as an assistant U.S. attorney in Los Angeles in 1997. There he prosecuted a broad array of crimes, including bank robberies, firearms offenses, immigration violations, alien smuggling, and various types of fraud.

He later served in the major fraud section of the criminal division, focusing on white collar crime. Among his many cases, he prosecuted the first case of an online auction fraud on eBay in California. During his tenure as a Federal prosecutor, Mr. Watford appeared in court frequently, typically several times per week. He tried seven cases to verdict, and he worked 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 2000, Watford rejoined Munger, Tolles, and Olson where he is currently a partner. This is one of the premiere 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 business 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 two complex patent infringement cases. 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 ''do[es] 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 the nomination. These 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 that quite amazing.

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 Duggan, and Ted Ullyot 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 short, Paul 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 filibusterable. I hope people see the fine and keen intellect this man is, and 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 in committee and clearly are 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 the 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 Friendly House plaintiffs. 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 very 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 argument in his brief that the 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 related to whether illegal immigrants 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 that he would 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.

Finally, Republicans continue 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 history of President Bush'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 nominated six individuals to the ninth circuit. 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 nominated to serve 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 University of California, Berkeley in 1989 and his J.D. from the University of California, Los Angeles (UCLA) School of Law in 1994. 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 prosecutions, 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 Sidley & 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 commercial 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 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.

UNANIMOUS CONSENT AGREEMENT—S. 3187

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; that the 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 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 role.

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. Without objection, it is so ordered.

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 Paul J. 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 (Mrs. 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 (Mrs. HAGAN). Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 61, nays 34, as follows:

[Rollcall Vote No. 104 Ex.]

YEAS—61

Akaka	Graham	Murray
Alexander	Hagan	Nelson (NE)
Baucus	Harkin	Nelson (FL)
Begich	Inouye	Pryor
Bennet	Johnson (SD)	Reed
Bingaman	Kerry	Reid
Blumenthal	Klobuchar	Rockefeller
Boxer	Kohl	Sanders
Brown (MA)	Kyl	Schumer
Brown (OH)	Landrieu	Shaheen
Cantwell	Lautenberg	Snowe
Cardin	Leahy	Stabenow
Carper	Levin	Tester
Casey	Lieberman	Udall (CO)
Collins	Lugar	Udall (NM)
Conrad	Manchin	Warner
Coons	McCain	Webb
Durbin	Menendez	Whitehouse
Feinstein	Merkley	Wyden
Franken	Mikulski	
Gillibrand	Murkowski	

NAYS—34

Ayotte	Enzi	Paul
Barrasso	Grassley	Portman
Blunt	Hatch	Risch
Boozman	Hoeven	Roberts
Burr	Hutchison	Rubio
Chambliss	Inhofe	Sessions
Coats	Isakson	Shelby
Coburn	Johanns	Thune
Cochran	Johnson (WI)	Toomey
Corker	Lee	Wicker
Cornyn	McConnell	
Crapo	Moran	

NOT VOTING—5

DeMint	Kirk	Vitter
Heller	McCaskill	

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, reserving the right to object, and 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 words 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 one stated by President Barack Obama 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 since this resolution contemplates 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 finals of the National Hockey League 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 resolution 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 having 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.

(The amendment is printed in today's RECORD under ''Text of Amendments.'')

The amendment (No. 2124) was agreed to.

(The amendment is printed in today's RECORD under ''Text of Amendments.'')

The substitute amendment, as amended, was agreed to.

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

The bill was read the third time.

The PRESIDING OFFICER. The question is on passage of the bill as amended.

The bill (H.R. 1905), as amended, was passed.

Mr. REID. Madam President, I ask unanimous consent that the motion to reconsider be laid upon the table and that any statements related to this matter be printed in the RECORD in the appropriate place as if read.

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 has been stalwart in this issue. He and Senator SHELBY worked together. It has been very heartwarming.

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.

(See exhibit 1.)

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 weapons and other 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 Asad 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 members of the Banking Committee for their work, including Ranking Member SHELBY and Senators 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. Mr. 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—politically, economically, and diplomatically—to avoid that result. The meetings here in Washington in March between Israeli Prime Minister Netanyahu and President Obama underscored 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 re-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 actually be willing to 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 confront this very serious threat to our national security, to Israel and to our other allies in the Middle East and Europe. S. 2101, the Iran Sanctions Accountability and Human Rights 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 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 manager's amendment to address 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 503, to narrow its application while preserving his original intent to enable attachment of assets in which the government of Iran has an interest, to satisfy certain terror-related judgments against Iran.

In pressing this bill forward we recognize that economic sanctions are not an end: they are a means to an end. That end is to apply 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 deadly serious about 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 Congress have taken. Since here in the Senate we sometimes cannot even agree to cross the street together, in today's hyperpartisan environment bipartisan agreement on this bill is notable. On Iran sanctions we 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 of Iran and other banks 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 $60 billion in energy-related projects in Iran have been put on hold or discontinued. Oil shipments have sharply declined due to sanctions. The Wall Street Journal recently reported that Iran's crude oil output has dropped 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 monthly to load at the country's largest terminal didn't complete the voyages, according to brokers, company officials and shiptracking 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 oil. Some estimate the losses in 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 the European Union'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 sanctions recently, 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 more 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, in a ''world of hurt.'' Many believe the recent shift by Iran's leaders on the nuclear issue is the result of that pain, and the intense pressure of heightened sanctions. But while it is clear that existing sanctions are biting, they have not yet persuaded Iran's leaders to drop their nuclear ambitions. We must not let up now, as negotiations on these issues are continuing.

I believe that further progress in those negotiations depends on intensifying that pressure on Iran's leaders, and that's what this 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 clear choice. They can 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.

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 bill, including from S. 1048 sponsored by Senator Menendez. Senator Menendez has been a leader on these issues, along with Senator Kirk, and we acknowledge their many contributions. The bill also borrows and refines ideas from legislation developed by Senators Lautenberg, Gillibrand, Schumer, Kyl, 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 my remarks. Our legislation will: broaden the list of available sanctions, require intensified targeting of Iran's Revolutionary Guard Corps, require firms traded on US stock exchanges to disclose Iran-related activity to the Securities and Exchange Commission, sanction energy and uranium mining joint ventures with Iran, penalize US parent firms for certain Iran-related activities of their foreign subsidiaries, mandate sanctions for those who supply Iran with weapons and other technologies used to commit human rights abuses, including those used to impose an ''Electronic Curtain'' on Iran's citizens, and provide for other similar measures designed to increase pressure on Iran's government.

All told, when enacted the bill will significantly increase pressure on Iran's leaders, and that must be our goal as we move forward in this process. I hope and expect my colleagues will support this bill enthusiastically, and that we will be able to reconcile it with the House bill and move it forward quickly into law this year. I look forward to working with my House colleagues, including Chairman Ros-Lehtinen and Ranking Member Berman, who as former Foreign Affairs Committee Chairman has led the sanctions effort against Iran for many years, and played a key role in developing both CISADA and the House version of this measure, to get a bill enacted this year.

IRAN SANCTIONS, ACCOUNTABILITY AND HUMAN RIGHTS ACT OF 2012

SECTION-BY-SECTION SUMMARY

Sec. 1—Short Title, Table of Contents
Sec. 2—Findings

Contains a series of findings about the threat posed by Iran, the bipartisan understanding of the implications of its achieving a nuclear weapons capability, steps taken thus far by the US, its allies and the United Nations Security Council to counter that threat, and the need to intensify those efforts to counter that threat and deter Iran's nuclear ambitions.

Sec. 3—Definitions

Provides that the definitions of key terms (''appropriate congressional committees,'' ''credible information,'' and ''knowingly,'') will be those found in the Iran Sanctions Act (ISA) of 1996, as amended, and that the definition of ''United States person'' will be that found in the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (CISADA).

Sec. 101—Statement of Policy

Defines US policy to be to prevent Iran from (i) acquiring or developing nuclear weapons and advanced conventional weapons and ballistic missile capabilities, (ii) continuing its support for international terrorism, and (iii) engaging in other activities designed to destabilize its neighbors in the region. It also outlines the US policy of support for full implementation of all sanctions against Iran as part of multilateral efforts to compel Iran to abandon its illicit nuclear program.

Sec. 102—Expansion and Implementation of Multilateral Sanctions Regime

States the sense of Congress that expansion and vigorous implementation of bilateral and multilateral sanctions against Iran, and vigorous enforcement of all U.S. sanctions, is an effective way to achieve the goal of compelling Iran to abandon its efforts to achieve a nuclear weapons capability.

Sec. 103—Diplomatic Efforts to Expand Multilateral Sanctions Regime

Urges efforts by the US to expand the UN sanctions regime to include (i) imposing additional travel restrictions on Iranian officials responsible for human rights violations, the development of Iran's nuclear and ballistic missile programs, and Iran's support for terrorism; (ii) withdrawing sea- and airport landing rights for Iran Shipping Lines and Iran Air, for their role in nuclear proliferation and illegal arms sales; (iii) expanding the range of sanctions to which Iran is subject; (iv) expanding sanctions to limit Iran's petroleum development, imports of refined petroleum products and reduce its revenue from sale of petrochemical products, and (v) accelerating US diplomatic and economic efforts to help allies reduce their dependence on Iranian crude oil and other petroleum products. Requires periodic reporting to Congress.

Sec. 104—Imposition of Sanctions with regard to Iran

Declares the sense of Congress that efforts should be made to maximize the effects of sanctions and to preserve information-sharing.

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 through which Iran could otherwise receive energy sector technology or know-how not previously available to its government.

Sec. 202—Expands Sanctions on Providers of Goods and 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), or infrastructure predominantly used for the transportation of refined petroleum products, that could directly and significantly contribute to its petroleum resources development or refining 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 at least three ISA sanctions to persons who knowingly sell, lease, or provide to Iran goods, services, technology or support for its petrochemical sector in a single transaction of $250,000 or more, or multiple transactions aggregating to $1,000,000 or more in any 12-month period. In so doing, codifies the President's decision to extend US sanctions to Iran's petrochemical sector, adopting the standards, thresholds and petrochemicals list contained in Executive Order 13590.

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 withdraw from such joint ventures within 6 months after the date of enactment.

Sec. 204—Expansion of Sanctions Available under the Iran Sanctions Act of 1996

Expands the current menu of sanctions, available to the President under the ISA, to authorize exclusion from the United States of aliens who are corporate officers, principals or controlling shareholders in a sanctioned firm, and permits applicable ISA sanctions to be applied to the CEO or other principal executive officers (or persons performing similar functions) of a sanctioned firm, which could include a freeze of their US assets.

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 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, or other shipping services, for 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 or affiliates that knowingly participated in the activity. Provides for Presidential national security interest waiver; requires a report to Congress regarding the use of such a 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 reach those persons acting on behalf of, at the direction of, or owned or controlled by, the designated entities. Requires the Treasury Department to revise its regulations within 90 days of enactment to implement the change.

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 holds more than fifty percent equity 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 with Iran and would apply 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 traded 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); (iii) in 105A(b)(2) of CISADA (related to those who transfer weapons and other technologies to Iran likely to be used for human rights abuses); (iv) with persons whose property is blocked for WMD/terrorism and; (v) persons in the government of Iran. Provides for periodic public disclosure of such information, and conveyance of that information by 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. Also includes their family members. Provides for Presidential national security interest and UN obligations waiver; requires a report to Congress regarding the use of such a waiver.

Sec. 216—Sanctions with respect to the Provision of Certain Financial Communications Services to the Central Bank of Iran and Sanctioned Iranian Financial 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 terminate services to Iranian financial institutions designated for the imposition of sanctions pursuant to IEEPA. Requires the Comptroller General of the United States to submit a list, within 60 days of the date of enactment, of entities that provide financial communications services to or facilitate access to such services for the Central Bank of Iran or financial institutions described in 104(c)(2)(E)(ii) of CISADA (i.e., institutions whose property is blocked in connection with Iran's proliferation of 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 the provision of services to the Central Bank of Iran and Iranian financial institutions designated for sanction. Authorizes the imposition of sanctions under CISADA or IEEPA with respect to a financial communications services provider, and the directors of, and shareholders with a significant interest in, a provider, that has not terminated such services to the Central Bank of Iran or designated Iranian financial institutions.

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

Mandates regular reports from GAO on foreign investment in Iran's energy sector, exporters of refined petroleum products to Iran, entities providing shipping and insurance services to Iran, Iranian energy joint ventures worldwide, and countries where Iranian petroleum is produced or refined.

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

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 persons selling and transporting crude oil and refined petroleum products, the 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, importing advanced technology to upgrade existing Iranian refineries, converting existing chemical plants to petroleum refineries and maintaining, upgrading or expanding refineries or constructing new refineries.

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

Requires the President to identify, and designate for sanctions, officials, affiliates and 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 transaction—including barter transactions—with officials of the IRGC, its agents or affiliates. Requires imposition of similar sanctions against those persons who engage in significant transactions with UN-sanctioned persons, those acting for or on their behalf, or those owned or controlled by them. Provides for additional sanctions under IEEPA as the President deems appropriate. Requires the President to report on designations and waivers, as applicable.

Sec. 303—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 in volume 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 Iran with equipment and technologies—including weapons, rubber bullets, tear gas and other riot control equipment, and jamming, monitoring and surveillance equipment—which the President determines are likely to be used by Iranian officials to commit human rights abuses. Requires the President to maintain and update lists of such persons who commit human rights abuses, submit updated lists to Congress, and make the unclassified portion of those lists public. Requires the President to report on designations and waivers, as applicable.

Sec. 402—Sanctions on those Engaging in Censorship and Repression in Iran

Requires imposition of 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, Humanitarian, and Democracy Aid

Requires the Office of Foreign Assets Control (OFAC) of the Treasury Department to establish a 90-day process to expedite processing of US Iran-related humanitarian, human rights and democratization aid by entities receiving funds from the State Department; the Broadcasting Board of Governors; and other federal agencies. Requires the State Department to conduct a foreign policy review within 30 days of request submission. Provides for additional time for processing of applications involving certain specified sensitive goods and technology, and requests involving novel or extraordinary circumstances.

Sec. 412—Comprehensive Strategy to Promote Internet Freedom in Iran

Requires the Administration to devise a comprehensive strategy and report to Congress on how best to assist Iran's citizens in freely and safely accessing the Internet, developing counter-censorship technologies, expanding access to ''surrogate'' programming including Voice of America's Persian News Network, and Radio FARDA inside Iran, and taking other similar measures.

Sec. 413—Sense of Congress on Political Prisoners

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

Sec. 501—Exclusion of Certain Iranian Students from the US

Requires the Secretary of State to deny visas and the Secretary of Homeland Security to exclude certain Iranian university students who may seek to come to the U.S. to study to prepare for work in Iran's energy sector or in fields related to its nuclear program, including nuclear sciences or nuclear engineering.

Sec. 502—Technical Correction

Reaffirms longstanding US policy allowing the sale of certain licensed agricultural commodities to Iran by amending section 1245(d)2 of the National Defense Authorization Act to allow for continued payments related to such commodities.

Sec. 503 Interests in Financial Assets of Iran

Deems blocked assets of Iran seized or frozen in 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 section, including ''blocked asset,'' ''clearing corporation,'' ''financial asset,'' ''security,'' and ''securities Intermediary.''

Sec. 504—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. 601—Technical implementation; penalties

Provides the President with the necessary procedural tools to administer the provisions of this new law, drawing on relevant provisions of IEEPA, including ensuring that the Administration can require recordkeeping of certain persons, and has subpoena and enforcement authority for certain specified provisions of the bill.

Sec. 602—Applicability to Authorized Intelligence Activities

Provides a general exemption for authorized intelligence activities of the U.S.

Sec. 603—Termination

Provides for termination of some provisions of the new law if the President certifies as required in CISADA that Iran has ceased its support for terrorism and ceased efforts to pursue, acquire or develop weapons of mass destruction and ballistic missiles and ballistic missile launch technology.

Sec. 701—Short Title for Title VII

The ''Syria Human Rights Accountability Act of 2012.''

Sec. 702—Sanctions on Those Responsible for Human Rights Abuses of Syria's Citizens

Requires the President to identify within 90 days, and sanction under IEEPA, officials of the Syrian government or those acting on their behalf who are complicit in or responsible for the commission of serious human rights abuses against Syria's citizens, regardless of whether the abuses occurred in Syria.

Sec. 703—Sanctions on those Transferring to Syria Technologies for Human Rights Abuses

Requires the President to identify and sanction persons determined to have engaged in the transfer of technologies—including weapons, rubber bullets, tear gas and other riot control equipment, and jamming, monitoring and surveillance equipment—which the President determines are likely to be used by Syrian officials to commit human rights abuses or restrict the free flow of information in Syria. Provides for exceptions where a person has agreed to stop providing such technologies, and agreed not to knowingly provide such technologies in the future. Requires the President to report on designations and waivers, where applicable, and to update the list periodically.

Sec. 704—Sanctions on those Engaging in Censorship and Repression in Syria

Requires the President to identify and report to Congress within 90 days of enactment those persons and firms found to have engaged in censorship or repression of the rights of freedom of expression or assembly of Syria's citizens, and impose sanctions 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. 705—Waiver

Provides for Presidential national security interest waiver for Syria provisions; requires a report to Congress on the reasons for the waiver.

Sec. 706—Termination

Provides for termination of the Syria provisions if the President certifies that the Government of Syria is democratically elected and 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 released political prisoners, ceased the abuse of citizens engaged in peaceful political activity, ceased the practice of procuring sensitive technology to restrict the free expression rights of its citizens, ended support for terrorist organizations, ceased development of missile programs, is not engaged in the development or acquisition of biological, chemical 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 is 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 as it prepares for the 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 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, Madam President, as negotiators head to Baghdad this week for the P5+1 talks, this bill is another tool that will demonstrate to Iran that the United States is not backing down and that buying time and just thinking that you can go and talk without substantive, meaningful concessions here is just not going to work.

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 may 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 inspection that revealed 43.5 pounds of a component used to arm nuclear warheads was unaccounted for in Iran, and that Iran is working on an indigenous design for a 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 satellite services to the Iranian 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 sanctioned Iranian 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 perfecting legislation to CISADA and I am so thrilled we are seeing it today.

Finally, I wish to also comment on one particular section 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 for attachment and execution of certain blocked assets of the state of Iran, identified in the section, for judgments against Iran for the execution of terrorist acts, including the marine corps barracks bombing in Lebanon in 1983, which killed 241 U.S. servicemen, and the Khobar Towers bombing in Saudi Arabia in 1996 which killed 19 U.S. servicemen. Nothing in this legislation alters any other applicable law.

As someone 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 not be able to avoid having its assets attached and pursued 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. He worked in tandem with 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 noose on Iran. I wish to thank my friend and colleague Senator GRAHAM from South Carolina as well for being so instructive on this issue.

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 bring Democrats and Republicans together. I hope the Iranian Government 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 just about all of the civilized world is against her gaining a nuclear weapon. The Iranians can't talk about why shouldn't 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 the Iranian leadership and, unfortunately, 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, about 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 of its people 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 Iran to recognize it is in 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 the 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 Shefton in Cleveland at a property that is within breathing distance of an old lead smelter site. 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.

For too long regulators have overlooked or neglected to fully investigate toxic sites in our communities. That is why I am urging the Federal Government to take action. I have called on the Senate Environment and Public Works Committee to hold a hearing on what we can do to address this issue. We need to prioritize testing our schools and playgrounds in those neighborhoods close to abandoned sites.

I am asking the EPA to take immediate action to review sites that have not yet been tested. But that is not enough. After the results come in, we need 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 address it now. 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, in fact my love, 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 113th House of Representatives 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.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. 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 and maintain positive relationships 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.'s work serves as a model for other police departments across the Nation to ensure public safety in immigrant communities by keeping them informed and engaged.

On May 23, 2012, H.A.R.T. will be celebrating the graduation of individuals serving in the 10th Hispanic Citizens Academy, a stage shared by more than 500 alumni of the program. I am a proud supporter of the H.A.R.T. program, and I applaud the leadership 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.RT 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 bloodiest 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 the only member 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 promoted from private to corporal after killing a Japanese officer and obtaining 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:

[From the Lexington Herald-Leader, May 15, 2012]

SOLE SURVIVING MARINES' LEXINGTON PLATOON MEMBER TO BE HONORED

(By Tom Eblen)

Eight months after the Japanese bombed Pearl Harbor, hundreds of 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 Havely 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,'' he said.

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

''We're losing so many of these guys every day, it's good any time we can honor them,'' McChord said. ''We need to remind ourselves of who they are and what they did.''

Cecil and Mitch Alcorn, his Lafayette High School buddy and the longtime Midway postmaster, began tracking down their fellow Lexington Platoon members several years ago, searching the Internet and running ads in veterans magazines.

By this time last year, the group had dwindled to the two of them and Elwood Watkins, who earned a Silver Star and three Purple Hearts in battle. Watkins died July 12. Alcorn, who earned a Purple Heart and later fought in the Korean and Vietnam wars as an Army officer, died February 18.

Cecil grew up on a tobacco farm off Nicholasville Road. ''We didn't have any money, but we had plenty to eat,'' he said. ''We had milk cows, chickens and a big garden.''

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 water, watching 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 next.''

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 her, their sons and their grandsons.

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 patch and going 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 provisions 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, on the condition that such 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 is 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 consistently issues 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 be best 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 that clear in public statements, in private meetings with foreign financial institutions, and elsewhere as appropriate.

Misinterpretation of U.S. law by foreign financial institutions should no longer deny the people of Iran the benefit of OFAC-approved humanitarian trade.

I want to close by again thanking my colleagues for their support of ISHRA. I think this action sends an important message to the Iranians and the world that the U.S. will continue to increase sanctions until Iran verifiably abandons its illicit nuclear program. As we begin our work with the House, I will continue to press for the strongest and most effective sanctions legislation possible.

I yield the floor.

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 gained 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 tyranny of an authoritarian 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. Two 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 make such 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. It has been said that basic human rights and free and fair elections are nothing but dreams for all except for the developed countries of the world. I do not believe that to be true; Ethiopia is ready to realize that dream. To foster the benefits of a diverse citizenry, the many political prisoners and journalists should be released, the Charities and Societies Act, as designed and as it is implemented, should be prevented from strangling peaceful civil society advocacy.

Beginning in 1903, 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 Italy 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 failed, 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's citizens. We are hopeful this 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 in Ethiopia: robust public 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 accountability 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 this season with a record of 11–0. The team earned a spot in the national semifinals when it defeated Tufts University on November 13, 2011, in the New England Championship and then went on to defeat Molloy College on November 19, 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 Baik, Jeffrey Bouley, Patrick Brown, Chris Buckman, Michael Burlingame, Brian Cronin, Christopher Dieselman, Matt Dougenik, Zachary Faiella, Brian Goodridge, James Horn, Martin Kelliher, 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, Anthony Pesce, Russell Petrucci, Jacob Piazza, Nicholas Pinto, Evan Raiff, Rylan Richard, Nathan Rose, Kyle Russell, Justin Ryel, Carlos Santos, David Seguin, Colby Sherman, Ryan Shilalis, Connor Taub, Grant Thiem, 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. GILLIBRAND. 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 president 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 and construction 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, 89 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 and wit 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's 60-person 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 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, educational 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, during his tenure, the number 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 career paths.

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 leadership throughout the University experience, Lawrence Tech now includes leadership training as part of its undergraduate experience. Under Dr. Walker's leadership Lawrence Tech also forged a partnership with the Ferndale Public Schools to establish the University High School, a high school designed to challenge its students academically and expose them to the university experience. Its core focus is to prepare public high school students for success in college and beyond.

Dr. Walker has a distinguished academic background. He holds 3 degrees, including a Ph.D. in electrical engineering and has published more than 50 technical papers. Before joining Lawrence Tech, he served at the University of Hartford in various capacities, including dean of engineering and special assistant to the president. Earlier this year, he was awarded the 2012 Gold Award from the Affiliate Council of Engineering Society of Detroit for his outstanding work in science and engineering.

Throughout his professional career, Dr. Walker has worked tirelessly to find solutions to pressing concerns and to position Lawrence Tech to meet the challenges of tomorrow. The Lawrence Tech community is a better place as a result of his efforts, and we know his wife, Nancy and their children and grandchildren are proud of his many accomplishments over his long and illustrious career. We wish Dr. Walker and his family the best as he embarks on the next chapter of his life.●

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. 1622(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 28, 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.

Obstacles 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 that national emergency.

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 13303 of May 22, 2003, as amended by Executive Order 13364 of November 29, 2004, on any attachment, judgment, decree, lien, execution, 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 products, which are in addition to the sovereign immunity accorded Iraq under otherwise applicable law.

BARACK OBAMA.

THE WHITE HOUSE, *May 18, 2012*.

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. 2072. 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, 2011, 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. 4970. An act to reauthorize the Violence Against Women Act of 1994.

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

The message further announced that the House agree to the amendment of the Senate to the bill (H.R. 4849) to direct the Secretary of the Interior to issue commercial use authorizations to commercial stock operators for operations in designated wilderness within the Sequoia and Kings Canyon National Parks, and for other purposes.

The message also announced that pursuant to 22 U.S.C. 276I, and the order of the House of January 5, 2011, the Speaker appoints the following Members of the House of Representatives to the British-American Interparliamentary Group: Mr. PETRI of Wisconsin, Mr. CRENSHAW of Florida, Mr. LATTA of Ohio, and Mr. ADERHOLT of Alabama.

The message further announced that pursuant to section 703(c) of the Public Interest Declassification Act of 2000 (50 U.S.C. 435 note), and the order of the House of January 5, 2011, the Speaker reappoints the following member on the part of the House of Representatives to the Public Interest Declassification Board for a term of 3 years: Admiral William O. Studeman of Great Falls, VA.

MEASURES PLACED ON THE CALENDAR

The following bills were read the first and second times by unanimous consent, and placed on the calendar:

H.R. 4970. An act to reauthorize the Violence Against Women Act of 1994.

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–2012–0187)) 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 Standard Numbering System, Vessel Identification 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 ''Seagoing Barges—Correcting Amendment'' ((RIN1625–AB71) (Docket No. USCG–2011–0363)) 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 ''Regulated Navigation Area; 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 ''Regulated Navigation Area; Pacific Sound Resources and Lockheed Shipyard EPA Superfund Cleanup Sites, Elliott Bay, Seattle, WA'' ((RIN1625–AA11) (Docket No. USCG–2010–1145)) received in the Office of the President of the Senate on May 9, 2012; to the Committee on Commerce, Science, and Transportation.

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 ''Anchorage Regulations; Wells, ME'' ((RIN1625–AA01) (Docket No. USCG–2011–0231)) received in the Office of the President of the Senate on May 9, 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–2010–0929)) 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 ''Innovation in the Broadcast Television Bands: Allocations, Channel Sharing and Improvements to VHF'' (ET Docket No. 10–235; FCC 12–45) received in the Office of the President of the Senate on May 9, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6169. 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 Requirement For Children's Television Programming Report'' (MB Docket Nos. 00–168 and 00–44; FCC 12–44) received in the Office of the President of the Senate on May 9, 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 Turbofan Engines'' ((RIN2120–AA64) (Docket No. FAA–2010–0959)) 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 Off Alaska; Pacific Cod by Catcher/processors Using Trawl Gear in the Central Regulatory Area of the Gulf of Alaska'' (RIN0648–XB174) 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 Sustainable Fisheries, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled

''Fisheries Off West Coast States; Modifications of the West Coast Commercial and Recreational Salmon Fisheries; Inseason Actions Nos. 1, 2, and 3'' (RIN0648–XB120) received in the Office of the President of the Senate on May 9, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6174. A communication from the Acting Director, Office of Sustainable Fisheries, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Magnuson-Stevens Act Provisions; Fisheries Off West Coast States; Biennial Specifications and Management Measures; Inseason Adjustments'' (RIN0648–BC02) received in the Office of the President of the Senate on May 9, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6175. 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; Summer Flounder Fishery; Quota Transfer'' (RIN0648–XC002) received in the Office of the President of the Senate on May 9, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6176. 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 Off Alaska; Pacific Cod by Catcher Vessels Using Trawl Gear in the Bering Sea and Aleutian Islands Management Area'' (RIN0648–XB176) received in the Office of the President of the Senate on May 9, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6177. 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 Off Alaska; Pacific Cod by Catcher Vessels Using Hook-and-Line Gear in the Western Regulatory Area of the Gulf of Alaska'' (RIN0648–XB119) received in the Office of the President of the Senate on May 9, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6178. A communication from the Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; 2012 Atlantic Bluefish Specifications'' (RIN0648–XA904) received in the Office of the President of the Senate on May 9, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6179. A communication from the Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Shrimp Fisheries of the Gulf of Mexico and South Atlantic; Revisions of Bycatch Reduction Device Testing Protocols'' (RIN0648–BB61) received in the Office of the President of the Senate on May 9, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6180. A communication from the Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Fisheries of the Northeastern United States; Summer Flounder, Scup, and Black Sea Bass Fisheries; Final 2012 Summer Flounder, Scup, and Black Sea Bass Specifications'' (RIN0648–XA795) received in the Office of the President of the Senate on May 9, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6181. A communication from the Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service, Department of Commerce, transmitting, pursuant to law, the report of a rule entitled ''Fisheries of the Northeastern United States; 2012–2013 Northeast Skate Complex Fishery Specifications'' (RIN0648–BB83) received in the Office of the President of the Senate on May 9, 2012; to the Committee on Commerce, Science, and Transportation.

EC–6182. A communication from the Under Secretary of Defense (Comptroller), transmitting, pursuant to law, a report relative to a violation of the Antideficiency Act that occurred within the Procurement, Defense-Wide, account 97*0300 during fiscal years 2004 through 2010 and was assigned United States Special Operations Command case number 09–02; to the Committee on Appropriations.

EC–6183. A communication from the Assistant Director, Executive and Political Personnel, Department of Defense, transmitting, (62) reports relative to vacancies in the Department of Defense, received in the Office of the President of the Senate on May 16, 2012; to the Committee on Armed Services.

EC–6184. A communication from the Assistant Secretary of Defense (Global Strategic Affairs), transmitting, pursuant to law, a report entitled ''Cooperative Biological Engagement Program (CBEP) Report to Congress Pursuant to Section 1303(a) (1) and (2) of the NDAA for FY 2012''; to the Committee on Armed Services.

EC–6185. A communication from the Chief Counsel, Federal Emergency Management Agency, Department of Homeland Security, transmitting, pursuant to law, the report of a rule entitled ''Suspension of Community Eligibility'' ((44 CFR Part 64) (Docket No. FEMA–2012–0003)) received in the Office of the President of the Senate on May 16, 2012; to the Committee on Banking, Housing, and Urban Affairs.

EC–6186. A communication from the Assistant General Counsel for Legislation, Regulation and Energy Efficiency, Department of Energy, transmitting, pursuant to law, the report of a rule entitled ''Energy Conservation Program for Certain Industrial Equipment: Energy Conservation Standards and Test Procedures for Commercial Heating, Air-Conditioning, and Water-Heating Equipment'' (RIN1904–AC47) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Energy and Natural Resources.

EC–6187. A communication from the General Counsel, Federal Energy Regulatory Commission, transmitting, pursuant to law, the report of a rule entitled ''Transmission Planning Reliability Standards'' (Docket No. RM11–18–000) received in the Office of the President of the Senate on May 16, 2012; to the Committee on Energy and Natural Resources.

EC–6188. A communication from the Chairman of the Office of Proceedings, Surface Transportation Board, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''National Trails System Act and Railroad Rights-of-Way'' (RIN2140–AB04) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Energy and Natural Resources.

EC–6189. A communication from the Director of Congressional Affairs, Nuclear Reactor Regulation, Nuclear Regulatory Commission, transmitting, pursuant to law, the report of a rule entitled ''Aging Management of Stainless Steel Structures and Components in Treated Borated Water'' (LR–ISG–2011–01) received in the Office of the President of the Senate on May 16, 2012; to the Committee on Environment and Public Works.

EC–6190. A communication from the Director of Congressional Affairs, Nuclear Reactor Regulation, Nuclear Regulatory Commission, transmitting, pursuant to law, the report of a rule entitled ''Filing a Renewed License Application'' (Docket No. PRM–54–6; NRC–2010–0291) received in the Office of the President of the Senate on May 16, 2012; to the Committee on Environment and Public Works.

EC–6191. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, the Uniform Resource Locator (URL) for a report entitled ''OSRE–RCRA 9003(h) Corrective Action Model Unilateral Order for LUST Enforcement''; to the Committee on Environment and Public Works.

EC–6192. A communication from the Acting Fiscal Assistant Secretary, Department of the Treasury, transmitting, pursuant to law, the annual reports that appeared in the March 2012 Treasury Bulletin; to the Committee on Finance.

EC–6193. A communication from the Director of Regulations and Policy Management Staff, Food and Drug Administration, Department of Health and Human Services, transmitting, pursuant to law, the report of a rule entitled ''Irradiation in the Production, Processing and Handling of Food'' (Docket No. FDA–1999–F–0021) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Health, Education, Labor, and Pensions.

EC–6194. A communication from the Director of Regulations and Policy Management Staff, Food and Drug Administration, Department of Health and Human Services, transmitting, pursuant to law, the report of a rule entitled ''Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Delay of Compliance Dates'' (Docket No. FDA–1978–N–0018) received in the Office of the President of the Senate on May 17, 2012; to the Committee on Health, Education, Labor, and Pensions.

EC–6195. A communication from the Secretary of Health and Human Services, transmitting, pursuant to law, the report of a petition to add workers from at the Clinton Engineer Works in Oakridge, Tennessee, to the Special Exposure Cohort; to the Committee on Health, Education, Labor, and Pensions.

EC–6196. A communication from the Secretary of Health and Human Services, transmitting, pursuant to law, the report of a petition to add workers from the Electro Metallurgical site in Niagara Falls, New York, to the Special Exposure Cohort; to the Committee on Health, Education, Labor, and Pensions.

EC–6197. A communication from the Secretary of Health and Human Services, transmitting, pursuant to law, the report of a petition to add workers from Hangar 481 on the premises of Kirtland Air Force Base, Albuquerque, New Mexico, to the Special Exposure Cohort; to the Committee on Health, Education, Labor, and Pensions.

EC–6198. A communication from the Secretary of Health and Human Services, transmitting, pursuant to law, the report of a petition to add workers from the Brookhaven National Laboratory in Upton, New York, to the Special Exposure Cohort; to the Committee on Health, Education, Labor, and Pensions.

EC–6199. A communication from the Secretary of Health and Human Services, transmitting, pursuant to law, the report of a petition to add workers from the Sandia National Laboratories in Albuquerque, New Mexico, to the Special Exposure Cohort; to the Committee on Health, Education, Labor, and Pensions.

EC–6200. A communication from the Secretary of Health and Human Services, transmitting, pursuant to law, the ninth annual

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 and Chief Executive Officer, Farm Credit Administration, transmitting, pursuant to law, the Administration's Semiannual Report of the Inspector General and the Semiannual Management Report on the Status of Audits 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 21, 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'' (RIN3245–AG42) received in the Office of the President of the Senate 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'' (RIN3245–AG08) received in the Office of the President of the Senate 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. 112–167).

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 Multinational 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. BURR):

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, and referred (or acted upon), as indicated:

By Mr. BLUMENTHAL (for himself, Mr. CASEY, 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. PRYOR, Mr. LIEBERMAN, Mr. ENZI, Mr. KERRY, Mr. BROWN of Massachusetts, Ms. CANTWELL, Ms. AYOTTE, Mr. RISCH, Mr. CARDIN, 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. PRYOR, 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. 1578

At the request of Mr. TOOMEY, 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. 1696

At the request of Mr. LEAHY, the name 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. 1749

At the request of Mr. WARNER, the name of the Senator from Pennsylvania (Mr. CASEY) was added as a cosponsor of S. 1749, a bill to establish and operate a National Center for Campus Public Safety.

S. 1872

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. 1872, 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. 1878

At the request of Mr. MENENDEZ, the name of the Senator from Montana (Mr. TESTER) was added as a cosponsor of S. 1878, a bill to assist low-income individuals in obtaining recommended dental care.

S. 1884

At the request of Mr. DURBIN, the name of the Senator from Missouri (Mr. BLUNT) was added as a cosponsor of S. 1884, 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. 1910

At the request of Mr. LIEBERMAN, the name of the Senator from New Jersey (Mr. MENENDEZ) was added as a cosponsor of S. 1910, 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. THUNE) 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. 2047

At the request of Mr. SCHUMER, the name of the Senator from New Mexico (Mr. BINGAMAN) was added as a cosponsor of S. 2047, 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 delivery team 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. 2320

At the request of Ms. AYOTTE, the name of the Senator from Alaska (Ms. MURKOWSKI) was added as a cosponsor of S. 2320, a bill to direct the American Battle Monuments Commission to provide for the ongoing maintenance of Clark Veterans 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 Island (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. 3188

At the request of Mrs. GILLIBRAND, the name of the Senator from New York (Mr. SCHUMER) was added as a cosponsor of S. 3188, a bill to increase the authorized number of Weapons of Mass Destruction Civil Support Teams.

S. 3199

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. 2107

At the request of Mr. MCCAIN, the names of the Senator from Minnesota (Mr. FRANKEN) and the Senator from Maine (Ms. SNOWE) were added as cosponsors of amendment No. 2107 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.

AMENDMENT NO. 2108

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

AMENDMENT NO. 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; to the Committee on Indian Affairs.

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 those 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 for everybody. They are much faster than litigation. They allow individuals to participate in the outcome. They provide a greater degree of certainty to everybody 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 for 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—EXPRESSING 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 a 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 between 20 percent and 40 percent of children who suffer a stroke die as a result;

Whereas stroke recurs 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 24 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 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 have a 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'';

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

(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 prognoses 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. PRYOR, Mr. LIEBERMAN, Mr. ENZI, Mr. KERRY, Mr. BROWN of Massachusetts, Ms. CANTWELL, Ms. AYOTTE, Mr. RISCH, Mr. CARDIN, Mrs. HAGAN, Mr. RUBIO, and Mr. MERKLEY) submitted the following resolution; which was considered and agreed to:

S. RES. 469

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 all exporters and produce 31 percent 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 free and competitive enterprise, to ensure that a fair proportion of the total Federal Government purchases, contracts, 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 every year since 1963, 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 of owning 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 key part 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 efficient 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. 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.

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. SHELBY)) proposed an amendment 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.

SA 2124. Mr. REID (for Mr. JOHNSON of South Dakota (for himself and Mr. SHELBY)) proposed an amendment to amendment SA 2123 proposed by Mr. REID (for Mr. JOHNSON of South Dakota (for himself and Mr. SHELBY)) to the bill H.R. 1905, 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 Prime Minister 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 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:

''(f)(1) 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 district court of the United States for the judicial district in which such investigation or proceeding is conducted, or in which the subpoenaed person 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 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. 213a(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 261 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.''.

SA 2116. 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.

Section 221(a) of the Public Health Service Act (42 U.S.C. 213a(a)) is amended by adding at the end the following:

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

SA 2117. 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. 11___. PRACTITIONER EDUCATION.

(a) EDUCATION REQUIREMENTS.—

(1) REGISTRATION CONSIDERATION.—Section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) is amended by inserting after paragraph (5) the following:

''(6) 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.''.

(2) TRAINING REQUIREMENTS.—Section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) is amended by adding at the end the following:

''(3)(A) To be registered to prescribe or otherwise dispense methadone or other opioids, a practitioner described in paragraph (1) 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, 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 shall comply with the requirements of 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 8.2 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. 11___. PRESCRIPTION MONITORING PROGRAM.

Section 399O of the Public Health Service Act (42 U.S.C. 280g–3) is amended—

(1) in subsection (d)(1), by inserting ''(including prescribers of methadone)'' after ''dispensers''; and

(2) 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.''.

SA 2119. 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:

Subtitle D—Prescription Drug Abuse Prevention and Treatment

SEC. 1141. SHORT TITLE; FINDINGS.

(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 more than 400 percent between 1998 and 2008, from 2.2 to 9.8 percent.

(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 serious adverse health effects, resulting in dependence, abuse, and death.

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

(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, morphine, and other opioid drugs.

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

(8) Prescriptions for methadone have 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 almost 5,420 in 2006, which is the most rapid increase among opioid analgesics and other narcotics involved in poisoning deaths.

(10) The age-specific rates of methadone death are higher for persons age 35 to 44 and 45 to 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 2005.

(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 requirement as a 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.

SEC. 1142. CONSUMER EDUCATION CAMPAIGN.

Part A of title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by adding at the end the following:

''SEC. 506C. CONSUMER EDUCATION CAMPAIGN.

''(a) IN GENERAL.—The Administrator shall award grants to States and nonprofit entities for the purpose of conducting culturally sensitive consumer education about opioid abuse, including methadone abuse. Such education shall include information on the dangers of opioid abuse, how to prevent opioid abuse including through safe disposal of prescription medications and other safety precautions, and detection of early warning signs of addiction.

''(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall—

''(1) be a State or nonprofit entity; and

''(2) submit to the Administrator an application at such time, in such manner, and containing such information as the Administrator may require.

''(c) PRIORITY.—In awarding grants under this section, the Administrator shall give priority to applicants that are States or communities with a high incidence of abuse of methadone and other opioids, and opioid-related deaths.

''(d) EVALUATIONS.—The Administrator shall develop a process to evaluate the effectiveness of activities carried out by grantees under this section at reducing abuse of methadone and other opioids.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2013 through 2017.''.

SEC. 1143. PRACTITIONER EDUCATION.

(a) EDUCATION REQUIREMENTS.—

(1) REGISTRATION CONSIDERATION.—Section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) is amended by inserting after paragraph (5) the following:

''(6) 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.''.

(2) TRAINING REQUIREMENTS.—Section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) is amended by adding at the end the following:

''(3)(A) To be registered to prescribe or otherwise dispense methadone or other opioids, a practitioner described in paragraph (1) 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, 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 shall comply with the requirements of 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 8.2 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.).

SEC. 1144. MORATORIUM ON METHADONE HYDROCHLORIDE TABLETS.

(a) IN GENERAL.—Notwithstanding any other provision of law, during the period beginning on the date of enactment of this Act and ending on the date described in subsection (b), no individual or entity may prescribe or otherwise dispense a 40-mg diskette of methadone unless such prescription or dispensation is consistent with the methadone 40-mg diskette policy of the Drug Enforcement Administration as in effect on the date of enactment of this Act, except that such prohibition shall extend to hospitals unless such hospitals provide for direct patient supervision with respect to such methadone.

(b) ENDING DATE OF MORATORIUM.—The moratorium under subsection (a) shall cease to have force and effect—

(1) on the date that the Controlled Substances Clinical Standards Commission publishes in the Federal Register dosing guidelines for all forms of methadone, in accordance with section 506D(b)(1)(A) of the Public Health Service Act (as added by section 1146); and

(2) if, as part of such dosing guidelines, such Commission finds that 40-mg diskettes of methadone are safe and clinically appropriate.

SEC. 1145. OPERATION OF OPIOID TREATMENT PROGRAMS.

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

''(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 each patient who is restricted, by Federal regulation or guideline or 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 regulations on acceptable arrangements 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. 290aa et seq.), as amended by section 1142, is further amended by adding at the end 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—

''(1) 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);

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

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

''(4) specific guidelines for initiating pain management with methadone that prescribing practitioners shall comply with in order to meet certification requirements set forth in part C of the Controlled Substances Act (21 U.S.C. 821 et seq.); and

''(5) patient and practitioner education guidelines for both methadone maintenance therapy and pain management that apply to safe and effective use and include detoxification.

''(b) GUIDELINES.—

''(1) PUBLICATION OF DOSING GUIDELINES.—

''(A) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Commission established under subsection (a) shall publish in the Federal Register—

''(i) safe and clinically appropriate dosing guidelines for all forms of methadone used for both pain management and opioid treatment programs, including recommendations for maximum daily doses of all forms, including recommendations for the induction process for patients who are newly prescribed methadone;

''(ii) requirements for individual patient care plans, including initial and follow-up patient physical examination guidelines, and recommendations for screening patients for chronic or acute medical conditions that may cause an immediate and adverse reaction to methadone;

''(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 opioid drugs.

''(B) UPDATING OF GUIDELINES.—Not later than 3 years after the publication of guidelines under subparagraph (A), and at least every 3 years thereafter, the Commission shall update such guidelines.

''(2) PUBLICATION OF BENCHMARK GUIDELINES.—

''(A) IN GENERAL.—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—

''(i) the initial benchmark guidelines for the reduction of methadone abuse to be used—

''(I) by opioid treatment programs in providing methadone therapy; and

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

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

''(iii) 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 303(g)(3) of the Controlled Substances Act (21 U.S.C. 823(g)(3)), which should include a minimum of 16 training hours at least every 3 years that include the integration of both addiction and pain management curricula; and

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

''(B) UPDATING OF GUIDELINES.—Not later than 1 year after the publication of guidelines under subparagraph (A), and at least annually thereafter, the Commission shall update the guidelines published under clauses (iii) and (iv) of such subparagraph.

''(3) CONSULTATION.—In developing and publishing the guidelines under 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 pain management, physician groups, 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.

''(c) WEBSITE.—Not later than 180 days after the date of enactment of this section, the Commission shall establish and operate a Commission website.

''(d) METHADONE TOOLKIT.—Not later than 1 year after the date of enactment of this section, the Commission shall establish, and distribute to practitioners that are registered to prescribe or otherwise dispense methadone, a methadone toolkit. The Commission shall make the components of the toolkit that are available in electronic form available on the Commission website.

''(e) PRACTITIONER EDUCATION PROGRAM.—The Commission shall develop a practitioner education program that shall be used for the practitioner education described in section 303(g)(3) of the Controlled Substances Act, and shall make such program available to providers of such practitioner education.

''(f) AUTHORIZATION OF 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. 280g–3) is amended—

(1) in subsection (d)(1), by inserting ''(including prescribers of methadone)'' after ''dispensers'';

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

''(5) 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 relating to drugs, 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. 290aa et seq.), as amended by section 1146, is further amended by adding at the end 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 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 (3). 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).

''(b) 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 Director of 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) REQUIREMENTS.—The registry shall be designed as a uniform reporting system for opioid-related deaths and shall require the reporting of information with respect to such deaths, including—

''(A) the particular drug formulation used at the time of death;

''(B) the dosage level;

''(C) a description of the circumstances surrounding the death in relation to the recommended dosage involved;

''(D) a disclosure of whether the medication involved can be traced back to a physician's prescription;

''(E) a disclosure of whether the individual was in an opioid treatment program at the time of death;

''(F) the age and sex of the individual; and

''(G) other non-personal information such as that included in filed National Association of Medical Examiners Pediatric Toxicology Registry case reports as required under the privacy standard for the de-identification of health information pursuant to the regulations contained in part 164 of title 45, Code of Federal Regulations.

''(4) AUTHORIZATION.—There is authorized to be appropriated $5,000,000 for each of fiscal years 2013 through 2017 to carry out this subsection.

''(c) REPORT ON REGISTRY INFORMATION.—Not later than the January 1 of the first fiscal year beginning 2 years after the date of enactment of this section, and each January 1 thereafter, the Director of the Centers for Disease Control and Prevention shall submit to the Secretary a report, based on information contained in the Registry described in subsection (b), concerning the number of methadone-related deaths in the United States for the year for which the report is submitted.''.

SEC. 1149. ADDITIONAL REPORTING.

Part A of title V of the Public Health Service Act (42 U.S.C. 290aa et seq.), as amended by section 1148, is further amended by adding at the end the following:

''SEC. 506F. ADDITIONAL REPORTING.

''(a) REPORT ON METHADONE USAGE.—

''(1) IN GENERAL.—Not later than January 1 of the first fiscal year beginning 2 years after the date of enactment of this section, and each January 1 thereafter, the Administrator and the Commissioner of Food and Drugs shall submit to the Secretary a report containing detailed statistics on methadone usage for opioid treatment and pain management. Such statistics shall include—

''(A) information on the distribution of prescribed doses of methadone at federally qualified health centers, opioid treatment clinics, other health-related clinics, physician offices, pharmacies, and hospitals; and

''(B) information relating to adverse health events resulting from such methadone usage.

''(2) AVAILABILITY OF INFORMATION.—The Secretary shall make the reports submitted under paragraph (1) available to the general public, including through the use of the Internet website of the Department of Health and Human Services.

''(b) ANNUAL REPORT ON EFFECTIVENESS.—Not later than September 30, 2013, and annually thereafter until September 30, 2017, the Secretary shall submit to the appropriate committees of Congress, a report concerning the effectiveness of the methadone maintenance therapy program. Such report shall evaluate the success of efforts to reduce opioid addiction and methadone-related deaths, including the impact of health care provider and patient education.

''(c) AUTHORIZATION OF 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.''.

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 COMMISSIONED 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. 213a(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 261 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. 213a(b)) is amended by adding at the end the following: ''For purposes of paragraph (18) of subsection (a), the term 'Inspector General' in section 1034 of such title 10 shall mean the Inspector General of the Department of Health and Human Services.''.

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. 213a(a)) is amended by adding at the end the following:

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

(b) CONFORMING AMENDMENT.—Section 221(b) of the Public Health Service Act (42 U.S.C. 213a(b)) is amended by adding at the end the following: ''For purposes of paragraph (18) of subsection (a), the term 'Inspector General' in section 1034 of such title 10 shall mean the Inspector General of the Department of Health and Human Services.''.

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:

(b) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

TITLE I—FEES RELATING TO DRUGS

SEC. 101. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Prescription Drug User Fee Amendments of 2012''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 102. DEFINITIONS.

Paragraph (7) of section 735 (21 U.S.C. 379g) is amended, in the matter preceding subparagraph (A), by striking ''incurred''.

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

Section 736 (21 U.S.C. 379h) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking ''fiscal year 2008'' and inserting ''fiscal year 2013'';

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

(C) in the matter following clause (ii) in paragraph (2)(A)—

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

(ii) by striking ''payable on or before October 1 of each year'' and inserting ''due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section''; and

(D) in paragraph (3)—

(i) in subparagraph (A)—

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

(II) by striking ''payable on or before October 1 of each year.'' and inserting ''due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section.''; and

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

''(B) EXCEPTION.—A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is—

''(i) identified on the list compiled under section 505(j)(7) with a potency described in terms of per 100 mL;

''(ii) the same product as another product that—

''(I) was approved under an application filed under section 505(b) or 505(j); and

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

''(iii) the same product as another product that was approved under an abbreviated application filed under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997); or

''(iv) the same product as another product that was approved under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.'';

(2) in subsection (b)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking ''fiscal years 2008 through 2012'' and inserting ''fiscal years 2013 through 2017'';

(ii) in subparagraph (A), by striking ''$392,783,000; and'' and inserting ''$693,099,000;''; and

(iii) by striking subparagraph (B) and inserting the following:

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

''(C) the dollar amount equal to the workload adjustment for fiscal year 2013 (as determined under paragraph (3)(B)).''; and

(B) by striking paragraphs (3) and (4) and inserting the following:

''(3) FISCAL YEAR 2013 INFLATION AND WORKLOAD ADJUSTMENTS.—For purposes of paragraph (1), the dollar amount of the inflation and workload adjustments for fiscal year 2013 shall be determined as follows:

''(A) INFLATION ADJUSTMENT.—The inflation adjustment for fiscal year 2013 shall be the sum of—

''(i) $652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(B); and

''(ii) $652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(C).

''(B) WORKLOAD ADJUSTMENT.—Subject to subparagraph (C), the workload adjustment for fiscal 2013 shall be—

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

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

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

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

''(c) ADJUSTMENTS.—

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

''(A) one;

''(B) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years; and

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

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

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

''(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph), efficacy supplements, and manufacturing supplements submitted to the Secretary, and the change in the total number of active commercial investigational new drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available. The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

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

''(C) The Secretary shall contract with an independent accounting or consulting firm to periodically review the adequacy of the adjustment and publish the results of those reviews. The first review shall be conducted and published by the end of fiscal year 2013 (to examine the performance of the adjustment since fiscal year 2009), and the second review shall be conducted and published by the end of fiscal year 2015 (to examine the continued performance of the adjustment). The reports shall evaluate whether the adjustment reasonably represents actual changes in workload volume and complexity and present options to discontinue, retain, or modify any elements of the adjustment. The reports shall be published for public comment. After review of the reports and receipt of public comments, the Secretary shall, if warranted, adopt appropriate changes to the methodology. If the Secretary adopts changes to the methodology based on the first report, the changes shall be effective for the first fiscal year for which fees are set after the Secretary adopts such changes and each subsequent fiscal year.

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

''(4) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, application, product, and establishment fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

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

(4) in subsection (g)—

(A) in paragraph (1), by striking ''Fees authorized'' and inserting ''Subject to paragraph (2)(C), fees authorized'';

(B) in paragraph (2)—

(i) in subparagraph (A)—

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

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

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

''(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.'';

(C) in paragraph (3), by striking ''fiscal years 2008 through 2012'' and inserting ''fiscal years 2013 through 2017''; and

(D) in paragraph (4)—

(i) by striking ''fiscal years 2008 through 2010'' and inserting ''fiscal years 2013 through 2015'';

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

(iii) by striking ''fiscal years 2008 though 2011'' and inserting ''fiscal years 2013 through 2016''; and

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

SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 736B (21 U.S.C. 379h–2) is amended—

(1) by amending subsection (a) to read as follows:

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report under this subsection for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.'';

(2) in subsection (b), by striking ''2008'' and inserting ''2013''; and

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

SEC. 105. SUNSET DATES.

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

(b) REPORTING REQUIREMENTS.—Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) shall cease to be effective January 31, 2018.

(c) PREVIOUS SUNSET PROVISION.—Section 106 of the Prescription Drug User Fee Amendments of 2007 (Title I of Public Law 110–85) is repealed.

(d) TECHNICAL CLARIFICATIONS.—

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

(2) Effective September 30, 2002, section 107 of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115) is repealed.

(3) Effective September 30, 1997, section 105 of the Prescription Drug User Fee Act of 1992 (Public Law 102–571) is repealed.

SEC. 106. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later, except that fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all human drug applications received on or after October 1, 2012, regardless of the date of the enactment of this Act.

SEC. 107. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date

of the enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2007, but before October 1, 2012, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2012.

TITLE II—FEES RELATING TO DEVICES

SEC. 201. SHORT TITLE; FINDINGS.

(a) SHORT TITLE.—This title may be cited as the ''Medical Device User Fee Amendments of 2012''.

(b) FINDINGS.—The Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 202. DEFINITIONS.

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

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

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

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

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

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

(1) in paragraph (1), by striking ''fiscal year 2008'' and inserting ''fiscal year 2013'';

(2) in paragraph (2)(A)—

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

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

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

(iii) by striking ''subsection (c)(1)'' and inserting ''subsection (c)''; and

(B) in clause (viii), by striking ''1.84'' and inserting ''2''; and

(3) in paragraph (3)—

(A) in subparagraph (A)—

(i) by inserting ''and subsection (f)'' after ''subparagraph (B)''; and

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

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

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

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

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

''(b) FEE AMOUNTS.—

''(1) IN GENERAL.—Subject to subsections (c), (d), (e), (f), and (i), for each of fiscal years 2013 through 2017, fees under subsection (a) shall be derived from the base fee amounts specified in paragraph (2), to generate the total revenue amounts specified in paragraph (3).

''(2) BASE FEE AMOUNTS.—For purposes of paragraph (1), the base fee amounts specified in this paragraph are as follows:

''Fee Type	Fiscal Year 2013	Fiscal Year 2014	Fiscal Year 2015	Fiscal Year 2016	Fiscal Year 2017
Premarket Application	$248,000	$252,960	$258,019	$263,180	$268,443
Establishment Registration	$2,575	$3,200	$3,750	$3,872	$3,872

''(3) TOTAL REVENUE AMOUNTS.—For purposes of paragraph (1), the total revenue amounts specified in this paragraph are as follows:

''(A) $97,722,301 for fiscal year 2013.

''(B) $112,580,497 for fiscal year 2014.

''(C) $125,767,107 for fiscal year 2015.

''(D) $129,339,949 for fiscal year 2016.

''(E) $130,184,348 for fiscal year 2017.''.

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section 738(c) (21 U.S.C. 379j(c)) is amended—

(1) in the subsection heading, by inserting ''; ADJUSTMENTS'' after ''SETTING'';

(2) by striking paragraphs (1) and (2);

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

(4) by inserting before paragraph (4), as so redesignated, the following:

''(1) IN GENERAL.—The Secretary shall, 60 days before the start of each fiscal year after September 30, 2012, establish fees under subsection (a), based on amounts specified under subsection (b) and the adjustments provided under this subsection, and publish such fees, and the rationale for any adjustments to such fees, in the Federal Register.

''(2) INFLATION ADJUSTMENTS.—

''(A) ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—For fiscal year 2014 and each subsequent fiscal year, the Secretary shall adjust the total revenue amount specified in subsection (b)(3) for such fiscal year by multiplying such amount by the applicable inflation adjustment under subparagraph (B) for such year.

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

''(i) for fiscal year 2014, the base inflation adjustment under subparagraph (C) for such fiscal year; and

''(ii) for fiscal year 2015 and each subsequent fiscal year, the product of—

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

''(II) the product of the base inflation adjustment under subparagraph (C) for each of the fiscal years preceding such fiscal year, beginning with fiscal year 2014.

''(C) BASE INFLATION ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—

''(i) IN GENERAL.—Subject to further adjustment under clause (ii), the base inflation adjustment for a fiscal year is the sum of one plus—

''(I) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by 0.60; and

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

''(ii) LIMITATIONS.—For purposes of subparagraph (B), if the base inflation adjustment for a fiscal year under clause (i)—

''(I) is less than 1, such adjustment shall be considered to be equal to 1; or

''(II) is greater than 1.04, such adjustment shall be considered to be equal to 1.04.

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

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

(d) FEE WAIVER OR REDUCTION.—Section 738 (21 U.S.C. 379j) is amended by—

(1) redesignating subsections (f) through (k) as subsections (g) through (l), respectively; and

(2) by inserting after subsection (e) the following new subsection:

''(f) FEE WAIVER OR REDUCTION.—

''(1) IN GENERAL.—The Secretary may, at the Secretary's sole discretion, grant a waiver or reduction of fees under subsection (a)(2) or (a)(3) if the Secretary finds that such waiver or reduction is in the interest of public health.

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

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

(e) CONDITIONS.—Section 738(h)(1)(A) (21 U.S.C. 379j(h)(1)(A)), as redesignated by subsection (d)(1), is amended by striking ''$205,720,000'' and inserting ''$280,587,000''.

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

(1) in paragraph (1), by striking ''Fees authorized'' and inserting ''Subject to paragraph (2)(C), fees authorized'';

(2) in paragraph (2)—

(A) in subparagraph (A)—

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

(ii) in clause (ii)—

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

(II) by striking ''fiscal year 2002'' and inserting ''fiscal year 2009''; and

(B) by adding at the end, the following:

''(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.'';

(3) by amending paragraph (3) to read as follows:

''(3) AUTHORIZATIONS OF APPROPRIATIONS.—For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount specified under subsection (b)(3) for the fiscal year, as adjusted under subsection (c) and, for fiscal year 2017 only, as further adjusted under paragraph (4).''; and

(4) in paragraph (4)—

(A) by striking ''fiscal years 2008, 2009, and 2010'' and inserting ''fiscal years 2013, 2014, and 2015'';

(B) by striking ''fiscal year 2011'' and inserting ''fiscal year 2016'';

(C) by striking ''June 30, 2011'' and inserting ''June 30, 2016'';

(D) by striking ''the amount of fees specified in aggregate in'' and inserting ''the cumulative amount appropriated pursuant to'';

(E) by striking ''aggregate amount in'' before ''excess shall be credited''; and

(F) by striking ''fiscal year 2012'' and inserting ''fiscal year 2017''.

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

SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) REAUTHORIZATION.—Section 738A(b) (21 U.S.C. 379j–1(b)) is amended—

(1) in paragraph (1), by striking ''2012'' and inserting ''2017''; and

(2) in paragraph (5), by striking ''2012'' and inserting ''2017''.

(b) REPORTS.—Section 738A(a) (21 U.S.C. 379j–1(a)) is amended—

(1) by striking ''2008 through 2012'' each place it appears and inserting ''2013 through 2017''; and

(2) by striking ''section 201(c) of the Food and Drug Administration Amendments Act of 2007'' and inserting ''section 201(b) of the Medical Device User Fee Amendments of 2012''.

SEC. 205. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to submissions described in section 738(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (as in effect as of such day) that on or after October 1, 2007, but before October 1, 2012, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2013.

SEC. 206. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for submissions described in section 738(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act received on or after October 1, 2012, regardless of the date of the enactment of this Act.

SEC. 207. SUNSET DATES.

(a) AUTHORIZATIONS.—Sections 737 and 738 (21 U.S.C. 739i; 739j) shall cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.—Section 738A (21 U.S.C. 739j–1) shall cease to be effective January 31, 2018.

(c) PREVIOUS SUNSET PROVISION.—Section 217 of the Medical Device User Fee Amendments of 2007 (Title II of Public Law 110–85) is repealed.

(d) TECHNICAL CLARIFICATION.—Effective September 30, 2007, section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107– 250) is repealed.

SEC. 208. STREAMLINED HIRING AUTHORITY TO SUPPORT ACTIVITIES RELATED TO THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS.

Subchapter A of chapter VII (21 U.S.C. 371 et seq.) is amended by inserting after section 713 the following new section:

''SEC. 714. STREAMLINED HIRING AUTHORITY.

''(a) IN GENERAL.—In addition to any other personnel authorities under other provisions of law, the Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, appoint employees to positions in the Food and Drug Administration to perform, administer, or support activities described in subsection (b), if the Secretary determines that such appointments are needed to achieve the objectives specified in subsection (c).

''(b) ACTIVITIES DESCRIBED.—The activities described in this subsection are activities under this Act related to the process for the review of device applications (as defined in section 737(8)).

''(c) OBJECTIVES SPECIFIED.—The objectives specified in this subsection are with respect to the activities under subsection (b), the goals referred to in section 738A(a)(1).

''(d) INTERNAL CONTROLS.—The Secretary shall institute appropriate internal controls for appointments under this section.

''(e) SUNSET.—The authority to appoint employees under this section shall terminate on the date that is three years after the date of enactment of this section.''.

TITLE III—FEES RELATING TO GENERIC DRUGS

SEC. 301. SHORT TITLE.

(a) SHORT TITLE.—This title may be cited as the ''Generic Drug User Fee Amendments of 2012''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to human generic drug activities, as set forth in the goals identified for purposes of part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

''PART 7—FEES RELATING TO GENERIC DRUGS

''SEC. 744A. DEFINITIONS.

''For purposes of this part:

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

''(A) means an application submitted under section 505(j), an abbreviated application submitted under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997), or an abbreviated new drug application submitted pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984; and

''(B) does not include an application for a positron emission tomography drug.

''(2) The term 'active pharmaceutical ingredient' means—

''(A) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended—

''(i) to be used as a component of a drug; and

''(ii) to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or

''(B) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture described in subparagraph (A).

''(3) The term 'adjustment factor' means a factor applicable to a fiscal year that is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2011.

''(4) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control, both of the business entities.

''(5)(A) The term 'facility'—

''(i) means a business or other entity—

''(I) under one management, either direct or indirect; and

''(II) at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form; and

''(ii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: repackaging, relabeling, or testing.

''(B) For purposes of subparagraph (A), separate buildings within close proximity are considered to be at one geographic location or address if the activities in them are—

''(i) closely related to the same business enterprise;

''(ii) under the supervision of the same local management; and

''(iii) capable of being inspected by the Food and Drug Administration during a single inspection.

''(C) If a business or other entity would meet the definition of a facility under this paragraph but for being under multiple management, the business or other entity is deemed to constitute multiple facilities, one per management entity, for purposes of this paragraph.

''(6) The term 'finished dosage form' means—

''(A) a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;

''(B) a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or

''(C) any combination of an active pharmaceutical ingredient with another component of a drug product for purposes of production of a drug product described in subparagraph (A) or (B).

''(7) The term 'generic drug submission' means an abbreviated new drug application, an amendment to an abbreviated new drug application, or a prior approval supplement to an abbreviated new drug application.

''(8) The term 'human generic drug activities' means the following activities of the Secretary associated with generic drugs and

inspection of facilities associated with generic drugs:

''(A) The activities necessary for the review of generic drug submissions, including review of drug master files referenced in such submissions.

''(B) The issuance of—

''(i) approval letters which approve abbreviated new drug applications or supplements to such applications; or

''(ii) complete response letters which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

''(C) The issuance of letters related to Type II active pharmaceutical drug master files which—

''(i) set forth in detail the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies; or

''(ii) document that no deficiencies need to be addressed.

''(D) Inspections related to generic drugs.

''(E) Monitoring of research conducted in connection with the review of generic drug submissions and drug master files.

''(F) Postmarket safety activities with respect to drugs approved under abbreviated new drug applications or supplements, including the following activities:

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

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

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

''(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies) insofar as those activities relate to abbreviated new drug applications.

''(v) Carrying out section 505(k)(5) (relating to adverse-event reports and postmarket safety activities).

''(G) Regulatory science activities related to generic drugs.

''(9) The term 'positron emission tomography drug' has the meaning given to the term 'compounded positron emission tomography drug' in section 201(ii), except that paragraph (1)(B) of such section shall not apply.

''(10) The term 'prior approval supplement' means a request to the Secretary to approve a change in the drug substance, drug product, production process, quality controls, equipment, or facilities covered by an approved abbreviated new drug application when that change has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

''(11) The term 'resources allocated for human generic drug activities' means the expenses for—

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

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

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

''(D) collecting fees under subsection (a) and accounting for resources allocated for the review of abbreviated new drug applications and supplements and inspection related to generic drugs.

''(12) The term 'Type II active pharmaceutical ingredient drug master file' means a submission of information to the Secretary by a person that intends to authorize the Food and Drug Administration to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.

''SEC. 744B. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

''(a) TYPES OF FEES.—Beginning in fiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

''(1) ONE-TIME BACKLOG FEE FOR ABBREVIATED NEW DRUG APPLICATIONS PENDING ON OCTOBER 1, 2012.—

''(A) IN GENERAL.—Each person that owns an abbreviated new drug application that is pending on October 1, 2012, and that has not received a tentative approval prior to that date, shall be subject to a fee for each such application, as calculated under subparagraph (B).

''(B) METHOD OF FEE AMOUNT CALCULATION.—The amount of each one-time backlog fee shall be calculated by dividing $50,000,000 by the total number of abbreviated new drug applications pending on October 1, 2012, that have not received a tentative approval as of that date.

''(C) NOTICE.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the fee required by subparagraph (A).

''(D) FEE DUE DATE.—The fee required by subparagraph (A) shall be due no later than 30 calendar days after the date of the publication of the notice specified in subparagraph (C).

''(2) DRUG MASTER FILE FEE.—

''(A) IN GENERAL.—Each person that owns a Type II active pharmaceutical ingredient drug master file that is referenced on or after October 1, 2012, in a generic drug submission by any initial letter of authorization shall be subject to a drug master file fee.

''(B) ONE-TIME PAYMENT.—If a person has paid a drug master file fee for a Type II active pharmaceutical ingredient drug master file, the person shall not be required to pay a subsequent drug master file fee when that Type II active pharmaceutical ingredient drug master file is subsequently referenced in generic drug submissions.

''(C) NOTICE.—

''(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the drug master file fee for fiscal year 2013.

''(ii) FISCAL YEAR 2014 THROUGH 2017.—Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall publish in the Federal Register the amount of the drug master file fee established by this paragraph for such fiscal year.

''(D) AVAILABILITY FOR REFERENCE.—

''(i) IN GENERAL.—Subject to subsection (g)(2)(C), for a generic drug submission to reference a Type II active pharmaceutical ingredient drug master file, the drug master file must be deemed available for reference by the Secretary.

''(ii) CONDITIONS.—A drug master file shall be deemed available for reference by the Secretary if—

''(I) the person that owns a Type II active pharmaceutical ingredient drug master file has paid the fee required under subparagraph (A) within 20 calendar days after the applicable due date under subparagraph (E); and

''(II) the drug master file has not failed an initial completeness assessment by the Secretary, in accordance with criteria to be published by the Secretary.

''(iii) LIST.—The Secretary shall make publicly available on the Internet Web site of the Food and Drug Administration a list of the drug master file numbers that correspond to drug master files that have successfully undergone an initial completeness assessment, in accordance with criteria to be published by the Secretary, and are available for reference.

''(E) FEE DUE DATE.—

''(i) IN GENERAL.—Subject to clause (ii), a drug master file fee shall be due no later than the date on which the first generic drug submission is submitted that references the associated Type II active pharmaceutical ingredient drug master file.

''(ii) LIMITATION.—No fee shall be due under subparagraph (A) for a fiscal year until the later of—

''(I) 30 calendar days after publication of the notice provided for in clause (i) or (ii) of subparagraph (C), as applicable; or

''(II) 30 calendar days after the date of enactment of an appropriations Act providing for the collection and obligation of fees under this section.

''(3) ABBREVIATED NEW DRUG APPLICATION AND PRIOR APPROVAL SUPPLEMENT FILING FEE.—

''(A) IN GENERAL.—Each applicant that submits, on or after October 1, 2012, an abbreviated new drug application or a prior approval supplement to an abbreviated new drug application shall be subject to a fee for each such submission in the amount established under subsection (d).

''(B) NOTICE.—

''(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the fees under subparagraph (A) for fiscal year 2013.

''(ii) FISCAL YEARS 2014 THROUGH 2017.—Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

''(C) FEE DUE DATE.—

''(i) IN GENERAL.—Except as provided in clause (ii), the fees required by subparagraphs (A) and (F) shall be due no later than the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies.

''(ii) SPECIAL RULE FOR 2013.—For fiscal year 2013, such fees shall be due on the later of—

''(I) the date on which the fee is due under clause (i);

''(II) 30 calendar days after publication of the notice referred to in subparagraph (B)(i); or

''(III) if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of submission of the application or prior approval supplement for which the fees under subparagraphs (A) and (F) apply, 30 calendar days after the date that such an appropriations Act is enacted.

''(D) REFUND OF FEE IF ABBREVIATED NEW DRUG APPLICATION IS NOT CONSIDERED TO HAVE BEEN RECEIVED.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any abbreviated new drug application or prior approval supplement to an abbreviated new drug application that the Secretary considers not to have been received within the meaning of section 505(j)(5)(A) for a cause other than failure to pay fees.

''(E) FEE FOR AN APPLICATION THE SECRETARY CONSIDERS NOT TO HAVE BEEN RECEIVED, OR THAT HAS BEEN WITHDRAWN.—An abbreviated new drug application or prior approval supplement that was submitted on or after October 1, 2012, and that the Secretary considers not to have been received, or that has been withdrawn, shall, upon resubmission of the application or a subsequent new submission following the applicant's withdrawal of the application, be subject to a full fee under subparagraph (A).

''(F) ADDITIONAL FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—An applicant that submits a generic drug submission on or after October 1, 2012, shall pay a fee, in the amount determined under subsection (d)(3), in addition to the fee required under subparagraph (A), if—

''(i) such submission contains information concerning the manufacture of an active pharmaceutical ingredient at a facility by means other than reference by a letter of authorization to a Type II active pharmaceutical drug master file; and

''(ii) a fee in the amount equal to the drug master file fee established in paragraph (2) has not been previously paid with respect to such information.

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

''(A) IN GENERAL.—Facilities identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce a finished dosage form of a human generic drug or an active pharmaceutical ingredient contained in a human generic drug shall be subject to fees as follows:

''(i) GENERIC DRUG FACILITY.—Each person that owns a facility which is identified or intended to be identified in at least one generic drug submission that is pending or approved to produce one or more finished dosage forms of a human generic drug shall be assessed an annual fee for each such facility.

''(ii) ACTIVE PHARMACEUTICAL INGREDIENT FACILITY.—Each person that owns a facility which produces, or which is pending review to produce, one or more active pharmaceutical ingredients identified, or intended to be identified, in at least one generic drug submission that is pending or approved or in a Type II active pharmaceutical ingredient drug master file referenced in such a generic drug submission, shall be assessed an annual fee for each such facility.

''(iii) FACILITIES PRODUCING BOTH ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED DOSAGE FORMS.—Each person that owns a facility identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce both one or more finished dosage forms subject to clause (i) and one or more active pharmaceutical ingredients subject to clause (ii) shall be subject to fees under both such clauses for that facility.

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

''(C) NOTICE.—

''(i) FISCAL YEAR 2013.—For fiscal year 2013, the Secretary shall publish in the Federal Register a notice announcing the amount of the fees provided for in subparagraph (A) within the timeframe specified in subsection (d)(1)(B).

''(ii) FISCAL YEARS 2014 THROUGH 2017.—Within the timeframe specified in subsection (d)(2), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

''(D) FEE DUE DATE.—

''(i) FISCAL YEAR 2013.—For fiscal year 2013, the fees under subparagraph (A) shall be due on the later of—

''(I) not later than 45 days after the publication of the notice under subparagraph (B); or

''(II) if an appropriations Act is not enacted providing for the collection and obligation of fees under this section by the date of the publication of such notice, 30 days after the date that such an appropriations Act is enacted.

''(ii) FISCAL YEARS 2014 THROUGH 2017.—For each of fiscal years 2014 through 2017, the fees under subparagraph (A) for such fiscal year shall be due on the later of—

''(I) the first business day on or after October 1 of each such year; or

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

''(5) DATE OF SUBMISSION.—For purposes of this Act, a generic drug submission or Type II pharmaceutical master file is deemed to be 'submitted' to the Food and Drug Administration—

''(A) if it is submitted via a Food and Drug Administration electronic gateway, on the day when transmission to that electronic gateway is completed, except that a submission or master file that arrives on a weekend, Federal holiday, or day when the Food and Drug Administration office that will review that submission is not otherwise open for business shall be deemed to be submitted on the next day when that office is open for business; or

''(B) if it is submitted in physical media form, on the day it arrives at the appropriate designated document room of the Food and Drug Administration.

''(b) FEE REVENUE AMOUNTS.—

''(1) IN GENERAL.—

''(A) FISCAL YEAR 2013.—For fiscal year 2013, fees under subsection (a) shall be established to generate a total estimated revenue amount under such subsection of $299,000,000. Of that amount—

''(i) $50,000,000 shall be generated by the one-time backlog fee for generic drug applications pending on October 1, 2012, established in subsection (a)(1); and

''(ii) $249,000,000 shall be generated by the fees under paragraphs (2) through (4) of subsection (a).

''(B) FISCAL YEARS 2014 THROUGH 2017.—For each of the fiscal years 2014 through 2017, fees under paragraphs (2) through (4) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to $299,000,000, as adjusted pursuant to subsection (c).

''(2) TYPES OF FEES.—In establishing fees under paragraph (1) to generate the revenue amounts specified in paragraph (1)(A)(ii) for fiscal year 2013 and paragraph (1)(B) for each of fiscal years 2014 through 2017, such fees shall be derived from the fees under paragraphs (2) through (4) of subsection (a) as follows:

''(A) 6 percent shall be derived from fees under subsection (a)(2) (relating to drug master files).

''(B) 24 percent shall be derived from fees under subsection (a)(3) (relating to abbreviated new drug applications and supplements). The amount of a fee for a prior approval supplement shall be half the amount of the fee for an abbreviated new drug application.

''(C) 56 percent shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than $15,000 and not more than $30,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States, including its territories and possessions, and those located outside of the United States and its territories and possessions.

''(D) 14 percent shall be derived from fees under subsection (a)(4)(A)(ii) (relating to active pharmaceutical ingredient facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than $15,000 and not more than $30,000 higher than the amount of the fee for a facility located in the United States, including its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States and its territories and possessions and those located outside of the United States and its territories and possessions.

''(c) ADJUSTMENTS.—

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

''(A) one;

''(B) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years multiplied by the proportion of personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years; and

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

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

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

''(d) ANNUAL FEE SETTING.—

''(1) FISCAL YEAR 2013.—For fiscal year 2013—

''(A) the Secretary shall establish, by October 31, 2012, the one-time generic drug backlog fee for generic drug applications pending on October 1, 2012, the drug master file fee, the abbreviated new drug application fee, and the prior approval supplement fee under subsection (a), based on the revenue amounts established under subsection (b); and

''(B) the Secretary shall establish, not later than 45 days after the date to comply

with the requirement for identification of facilities in subsection (f)(2), the generic drug facility fee and active pharmaceutical ingredient facility fee under subsection (a) based on the revenue amounts established under subsection (b).

''(2) FISCAL YEARS 2014 THROUGH 2017.—Not more than 60 days before the first day of each of fiscal years 2014 through 2017, the Secretary shall establish the drug master file fee, the abbreviated new drug application fee, the prior approval supplement fee, the generic drug facility fee, and the active pharmaceutical ingredient facility fee under subsection (a) for such fiscal year, based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).

''(3) FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—In establishing the fees under paragraphs (1) and (2), the amount of the fee under subsection (a)(3)(F) shall be determined by multiplying—

''(A) the sum of—

''(i) the total number of such active pharmaceutical ingredients in such submission; and

''(ii) for each such ingredient that is manufactured at more than one such facility, the total number of such additional facilities; and

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

''(e) LIMIT.—The total amount of fees charged, as adjusted under subsection (c), for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for human generic drug activities.

''(f) IDENTIFICATION OF FACILITIES.—

''(1) PUBLICATION OF NOTICE; DEADLINE FOR COMPLIANCE.—Not later than October 1, 2012, the Secretary shall publish in the Federal Register a notice requiring each person that owns a facility described in subsection (a)(4)(A), or a site or organization required to be identified by paragraph (4), to submit to the Secretary information on the identity of each such facility, site, or organization. The notice required by this paragraph shall specify the type of information to be submitted and the means and format for submission of such information.

''(2) REQUIRED SUBMISSION OF FACILITY IDENTIFICATION.—Each person that owns a facility described in subsection (a)(4)(A) or a site or organization required to be identified by paragraph (4) shall submit to the Secretary the information required under this subsection each year. Such information shall—

''(A) for fiscal year 2013, be submitted not later than 60 days after the publication of the notice under paragraph (1); and

''(B) for each subsequent fiscal year, be submitted, updated, or reconfirmed on or before June 1 of the previous year.

''(3) CONTENTS OF NOTICE.—At a minimum, the submission required by paragraph (2) shall include for each such facility—

''(A) identification of a facility identified or intended to be identified in an approved or pending generic drug submission;

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

''(C) whether or not the facility is located within the United States and its territories and possessions;

''(D) whether the facility manufactures positron emission tomography drugs solely, or in addition to other drugs; and

''(E) whether the facility manufactures drugs that are not generic drugs.

''(4) CERTAIN SITES AND ORGANIZATIONS.—

''(A) IN GENERAL.—Any person that owns or operates a site or organization described in subparagraph (B) shall submit to the Secretary information concerning the ownership, name, and address of the site or organization.

''(B) SITES AND ORGANIZATIONS.—A site or organization is described in this subparagraph if it is identified in a generic drug submission and is—

''(i) a site in which a bioanalytical study is conducted;

''(ii) a clinical research organization;

''(iii) a contract analytical testing site; or

''(iv) a contract repackager site.

''(C) NOTICE.—The Secretary may, by notice published in the Federal Register, specify the means and format for submission of the information under subparagraph (A) and may specify, as necessary for purposes of this section, any additional information to be submitted.

''(D) INSPECTION AUTHORITY.—The Secretary's inspection authority under section 704(a)(1) shall extend to all such sites and organizations.

''(g) EFFECT OF FAILURE TO PAY FEES.—

''(1) GENERIC DRUG BACKLOG FEE.—Failure to pay the fee under subsection (a)(1) shall result in the Secretary placing the person that owns the abbreviated new drug application subject to that fee on an arrears list, such that no new abbreviated new drug applications or supplement submitted on or after October 1, 2012, from that person, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

''(2) DRUG MASTER FILE FEE.—

''(A) Failure to pay the fee under subsection (a)(2) within 20 calendar days after the applicable due date under subparagraph (E) of such subsection (as described in subsection (a)(2)(D)(ii)(I)) shall result in the Type II active pharmaceutical ingredient drug master file not being deemed available for reference.

''(B)(i) Any generic drug submission submitted on or after October 1, 2012, that references, by a letter of authorization, a Type II active pharmaceutical ingredient drug master file that has not been deemed available for reference shall not be received within the meaning of section 505(j)(5)(A) unless the condition specified in clause (ii) is met.

''(ii) The condition specified in this clause is that the fee established under subsection (a)(2) has been paid within 20 calendar days of the Secretary providing the notification to the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the drug master file fee as specified in subparagraph (C).

''(C)(i) If an abbreviated new drug application or supplement to an abbreviated new drug application references a Type II active pharmaceutical ingredient drug master file for which a fee under subsection (a)(2)(A) has not been paid by the applicable date under subsection (a)(2)(E), the Secretary shall notify the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the applicable fee.

''(ii) If such fee is not paid within 20 calendar days of the Secretary providing the notification, the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of 505(j)(5)(A).

''(3) ABBREVIATED NEW DRUG APPLICATION FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—Failure to pay a fee under subparagraph (A) or (F) of subsection (a)(3) within 20 calendar days of the applicable due date under subparagraph (C) of such subsection shall result in the abbreviated new drug application or the prior approval supplement to an abbreviated new drug application not being received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

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

''(A) IN GENERAL.—Failure to pay the fee under subsection (a)(4) within 20 calendar days of the due date as specified in subparagraph (D) of such subsection shall result in the following:

''(i) The Secretary shall place the facility on a publicly available arrears list, such that no new abbreviated new drug application or supplement submitted on or after October 1, 2012, from the person that is responsible for paying such fee, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A).

''(ii) Any new generic drug submission submitted on or after October 1, 2012, that references such a facility shall not be received, within the meaning of section 505(j)(5)(A) if the outstanding facility fee is not paid within 20 calendar days of the Secretary providing the notification to the sponsor of the failure of the owner of the facility to pay the facility fee under subsection (a)(4)(C).

''(iii) All drugs or active pharmaceutical ingredients manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 502(aa).

''(B) APPLICATION OF PENALTIES.—The penalties under this paragraph shall apply until the fee established by subsection (a)(4) is paid or the facility is removed from all generic drug submissions that refer to the facility.

''(C) NONRECEIVAL FOR NONPAYMENT.—

''(i) NOTICE.—If an abbreviated new drug application or supplement to an abbreviated new drug application submitted on or after October 1, 2012, references a facility for which a facility fee has not been paid by the applicable date under subsection (a)(4)(C), the Secretary shall notify the sponsor of the generic drug submission of the failure of the owner of the facility to pay the facility fee.

''(ii) NONRECEIVAL.—If the facility fee is not paid within 20 calendar days of the Secretary providing the notification under clause (i), the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of section 505(j)(5)(A).

''(h) LIMITATIONS.—

''(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2012, unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor (as defined in section 744A) applicable to the fiscal year involved.

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for Type II active pharmaceutical ingredient drug master files, abbreviated new drug applications and prior approval supplements, and generic drug facilities and active pharmaceutical ingredient facilities at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

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

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, subject to paragraph (2). Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for human generic drug activities.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—The fees authorized by this section—

''(i) subject to subparagraphs (C) and (D), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

''(ii) shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of human generic drug activities (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activities), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $97,000,000 multiplied by the adjustment factor, as defined in section 744A(3), applicable to the fiscal year involved.

''(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for human generic activities are not more than 10 percent below the level specified in such subparagraph.

''(C) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2013 for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013, may be collected and shall be credited to such account and remain available until expended.

''(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2013), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted under subsection (c), if applicable, or as otherwise affected under paragraph (2) of this subsection.

''(j) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(k) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in human generic drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

''(1) EXEMPTION FROM FEES.—Submission of an application for a positron emission tomography drug or active pharmaceutical ingredient for a positron emission tomography drug shall not require the payment of any fee under this section. Facilities that solely produce positron emission tomography drugs shall not be required to pay a facility fee as established in subsection (a)(4).

''(2) IDENTIFICATION REQUIREMENT.—Facilities that produce positron emission tomography drugs or active pharmaceutical ingredients of such drugs are required to be identified pursuant to subsection (f).

''(m) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under this section, a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

''(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—An abbreviated new drug application that is not considered to be received within the meaning of section 505(j)(5)(A) because of failure to pay an applicable fee under this provision within the time period specified in subsection (g) shall be deemed not to have been 'substantially complete' on the date of its submission within the meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbreviated new drug application that is not substantially complete on the date of its submission solely because of failure to pay an applicable fee under the preceding sentence shall be deemed substantially complete and received within the meaning of section 505(j)(5)(A) as of the date such applicable fee is received.''.

SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 7 of subchapter C of chapter VII, as added by section 302 of this Act, is amended by inserting after section 744B the following:

''SEC. 744C. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

''(b) FISCAL REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

''(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

''(d) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for human generic drug activities for the first 5 fiscal years after fiscal year 2017, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

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

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

''(C) scientific and academic experts;

''(D) health care professionals;

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

''(F) the generic drug industry.

''(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the generic drug industry on the reauthorization of this part, the Secretary shall—

''(A) publish a notice in the Federal Register requesting public input on the reauthorization;

''(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

''(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

''(D) publish the comments on the Food and Drug Administration's Internet Web site.

''(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the generic drug industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

''(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the generic drug industry, the Secretary shall—

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

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

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

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

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

''(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

''(6) MINUTES OF NEGOTIATION MEETINGS.—

''(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the generic drug industry.

''(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.''.

SEC. 304. SUNSET DATES.

(a) AUTHORIZATION.—The amendments made by section 302 cease to be effective October 1, 2017.

(b) REPORTING REQUIREMENTS.—The amendments made by section 303 cease to be effective January 31, 2018.

SEC. 305. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2012, or the date of the enactment of this title, whichever is later, except that fees under section 302 shall be assessed for all human generic drug submissions and Type II active pharmaceutical drug master files received on or after October 1, 2012, regardless of the date of enactment of this title.

SEC. 306. AMENDMENT WITH RESPECT TO MISBRANDING.

Section 502 (21 U.S.C. 352) is amended by adding at the end the following:

''(aa) If it is a drug, or an active pharmaceutical ingredient, and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744A(a)(4) or for which identifying information required by section 744B(f) has not been submitted, or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility.''.

SEC. 307. STREAMLINED HIRING AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION TO SUPPORT ACTIVITIES RELATED TO HUMAN GENERIC DRUGS.

Section 714 of the Federal Food, Drug, and Cosmetic Act, as added by section 208, is amended—

(1) in subsection (b)—

(A) by striking ''are activities'' and inserting ''are—

''(1) activities'';

(B) by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(2) activities under this Act related to human generic drug activities (as defined in section 744A).''; and

(2) by amending subsection (c) to read as follows:

''(c) OBJECTIVES SPECIFIED.—The objectives specified in this subsection are—

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

''(2) with respect to the activities under subsection (b)(2), the performance goals with respect to section 744A (regarding assessment and use of human generic drug fees), as set forth in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2012.''.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 401. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Biosimilar User Fee Act of 2012''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 402. FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS.

Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by inserting after part 7, as added by title III of this Act, the following:

''PART 8—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

''SEC. 744G. DEFINITIONS.

''For purposes of this part:

''(1) The term 'adjustment factor' applicable to a fiscal year that is the Consumer Price Index for all urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items) of the preceding fiscal year divided by such Index for September 2011.

''(2) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control, both of the business entities.

''(3) The term 'biosimilar biological product' means a product for which a biosimilar biological product application has been approved.

''(4)(A) Subject to subparagraph (B), the term 'biosimilar biological product application' means an application for licensure of a biological product under section 351(k) of the Public Health Service Act.

''(B) Such term does not include—

''(i) a supplement to such an application;

''(ii) an application filed under section 351(k) of the Public Health Service Act that cites as the reference product a bovine blood product for topical application licensed before September 1, 1992, or a large volume parenteral drug product approved before such date;

''(iii) an application filed under section 351(k) of the Public Health Service Act with respect to—

''(I) whole blood or a blood component for transfusion;

''(II) an allergenic extract product;

''(III) an in vitro diagnostic biological product; or

''(IV) a biological product for further manufacturing use only; or

''(iv) an application for licensure under section 351(k) of the Public Health Service Act that is submitted by a State or Federal Government entity for a product that is not distributed commercially.

''(5) The term 'biosimilar biological product development meeting' means any meeting, other than a biosimilar initial advisory meeting, regarding the content of a development program, including a proposed design for, or data from, a study intended to support a biosimilar biological product application.

''(6) The term 'biosimilar biological product development program' means the program under this part for expediting the process for the review of submissions in connection with biosimilar biological product development.

''(7)(A) The term 'biosimilar biological product establishment' means a foreign or domestic place of business—

''(i) that is at one general physical location consisting of one or more buildings, all of which are within five miles of each other; and

''(ii) at which one or more biosimilar biological products are manufactured in final dosage form.

''(B) For purposes of subparagraph (A)(ii), the term 'manufactured' does not include packaging.

''(8) The term 'biosimilar initial advisory meeting'—

''(A) means a meeting, if requested, that is limited to—

''(i) a general discussion regarding whether licensure under section 351(k) of the Public Health Service Act may be feasible for a particular product; and

''(ii) if so, general advice on the expected content of the development program; and

''(B) does not include any meeting that involves substantive review of summary data or full study reports.

''(9) The term 'costs of resources allocated for the process for the review of biosimilar biological product applications' means the expenses in connection with the process for the review of biosimilar biological product applications for—

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

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

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

''(D) collecting fees under section 744H and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

''(10) The term 'final dosage form' means, with respect to a biosimilar biological product, a finished dosage form which is approved for administration to a patient without substantial further manufacturing (such as lyophilized products before reconstitution).

''(11) The term 'financial hold'—

''(A) means an order issued by the Secretary to prohibit the sponsor of a clinical investigation from continuing the investigation if the Secretary determines that the investigation is intended to support a biosimilar biological product application and the sponsor has failed to pay any fee for the product required under subparagraph (A), (B), or (D) of section 744H(a)(1); and

''(B) does not mean that any of the bases for a 'clinical hold' under section 505(i)(3) have been determined by the Secretary to exist concerning the investigation.

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

''(13) The term 'process for the review of biosimilar biological product applications' means the following activities of the Secretary with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements:

''(A) The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

''(B) Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or which set forth in detail the specific deficiencies in such applications, and where appropriate, the actions necessary to place such applications in condition for approval.

''(C) The inspection of biosimilar biological product establishments and other facilities undertaken as part of the Secretary's review of pending biosimilar biological product applications and supplements.

''(D) Activities necessary for the release of lots of biosimilar biological products under section 351(k) of the Public Health Service Act.

''(E) Monitoring of research conducted in connection with the review of biosimilar biological product applications.

''(F) Postmarket safety activities with respect to biologics approved under biosimilar

biological product applications or supplements, including the following activities:

''(i) Collecting, developing, and reviewing safety information on biosimilar biological products, including adverse-event reports.

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

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

''(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies).

''(v) Carrying out section 505(k)(5) (relating to adverse-event reports and postmarket safety activities).

''(14) The term 'supplement' means a request to the Secretary to approve a change in a biosimilar biological product application which has been approved, including a supplement requesting that the Secretary determine that the biosimilar biological product meets the standards for interchangeability described in section 351(k)(4) of the Public Health Service Act.

''SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES.

''(a) TYPES OF FEES.—Beginning in fiscal year 2013, the Secretary shall assess and collect fees in accordance with this section as follows:

''(1) BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

''(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

''(i) IN GENERAL.—Each person that submits to the Secretary a meeting request described under clause (ii) or a clinical protocol for an investigational new drug protocol described under clause (iii) shall pay for the product named in the meeting request or the investigational new drug application the initial biosimilar biological product development fee established under subsection (b)(1)(A).

''(ii) MEETING REQUEST.—The meeting request described in this clause is a request for a biosimilar biological product development meeting for a product.

''(iii) CLINICAL PROTOCOL FOR IND.—A clinical protocol for an investigational new drug protocol described in this clause is a clinical protocol consistent with the provisions of section 505(i), including any regulations promulgated under section 505(i), (referred to in this section as 'investigational new drug application') describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for a product.

''(iv) DUE DATE.—The initial biosimilar biological product development fee shall be due by the earlier of the following:

''(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

''(II) The date of submission of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application.

''(v) TRANSITION RULE.—Each person that has submitted an investigational new drug application prior to the date of enactment of the Biosimilars User Fee Act of 2012 shall pay the initial biosimilar biological product development fee by the earlier of the following:

''(I) Not later than 60 days after the date of the enactment of the Biosimilars User Fee Act of 2012, if the Secretary determines that the investigational new drug application describes an investigation that is intended to support a biosimilar biological product application.

''(II) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

''(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

''(i) IN GENERAL.—A person that pays an initial biosimilar biological product development fee for a product shall pay for such product, beginning in the fiscal year following the fiscal year in which the initial biosimilar biological product development fee was paid, an annual fee established under subsection (b)(1)(B) for biosimilar biological product development (referred to in this section as 'annual biosimilar biological product development fee').

''(ii) DUE DATE.—The annual biosimilar biological product development program fee for each fiscal year will be due on the later of—

''(I) the first business day on or after October 1 of each such year; or

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

''(iii) EXCEPTION.—The annual biosimilar development program fee for each fiscal year will be due on the date specified in clause (ii), unless the person has—

''(I) submitted a marketing application for the biological product that was accepted for filing; or

''(II) discontinued participation in the biosimilar biological product development program for the product under subparagraph (C).

''(C) DISCONTINUATION OF FEE OBLIGATION.—A person may discontinue participation in the biosimilar biological product development program for a product effective October 1 of a fiscal year by, not later than August 1 of the preceding fiscal year—

''(i) if no investigational new drug application concerning the product has been submitted, submitting to the Secretary a written declaration that the person has no present intention of further developing the product as a biosimilar biological product; or

''(ii) if an investigational new drug application concerning the product has been submitted, by withdrawing the investigational new drug application in accordance with part 312 of title 21, Code of Federal Regulations (or any successor regulations).

''(D) REACTIVATION FEE.—

''(i) IN GENERAL.—A person that has discontinued participation in the biosimilar biological product development program for a product under subparagraph (C) shall pay a fee (referred to in this section as 'reactivation fee') by the earlier of the following:

''(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued).

''(II) Upon the date of submission (after the date on which such participation was discontinued) of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for that product.

''(ii) APPLICATION OF ANNUAL FEE.—A person that pays a reactivation fee for a product shall pay for such product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B).

''(E) EFFECT OF FAILURE TO PAY BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

''(i) NO BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT MEETINGS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting relating to the product for which fees are owed.

''(ii) NO RECEIPT OF INVESTIGATIONAL NEW DRUG APPLICATIONS.—Except in extraordinary circumstances, the Secretary shall not consider an investigational new drug application to have been received under section 505(i)(2) if—

''(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

''(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

''(iii) FINANCIAL HOLD.—Notwithstanding section 505(i)(2), except in extraordinary circumstances, the Secretary shall prohibit the sponsor of a clinical investigation from continuing the investigation if—

''(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

''(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee for the product as required under subparagraph (D).

''(iv) NO ACCEPTANCE OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS OR SUPPLEMENTS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), any biosimilar biological product application or supplement submitted by that person shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.

''(F) LIMITS REGARDING BIOSIMILAR DEVELOPMENT PROGRAM FEES.—

''(i) NO REFUNDS.—The Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or any reactivation fee paid under subparagraph (D).

''(ii) NO WAIVERS, EXEMPTIONS, OR REDUCTIONS.—The Secretary shall not grant a waiver, exemption, or reduction of any initial or annual biosimilar biological product development fee due or payable under subparagraph (A) or (B), or any reactivation fee due or payable under subparagraph (D).

''(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION AND SUPPLEMENT FEE.—

''(A) IN GENERAL.—Each person that submits, on or after October 1, 2012, a biosimilar biological product application or a supplement shall be subject to the following fees:

''(i) A fee for a biosimilar biological product application that is equal to—

''(I) the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application; minus

''(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for the product that is the subject of the application.

''(ii) A fee for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required, that is equal to—

''(I) half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application; minus

''(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

''(iii) A fee for a supplement for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required, that is equal to half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application.

''(B) REDUCTION IN FEES.—Notwithstanding section 404 of the Biosimilars User Fee Act of 2012, any person who pays a fee under subparagraph (A), (B), or (D) of paragraph (1) for a product before October 1, 2017, but submits a biosimilar biological product application for that product after such date, shall be entitled to the reduction of any biosimilar biological product application fees that may be assessed at the time when such biosimilar biological product application is submitted, by the cumulative amount of fees paid under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

''(C) PAYMENT DUE DATE.—Any fee required by subparagraph (A) shall be due upon submission of the application or supplement for which such fee applies.

''(D) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If a biosimilar biological product application or supplement was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a biosimilar biological product application or a supplement for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

''(E) REFUND OF APPLICATION FEE IF APPLICATION REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under this paragraph for any application or supplement which is refused for filing or withdrawn without a waiver before filing.

''(F) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A biosimilar biological product application or supplement that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived under subsection (c).

''(3) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (E), each person that is named as the applicant in a biosimilar biological product application shall be assessed an annual fee established under subsection (b)(1)(E) for each biosimilar biological product establishment that is listed in the approved biosimilar biological product application as an establishment that manufactures the biosimilar biological product named in such application.

''(B) ASSESSMENT IN FISCAL YEARS.—The establishment fee shall be assessed in each fiscal year for which the biosimilar biological product named in the application is assessed a fee under paragraph (4) unless the biosimilar biological product establishment listed in the application does not engage in the manufacture of the biosimilar biological product during such fiscal year.

''(C) DUE DATE.—The establishment fee for a fiscal year shall be due on the later of—

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

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

''(D) APPLICATION TO ESTABLISHMENT.—

''(i) Each biosimilar biological product establishment shall be assessed only one fee per biosimilar biological product establishment, notwithstanding the number of biosimilar biological products manufactured at the establishment, subject to clause (ii).

''(ii) In the event an establishment is listed in a biosimilar biological product application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose biosimilar biological products are manufactured by the establishment during the fiscal year and assessed biosimilar biological product fees under paragraph (4).

''(E) EXCEPTION FOR NEW PRODUCTS.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a biosimilar biological product at an establishment listed in its biosimilar biological product application—

''(i) that did not manufacture the biosimilar biological product in the previous fiscal year; and

''(ii) for which the full biosimilar biological product establishment fee has been assessed in the fiscal year at a time before manufacture of the biosimilar biological product was begun,

the applicant shall not be assessed a share of the biosimilar biological product establishment fee for the fiscal year in which the manufacture of the product began.

''(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

''(A) IN GENERAL.—Each person who is named as the applicant in a biosimilar biological product application shall pay for each such biosimilar biological product the annual fee established under subsection (b)(1)(F).

''(B) DUE DATE.—The biosimilar biological product fee for a fiscal year shall be due on the later of—

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

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

''(C) ONE FEE PER PRODUCT PER YEAR.—The biosimilar biological product fee shall be paid only once for each product for each fiscal year.

''(b) FEE SETTING AND AMOUNTS.—

''(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, the fees under subsection (a). Except as provided in subsection (c), such fees shall be in the following amounts:

''(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The initial biosimilar biological product development fee under subsection (a)(1)(A) for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

''(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The annual biosimilar biological product development fee under subsection (a)(1)(B) for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

''(C) REACTIVATION FEE.—The reactivation fee under subsection (a)(1)(D) for a fiscal year shall be equal to 20 percent of the amount of the fee established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

''(D) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—The biosimilar biological product application fee under subsection (a)(2) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

''(E) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—The biosimilar biological product establishment fee under subsection (a)(3) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug establishment for that fiscal year.

''(F) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—The biosimilar biological product fee under subsection (a)(4) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug product for that fiscal year.

''(2) LIMIT.—The total amount of fees charged for a fiscal year under this section may not exceed the total amount for such fiscal year of the costs of resources allocated for the process for the review of biosimilar biological product applications.

''(c) APPLICATION FEE WAIVER FOR SMALL BUSINESS.—

''(1) WAIVER OF APPLICATION FEE.—The Secretary shall grant to a person who is named in a biosimilar biological product application a waiver from the application fee assessed to that person under subsection (a)(2)(A) for the first biosimilar biological product application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

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

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

''(2) CONSIDERATIONS.—In determining whether to grant a waiver of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

''(3) SMALL BUSINESS DEFINED.—In this subsection, the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates, and does not have a drug product that has been approved under a human drug application (as defined in section 735) or a biosimilar biological product application (as defined in section 744G(4)) and introduced or delivered for introduction into interstate commerce.

''(d) EFFECT OF FAILURE TO PAY FEES.—A biosimilar biological product application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

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

''(1) IN GENERAL.—Subject to paragraph (2), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of biosimilar biological product applications.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available

in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year.

''(B) USE OF FEES AND LIMITATION.—The fees authorized by this section shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of the process for the review of biosimilar biological product applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $20,000,000, multiplied by the adjustment factor applicable to the fiscal year involved.

''(C) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2013, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013 may be collected and shall be credited to such account and remain available until expended.

''(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2013), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2013 through 2017, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.

''(f) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(g) WRITTEN REQUESTS FOR WAIVERS AND REFUNDS.—To qualify for consideration for a waiver under subsection (c), or for a refund of any fee collected in accordance with subsection (a)(2)(A), a person shall submit to the Secretary a written request for such waiver or refund not later than 180 days after such fee is due.

''(h) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of biosimilar biological product applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.''.

SEC. 403. REAUTHORIZATION; REPORTING REQUIREMENTS.

Part 8 of subchapter C of chapter VII, as added by section 402, is further amended by inserting after section 744H the following:

''SEC. 744I. REAUTHORIZATION; REPORTING REQUIREMENTS.

''(a) PERFORMANCE REPORT.—Beginning with fiscal year 2013, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 401(b) of the Biosimilar User Fee Act of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting such goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all biosimilar biological product applications and supplements in the cohort.

''(b) FISCAL REPORT.—Not later than 120 days after the end of fiscal year 2013 and each subsequent fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

''(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

''(d) STUDY.—

''(1) IN GENERAL.—The Secretary shall contract with an independent accounting or consulting firm to study the workload volume and full costs associated with the process for the review of biosimilar biological product applications.

''(2) INTERIM RESULTS.—Not later than June 1, 2015, the Secretary shall publish, for public comment, interim results of the study described under paragraph (1).

''(3) FINAL RESULTS.—Not later than September 30, 2016, the Secretary shall publish, for public comment, the final results of the study described under paragraph (1).

''(e) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for the process for the review of biosimilar biological product applications for the first 5 fiscal years after fiscal year 2017, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

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

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

''(C) scientific and academic experts;

''(D) health care professionals;

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

''(F) the regulated industry.

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

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

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

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

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

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

''(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2017, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.''.

SEC. 404. SUNSET DATES.

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

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

SEC. 405. EFFECTIVE DATE.

(a) IN GENERAL.—Except as provided under subsection (b), the amendments made by this title shall take effect on the later of—

(1) October 1, 2012; or

(2) the date of the enactment of this title.

(b) EXCEPTION.—Fees under part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as added by this title, shall be assessed for all biosimilar biological product applications received on or after October 1, 2012, regardless of the date of the enactment of this title.

SEC. 406. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that were accepted by the Food and Drug Administration for filing on or after October 1, 2007, but before October 1, 2012, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2013.

SEC. 407. CONFORMING AMENDMENT.

Section 735(1)(B) (21 U.S.C. 379g(1)(B)) is amended by striking ''or (k)''.

TITLE V—PEDIATRIC DRUGS AND DEVICES

SEC. 501. PERMANENCE.

(a) PEDIATRIC STUDIES OF DRUGS.—Subsection (q) of section 505A (21 U.S.C. 355a) is amended—

(1) in the subsection heading, by striking ''SUNSET'' and inserting ''PERMANENCE'';

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

(3) in paragraph (2), by striking ''on or before October 1, 2012,''.

(b) RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.—Section 505B (21 U.S.C. 355c) is amended—

(1) by striking subsection (m); and

(2) by redesignating subsection (n) as subsection (m).

SEC. 502. WRITTEN REQUESTS.

(a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Subsection (h) of section 505A (21 U.S.C. 355a) is amended to read as follows:

''(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Exclusivity under this section shall only be granted for the completion of a study or studies that are the subject of a written request and for which reports are submitted and accepted in accordance with subsection (d)(3). Written requests under this section may consist of a study or studies required under section 505B.''.

(b) PUBLIC HEALTH SERVICE ACT.—Section 351(m)(1) of the Public Health Service Act (42 U.S.C. 262(m)(1)) is amended by striking ''(f), (i), (j), (k), (l), (p), and (q)'' and inserting ''(f), (h), (i), (j), (k), (l), (n), and (p)''.

SEC. 503. COMMUNICATION WITH PEDIATRIC REVIEW COMMITTEE.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this title as the ''Secretary'') shall issue internal standard operating procedures that provide for the review by the internal review committee established under section 505C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355d) of any significant modifications to initial pediatric study plans, agreed initial pediatric study plans, and written requests under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c). Such internal standard operating procedures shall be made publicly

available on the Internet website of the Food and Drug Administration.

SEC. 504. ACCESS TO DATA.

Not later than 3 years after the date of enactment of this Act, the Secretary shall make available to the public, including through posting on the Internet website of the Food and Drug Administration, the medical, statistical, and clinical pharmacology reviews of, and corresponding written requests issued to an applicant, sponsor, or holder for, pediatric studies submitted between January 4, 2002 and September 27, 2007 under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) for which 6 months of market exclusivity was granted and that resulted in a labeling change. The Secretary shall make public the information described in the preceding sentence in a manner consistent with how the Secretary releases information under section 505A(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(k)).

SEC. 505. ENSURING THE COMPLETION OF PEDIATRIC STUDIES.

(a) EXTENSION OF DEADLINE FOR DEFERRED STUDIES.—Section 505B (21 U.S.C. 355c) is amended—

(1) in subsection (a)(3)—

(A) by redesignating subparagraph (B) as subparagraph (C);

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

''(B) DEFERRAL EXTENSION.—

''(i) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may grant an extension of a deferral approved under subparagraph (A) for submission of some or all assessments required under paragraph (1) if—

''(I) the Secretary determines that the conditions described in subclause (II) or (III) of subparagraph (A)(i) continue to be met; and

''(II) the applicant submits a new timeline under subparagraph (A)(ii)(IV) and any significant updates to the information required under subparagraph (A)(ii).

''(ii) TIMING AND INFORMATION.—If the deferral extension under this subparagraph is requested by the applicant, the applicant shall submit the deferral extension request containing the information described in this subparagraph not less than 90 days prior to the date that the deferral would expire. The Secretary shall respond to such request not later than 45 days after the receipt of such letter. If the Secretary grants such an extension, the specified date shall be the extended date. The sponsor of the required assessment under paragraph (1) shall not be issued a letter described in subsection (d) unless the specified or extended date of submission for such required studies has passed or if the request for an extension is pending. For a deferral that has expired prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act or that will expire prior to 270 days after the date of enactment of such Act, a deferral extension shall be requested by an applicant not later than 180 days after the date of enactment of such Act. The Secretary shall respond to any such request as soon as practicable, but not later than 1 year after the date of enactment of such Act. Nothing in this clause shall prevent the Secretary from updating the status of a study or studies publicly if components of such study or studies are late or delayed.''; and

(C) in subparagraph (C), as so redesignated—

(i) in clause (i), by adding at the end the following:

''(III) Projected completion date for pediatric studies.

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

(ii) in clause (ii)—

(I) by inserting '', as well as the date of each deferral or deferral extension, as applicable,'' after ''clause (i)''; and

(II) by inserting ''not later than 90 days after submission to the Secretary or with the next routine quarterly update'' after ''Administration''; and

(2) in subsection (f)—

(A) in the subsection heading, by inserting ''DEFERRAL EXTENSIONS,'' after ''DEFERRALS,'';

(B) in paragraph (1), by inserting '', deferral extension,'' after ''deferral''; and

(C) in paragraph (4)—

(i) in the paragraph heading, by inserting ''DEFERRAL EXTENSIONS,'' after ''DEFERRALS,''; and

(ii) by inserting '', deferral extensions,'' after ''deferrals''.

(b) TRACKING OF EXTENSIONS; ANNUAL INFORMATION.—Section 505B(f)(6)(D) (21 U.S.C. 355c(f)(6)(D)) is amended to read as follows:

''(D) aggregated on an annual basis—

''(i) the total number of deferrals and deferral extensions requested and granted under this section and, if granted, the reasons for each such deferral or deferral extension;

''(ii) the timeline for completion of the assessments; and

''(iii) the number of assessments completed and pending;''.

(c) ACTION ON FAILURE TO COMPLETE STUDIES.—

(1) ISSUANCE OF LETTER.—Subsection (d) of section 505B (21 U.S.C. 355c) is amended to read as follows:

''(d) SUBMISSION OF ASSESSMENTS.—If a person fails to submit a required assessment described in subsection (a)(2), fails to meet the applicable requirements in subsection (a)(3), or fails to submit a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b), the following shall apply:

''(1) Beginning 270 days after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall issue a non-compliance letter to such person informing them of such failure to submit or meet the requirements of the applicable subsection. Such letter shall require the person to respond in writing within 45 calendar days of issuance of such letter. Such response may include the person's request for a deferral extension if applicable. Such letter and the person's written response to such letter shall be made publicly available on the Internet Web site of the Food and Drug Administration 60 calendar days after issuance, with redactions for any trade secrets and confidential commercial information. If the Secretary determines that the letter was issued in error, the requirements of this paragraph shall not apply.

''(2) The drug or biological product that is the subject of an assessment described in subsection (a)(2), applicable requirements in subsection (a)(3), or request for approval of a pediatric formulation, may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303), but such failure shall not be the basis for a proceeding—

''(A) to withdraw approval for a drug under section 505(e); or

''(B) to revoke the license for a biological product under section 351 of the Public Health Service Act.''.

(2) TRACKING OF LETTERS ISSUED.—Subparagraph (D) of section 505B(f)(6) (21 U.S.C. 355c(f)(6)), as amended by subsection (b), is further amended—

(A) in clause (ii), by striking ''; and'' and inserting a semicolon;

(B) in clause (iii), by adding ''and'' at the end; and

(C) by adding at the end the following:

''(iv) the number of postmarket non-compliance letters issued pursuant to subsection (d), and the recipients of such letters;''.

SEC. 506. PEDIATRIC STUDY PLANS.

(a) IN GENERAL.—Subsection (e) of section 505B (21 U.S.C. 355c) is amended to read as follows:

''(e) PEDIATRIC STUDY PLANS.—

''(1) IN GENERAL.—An applicant subject to subsection (a) shall submit to the Secretary an initial pediatric study plan prior to the submission of the assessments described under subsection (a)(2).

''(2) TIMING; CONTENT; MEETING.—

''(A) TIMING.—An applicant shall submit an initial pediatric study plan to the Secretary not later than 60 calendar days after the date of the end of phase II meeting or such other equivalent time agreed upon between the Secretary and the applicant. Nothing in this paragraph shall preclude the Secretary from accepting the submission of an initial pediatric study plan earlier than the date described under the preceding sentence.

''(B) CONTENT OF INITIAL PLAN.—The initial pediatric study plan shall include—

''(i) an outline of the pediatric study or studies that the applicant plans to conduct (including, to the extent practicable study objectives and design, age groups, relevant endpoints, and statistical approach);

''(ii) any request for a deferral, partial waiver, or waiver under this section, if applicable, along with any supporting information; and

''(iii) other information specified in the regulations promulgated under paragraph (4).

''(C) MEETING.—The Secretary—

''(i) shall meet with the applicant to discuss the initial pediatric study plan as soon as practicable, but not later than 90 calendar days after the receipt of such plan under subparagraph (A);

''(ii) may determine that a written response to the initial pediatric study plan is sufficient to communicate comments on the initial pediatric study plan, and that no meeting is necessary; and

''(iii) if the Secretary determines that no meeting is necessary, shall so notify the applicant and provide written comments of the Secretary as soon as practicable, but not later than 90 calendar days after the receipt of the initial pediatric study plan.

''(3) AGREED INITIAL PEDIATRIC STUDY PLAN.—Not later than 90 calendar days following the meeting under paragraph (2)(C)(i) or the receipt of a written response from the Secretary under paragraph (2)(C)(iii), the applicant shall document agreement on the initial pediatric study plan in a submission to the Secretary marked 'Agreed Initial Pediatric Study Plan', and the Secretary shall confirm such agreement to the applicant in writing not later than 30 calendar days of receipt of such agreed initial pediatric study plan.

''(4) DEFERRAL AND WAIVER.—If the agreed initial pediatric study plan contains a request from the applicant for a deferral, partial waiver, or waiver under this section, the written confirmation under paragraph (3) shall include a recommendation from the Secretary as to whether such request meets the standards under paragraphs (3) or (4) of subsection (a).

''(5) AMENDMENTS TO THE PLAN.—At the initiative of the Secretary or the applicant, the agreed initial pediatric study plan may be amended at any time. The requirements of paragraph (2)(C) shall apply to any such proposed amendment in the same manner and to

the same extent as such requirements apply to an initial pediatric study plan under paragraph (1). The requirements of paragraphs (3) and (4) shall apply to any agreement resulting from such proposed amendment in the same manner and to the same extent as such requirements apply to an agreed initial pediatric study plan.

''(6) INTERNAL COMMITTEE.—The Secretary shall consult the internal committee under section 505C on the review of the initial pediatric study plan, agreed initial pediatric plan, and any significant amendments to such plans.

''(7) REQUIRED RULEMAKING.—Not later than 1 year after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall promulgate proposed regulations and issue proposed guidance to implement the provisions of this subsection.''.

(b) CONFORMING AMENDMENTS.—Section 505B (21 U.S.C. 355c)is amended—

(1) by amending subclause (II) of subsection (a)(3)(A)(ii) to read as follows:

''(II) a pediatric study plan as described in subsection (e);''; and

(2) in subsection (f)—

(A) in the subsection heading, by striking ''PEDIATRIC PLANS,'' and inserting ''PEDIATRIC STUDY PLANS,'';

(B) in paragraph (1), by striking ''all pediatric plans'' and inserting ''initial pediatric study plans, agreed initial pediatric study plans,''; and

(C) in paragraph (4)—

(i) in the paragraph heading, by striking ''PEDIATRIC PLANS,'' and inserting ''PEDIATRIC STUDY PLANS,''; and

(ii) by striking ''pediatric plans'' and inserting ''initial pediatric study plans, agreed initial pediatric study plans,''.

(c) EFFECTIVE DATES.—

(1) PEDIATRIC STUDY PLANS.—Subsection (e) of section 505B of the Federal Food, Drug, and Cosmetic Act (other than paragraph (4) of such subsection), as amended by subsection (a), shall take effect 180 days after the date of enactment of this Act, without regard to whether the Secretary has promulgated final regulations under paragraph (4) of such subsection by such date.

(2) CONFORMING AMENDMENTS.—The amendments made by subsection (b) shall take effect 180 days after the date of enactment of this Act.

SEC. 507. REAUTHORIZATIONS.

(a) PEDIATRIC ADVISORY COMMITTEE.—Section 14(d) of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by striking ''Notwithstanding section 14 of the Federal Advisory Committee Act, the advisory committee shall continue to operate during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007'' and inserting ''Section 14 of the Federal Advisory Committee Act shall not apply to the advisory committee''.

(b) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC DRUGS ADVISORY COMMITTEE.—Section 15(a)(3) of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by striking ''during the five-year period beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007'' and inserting ''for the duration of the operation of the Oncologic Drugs Advisory Committee''.

(c) HUMANITARIAN DEVICE EXEMPTION EXTENSION.—Section 520(m)(6)(A)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is amended by striking ''2012'' and inserting ''2017''.

(d) DEMONSTRATION GRANTS TO IMPROVE PEDIATRIC DEVICE AVAILABILITY.—Section 305(e) of Pediatric Medical Device Safety and Improvement Act (Public Law 110–85; 42 U.S.C. 282 note)) is amended by striking ''$6,000,000 for each of fiscal years 2008 through 2012'' and inserting ''$4,500,000 for each of fiscal years 2013 through 2017''.

(e) PROGRAM FOR PEDIATRIC STUDY OF DRUGS IN PHSA.—Section 409I(e)(1) of the Public Health Service Act (42 U.S.C. 284m(e)(1)) is amended by striking ''to carry out this section'' and all that follows through the end of paragraph (1) and inserting ''to carry out this section $25,000,000 for each of fiscal years 2012 through 2017.''.

SEC. 508. REPORT.

(a) IN GENERAL.—Not later than October 31, 2016, and at the end of each subsequent 5-year period, the Secretary shall submit to Congress a report that evaluates the effectiveness of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) and section 409I of the Public Health Service Act (42 U.S.C. 284m) in ensuring that medicines used by children are tested in pediatric populations and properly labeled for use in children.

(b) CONTENTS.—The report under subsection (a) shall include—

(1) the number and importance of drugs and biological products for children for which studies have been requested or required (as of the date of such report) under 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) and section 409I of the Public Health Service Act (42 U.S.C. 284m), including—

(A) the number of labeling changes made to drugs and biological products pursuant to such sections since the date of enactment of this Act; and

(B) the importance of such drugs and biological products in the improvement of the health of children;

(2) the number of required studies under such section 505B that have not met the initial deadline provided under such section, including—

(A) the number of deferrals and deferral extensions granted and the reasons such extensions were granted;

(B) the number of waivers and partial waivers granted; and

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

(3) the number of written requests issued, declined, and referred to the National Institutes of Health under such section 505A since the date of enactment of this Act (including the reasons for such declination), and a description and status of referrals made under subsection (n) of such section 505A;

(4) the number of proposed pediatric study plans submitted and agreed to as identified in the marketing application under such section 505B;

(5) any labeling changes recommended by the Pediatric Advisory Committee as a result of the review by such Committee of adverse events reports;

(6) the number and current status of pediatric postmarketing requirements;

(7) the number and importance of drugs and biological products for children that are not being tested for use in pediatric populations, notwithstanding the existence of the programs under such sections 505A and 505B and section 409I of the Public Health Service Act;

(8) the possible reasons for the lack of testing reported under paragraph (7);

(9) the number of drugs and biological products for which testing is being done (as of the date of the report) and for which a labeling change is required under the programs described in paragraph (7), including—

(A) the date labeling changes are made;

(B) which labeling changes required the use of the dispute resolution process; and

(C) for labeling changes that required such dispute resolution process, a description of—

(i) the disputes;

(ii) the recommendations of the Pediatric Advisory Committee; and

(iii) the outcomes of such process; and

(D) an assessment of the effectiveness in improving information about pediatric uses of drugs and biological products;

(10)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonatal population (including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of the studies ethical and safe); and

(B) the results of such efforts;

(11)(A) the number and importance of drugs and biological products for children with cancer that are being tested as a result of the programs described in paragraph (7); and

(B) any recommendations for modifications to such programs that would lead to new and better therapies for children with cancer, including a detailed rationale for each recommendation;

(12) an assessment of progress made in addressing the recommendations and findings of any prior report issued by the Comptroller General, the Institute of Medicine, or the Secretary regarding the topics addressed in the report under this section, including with respect to—

(A) improving public access to information from pediatric studies conducted under such sections 505A and 505B; and

(B) improving the timeliness of pediatric studies and pediatric study planning under such sections 505A and 505B;

(13) any recommendations for modification to the programs that would improve pediatric drug research and increase pediatric labeling of drugs and biological products; and

(14) an assessment of the successes of and limitations to studying drugs for rare diseases under such sections 505A and 505B.

(c) CONSULTATION ON RECOMMENDATIONS.—At least 180 days before the report is due under subsection (a), and no sooner than 4 years after the date of enactment of this Act, the Secretary shall consult with representatives of patient groups, including pediatric patient groups, consumer groups, regulated industry, scientific and medical communities, academia, and other interested parties to obtain any recommendations or information relevant to the effectiveness of the programs described in subsection (b)(7), including suggestions for modifications to such programs.

SEC. 509. TECHNICAL AMENDMENTS.

(a) PEDIATRIC STUDIES OF DRUGS IN FFDCA.—Section 505A (21 U.S.C. 355a) is amended—

(1) in subsection (k)(2), by striking ''subsection (f)(3)(F)'' and inserting ''subsection (f)(6)(F)'';

(2) in subsection (n)—

(A) in the subsection heading, by striking ''COMPLETED'' and inserting ''SUBMITTED''; and

(B) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking ''have not been completed'' and inserting ''have not been submitted by the date specified in the written request issued or if the applicant or holder does not agree to the request'';

(ii) in subparagraph (A)—

(I) in the first sentence, by inserting '', or for which a period of exclusivity eligible for extension under subsection (b)(1) or (c)(1) of this section or under subsection (m)(2) or (m)(3) of section 351 of the Public Health Service Act has not ended'' after ''expired''; and

(II) by striking ''Prior to'' and all that follows through the period at the end; and

(iii) in subparagraph (B), by striking ''no listed patents or has 1 or more listed patents that have expired,'' and inserting ''no unexpired listed patents and for which no unexpired periods of exclusivity eligible for extension under subsection (b)(1) or (c)(1) of this section or under subsection (m)(2) or (m)(3) of section 351 of the Public Health Service Act apply,''; and

(3) in subsection (o)(2), by amendment subparagraph (B) to read as follows:

''(B) a statement of any appropriate pediatric contraindications, warnings, precautions, or other information that the Secretary considers necessary to assure safe use.''.

(b) RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PROJECTS IN FFDCA.—Section 505B (21 U.S.C. 355c) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by inserting ''for a drug'' after ''(or supplement to an application)'';

(ii) in subparagraph (A), by striking ''for a'' and inserting '', including, with respect to a drug, an application (or supplement to an application) for a'';

(iii) in subparagraph (B), by striking ''for a'' and inserting '', including, with respect to a drug, an application (or supplement to an application) for a''; and

(iv) in the matter following subparagraph (B), by inserting ''(or supplement)'' after ''application''; and

(B) in paragraph (4)(C)—

(i) in the first sentence, by inserting ''partial'' before ''waiver is granted''; and

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

(2) in subsection (b)(1), in the matter preceding subparagraph (A), by striking ''After providing notice'' and all that follows through ''studies), the'' and inserting ''The'';

(3) in subsection (g)—

(A) in paragraph (1)(A), by inserting ''that receives a priority review or 330 days after the date of the submission of an application or supplement that receives a standard review'' after ''after the date of the submission of the application or supplement''; and

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

(4) in subsection (h)(1)—

(A) by inserting ''an application (or supplement to an application) that contains'' after ''date of submission of''; and

(B) by inserting '', if the application (or supplement) receives a priority review, or not later than 330 days after the date of submission of an application (or supplement to an application) that contains a pediatric assessment under this section, if the application (or supplement) receives a standard review,'' after ''under this section,''.

(c) INTERNAL REVIEW COMMITTEE.—The heading of section 505C (21 U.S.C. 355d) is amended by inserting ''and deferral extensions'' after ''deferrals''.

(d) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—Section 409I(c) of the Public Health Service Act (42 U.S.C. 284m(c)) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by inserting ''or section 351(m) of this Act,'' after ''Cosmetic Act,'';

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

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

''(B) there remains no patent listed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, and every three-year and five-year period referred to in subsection (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act, or applicable twelve-year period referred to in section 351(k)(7) of this Act, and any seven-year period referred to in section 527 of the Federal Food, Drug, and Cosmetic Act has ended for at least one form of the drug; and''; and

(2) in paragraph (2)—

(A) in the paragraph heading, by striking ''FOR DRUGS LACKING EXCLUSIVITY''; and

(B) by striking ''under section 505 of the Federal Food, Drug, and Cosmetic Act''; and

(C) by striking ''505A of such Act'' and inserting ''505A of the Federal Food, Drug, and Cosmetic Act or section 351(m) of this Act''.

(e) PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC ADVISORY COMMITTEE.—Section 15(a) of the Best Pharmaceuticals for Children Act (Public Law 107–109), as amended by section 502(e) of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85), is amended in paragraph (1)(D), by striking ''section 505B(f)'' and inserting '' 'section 505C' ''.

(f) FOUNDATION OF NATIONAL INSTITUTES OF HEALTH.—Section 499(c)(1)(C) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by striking ''for which the Secretary issues a certification in the affirmative under section 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act''.

(g) APPLICATION.—Notwithstanding any provision of section 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) stating that a provision applies beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007 or the date of the enactment of the Pediatric Research Equity Act of 2007, any amendment made by this title to such a provision applies beginning on the date of the enactment of this Act.

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

(a) IN GENERAL.—Section 505 (21 U.S.C. 351) is amended by adding at the end the following:

''(w) RELATIONSHIP BETWEEN PEDIATRIC LABELING AND NEW CLINICAL INVESTIGATION EXCLUSIVITY.—The period of market exclusivity described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) shall not apply to a pediatric study conducted under section 505A or 505B that results, pursuant to section 505B(g)(2), in the inclusion in the labeling of the product a determination that the product is not indicated for use in pediatric populations or subpopulations or information indicating that the results of a study were inconclusive or did not demonstrate that the product is safe or effective in pediatric populations or subpopulations.''.

(b) PEDIATRIC STUDIES OF DRUGS.—Section 505A(m) (21 U.S.C. 355a(m)) is amended—

(1) by striking ''(m) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 505(j).—If a'' and all that follows through the end of the matter that precedes paragraph (1) and inserting the following:

''(m) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICATION OR SUPPLEMENT UNDER SUBSECTION (C) OR (J) OF SECTION 505.—

''(1) 180-DAY EXCLUSIVITY PERIOD.—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month exclusivity period under this section, so that the applicant for approval of a drug under section 505(j) entitled to the 180-day period under that section loses a portion of the 180-day period to which the applicant is entitled for the drug, the 180-day period shall be extended from—'';

(2) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B) and moving such subparagraphs, as so redesignated, 2 ems to the right; and

(3) by adding at the end the following:

''(2) 3-YEAR EXCLUSIVITY PERIOD.—The 3-year period of exclusivity under clauses (iii) and (iv) of subsection 505(c)(3)(E) and clauses (iii) and (iv) of subsection 505(j)(5)(F) are not available for approval of applications or supplements to applications based on reports of pediatric studies conducted under sections 505A or 505B that resulted, pursuant to section 505A(j) or 505B(g)(2), in the inclusion in the labeling of the product a determination that the product is not indicated for use in pediatric populations or subpopulations or information indicating that the results of an assessment were inconclusive or did not demonstrate that the product is safe or effective in pediatric populations or subpopulation.''.

(c) PROMPT APPROVAL OF DRUGS.—Section 505A(o) (21 U.S.C. 355a(o)) is amended—

(1) in the heading, by striking ''SECTION 505(J)'' and inserting ''SUBSECTIONS (C) AND (J) OF SECTION 505'';

(2) in paragraph (1), by striking ''under section 505(j)'' and inserting ''under subsection (b)(2), (c), or (j) of section 505'';

(3) in paragraph (2), in the matter preceding subparagraph (A), by inserting ''clauses (iii) and (iv) of section 505(c)(3)(E) or'' after ''Notwithstanding''; and

(4) in paragraph (3)—

(A) in subparagraph (B), by inserting ''that differ from adult formulations'' before the semicolon at the end; and

(B) in subparagraph (C)—

(i) by striking ''under section 505(j)'' and inserting ''under subsection (c) or (j) of section 505''; and

(ii) by inserting ''clauses (iii) or (iv) of section 505(c)(3)(E) or'' after ''exclusivity under''.

SEC. 511. PEDIATRIC RARE DISEASES.

(a) PUBLIC MEETING.—Not later than 18 months after the date of enactment of this Act, the Secretary shall hold a public meeting to discuss ways to encourage and accelerate the development of new therapies for pediatric rare diseases.

(b) REPORT.—Not later than 180 days after the date of the public meeting under subsection (a), the Secretary shall issue a report that includes a strategic plan for encouraging and accelerating the development of new therapies for treating pediatric rare diseases.

TITLE VI—MEDICAL DEVICE REGULATORY IMPROVEMENTS

SEC. 601. RECLASSIFICATION PROCEDURES.

(a) CLASSIFICATION CHANGES.—

(1) IN GENERAL.—Section 513(e)(1) (21 U.S.C. 360c(e)(1)) is amended to read as follows:

''(e)(1)(A) Based on new information respecting a device, the Secretary may, upon the initiative of the Secretary or upon petition of an interested person, change the classification of such device, and revoke, on account of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device, by administrative order published in the Federal Register following publication of a proposed reclassification order in the Federal Register, a meeting of a device classification panel described in subsection (b), and consideration of comments to a public docket, notwithstanding subchapter II of Chapter 5 of title 5 of the United States Code. An order under this subsection changing the classification of a device from class

III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such device.

''(B) Authority to issue such administrative order shall not be delegated below the Commissioner. The Commissioner shall issue such an order as proposed by the Director of the Center for Devices and Radiological Health unless the Commissioner, in consultation with the Office of the Secretary of Health and Human Services, concludes that the order exceeds the legal authority of the Food and Drug Administration or that the order would be lawful, but unlikely to advance the public health.''.

(2) TECHNICAL AND CONFORMING AMENDMENTS.—

(A) Section 513(e)(2) (21 U.S.C. 360c(e)(2)) is amended by striking ''regulation promulgated'' and inserting ''an order issued''.

(B) Section 514(a)(1) (21 U.S.C. 360d(a)(1)) is amended by striking ''under a regulation under section 513(e) but such regulation'' and inserting ''under an administrative order under section 513(e) (or a regulation promulgated under such section prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act) but such order (or regulation)'';

(C) Section 517(a)(1) (21 U.S.C. 360g(a)(1)) is amended by striking ''or changing the classification of a device to class I'' and inserting '', an administrative order changing the classification of a device to class I,''.

(3) DEVICES RECLASSIFIED PRIOR TO THE DATE OF ENACTMENT OF THIS ACT.—

(A) IN GENERAL.—The amendments made by this subsection shall have no effect on a regulation promulgated with respect to the classification of a device under section 513(e) of the Federal Food, Drug, and Cosmetic Act prior to the date of enactment of this Act.

(B) APPLICABILITY OF OTHER PROVISIONS.—In the case of a device reclassified under section 513(e) of the Federal Food, Drug, and Cosmetic Act by regulation prior to the date of enactment of this Act, section 517(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g(a)(1)) shall apply to such regulation promulgated under section 513(e) of such Act with respect to such device in the same manner such section 517(a)(1) applies to an administrative order issued with respect to a device reclassified after the date of enactment of this Act.

(b) DEVICES MARKETED BEFORE MAY 28, 1976.—

(1) PREMARKET APPROVAL.—Section 515 (21 U.S.C. 360e) is amended—

(A) in subsection (a), by striking ''regulation promulgated under subsection (b)'' and inserting ''an order issued under subsection (b) (or a regulation promulgated under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act)'';

(B) in subsection (b)—

(i) in paragraph (1)—

(I) in the heading, by striking ''Regulation'' and inserting ''Order''; and

(II) in the matter following subparagraph (B)—

(aa) by striking ''by regulation, promulgated in accordance with this subsection'' and inserting ''by administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, United States Code''; and

(bb) by adding at the end the following:

''Authority to issue such administrative order shall not be delegated below the Commissioner. Before publishing such administrative order, the Commissioner shall consult with the Office of the Secretary. The Commissioner shall issue such an order as proposed by the Director of the Center for Devices and Radiological Health unless the Commissioner, in consultation with the Office of the Secretary, concludes that the order exceeds the legal authority of the Food and Drug Administration or that the order would be lawful, but unlikely to advance the public health.'';

(ii) in paragraph (2)—

(I) by striking subparagraph (B); and

(II) in subparagraph (A)—

(aa) by striking ''(2)(A) A proceeding for the promulgation of a regulation under paragraph (1) respecting a device shall be initiated by the publication in the Federal Register of a notice of proposed rulemaking. Such notice shall contain—'' and inserting ''(2) A proposed order required under paragraph (1) shall contain—'';

(bb) by redesignating clauses (i) through (iv) as subparagraphs (A) through (D), respectively;

(cc) in subparagraph (A), as so redesignated, by striking ''regulation'' and inserting ''order''; and

(dd) in subparagraph (C), as so redesignated, by striking ''regulation'' and inserting ''order'';

(iii) in paragraph (3)—

(I) by striking ''proposed regulation'' each place such term appears and inserting ''proposed order'';

(II) by striking ''paragraph (2) and after'' and inserting ''paragraph (2),'';

(III) by inserting ''and a meeting of a device classification panel described in section 513(b),'' after ''such proposed regulation and findings,'';

(IV) by striking ''(A) promulgate such regulation'' and inserting ''(A) issue an administrative order under paragraph (1)'';

(V) by striking ''paragraph (2)(A)(ii)'' and inserting ''paragraph (2)(B)''; and

(VI) by striking ''promulgation of the regulation'' and inserting ''issuance of the administrative order''; and

(iv) by striking paragraph (4); and

(C) in subsection (i)—

(i) in paragraph (2)—

(I) in the matter preceding subparagraph (A)—

(aa) by striking ''December 1, 1995'' and inserting ''the date that is 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act''; and

(bb) by striking ''publish a regulation in the Federal Register'' and inserting ''issue an administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, United States Code,'';

(II) in subparagraph (B), by striking ''final regulation has been promulgated under section 515(b)'' and inserting ''administrative order has been issued under subsection (b) (or no regulation has been promulgated under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act)'';

(III) in the matter following subparagraph (B), by striking ''regulation requires'' and inserting ''administrative order issued under this paragraph requires''; and

(IV) by striking the third and fourth sentences; and

(ii) in paragraph (3)—

(I) by striking ''regulation requiring'' each place such term appears and inserting ''order requiring''; and

(II) by striking ''promulgation of a section 515(b) regulation'' and inserting ''issuance of an administrative order under subsection (b)''.

(2) TECHNICAL AND CONFORMING AMENDMENTS.—Section 501(f) (21 U.S.C. 351(f)) is amended—

(A) in subparagraph (1)(A)—

(i) in subclause (i), by striking ''a regulation promulgated'' and inserting ''an order issued''; and

(ii) in subclause (ii), by striking ''promulgation of such regulation'' and inserting ''issuance of such order'';

(B) in subparagraph (2)(B)—

(i) by striking ''a regulation promulgated'' and inserting ''an order issued''; and

(ii) by striking ''promulgation of such regulation'' and inserting ''issuance of such order''; and

(C) by adding at the end the following:

''(3) In the case of a device with respect to which a regulation was promulgated under section 515(b) prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act, a reference in this subsection to an order issued under section 515(b) shall be deemed to include such regulation.''.

(3) APPROVAL BY REGULATION PRIOR TO THE DATE OF ENACTMENT OF THIS ACT.—The amendments made by this subsection shall have no effect on a regulation that was promulgated prior to the date of enactment of this Act requiring that a device have an approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) of an application for premarket approval.

(c) REPORTING.—The Secretary of Health and Human Services shall annually post on the Internet website of the Food and Drug Administration—

(1) the number and type of class I and class II devices reclassified as class II or class III in the previous calendar year under section 513(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(e)(1));

(2) the number and type of class II and class III devices reclassified as class I or class II in the previous calendar year under such section 513(e)(1); and

(3) the number and type of devices reclassified in the previous calendar year under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e).

SEC. 602. CONDITION OF APPROVAL STUDIES.

Section 515(d)(1)(B)(ii) (21 U.S.C. 360e(d)(1)(B)(ii)) is amended—

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

(2) by adding at the end the following:

''(II) An order approving an application for a device may require as a condition to such approval that the applicant conduct a postmarket study regarding the device.''.

SEC. 603. POSTMARKET SURVEILLANCE.

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

(1) in subsection (a)(1)(A), in the matter preceding clause (i), by inserting '', at the time of approval or clearance of a device or at any time thereafter,'' after ''by order''; and

(2) in subsection (b)(1), by inserting ''The manufacturer shall commence surveillance under this section not later than 15 months after the day on which the Secretary issues an order under this section.'' after the second sentence.

SEC. 604. SENTINEL.

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

''(h) INCLUSION OF DEVICES IN THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

''(1) IN GENERAL.—

''(A) APPLICATION TO DEVICES.—The Secretary shall amend the procedures established and maintained under clauses (i), (ii),

(iii), and (v) of section 505(k)(3)(C) in order to expand the postmarket risk identification and analysis system established under such section to include and apply to devices.

''(B) EXCEPTION.—Subclause (II) of clause (i) of section 505(k)(3)(C) shall not apply to devices.

''(C) CLARIFICATION.—With respect to devices, the private sector health-related electronic data provided under section 505(k)(3)(C)(i)(III)(bb) may include medical device utilization data, health insurance claims data, and procedure and device registries.

''(2) DATA.—In expanding the system as described in paragraph (1)(A), the Secretary shall use relevant data with respect to devices cleared under section 510(k) or approved under section 515, including claims data, patient survey data, and any other data deemed appropriate by the Secretary.

''(3) STAKEHOLDER INPUT.—To help ensure effective implementation of the system described in paragraph (1)(A), the Secretary shall engage outside stakeholders in development of the system through a public hearing, advisory committee meeting, public docket, or other like public measures, as appropriate.

''(4) VOLUNTARY SURVEYS.—Chapter 35 of title 44, United States Code, shall not apply to the collection of voluntary information from health care providers, such as voluntary surveys or questionnaires, initiated by the Secretary for purposes of postmarket risk identification for devices.''.

SEC. 605. RECALLS.

(a) ASSESSMENT OF DEVICE RECALL INFORMATION.—

(1) IN GENERAL.—

(A) ASSESSMENT PROGRAM.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall enhance the Food and Drug Administration's recall program to routinely and systematically assess—

(i) information submitted to the Secretary pursuant to a device recall order under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)); and

(ii) information required to be reported to the Secretary regarding a correction or removal of a device under section 519(g) of such Act (21 U.S.C. 360i(g)).

(B) USE.—The Secretary shall use the assessment of information described under subparagraph (A) to proactively identify strategies for mitigating health risks presented by defective or unsafe devices.

(2) DESIGN.—The program under paragraph (1) shall, at a minimum, identify—

(A) trends in the numbers and types of device recalls;

(B) the types of devices in each device class that are most frequently recalled;

(C) the causes of device recalls; and

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

(b) AUDIT CHECK PROCEDURES.—The Secretary shall clarify procedures for conducting device recall audit checks to improve the ability of investigators to perform these checks in a consistent manner.

(c) ASSESSMENT CRITERIA.—The Secretary shall develop explicit criteria for assessing whether a person subject to a recall order under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)) or to a requirement under section 519(g) of such Act (21 U.S.C. 360i(g)) has performed an effective recall under such section 518(e) or an effective correction or removal action under such section 519(g), respectively.

(d) TERMINATION OF RECALLS.—The Secretary shall document the basis for the termination by the Food and Drug Administration of—

(1) an individual device recall ordered under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)); and

(2) any correction or removal action for which a report is required to be submitted to the Secretary under section 519(g) of such Act (21 U.S.C. 360i(g)).

SEC. 606. CLINICAL HOLDS ON INVESTIGATIONAL DEVICE EXEMPTIONS.

Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

''(8)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a 'clinical hold') if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

''(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is a determination that—

''(i) the device involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the device, the design of the clinical investigation, the condition for which the device is to be investigated, and the health status of the subjects involved; or

''(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish.

''(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.''.

SEC. 607. UNIQUE DEVICE IDENTIFIER.

Section 519(f) (21 U.S.C. 360i(f)) is amended—

(1) by striking ''The Secretary shall promulgate'' and inserting ''Not later than December 31, 2012, the Secretary shall issue proposed''; and

(2) by adding at the end the following: ''The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized.''.

SEC. 608. CLARIFICATION OF LEAST BURDENSOME STANDARD.

(a) PREMARKET APPROVAL.—Section 513(a)(3)(D) (21 U.S.C. 360c(a)(3)(D)) is amended—

(1) by redesignating clause (iii) as clause (v); and

(2) by inserting after clause (ii) the following:

''(iii) For purposes of clause (ii), the term 'necessary' means the minimum required information that would support a determination by the Secretary that an application provides reasonable assurance of the effectiveness of the device.

''(iv) Nothing in this subparagraph shall alter the criteria for evaluating an application for premarket approval of a device.''.

(b) PREMARKET NOTIFICATION UNDER SECTION 510(K).—Section 513(i)(1)(D) (21 U.S.C. 360c(i)(1)(D)) is amended—

(1) by striking ''(D) Whenever'' and inserting ''(D)(i) Whenever''; and

(2) by adding at the end the following:

''(ii) For purposes of clause (i), the term 'necessary' means the minimum required information that would support a determination of substantial equivalence between a new device and a predicate device.

''(iii) Nothing in this subparagraph shall alter the standard for determining substantial equivalence between a new device and a predicate device.''.

SEC. 609. CUSTOM DEVICES.

Section 520(b) (21 U.S.C. 360j(b)) is amended to read as follows:

''(b) CUSTOM DEVICES.—

''(1) IN GENERAL.—The requirements of sections 514 and 515 shall not apply to a device that—

''(A) is created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing);

''(B) in order to comply with an order described in subparagraph (A), necessarily deviates from an otherwise applicable performance standard under section 514 or requirement under section 515;

''(C) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;

''(D) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat;

''(E)(i) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated); or

''(ii) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated);

''(F) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs described in clause (i) or (ii) of subparagraph (E); and

''(G) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

''(2) LIMITATIONS.—Paragraph (1) shall apply to a device only if—

''(A) such device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on such device would be impractical;

''(B) production of such device under paragraph (1) is limited to no more than 5 units per year of a particular device type, provided that such replication otherwise complies with this section; and

''(C) the manufacturer of such device created or modified as described in paragraph (1) notifies the Secretary on an annual basis, in a manner prescribed by the Secretary, of the manufacture of such device.

''(3) EXCEPTION.—Paragraph (1) shall not apply to oral facial devices.

''(4) GUIDANCE.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue final guidance on replication of multiple devices described in paragraph (2)(B).''.

SEC. 610. AGENCY DOCUMENTATION AND REVIEW OF CERTAIN DECISIONS REGARDING DEVICES.

Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 517 the following:

''SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF CERTAIN DECISIONS REGARDING DEVICES.

''(a) DOCUMENTATION OF RATIONALE FOR DENIAL.—If the Secretary renders a final decision to deny clearance of a premarket notification under section 510(k) or approval of a

premarket application under section 515, or when the Secretary disapproves an application for an investigational exemption under 520(g), the written correspondence to the applicant communicating that decision shall provide a substantive summary of the scientific and regulatory rationale for the decision.

''(b) REVIEW OF DENIAL.—

''(1) IN GENERAL.—A person who has submitted a report under section 510(k), an application under section 515, or an application for an exemption under section 520(g) and for whom clearance of the report or approval of the application is denied may request a supervisory review of the decision to deny such clearance or approval. Such review shall be conducted by an individual at the organizational level above the organization level at which the decision to deny the clearance of the report or approval of the application is made.

''(2) SUBMISSION OF REQUEST.—A person requesting a supervisory review under paragraph (1) shall submit such request to the Secretary not later than 30 days after such denial and shall indicate in the request whether such person seeks an in-person meeting or a teleconference review.

''(3) TIMEFRAME.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall schedule an in-person or teleconference review, if so requested, not later than 30 days after such request is made. The Secretary shall issue a decision to the person requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a person who requests an in-person meeting or teleconference, 30 days after such meeting or teleconference.

''(B) EXCEPTION.—Subparagraph (A) shall not apply in cases that involve consultation with experts outside of the Food and Drug Administration, or in cases in which the sponsor seeks to introduce evidence not already in the administrative record at the time the denial decision was made.''.

SEC. 611. GOOD GUIDANCE PRACTICES RELATING TO DEVICES.

Subparagraph (C) of section 701(h)(1) (21 U.S.C. 371(h)(1)) is amended—

(1) by striking ''(C) For guidance documents'' and inserting ''(C)(i) For guidance documents''; and

(2) by adding at the end the following:

''(ii) With respect to devices, if a notice to industry guidance letter, a notice to industry advisory letter, or any similar notice sets forth initial interpretations of a regulation or policy or sets forth changes in interpretation or policy, such notice shall be treated as a guidance document for purposes of this subparagraph.''.

SEC. 612. MODIFICATION OF DE NOVO APPLICATION PROCESS.

(a) IN GENERAL.—Section 513(f)(2) (21 U.S.C. 360c(f)(2)) is amended—

(1) by redesignating subparagraphs (B) and (C) as subparagraphs (C) and (D), respectively;

(2) by amending subparagraph (A) to read as follows:

''(A) In the case of a type of device that has not previously been classified under this Act, a person may do one of the following:

''(i) Submit a report under section 510(k), and, if the device is classified into class III under paragraph (1), such person may request, not later than 30 days after receiving written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

''(ii) Submit a request for initial classification of the device under this subparagraph, if the person declares that there is no legally marketed device upon which to base a substantial equivalence determination as that term is defined in subsection (i). Subject to subparagraph (B), the Secretary shall classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device and shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such assurance. Requests under this clause shall be subject to the electronic copy requirements of section 745A(b).'';

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

''(B) The Secretary may decline to undertake a classification request submitted under clause (2)(A)(ii) if the Secretary identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence under paragraph (1), or when the Secretary determines that the device submitted is not of low-moderate risk or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.''; and

(4) in subparagraph (C), as so redesignated—

(A) in clause (i), by striking ''Not later than 60 days after the date of the submission of the request under subparagraph (A),'' and inserting ''Not later than 120 days after the date of the submission of the request under subparagraph (A)(i) or 150 days after the date of the submission of the request under subparagraph (A)(ii),''; and

(B) in clause (ii), by inserting ''or is classified in'' after ''remains in''.

(b) GAO REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall complete a study and submit to Congress a report on the effectiveness of the review pathway under section 513(f)(2)(A) of the Federal Food, Drug, and Cosmetic Act, as amended by this Act.

(c) CONFORMING AMENDMENT.—Section 513(f)(1)(B) (21 U.S.C. 360c(f)(1)(B)) is amended by inserting ''a request under paragraph (2) or'' after ''response to''.

SEC. 613. HUMANITARIAN DEVICE EXEMPTIONS.

(a) IN GENERAL.—Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (6)—

(A) in subparagraph (A)—

(i) by striking clause (i) and inserting the following:

''(i) The device with respect to which the exemption is granted—

''(I) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or

''(II) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.''; and

(ii) by striking clause (ii) and inserting the following:

''(ii) During any calendar year, the number of such devices distributed during that year under each exemption granted under this subsection does not exceed the annual distribution number for such device. In this paragraph, the term 'annual distribution number' means the number of such devices reasonably needed to treat, diagnose, or cure a population of 4,000 individuals in the United States. The Secretary shall determine the annual distribution number when the Secretary grants such exemption.''; and

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

''(C) A person may petition the Secretary to modify the annual distribution number determined by the Secretary under subparagraph (A)(ii) with respect to a device if additional information arises, and the Secretary may modify such annual distribution number.'';

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

(3) in paragraph (8), by striking ''of all devices described in paragraph (6)'' and inserting ''of all devices described in paragraph (6)(A)(i)(I)''.

(b) APPLICABILITY TO EXISTING DEVICES.—A sponsor of a device for which an exemption was approved under paragraph (2) of section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) before the date of enactment of this Act may seek a determination under subclause (I) or (II) of section 520(m)(6)(A)(i) (as amended by subsection (a)). If the Secretary of Health and Human Services determines that such subclause (I) or (II) applies with respect to a device, clauses (ii), (iii), and (iv) of subparagraph (A) and subparagraphs (B), (C), (D), and (E) of paragraph (6) of such section 520(m) shall apply to such device, and the Secretary shall determine the annual distribution number for purposes of clause (ii) of such subparagraph (A) when making the determination under this subsection.

(c) REPORT.—Not later than January 1, 2017, the Comptroller General of the United States shall submit to Congress a report that evaluates and describes—

(1) the effectiveness of the amendments made by subsection (a) in stimulating innovation with respect to medical devices, including any favorable or adverse impact on pediatric device development;

(2) the impact of such amendments on pediatric device approvals for devices that received a humanitarian use designation under section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) prior to the date of enactment of this Act;

(3) the status of public and private insurance coverage of devices granted an exemption under paragraph (2) of such section 520(m) (as amended by subsection (a)) and costs to patients of such devices;

(4) the impact that paragraph (4) of such section 520(m) has had on access to and insurance coverage of devices granted an exemption under paragraph (2) of such section 520(m); and

(5) the effect of the amendments made by subsection (a) on patients described in such section 520(m).

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

(a) THIRD PARTY REVIEW.—Section 523(c) (21 U.S.C. 360m(c)) is amended by striking ''2012'' and inserting ''2017''.

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

SEC. 615. 510(K) DEVICE MODIFICATIONS.

Having acknowledged to Congress potential unintended consequences that may result from the implementation of the Food

and Drug Administration guidance entitled ''Guidance for Industry and FDA Staff—510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device'', the Secretary of Health and Human Services shall withdraw such guidance promptly and ensure that, before any future guidance document on this issue is made final, affected stakeholders are provided with an opportunity to comment.

SEC. 616. HEALTH INFORMATION TECHNOLOGY.

(a) LIMITATION.—Notwithstanding any other provision of law, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may issue final guidance on medical mobile applications only after the requirements under subsections (b) and (c) are met.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary, in consultation with the Commissioner of Food and Drugs, the National Coordinator for Health Information Technology, and the Chairman of the Federal Communications Commission, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to medical device regulation and health information technology software, including mobile applications, that promotes innovation and protects patient safety.

(c) WORKING GROUP.—

(1) IN GENERAL.—In carrying out subsection (b), the Secretary shall convene a working group of external stakeholders and experts to provide appropriate input on the strategy and recommendations required for the report under subsection (b).

(2) REPRESENTATIVES.—The Secretary shall determine the number of representatives participating in the working group, and shall ensure that the working group is geographically diverse and includes representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise, as determined by the Secretary.

(3) OTHER REQUIREMENTS.—

(A) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the working group under this section.

(B) FFDCA ADVISORY COMMITTEES.—The requirements for advisory committees under section 712 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d–1), as amended by section 1121, shall not apply to the working group under this section.

TITLE VII—DRUG SUPPLY CHAIN

Subtitle A—Drug Supply Chain

SEC. 701. REGISTRATION OF DOMESTIC DRUG ESTABLISHMENTS.

Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (b)—

(A) in paragraph (1), by striking ''On or before'' and all that follows through the period at the end and inserting the following: ''During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register with the Secretary—

''(A) the name of such person, places of business of such person, all such establishments, the unique facility identifier of each such establishment, and a point of contact e-mail address; and

''(B) the name and place of business of each importer that takes physical possession of and supplies a drug (other than an excipient) to such person, including all establishments of each such drug importer, the unique facility identifier of each such drug importer establishment, and a point of contact e-mail address for each such drug importer.''; and

(B) by adding at the end the following:

''(3) The Secretary may specify the unique facility identifier system that shall be used by registrants under paragraph (1).''; and

(2) in subsection (c), by striking ''with the Secretary his name, place of business, and such establishment'' and inserting ''with the Secretary—

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

''(2) with respect to devices, the information described under subsection (b)(2).''.

SEC. 702. REGISTRATION OF FOREIGN ESTABLISHMENTS.

(a) ENFORCEMENT OF REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 502(o) (21 U.S.C. 352(o)) is amended by striking ''in any State''.

(b) REGISTRATION OF FOREIGN DRUG ESTABLISHMENTS.—Section 510(i) (U.S.C. 360(i)) is amended—

(1) in paragraph (1)—

(A) by amending the matter preceding subparagraph (A) to read as follows: ''Every person who owns or operates any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—'';

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

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

''(i) with respect to drugs, the name and place of business of such person, all such establishments, the unique facility identifier of each such establishment, a point of contact e-mail address, the name of the United States agent of each such establishment, the name and place of business of each drug importer with which such person conducts business to import or offer to import drugs into the United States, including all establishments of each such drug importer, the unique facility identifier of each such establishment, and a point of contact e-mail address for each such drug importer; and

''(ii) with respect to devices, the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such device in the United States that is known to the establishment, and the name of each person who imports or offers for import such device to the United States for purposes of importation; and''; and

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

''(B) each establishment subject to the requirements of subparagraph (A) shall thereafter register with the Secretary during the period beginning on October 1 and ending on December 31 of each year.''; and

(2) by adding at the end the following:

''(4) The Secretary may specify the unique facility identifier system that shall be used by registrants under paragraph (1) with respect to drugs.''.

SEC. 703. IDENTIFICATION OF DRUG EXCIPIENT INFORMATION WITH PRODUCT LISTING.

Section 510(j)(1) (21 U.S.C. 360(j)(1)) is amended—

(1) in subparagraph (C), by striking ''; and'' and inserting a semicolon;

(2) in subparagraph (D), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(E) in the case of a drug contained in the applicable list, the name and place of business of each manufacturer of an excipient of the listed drug with which the person listing the drug conducts business, including all establishments used in the production of such excipient, the unique facility identifier of each such establishment, and a point of contact e-mail address for each such excipient manufacturer.''.

SEC. 704. ELECTRONIC SYSTEM FOR REGISTRATION AND LISTING.

Section 510(p) (21 U.S.C. 360(p)) is amended—

(1) by striking ''(p) Registrations and listings'' and inserting the following:

''(p) ELECTRONIC REGISTRATION AND LISTING.—

''(1) IN GENERAL.—Registration and listing''; and

(2) by adding at the end the following:

''(2) ELECTRONIC DATABASE.—Not later than 2 years after the Secretary specifies a unique facility identifier system under subsections (b) and (i), the Secretary shall maintain an electronic database, which shall not be subject to inspection under subsection (f), populated with the information submitted as described under paragraph (1) that—

''(A) enables personnel of the Food and Drug Administration to search the database by any field of information submitted in a registration described under paragraph (1), or combination of such fields; and

''(B) uses the unique facility identifier system to link with other relevant databases within the Food and Drug Administration, including the database for submission of information under section 801(r).

''(3) RISK-BASED INFORMATION AND COORDINATION.—The Secretary shall ensure the accuracy and coordination of relevant Food and Drug Administration databases in order to identify and inform risk-based inspections under section 510(h).''.

SEC. 705. RISK-BASED INSPECTION FREQUENCY.

Section 510(h) (21 U.S.C. 360(h)) is amended to read as follows:

''(h) INSPECTIONS.—

''(1) IN GENERAL.—Every establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 704.

''(2) BIENNIAL INSPECTIONS FOR DEVICES.—Every establishment described in paragraph (1), in any State, that is engaged in the manufacture, propagation, compounding, or processing of a device or devices classified in class II or III shall be so inspected by one or more officers or employees duly designated by the Secretary, or by persons accredited to conduct inspections under section 704(g), at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter.

''(3) RISK-BASED SCHEDULE FOR DRUGS.—The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect establishments described in paragraph (1) that are engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs (referred to in this subsection as 'drug establishments') in accordance with a risk-based schedule established by the Secretary.

''(4) RISK FACTORS.—In establishing the risk-based scheduled under paragraph (3), the Secretary shall inspect establishments according to the known safety risks of such establishments, which shall be based on the following factors:

''(A) The compliance history of the establishment.

''(B) The record, history, and nature of recalls linked to the establishment.

''(C) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment.

''(D) The certifications described under sections 801(r) and 809 for the establishment.

''(E) Whether the establishment has been inspected in the preceding 4-year period.

''(F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

''(5) EFFECT OF STATUS.—In determining the risk associated with an establishment for purposes of establishing a risk-based schedule under paragraph (3), the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed by such establishment are drugs described in section 503(b).

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

''(A)(i) the number of domestic and foreign establishments registered pursuant to this section in the previous fiscal year; and

''(ii) the number of such domestic establishments and the number of such foreign establishments that the Secretary inspected in the previous fiscal year;

''(B) with respect to establishments that manufacture, prepare, propagate, compound, or process an active ingredient of a drug, a finished drug product, or an excipient of a drug, the number of each such type of establishment; and

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

''(7) PUBLIC AVAILABILITY OF ANNUAL REPORTS.—The Secretary shall make the report required under paragraph (6) available to the public on the Internet Web site of the Food and Drug Administration.''.

SEC. 706. RECORDS FOR INSPECTION.

Section 704(a) (21 U.S.C. 374(a)) is amended by adding at the end the following:

''(4)(A) Any records or other information that the Secretary is entitled to inspect under this section from a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug shall, upon the request of the Secretary, be provided to the Secretary by such person within a reasonable time frame, within reasonable limits and in a reasonable manner, and in electronic form, at the expense of such person. The Secretary's request shall include a clear description of the records requested.

''(B) Upon receipt of the records requested under subparagraph (A), the Secretary shall provide to the person confirmation of the receipt of such records.

''(C) Nothing in this paragraph supplants the authority of the Secretary to conduct inspections otherwise permitted under this Act in order to ensure compliance by an establishment with this Act.''.

SEC. 707. FAILURE TO ALLOW FOREIGN INSPECTION.

Section 801(a) (21 U.S.C. 381(a)) is amended by adding at the end the following: ''Notwithstanding any other provision of this subsection, the Secretary of Homeland Security shall, upon request from the Secretary of Health and Human Services refuse to admit into the United States any article if the article was manufactured, prepared, propagated, compounded, processed, or held at an establishment that has refused to permit the Secretary of Health and Human Services to enter or inspect the establishment in the same manner and to the same extent as the Secretary may inspect establishments under section 704.''.

SEC. 708. EXCHANGE OF INFORMATION.

Section 708 (21 U.S.C. 379) is amended—

(1) by striking ''CONFIDENTIAL INFORMATION'' and all that follows through ''The Secretary'' and inserting "confidential information.

''(a) CONTRACTORS.—The Secretary''; and

(2) by adding at the end the following:

''(b) ABILITY TO RECEIVE AND PROTECT CONFIDENTIAL INFORMATION.—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).

''(c) AUTHORITY TO ENTER INTO MEMORANDA OF UNDERSTANDING FOR PURPOSES OF INFORMATION EXCHANGE.—The Secretary may enter into written agreements regarding the exchange of information referenced in section 301(j) subject to the following criteria:

''(1) CERTIFICATION.—The Secretary may only enter into written agreements under this subsection with foreign governments that the Secretary has certified as having the authority and demonstrated ability to protect trade secret information from disclosure. Responsibility for this certification shall not be delegated to any officer or employee other than the Commissioner.

''(2) WRITTEN AGREEMENT.—The written agreement under this subsection shall include a commitment by the foreign government to protect information exchanged under this subsection from disclosure unless and until the sponsor gives written permission for disclosure or the Secretary makes a declaration of a public health emergency pursuant to section 319 of the Public Health Service Act that is relevant to the information.

''(3) INFORMATION EXCHANGE.—The Secretary may provide to a foreign government that has been certified under paragraph (1) and that has executed a written agreement under paragraph (2) information referenced in section 301(j) in the following circumstances:

''(A) Information concerning the inspection of a facility may be provided if—

''(i) the Secretary reasonably believes, or that the written agreement described in paragraph (2) establishes, that the government has authority to otherwise obtain such information; and

''(ii) the written agreement executed under paragraph (2) limits the recipient's use of the information to the recipient's civil regulatory purposes.

''(B) Information not described in subparagraph (A) may be provided as part of an investigation, or to alert the foreign government to the potential need for an investigation, if the Secretary has reasonable grounds to believe that a drug has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

''(4) EFFECT OF SUBSECTION.—Nothing in this subsection affects the ability of the Secretary to enter into any written agreement authorized by other provisions of law to share confidential information.''.

SEC. 709. ENHANCING THE SAFETY AND QUALITY OF THE DRUG SUPPLY.

Section 501 (21 U.S.C. 351) is amended by adding at the end the following flush text:

''For purposes of subsection (a)(2)(B), the term 'current good manufacturing practice' includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.''.

SEC. 710. ACCREDITATION OF THIRD-PARTY AUDITORS FOR DRUG ESTABLISHMENTS.

(a) IN GENERAL.—Chapter VIII (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

''SEC. 809. ACCREDITATION OF THIRD-PARTY AUDITORS FOR DRUG ESTABLISHMENTS.

''(a) DEFINITIONS.—In this section:

''(1) ACCREDITATION BODY.—The term 'accreditation body' means an authority that performs accreditation of third-party auditors.

''(2) ACCREDITED THIRD-PARTY AUDITOR.—The term 'accredited third-party auditor' means a third-party auditor (which may be an individual) accredited by an accreditation body to conduct drug safety and quality audits.

''(3) AUDIT AGENT.—The term 'audit agent' means an individual who is an employee or agent of an accredited third-party auditor and, although not individually accredited, is qualified to conduct drug safety and quality audits on behalf of an accredited third-party auditor.

''(4) CONSULTATIVE AUDIT.—The term 'consultative audit' means an audit of an eligible entity intended for internal purposes only to determine whether an establishment is in compliance with the provisions of this Act and applicable industry practices, or any other such service.

''(5) DRUG SAFETY AND QUALITY AUDIT.—The term 'drug safety and quality audit'—

''(A) means an audit of an eligible entity to certify that the eligible entity meets the requirements of this Act applicable to drugs, including the requirements of section 501 with respect to drugs; and

''(B) is not a consultative audit.

''(6) ELIGIBLE ENTITY.—The term 'eligible entity' means an entity, including a foreign drug establishment registered under section 510(c), in the drug supply chain that chooses to be audited by an accredited third-party auditor or the audit agent of such accredited third-party auditor.

''(7) THIRD-PARTY AUDITOR.—The term 'third-party auditor' means a foreign government, agency of a foreign government or any other third party (which may be an individual), as the Secretary determines appropriate in accordance with the criteria described in subsection (c)(1), that is eligible to be considered for accreditation to conduct drug safety and quality audits.

''(b) ACCREDITATION SYSTEM.—

''(1) RECOGNITION OF ACCREDITATION BODIES.—

''(A) IN GENERAL.—Not later than 2 years after date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall establish a system for the recognition of accreditation bodies that accredit third-party auditors to conduct drug safety and quality audits.

''(B) DIRECT ACCREDITATION.—

''(i) IN GENERAL.—If, by the date that is 2 years after the date of establishment of the system described in subparagraph (A), the Secretary has not identified and recognized an accreditation body to meet the requirements of this section, the Secretary may directly accredit third-party auditors.

''(ii) CERTAIN DIRECT ACCREDITATIONS.—Notwithstanding subparagraph (A) or clause (i), the Secretary may directly accredit any foreign government or any agency of a foreign government as a third-party auditor at any time after the date of enactment of the Food and Drug Administration Safety and Innovation Act.

''(2) NOTIFICATION.—Each accreditation body recognized by the Secretary shall submit to the Secretary—

''(A) a list of all accredited third-party auditors accredited by such body (including the name, contact information, and scope and duration of accreditation for each such auditor), and the audit agents of such auditors; and

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

''(3) REVOCATION OF RECOGNITION AS AN ACCREDITATION BODY.—The Secretary shall promptly revoke, after the opportunity for an informal hearing, the recognition of any accreditation body found not to be in compliance with the requirements of this section.

''(4) REINSTATEMENT.—The Secretary shall establish procedures to reinstate recognition of an accreditation body if the Secretary determines, based on evidence presented by such accreditation body, that revocation was inappropriate or that the body meets the requirements for recognition under this section.

''(5) MODEL ACCREDITATION STANDARDS.—

''(A) IN GENERAL.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall develop model standards, including standards for drug safety and quality audit results, reports, and certifications, and each recognized accreditation body shall ensure that third-party auditors and audit agents of such auditors meet such standards in order to qualify such third-party auditors as accredited third-party auditors under this section.

''(B) CONTENT.—The standards developed under subparagraph (A) may—

''(i) include a description of required standards relating to the training procedures, competency, management responsibilities, quality control, and conflict of interest requirements of accredited third-party auditors; and

''(ii) set forth procedures for the periodic renewal of the accreditation of accredited third-party auditors.

''(C) REQUIREMENT TO PROVIDE RESULTS AND REPORTS TO THE SECRETARY.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) may not accredit a third-party auditor unless such third-party auditor agrees to provide to the Secretary, upon request, the results and reports of any drug safety and quality audit conducted pursuant to the accreditation provided under this section.

''(6) DISCLOSURE.—The Secretary shall maintain on the Internet Web site of the Food and Drug Administration a list of recognized accreditation bodies and accredited third-party auditors under this section.

''(c) ACCREDITED THIRD-PARTY AUDITORS.—

''(1) REQUIREMENTS FOR ACCREDITATION AS A THIRD-PARTY AUDITOR.—

''(A) FOREIGN GOVERNMENTS.—Prior to accrediting a foreign government or an agency of a foreign government as an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) shall perform such reviews and audits of drug safety programs, systems, and standards of the government or agency of the government as the Secretary deems necessary, including requirements under the standards developed under subsection (b)(5), to determine that the foreign government or agency of the foreign government is capable of adequately ensuring that eligible entities or drugs certified by such government or agency meet the requirements of this Act.

''(B) OTHER THIRD PARTIES.—Prior to accrediting any other third party to be an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) shall perform such reviews and audits of the training and qualifications of audit agents used by that party and conduct such reviews of internal systems and such other investigation of the party as the Secretary deems necessary, including requirements under the standards developed under subsection (b)(5), to determine that the third-party auditor is capable of adequately ensuring that an eligible entity or drug certified by such third-party auditor meets the requirements of this Act.

''(2) USE OF AUDIT AGENTS.—An accredited third-party auditor may conduct drug safety and quality audits and may employ or use audit agents to conduct drug safety and quality audits, but must ensure that such audit agents comply with all requirements the Secretary deems necessary, including requirements under paragraph (1) and subsection (b)(5).

''(3) REVOCATION OF ACCREDITATION.—

''(A) IN GENERAL.—The Secretary shall promptly revoke, after the opportunity for an informal hearing, the accreditation of an accredited third-party auditor—

''(i) if, following an evaluation, the Secretary finds that the accredited third-party auditor is not in compliance with the requirements of this section; or

''(ii) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to determine compliance with the requirements set forth in this section.

''(B) ADDITIONAL BASIS FOR REVOCATION OF ACCREDITATION.—The Secretary may revoke accreditation from an accredited third-party auditor in the case that such third-party auditor is accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(3) is revoked, if the Secretary determines that there is good cause for the revocation of accreditation.

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

''(A) if the Secretary determines, based on evidence presented, that—

''(i) the third-party auditor satisfies the requirements of this section; and

''(ii) adequate grounds for revocation no longer exist; and

''(B) in the case of a third-party auditor accredited by an accreditation body for which recognition as an accreditation body is revoked under subsection (b)(3)—

''(i) if the third-party auditor becomes accredited not later than 1 year after revocation of accreditation under paragraph (3), through direct accreditation under subsection (b)(1)(B), or by an accreditation body in good standing; or

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

''(5) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES FOR COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICE.—

''(A) IN GENERAL.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(B), the Secretary) may not accredit a third-party auditor unless such third-party auditor agrees to issue a written and, as appropriate, electronic, document or certification, as the Secretary may require under this Act, regarding compliance with section 501. The Secretary may consider any such document or certification to satisfy requirements under section 801(r) and to target inspection resources under section 510(h).

''(B) REQUIREMENTS FOR ISSUING CERTIFICATION.—

''(i) IN GENERAL.—An accredited third-party auditor shall issue a drug certification described in subparagraph (A) only after conducting a drug safety and quality audit and such other activities that may be necessary to establish compliance with the provisions of section 501.

''(ii) PROVISION OF CERTIFICATION.—Only an accredited third-party auditor or the Secretary may provide a drug certification described in subparagraph (A).

''(C) RECORDS.—Following any accreditation of a third-party auditor, the Secretary may, at any time, require the accredited third-party auditor or any audit agent of such auditor to submit to the Secretary a drug safety and quality audit report and such other reports or documents required as part of the drug safety and quality audit process, for any eligible entity for which the accredited third-party auditor or audit agent of such auditor performed a drug safety and quality audit. The Secretary may require documentation that the eligible entity is in compliance with any applicable registration requirements.

''(D) LIMITATION.—The requirement under subparagraph (C) shall not include any report or other documents resulting from a consultative audit, except that the Secretary may access the results of a consultative audit in accordance with section 704.

''(E) DECLARATION OF AUDIT TYPE.—Before an accredited third-party auditor begins any audit or provides any consultative service to an eligible entity, both the accredited third-party auditor and eligible entity shall establish in writing whether the audit is intended to be a drug safety and quality audit. Any audit, inspection, or consultative service of any type provided by an accredited third-party auditor on behalf of an eligible entity shall be presumed to be a drug safety and quality audit in the absence of such a written agreement. Once a drug safety and quality audit is initiated, it shall be subject to the requirements of this section, and no person may withhold from the Secretary any document subject to subparagraph (C) on the grounds that the audit was a consultative audit or otherwise not a drug safety and quality audit.

''(F) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary under section 704.

''(6) REQUIREMENTS REGARDING SERIOUS RISKS TO THE PUBLIC HEALTH.—If, at any time during a drug safety and quality audit, an accredited third-party auditor or an audit agent of such auditor discovers a condition that could cause or contribute to a serious risk to the public health, such auditor shall immediately notify the Secretary of—

''(A) the identity and location of the eligible entity subject to the drug safety and quality audit; and

''(B) such condition.

''(7) LIMITATIONS.—

''(A) IN GENERAL.—An audit agent of an accredited third-party auditor may not perform a drug safety and quality audit of an eligible entity if such audit agent has performed a drug safety and quality audit or consultative audit of such eligible entity during the previous 13-month period.

''(B) WAIVER.—The Secretary may waive the application of subparagraph (A) if the Secretary determines that there is insufficient access to accredited third-party auditors in a country or region or that the use of the same audit agent or accredited third-party auditor is otherwise necessary.

''(8) CONFLICTS OF INTEREST.—

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

''(i) not be owned, managed, or controlled by any person that owns or operates a third-party auditor to be accredited by such body;

''(ii) in carrying out accreditation of third-party auditors under this section, have procedures to ensure against the use of any officer or employee of such body that has a financial conflict of interest regarding a third-party auditor to be accredited by such body; and

''(iii) annually make available to the Secretary disclosures of the extent to which such body and the officers and employees of such body have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

''(B) ACCREDITED THIRD-PARTY AUDITORS.—An accredited third-party auditor shall—

''(i) not be owned, managed, or controlled by any person that owns or operates an eligible entity to be certified by such auditor;

''(ii) in carrying out drug safety and quality audits of eligible entities under this section, have procedures to ensure against the use of any officer or employee of such auditor that has a financial conflict of interest regarding an eligible entity to be certified by such auditor; and

''(iii) annually make available to the Secretary disclosures of the extent to which such auditor and the officers and employees of such auditor have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

''(C) AUDIT AGENTS.—An audit agent shall—

''(i) not own or operate an eligible entity to be audited by such agent;

''(ii) in carrying out audits of eligible entities under this section, have procedures to ensure that such agent does not have a financial conflict of interest regarding an eligible entity to be audited by such agent; and

''(iii) annually make available to the Secretary disclosures of the extent to which such agent has maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

''(d) FALSE STATEMENTS.—Any statement or representation made—

''(1) by an employee or agent of an eligible entity to an accredited third-party auditor or audit agent; or

''(2) by an accreditation body, accredited third-party auditor, or audit agent of such auditor to the Secretary, shall be subject to section 1001 of title 18, United States Code.

''(e) MONITORING.—To ensure compliance with the requirements of this section, the Secretary—

''(1) shall periodically, or at least once every 4 years, reevaluate the accreditation bodies described in subsection (b)(1);

''(2) shall periodically, or at least once every 4 years, evaluate the performance of each accredited third-party auditor, through the review of regulatory audit reports by such auditors, the compliance history as available of eligible entities certified by such auditors, and any other measures deemed necessary by the Secretary;

''(3) may at any time, conduct an onsite audit of any eligible entity certified by an accredited third-party auditor, with or without the auditor present; and

''(4) shall take any other measures deemed necessary by the Secretary.

''(f) EFFECT OF AUDIT.—The results of a drug safety and quality audit by an accredited third-party auditor under this section—

''(1) may be used by the eligible entity—

''(A) as documentation of compliance with section 501(a)(2)(B) or section 801(r); and

''(B) for other purposes as determined appropriate by the Secretary; and

''(2) shall be used by the Secretary in establishing the risk-based inspection schedules under section 510(h).

''(g) COSTS.—

''(1) AUTHORIZED FEES OF SECRETARY.—The Secretary may assess fees on accreditation bodies and accredited third-party auditors in such an amount necessary to establish and administer the recognition and accreditation program under this section. The Secretary may require accredited third-party auditors and audit agents to reimburse the Food and Drug Administration for the work performed to carry out this section. The Secretary shall not generate surplus revenue from such a reimbursement mechanism. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to remain available until expended.

''(2) AUTHORIZED FEES FOR RECOGNIZED ACCREDITATION BODIES.—An accreditation body recognized by the Secretary under subsection (b) may assess a reasonable fee to accredit third-party auditors.

''(h) LIMITATIONS.—

''(1) NO EFFECT ON SECTION 704 INSPECTIONS.—The drug safety and quality audits performed under this section shall not be considered inspections under section 704.

''(2) NO EFFECT ON INSPECTION AUTHORITY.—Nothing in this section affects the authority of the Secretary to inspect any eligible entity pursuant to this Act.

''(i) REGULATIONS.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this section.

''(2) PROCEDURE.—In promulgating the regulations implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the effective date of the regulation.

''(3) CONTENT.—Such regulations shall include—

''(A) requirements that, to the extent practicable, drug safety and quality audits performed under this section be unannounced;

''(B) a structure to decrease the potential for conflicts of interest, including timing and public disclosure, for fees paid by eligible entities to accredited third-party auditors; and

''(C) appropriate limits on financial affiliations between an accredited third-party auditor or audit agents of such auditor and any person that owns or operates an eligible entity to be audited by such auditor, as described in subparagraphs (A) and (B).

''(4) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2).''.

(b) REPORT ON ACCREDITED THIRD-PARTY AUDITORS.—Not later than January 20, 2017, the Comptroller General of the United States shall submit to Congress a report that addresses the following, with respect to the period beginning on the date of implementation of section 809 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) and ending on the date of such report:

(1) The extent to which drug safety and quality audits completed by accredited third-party auditors under such section 809 are being used by the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') in establishing or applying the risk-based inspection schedules under section 510(h) of such Act (as amended by section 705).

(2) The extent to which drug safety and quality audits completed by accredited third-party auditors or agents are assisting the Food and Drug Administration in evaluating compliance with sections 501(a)(2)(B) of such Act (21 U.S.C. 351(a)(2)(B)) and 801(r) of such Act (as added by section 711).

(3) Whether the Secretary has been able to access drug safety and quality audit reports completed by accredited third-party auditors under such section 809.

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

(5) The extent to which the Secretary has audited recognized accreditation bodies or accredited third-party auditors to ensure compliance with the requirements of such section 809.

(6) The number of waivers under subsection (c)(7)(B) of such section 809 issued during the most recent 12-month period and the official justification by the Secretary for each determination that there was insufficient access to an accredited third-party auditor.

(7) The number of times a manufacturer has used the same accredited third-party auditor for 2 or more consecutive drug safety and quality audits under such section 809.

(8) Recommendations to Congress regarding the accreditation program under such section 809, including whether Congress should continue, modify, or terminate the program.

SEC. 711. STANDARDS FOR ADMISSION OF IMPORTED DRUGS.

Section 801 (21 U.S.C. 381) is amended—

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

(2) by adding at the end the following:

''(r)(1) The Secretary may require, as a condition of granting admission to a drug imported or offered for import into the United States, that the importer electronically submit information demonstrating that the drug complies with applicable requirements of this Act.

''(2) The information described under paragraph (1) may include—

''(A) information demonstrating the regulatory status of the drug, such as the new drug application, abbreviated new drug application, or investigational new drug or drug master file number;

''(B) facility information, such as proof of registration and the unique facility identifier;

''(C) indication of compliance with current good manufacturing practice, testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations; and

''(D) any other information deemed necessary and appropriate by the Secretary to assess compliance of the article being offered for import.

''(3) Information requirements referred to in paragraph (2)(C) may, at the discretion of the Secretary, be satisfied—

''(A) by certifications from accredited third parties, as described under section 809;

''(B) through representation by a foreign government, if such inspection is conducted using standards and practices as determined appropriate by the Secretary; or

''(C) other appropriate documentation or evidence as described by the Secretary.

''(4)(A) Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this subsection. Such requirements shall be appropriate for the type of import, such as whether the drug is for import into the United States for use in preclinical research or in a clinical investigation under an investigational new drug exemption under 505(i).

''(B) In promulgating the regulations implementing this subsection, the Secretary shall—

''(i) issue a notice of proposed rulemaking that includes the proposed regulation;

''(ii) provide a period of not less than 60 days for comments on the proposed regulation; and

''(iii) publish the final regulation not less than 30 days before the effective date of the regulation.

''(C) Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this subsection only as described in subparagraph (B).''.

SEC. 712. NOTIFICATION.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(aaa) The failure to notify the Secretary in violation of section 568.''.

(b) NOTIFICATION.—

(1) IN GENERAL.—Subchapter E of chapter V (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

''SEC. 568. NOTIFICATION.

''(a) NOTIFICATION TO SECRETARY.—With respect to a drug, the Secretary may require notification to the Secretary by a covered person if the covered person knows—

''(1) of a substantial loss or theft of such drug; or

''(2) that such drug—

''(A) has been or is being counterfeited; and

''(B)(i) is a counterfeit product in commerce in the United States; or

''(ii) is offered for import into the United States.

''(b) MANNER OF NOTIFICATION.—Notification under this section shall be made in a reasonable time, in such reasonable manner, and by such reasonable means as the Secretary may require by regulation or specify in guidance.

''(c) DEFINITION.—In this section, the term 'covered person' means—

''(1) a person who is required to register under section 510 with respect to an establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug; or

''(2) a person engaged in the wholesale distribution (as defined in section 503(e)(3)(B)) of a drug.''.

(2) APPLICABILITY.—Notifications under section 568 of the Federal Food, Drug, and Cosmetic Act (as added by paragraph (1)) apply to losses, thefts, or counterfeiting, as described in subsection (a) of such section 568, that occur on or after the date of enactment of this Act.

SEC. 713. PROTECTION AGAINST INTENTIONAL ADULTERATION.

Section 303(b) (21 U.S.C. 333(b)) is amended by adding at the end the following:

''(7) Notwithstanding subsection (a)(2), any person that knowingly and intentionally adulterates a drug such that the drug is adulterated under subsection (a)(1), (b), (c), or (d) of section 501 and has a reasonable probability of causing serious adverse health consequences or death to humans or animals shall be imprisoned for not more than 20 years or fined not more than $1,000,000, or both.''.

SEC. 714. ENHANCED CRIMINAL PENALTY FOR COUNTERFEITING DRUGS.

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

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

(b) TITLE 18.—Section 2320(b) of title 18, United States Code, is amended—

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

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

''(2) COUNTERFEIT DRUGS.—

''(A) IN GENERAL.—Whoever commits an offense under subsection (a) with respect to a drug (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) shall—

''(i) if an individual, be fined not more than $4,000,000, imprisoned not more than 20 years, or both; and

''(ii) if a person other than an individual, be fined not more than $10,000,000.

''(B) MULTIPLE OFFENSES.—In the case of an offense by a person under this paragraph that occurs after that person is convicted of another offense under this paragraph, the person convicted—

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

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

(c) SENTENCING.—

(1) DIRECTIVE TO SENTENCING COMMISSION.—Pursuant to its authority under section 994(p) of title 28, United States Code, and in accordance with this section, the United States Sentencing Commission shall review and amend, if appropriate, its guidelines and its policy statements applicable to persons convicted of an offense described in section 2320(b)(2) of title 18, United States Code, as amended by subsection (b), in order to reflect the intent of Congress that such penalties be increased in comparison to those currently provided by the guidelines and policy statements.

(2) REQUIREMENTS.—In carrying out this subsection, the Commission shall—

(A) ensure that the sentencing guidelines and policy statements reflect the intent of Congress that the guidelines and policy statements reflect the serious nature of the offenses described in paragraph (1) and the need for an effective deterrent and appropriate punishment to prevent such offenses;

(B) consider the extent to which the guidelines may or may not appropriately account for the potential and actual harm to the public resulting from the offense;

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

(D) account for any additional aggravating or mitigating circumstances that might justify exceptions to the generally applicable sentencing ranges;

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

(F) assure that the guidelines adequately meet the purposes of sentencing as set forth in section 3553(a)(2) of title 18, United States Code.

SEC. 715. EXTRATERRITORIAL JURISDICTION.

Chapter III (21 U.S.C. 331 et seq.) is amended by adding at the end the following:

''SEC. 311. EXTRATERRITORIAL JURISDICTION.

''There is extraterritorial jurisdiction over any violation of this Act relating to any article regulated under this Act if such article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.''.

SEC. 716. COMPLIANCE WITH INTERNATIONAL AGREEMENTS.

Nothing in this title (or an amendment made by this title) shall be construed in a manner inconsistent with the obligations of the United States under the Agreement Establishing the World Trade Organization, or any other treaty or international agreement to which the United States is a party.

Subtitle B—Pharmaceutical Distribution Integrity

SEC. 721. SHORT TITLE.

This subtitle may be referred to as the ''Securing Pharmaceutical Distribution Integrity to Protect the Public Health Act of 2012'' or the ''Securing Pharmaceutical Distribution Integrity Act of 2012''.

SEC. 722. SECURING THE PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter H—Pharmaceutical Distribution Integrity

''SEC. 581. DEFINITIONS.

''In this subchapter:

''(1) DATA CARRIER.—The term 'data carrier' means a machine-readable graphic that is intended to be affixed to, or imprinted upon, an individual saleable unit and a homogeneous case of product. The data carrier shall comply with a form and format developed by a widely recognized international standards development organization to ensure interoperability among distribution chain participants.

''(2) INDIVIDUAL SALEABLE UNIT.—The term 'individual saleable unit' means the smallest container of product put into interstate commerce by the manufacturer that is intended by the manufacturer for individual sale to a pharmacy or other dispenser of such product.

''(3) PRODUCT.—The term 'product' means a finished drug subject to section 503(b)(1).

''(4) PRODUCT TRACING.—The term 'product tracing' means—

''(A) identifying the immediate previous source and immediate subsequent recipient of a product in wholesale distribution at the lot level where a change of ownership of such product has occurred between non-affiliated entities, except as otherwise described in this subchapter;

''(B) identifying the immediate subsequent recipient of the product at the lot level when a manufacturer or repackager introduces such product into interstate commerce;

''(C) identifying that manufacturer and dispenser of a product at the lot level when a manufacturer ships a product at the lot level, without regard to the change in ownership involving the wholesale distributor; and

''(D) identifying the immediate previous source of a product at the lot level for dispensers.

''(5) RXTEC.—The term 'RxTEC' means a data carrier that includes the standardized numerical identifier (SNI), the lot number, and the expiration date of a product. The standard data carrier RxTEC shall be a 2D data matrix barcode affixed to each individual saleable unit of a product and a linear or 2D data matrix barcode on a homogenous case of a product. Such information shall be both machine readable and human readable.

''(6) SUSPECT PRODUCT.—The term 'suspect product' means a product that, based on credible evidence—

''(A) is potentially counterfeit, diverted, or stolen;

''(B) is reasonably likely to be intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; or

''(C) appears otherwise unfit for distribution such that the product would result in serious adverse health consequence or death to humans.

''(7) VERIFICATION.—The term 'verification' means the process of determining whether a product has the standardized numerical identifier or lot number, consistent with section 582, and expiration date assigned by the manufacturer, or the repackager as applicable, and identifying whether a product has the appearance of being a counterfeit, diverted, or stolen product, or a product otherwise unfit for distribution. Verification of the RxTEC data may occur by using either a human-readable, machine-readable, or other method such as through purchase records or invoices.

"SEC. 582. ENSURING THE SAFETY OF THE PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN THROUGH THE ESTABLISHMENT OF AN RXTEC SYSTEM.

''(a) MANUFACTURER REQUIREMENTS.—

''(1) PRODUCT TRACING.—A manufacturer, not later than 4½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) apply RxTEC to the individual saleable units and homogeneous case of all products intended to be introduced into interstate commerce;

''(B) maintain change of ownership and transaction information, including RxTEC data that associate unit and lot level data for each individual saleable unit of product and homogenous case introduced in interstate commerce; and

''(C) maintain, where a change of ownership has occurred between non-affiliated entities or, in the case of a return from the immediate previous source, change of ownership and transaction information relating to a product, including—

''(i) RxTEC data;

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

''(iii) the proprietary or established name or names of the product;

''(iv) the National Drug Code number of the product;

''(v) container size;

''(vi) number of containers;

''(vii) the lot number or numbers of the product; and

''(viii) the date of the transaction;

''(D) provide the following change of ownership and trans action information to the immediate subsequent recipient of such product—

''(i) the proprietary or established name or names of the product;

''(ii) the National Drug Code number of the product;

''(iii) container size;

''(iv) number of containers;

''(v) the lot number or numbers of the product; and

''(vi) a signed statement that the manufacturer did not knowingly and intentionally adulterate or knowingly and intentionally counterfeit such product; and

''(E) upon request by the Secretary, other appropriate Federal official, or State official, in the event of a recall or as determined necessary by the Secretary, or such other Federal or State official, to investigate a suspect product, provide in a reasonable time and in a reasonable manner—

''(i) RxTEC data by lot; and

''(ii) change of ownership and transaction information pursuant to subparagraphs (C) and (D) necessary to identify the immediate previous source or immediate subsequent recipient of such product, as applicable.

''(2) VERIFICATION REQUIREMENTS.—A manufacturer, not later than 4½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) utilize RxTEC data at the lot level, as part of ongoing activities to significantly minimize or prevent the incidences of a suspect product in the pharmaceutical distribution supply chain, as applicable and appropriate, which—

''(i) may include responding to an alert regarding a suspect product from a trading partner or the Secretary, routine monitoring of a suspect product at the lot level while such product is in the possession of the manufacturer, and checking inventory for a suspect product at the request of a trading partner or the Secretary in case of returns; and

''(ii) shall take into consideration—

''(I) the likelihood that a particular product has a high potential risk with respect to pharmaceutical distribution supply chain security;

''(II) the history and severity of incidences of counterfeit, diversion, and theft of such product;

''(III) the point in the pharmaceutical distribution supply chain where counterfeit, diversion, or theft has occurred or is most likely to occur;

''(IV) the likelihood that such activities will reduce the possibility of the counterfeit, diversion, and theft of such product;

''(V) whether the product could mitigate or prevent a drug shortage as defined in section 506C; and

''(VI) any guidance the Secretary issues regarding high-risk scenarios that could increase the risk of a suspect product entering the pharmaceutical distribution supply chain; and

''(B) conduct unit level verification upon the request of a licensed or registered repackager, wholesale distributor, dispenser, or the Secretary, regarding such product.

''(3) NOTIFICATION OF PRODUCT REMOVAL.—

''(A) IN GENERAL.—Not later than 4½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a manufacturer, upon confirming that a product does not have the standardized numerical identifier or lot number, consistent with this section, and expiration date assigned by the manufacturer, or has the appearance of being a counterfeit, diverted, or stolen product, or a product otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans, shall—

''(i) promptly notify the Secretary and impacted trading partners, as applicable and appropriate; and

''(ii) take steps to remove such product from the pharmaceutical distribution supply chain.

''(B) REDISTRIBUTION.—Any product subject to a notification under this subsection may not be redistributed as a saleable product unless the manufacturer, in consultation with the Secretary, determines such product may reenter the pharmaceutical distribution supply chain.

''(4) LIMITATION.—Nothing in this section shall require a manufacturer to aggregate unit level data to cases or pallets.

''(b) REPACKAGER REQUIREMENTS.—

''(1) PRODUCT TRACING.—A repackager, not later than 5½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) apply RxTEC to the individual saleable unit and the homogenous case of all product intended to be introduced into interstate commerce;

''(B) maintain change of ownership and transaction information, including RxTEC data, that associate unit and lot level data for each individual saleable unit of product and each homogenous case of product introduced in interstate commerce, including RxTEC data received for such products and for which a repackager applies a new RxTEC;

''(C) receive only products encoded with RxTEC data from a licensed or registered manufacturer or wholesaler;

''(D) maintain, where a change of ownership has occurred between non-affiliated entities in wholesale distribution, change of ownership and transaction information relating to a product, including—

''(i) RxTEC data;

''(ii) the business name and address of the immediate previous source and the immediate subsequent recipient of the product;

''(iii) the proprietary or established name or names of the product;

''(iv) the National Drug Code number of the product;

''(v) container size;

''(vi) number of containers;

''(vii) the lot number or numbers of the product; and

''(viii) the date of the transaction;

''(E) provide the following change of ownership and transaction information to the immediate subsequent recipient of such product—

''(i) the proprietary or established name or names of the product;

''(ii) the National Drug Code number of the product;

''(iii) container size;

''(iv) number of containers;

''(v) the lot number or numbers of the product; and

''(vi) a signed statement that the repackager—

''(I) is licensed or registered;

''(II) received the product from a manufacturer that is licensed or registered;

''(III) received a signed statement from the manufacturer of such product consistent with subsection (a)(1)(D)(vi); and

''(IV) did not knowingly and intentionally adulterate or knowingly and intentionally counterfeit such product; and

''(F) upon request by the Secretary, other appropriate Federal official, or State official, in the event of a recall, or as determined necessary by the Secretary or such other Federal or State official to investigate a suspect product, provide in a reasonable time and in a reasonable manner—

''(i) RxTEC data by lot; and

''(ii) change of ownership and transaction information pursuant to subparagraph (C) or (E) necessary to identify the immediate previous source or the immediate subsequent recipient of such product, as applicable.

''(2) VERIFICATION REQUIREMENTS.—A repackager, not later than 5½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) utilize RxTEC data at the lot level, as part of ongoing activities to significantly minimize or prevent the incidences of suspect product in the pharmaceutical distribution supply chain, as applicable and appropriate, which—

''(i) may include—

''(I) responding to alerts regarding a suspect product from a trading partner or the Secretary, routine monitoring of a suspect product at the lot level while such product is in the possession of the repackager; and

''(II) checking inventory for a suspect product at the request of a trading partner or the Secretary in the case of returns; and

''(ii) shall take into consideration—

''(I) the likelihood that a particular product has a high potential risk with respect to pharmaceutical distribution supply chain security;

''(II) the history and severity of incidences of counterfeit, diversion, and theft of such product;

''(III) the point in the pharmaceutical distribution supply chain where counterfeit, diversion, and theft has occurred or is most likely to occur;

''(IV) the likelihood that such activities will reduce the possibility of counterfeit, diversion, and theft of such product;

''(V) whether the product could mitigate or prevent a drug shortage as defined in section 506C; and

''(VI) any guidance the Secretary issues regarding high-risk scenarios that could increase the risk of a suspect product entering the pharmaceutical distribution supply chain; and

''(B) conduct unit level verification upon the request of a licensed or registered manufacturer, wholesale distributor, dispenser, or the Secretary, regarding such product.

''(3) NOTIFICATION AND PRODUCT REMOVAL.—

''(A) IN GENERAL.—Not later than 5½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a repackager, upon confirming that a product does not have the standardized numerical identifier or lot number, consistent with this section, and expiration date assigned by the manufacturer, or has the appearance of being a counterfeit, diverted, or stolen product, or a product otherwise unfit for distribution such that it would result in serious adverse health consequences or death to humans, shall—

''(i) promptly notify the Secretary and impacted trading partners, as applicable and appropriate; and

''(ii) take steps to remove such product from the pharmaceutical distribution supply chain.

''(B) REDISTRIBUTION.—Any product subject to a notification under this subsection may not be redistributed as a saleable product unless the repackager, in consultation with the Secretary, and manufacturer as applicable, determines such product may reenter the pharmaceutical distribution supply chain.

''(4) LIMITATION.—Nothing in this section shall require a repackager to aggregate unit level data to cases or pallets.

''(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

''(1) PRODUCT TRACING REQUIREMENTS.—A wholesale distributor engaged in wholesale distribution, not later than 6½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) receive only products encoded with RxTEC from a licensed or registered manufacturer, wholesaler, or repackager;

''(B) maintain, in wholesale distribution where a change of ownership has occurred between non-affiliated entities, change of ownership and transaction information, including—

''(i) RxTEC data by lot;

''(ii) the business name and address of the immediate previous source and the immediate subsequent recipient of the product;

''(iii) the proprietary or established name or names of the product;

''(iv) the National Drug Code number of the product;

''(v) container size;

''(vi) number of containers;

''(vii) the lot number or numbers of the product; and

''(viii) the date of the transaction;

''(C) provide the following change of ownership and transaction information to the immediate subsequent recipient of such product—

''(i) the proprietary or established name or names of the product;

''(ii) the National Drug Code number of the product;

''(iii) container size;

''(iv) number of containers;

''(v) the lot number or numbers of the product;

''(vi) the date of the transaction; and

''(vii) a signed statement that the wholesale distributor—

''(I) is licensed or registered;

''(II) received the product from a registered or licensed manufacturer, repackager, or wholesale distributor, as applicable;

''(III) received a signed statement from the immediate subsequent recipient of such product that such trading partner did not knowingly and intentionally adulterate or knowingly and intentionally counterfeit such product; and

''(IV) did not knowingly and intentionally adulterate or knowingly and intentionally counterfeit such product; and

''(D) upon request by the Secretary, other appropriate Federal official, or State official, in the event of a recall, return, or as determined necessary by the Secretary, or such other Federal or State official, to investigate a suspect product, provide in a reasonable time and in a reasonable manner—

''(i) RxTEC data by lot; and

''(ii) change of ownership and transaction information pursuant to subparagraphs (B) and (C), as necessary to identify the immediate previous source or the immediate subsequent recipient of such product.

''(2) VERIFICATION REQUIREMENTS.—

''(A) IN GENERAL.—A wholesale distributor engaged in wholesale distribution, not later than 6½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(i) utilize RxTEC data at the lot level, as part of ongoing activities to significantly minimize or prevent the incidence of suspect product in the pharmaceutical distribution supply chain, as applicable and appropriate, which—

''(I) may include responding to an alert regarding a suspect product from a trading partner or the Secretary, routine monitoring of a suspect product at the lot level while such product is in the possession of the wholesale distributor, and checking inventory for a suspect product at the request of a trading partner or the Secretary; and

''(II) shall take into consideration—

''(aa) the likelihood that a particular product has a high potential risk with respect to pharmaceutical distribution supply chain security;

''(bb) the history and severity of incidences of counterfeit, diversion, and theft of such product;

''(cc) the point in the pharmaceutical distribution supply chain where counterfeit, diversion, and theft has occurred or is most likely to occur;

''(dd) the likelihood that such activities will reduce the possibility of counterfeit, diversion, and theft of such product;

''(ee) whether the product could mitigate or prevent a drug shortage as defined in section 506C; and

''(ff) any guidance the Secretary issues regarding high-risk scenarios that could increase the risk of suspect product entering the pharmaceutical distribution supply chain;

''(ii) conduct lot-level verification in the event of a recall, including upon the request of a licensed or registered manufacturer, repackager, dispenser, or the Secretary, regarding such product and recall;

''(iii) conduct verification of a returned product to validate the return at the lot level for a sealed homogenous case of such product or at the individual saleable unit of such product if the unit is not in a sealed homogenous case; and

''(iv) conduct unit level verification of a suspect product—

''(I) upon the request of a licensed or registered manufacturer, repackager, wholesaler, dispenser, or the Secretary, regarding such product; or

''(II) upon the determination that a product is a suspect product.

''(B) LIMITATION.—Nothing in this paragraph shall require a wholesale distributor to verify product at the unit level except as required under clauses (iii) and (iv) of subparagraph (A).

''(3) NOTIFICATION AND PRODUCT REMOVAL.—

''(A) IN GENERAL.—Not later than 6½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a wholesale distributor, upon confirming that a product does not have the standardized numerical identifier or lot number, consistent with this section, and expiration date assigned by the manufacturer, or has the appearance of being a counterfeit, diverted, or stolen product, or a product otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans, shall—

''(i) promptly notify the Secretary and impacted trading partners, as applicable and appropriate; and

''(ii) take steps to remove such product from the pharmaceutical distribution supply chain.

''(B) REDISTRIBUTION.—Any product subject to a notification under this subsection may not be redistributed as a saleable product unless the wholesaler, in consultation with the Secretary, and manufacturer or repackager as applicable, determines such product may reenter the pharmaceutical distribution supply chain.

''(C) CONFIDENTIAL DATA.—A wholesale distributor may confidentially maintain RxTEC data for a direct trading partner and provide access to such information to such trading partner in lieu of data transmission, if mutually agreed upon by such trading partners.

''(d) DISPENSER REQUIREMENTS.—

''(1) PRODUCT TRACING REQUIREMENTS.—A dispenser, not later than 7½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, shall—

''(A) receive product only from a licensed or registered manufacturer, repackager, or wholesale distributor;

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

''(C) maintain RxTEC lot level data or allow the wholesale distributor to confidentially maintain and store the RxTEC lot level data sufficient to identify the product provided to the dispenser from the immediate previous source where a change of ownership has occurred between non-affiliated entities (if such arrangement is mutually agreed upon by the dispenser and the wholesale distributor);

''(D) use the RxTEC lot level data maintained by the dispenser or maintained by the wholesale distributor on behalf of the dispenser (if such arrangement is mutually agreed upon by the dispenser and the wholesale distributor), as necessary to respond to a request from the Secretary in the event of a suspect product or recall;

''(E) maintain lot level data upon change of ownership between non-affiliated entities and for recalled product; and

''(F) for investigation purposes only, and upon request by the Secretary, other appropriate Federal official, or State official, for the purpose of investigating a suspect or recalled product, provide the RxTEC data by lot and the immediate previous source or immediate subsequent receipt of the suspect or recalled product, as applicable.

''(2) VERIFICATION REQUIREMENTS.—Not later than 7 ½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a dispenser shall be required to conduct lot level verification of suspect product only.

''(3) NOTIFICATION AND PRODUCT REMOVAL.—

''(A) IN GENERAL.—Not later than 7 ½ years after the date of enactment of the Securing Pharmaceutical Distribution Integrity Act of 2012 and in accordance with this section, a

dispenser, upon confirming that a product is a suspect product or a product otherwise unfit for distribution, shall—

''(i) promptly notify the Secretary and impacted trading partners, as applicable and appropriate; and

''(ii) take steps to remove such product from the pharmaceutical distribution supply chain.

''(B) REDISTRIBUTION.—Any product subject to a notification under this paragraph may not be redistributed as a saleable product unless the dispenser, in consultation with the Secretary, and manufacturer, repackager, or wholesaler as applicable, determines such product may reenter the pharmaceutical distribution supply chain.

''(C) LIMITATIONS.—Nothing in this section shall—

''(i) require a dispenser to verify product at the unit level; or

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

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

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

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

''(3) not prescribe or proscribe specific technologies or systems for the maintenance and transmission of data other than the standard data carrier for RxTEC or specific methods of verification;

''(4) not require a record of the complete previous distribution history of the drug from the point of origin of such drug;

''(5) take into consideration whether the public health benefits of imposing any additional regulations outweigh the cost of compliance with such requirements;

''(6) be scale-appropriate and practicable for entities of varying sizes and capabilities;

''(7) with respect to cost and recordkeeping burdens, not require the creation and maintenance of duplicative records where the information is contained in other company records kept in the normal course of business;

''(8) to the extent practicable, not require specific business systems for compliance with such requirements;

''(9) include a process by which the Secretary may issue a waiver of such regulations for an individual entity if the Secretary determines that such requirements would result in an economic hardship or for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act; and

''(10) include a process by which the Secretary may determine exceptions to the standard data carrier RxTEC requirement if a drug is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with this section.

''(f) REGULATIONS AND GUIDANCE.—

''(1) IN GENERAL.—The Secretary may issue guidance consistent with this section regarding the circumstances surrounding suspect product and verification practices.

''(2) PROCEDURE.—The Secretary, in promulgating any regulation pursuant to this section, shall—

''(A) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the effective date of the regulation.

''(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2).

''(g) STANDARDS.—The Secretary shall, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale distributors, dispensers, and other supply chain stakeholders, prioritize and develop standards for the interoperable exchange of ownership and transaction information for tracking and tracing prescription drugs.''.

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by section 712, is further amended by inserting at the end the following:

''(bbb) The violation of any requirement under section 582.''.

(c) SMALL ENTITY COMPLIANCE GUIDE.—Not later than 180 days after enactment of this Act, the Secretary of Health and Human Services (referred to in this title as the ''Secretary'') shall issue a compliance guide setting forth in plain language the requirements under section 582 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), in order to assist small entities in complying with such section.

(d) LIMITATIONS.—

(1) SAVINGS CLAUSE.—Nothing in this subtitle or the amendments made by this subtitle shall preempt any State or local law or regulation.

(2) EFFECT ON CALIFORNIA LAW.—Notwithstanding any other provision of Federal or State law, including any provision of this subtitle or of subchapter H of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), such subchapter H shall not trigger California Business and Professions Code, section 4034.1.

(3) EFFECTIVE DATE.—Subsection (c) and the amendments made by subsections (a) and (b) shall take effect on January 1, 2022, or on the date on which Congress enacts a law providing for express preemption of any State law regulating the distribution of drugs, whichever is later.

TITLE VIII—GENERATING ANTIBIOTIC INCENTIVES NOW

SEC. 801. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 505D the following:

''SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS.

''(a) EXTENSION.—If the Secretary approves an application pursuant to section 505 for a drug that has been designated as a qualified infectious disease product under subsection (d), the 4- and 5-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, or the 7-year period described in section 527, as applicable, shall be extended by 5 years.

''(b) RELATION TO PEDIATRIC EXCLUSIVITY.—Any extension under subsection (a) of a period shall be in addition to any extension of the period under section 505A with respect to the drug.

''(c) LIMITATIONS.—Subsection (a) does not apply to the approval of—

''(1) a supplement to an application under section 505(b) for any qualified infectious disease product for which an extension described in subsection (a) is in effect or has expired;

''(2) a subsequent application filed with respect to a product approved under section 505 for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

''(3) an application for a product that is not approved for the use for which it received a designation under subsection (d).

''(d) DESIGNATION.—

''(1) IN GENERAL.—The manufacturer or sponsor of a drug may request the Secretary to designate a drug as a qualified infectious disease product at any time before the submission of an application under section 505(b) for such drug. The Secretary shall, not later than 60 days after the submission of such a request, determine whether the drug is a qualified infectious disease product.

''(2) LIMITATION.—Except as provided in paragraph (3), a designation under this subsection shall not be withdrawn for any reason, including modifications to the list of qualifying pathogens under subsection (f)(2)(C).

''(3) REVOCATION OF DESIGNATION.—The Secretary may revoke a designation of a drug as a qualified infectious disease product if the Secretary finds that the request for such designation contained an untrue statement of material fact.

''(e) REGULATIONS.—

''(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this section.

''(2) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the effective date of the regulation.

''(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2), except that the Secretary may issue interim guidance for sponsors seeking designation under subsection (d) prior to the promulgation of such regulations.

''(4) DESIGNATION PRIOR TO REGULATIONS.—The Secretary may designate drugs as qualified infectious disease products under subsection (d) prior to the promulgation of regulations under this subsection.

''(f) QUALIFYING PATHOGEN.—

''(1) DEFINITION.—In this section, the term 'qualifying pathogen' means a pathogen identified and listed by the Secretary under paragraph (2) that has the potential to pose a serious threat to public health, such as—

''(A) resistant gram positive pathogens, including methicillin-resistant Staphylococcus aureus, vancomycin-resistant Staphylococcus aureus, and vancomycin-resistant enterococcus;

''(B) multi-drug resistant gram negative bacteria, including Acinetobacter, Klebsiella, Pseudomonas, and E. coli species;

''(C) multi-drug resistant tuberculosis; and

''(D) Clostridium difficile.

''(2) LIST OF QUALIFYING PATHOGENS.—

''(A) IN GENERAL.—The Secretary shall establish and maintain a list of qualifying pathogens, and shall make public the methodology for developing such list.

''(B) CONSIDERATIONS.—In establishing and maintaining the list of pathogens described under this section the Secretary shall—

''(i) consider—

''(I) the impact on the public health due to drug-resistant organisms in humans;

''(II) the rate of growth of drug-resistant organisms in humans;

''(III) the increase in resistance rates in humans; and

''(IV) the morbidity and mortality in humans; and

''(ii) consult with experts in infectious diseases and antibiotic resistance, including the Centers for Disease Control and Prevention, the Food and Drug Administration, medical professionals, and the clinical research community.

''(C) REVIEW.—Every 5 years, or more often as needed, the Secretary shall review, provide modifications to, and publish the list of qualifying pathogens under subparagraph (A) and shall by regulation revise the list as necessary, in accordance with subsection (e).

''(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term 'qualified infectious disease product' means an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by—

''(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

''(2) qualifying pathogens listed by the Secretary under subsection (f).''.

(b) APPLICATION.—Section 505E of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to a drug that is first approved under section 505(c) of such Act (21 U.S.C. 355(c)) on or after the date of the enactment of this Act.

SEC. 802. PRIORITY REVIEW.

(a) AMENDMENT.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 524 the following:

''SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.

''If the Secretary designates a drug under section 505E(d) as a qualified infectious disease product, then the Secretary shall give priority review to any application submitted for approval for such drug under section 505(b).''.

(b) APPLICATION.—Section 524A of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies only with respect to an application that is submitted under section 505(b) of such Act (21 U.S.C. 355(b)) on or after the date of the enactment of this Act.

SEC. 803. FAST TRACK PRODUCT.

Section 506(a)(1) (21 U.S.C. 356(a)(1)), as amended by section 901(b), is amended by inserting '', or if the Secretary designates the drug as a qualified infectious disease product under section 505E(d)'' before the period at the end of the first sentence.

SEC. 804. GAO STUDY.

(a) IN GENERAL.—The Comptroller General of the United States shall—

(1) conduct a study—

(A) on the need for, and public health impact of, incentives to encourage the research, development, and marketing of qualified infectious disease biological products and antifungal products; and

(B) consistent with trade and confidentiality data protections, assessing, for all antibacterial and antifungal drugs, including biological products, the average or aggregate—

(i) costs of all clinical trials for each phase;

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

(iii) public versus private funding levels of the trials for each phase; and

(2) not later than 1 year after the date of enactment of this Act, submit a report to Congress on the results of such study, including any recommendations of the Comptroller General on appropriate incentives for addressing such need.

(b) CONTENTS.—The part of the study described in subsection (a)(1)(A) shall include—

(1) an assessment of any underlying regulatory issues related to qualified infectious disease products, including qualified infectious disease biological products;

(2) an assessment of the management by the Food and Drug Administration of the review of qualified infectious disease products, including qualified infectious disease biological products and the regulatory certainty of related regulatory pathways for such products;

(3) a description of any regulatory impediments to the clinical development of new qualified infectious disease products, including qualified infectious disease biological products, and the efforts of the Food and Drug Administration to address such impediments; and

(4) recommendations with respect to—

(A) improving the review and predictability of regulatory pathways for such products; and

(B) overcoming any regulatory impediments identified in paragraph (3).

(c) DEFINITIONS.—In this section:

(1) The term ''biological product'' has the meaning given to such term in section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) The term ''qualified infectious disease biological product'' means a biological product intended to treat a serious or life-threatening infection described in section 505E(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 801.

(3) The term ''qualified infectious disease product'' has the meaning given such term in section 505E(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 801.

SEC. 805. CLINICAL TRIALS.

(a) REVIEW AND REVISION OF GUIDANCE DOCUMENTS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall review and, as appropriate, revise not fewer than 3 guidance documents per year, which shall include—

(A) reviewing the guidance documents of the Food and Drug Administration for the conduct of clinical trials with respect to antibacterial and antifungal drugs; and

(B) as appropriate, revising such guidance documents to reflect developments in scientific and medical information and technology and to ensure clarity regarding the procedures and requirements for approval of antibacterial and antifungal drugs under chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.).

(2) ISSUES FOR REVIEW.—At a minimum, the review under paragraph (1) shall address the appropriate animal models of infection, in vitro techniques, valid micro-biological surrogate markers, the use of non-inferiority versus superiority trials, trial enrollment, data requirements, and appropriate delta values for non-inferiority trials.

(3) RULE OF CONSTRUCTION.—Except to the extent to which the Secretary makes revisions under paragraph (1)(B), nothing in this section shall be construed to repeal or otherwise effect the guidance documents of the Food and Drug Administration.

(b) RECOMMENDATIONS FOR INVESTIGATIONS.—

(1) REQUEST.—The sponsor of a drug intended to be designated as a qualified infectious disease product may request that the Secretary provide written recommendations for nonclinical and clinical investigations which the Secretary believes may be necessary to be conducted with the drug before such drug may be approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in treating, detecting, preventing, or identifying a qualifying pathogen, as defined in section 505E of such Act.

(2) RECOMMENDATIONS.—If the Secretary has reason to believe that a drug for which a request is made under this subsection is a qualified infectious disease product, the Secretary shall provide the person making the request written recommendations for the nonclinical and clinical investigations which the Secretary believes, on the basis of information available to the Secretary at the time of the request, would be necessary for approval under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) of such drug for the use described in paragraph (1).

(c) GAO STUDY.—Not later than January 1, 2016, the Comptroller General of the United States shall submit to Congress a report—

(1) regarding the review and revision of the clinical trial guidance documents required under subsection (a) and the impact such review and revision has had on the review and approval of qualified infectious disease products;

(2) assessing—

(A) the effectiveness of the results-oriented metrics managers employ to ensure that reviewers of such products are familiar with, and consistently applying, clinical trial guidance documents; and

(B) the predictability of related regulatory pathways and review;

(3) identifying any outstanding regulatory impediments to the clinical development of qualified infectious disease products;

(4) reporting on the progress the Food and Drug Administration has made in addressing the impediments identified under paragraph (3); and

(5) containing recommendations regarding how to improve the review of, and regulatory pathway for, such products.

(d) QUALIFIED INFECTIOUS DISEASE PRODUCT.—For purposes of this section, the term ''qualified infectious disease product'' has the meaning given such term in section 505E(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 801.

SEC. 806. REGULATORY CERTAINTY AND PREDICTABILITY.

(a) INITIAL STRATEGY AND IMPLEMENTATION PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall submit to Congress a strategy and implementation plan with respect to the requirements of this Act. The strategy and implementation plan shall include—

(1) a description of the regulatory challenges to clinical development, approval, and licensure of qualified infectious disease products;

(2) the regulatory and scientific priorities of the Secretary with respect to such challenges; and

(3) the steps the Secretary will take to ensure regulatory certainty and predictability with respect to qualified infectious disease products, including steps the Secretary will take to ensure managers and reviewers are familiar with related regulatory pathways, requirements of the Food and Drug Administration, guidance documents related to such products, and applying such requirements consistently.

(b) SUBSEQUENT REPORT.—Not later than 3 years after the date of enactment of this Act, the Secretary shall submit to Congress a report on—

(1) the progress made toward the priorities identified under subsection (a)(2);

(2) the number of qualified infectious disease products that have been submitted for approval or licensure on or after the date of enactment of this Act;

(3) a list of qualified infectious disease products with information on the types of

exclusivity granted for each product, consistent with the information published under section 505(j)(7)(A)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)(A)(iii));

(4) the number of such qualified infectious disease products and that have been approved or licensed on or after the date of enactment of this Act; and

(5) the number of calendar days it took for the approval or licensure of the qualified infectious disease products approved or licensed on or after the date of enactment of this Act.

(c) QUALIFIED INFECTIOUS DISEASE PRODUCT.—For purposes of this section, the term ''qualified infectious disease product'' has the meaning given such term in section 505E(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 801.

TITLE IX—DRUG APPROVAL AND PATIENT ACCESS

SEC. 901. ENHANCEMENT OF ACCELERATED PATIENT ACCESS TO NEW MEDICAL TREATMENTS.

(a) FINDINGS; SENSE OF CONGRESS.—

(1) FINDINGS.—Congress finds as follows:

(A) The Food and Drug Administration (referred to in this section as the ''FDA'') serves a critical role in helping to assure that new medicines are safe and effective. Regulatory innovation is 1 element of the Nation's strategy to address serious and life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs.

(B) During the 2 decades following the establishment of the accelerated approval mechanism, advances in medical sciences, including genomics, molecular biology, and bioinformatics, have provided an unprecedented understanding of the underlying biological mechanism and pathogenesis of disease. A new generation of modern, targeted medicines is under development to treat serious and life-threatening diseases, some applying drug development strategies based on biomarkers or pharmacogenomics, predictive toxicology, clinical trial enrichment techniques, and novel clinical trial designs, such as adaptive clinical trials.

(C) As a result of these remarkable scientific and medical advances, the FDA should be encouraged to implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions, including those for rare diseases or conditions, using a broad range of surrogate or clinical endpoints and modern scientific tools earlier in the drug development cycle when appropriate. This may result in fewer, smaller, or shorter clinical trials for the intended patient population or targeted subpopulation without compromising or altering the high standards of the FDA for the approval of drugs.

(D) Patients benefit from expedited access to safe and effective innovative therapies to treat unmet medical needs for serious or life-threatening diseases or conditions.

(E) For these reasons, the statutory authority in effect on the day before the date of enactment of this Act governing expedited approval of drugs for serious or life-threatening diseases or conditions should be amended in order to enhance the authority of the FDA to consider appropriate scientific data, methods, and tools, and to expedite development and access to novel treatments for patients with a broad range of serious or life-threatening diseases or conditions.

(2) SENSE OF CONGRESS.—It is the sense of Congress that the Food and Drug Administration should apply the accelerated approval and fast track provisions set forth in section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), as amended by this section, to help expedite the development and availability to patients of treatments for serious or life-threatening diseases or conditions while maintaining safety and effectiveness standards for such treatments.

(b) EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.—Section 506 (21 U.S.C. 356) is amended to read as follows:

''SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

''(a) DESIGNATION OF DRUG AS FAST TRACK PRODUCT.—

''(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. (In this section, such a drug is referred to as a 'fast track product'.)

''(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

''(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

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

''(1) IN GENERAL.—

''(A) ACCELERATED APPROVAL.—The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product, under section 505(c) or section 351(a) of the Public Health Service Act upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. The approval described in the preceding sentence is referred to in this section as 'accelerated approval'.

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

''(2) LIMITATION.—Approval of a product under this subsection may be subject to 1 or both of the following requirements:

''(A) That the sponsor conduct appropriate post-approval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

''(B) That the sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

''(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

''(A) the sponsor fails to conduct any required post-approval study of the drug with due diligence;

''(B) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

''(C) other evidence demonstrates that the product is not safe or effective under the conditions of use; or

''(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

''(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

''(A) provides a schedule for submission of information necessary to make the application complete; and

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

''(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

''(d) AWARENESS EFFORTS.—The Secretary shall—

''(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to accelerated approval and fast track products; and

''(2) establish a program to encourage the development of surrogate and clinical endpoints, including biomarkers, and other scientific methods and tools that can assist the Secretary in determining whether the evidence submitted in an application is reasonably likely to predict clinical benefit for serious or life-threatening conditions for which significant unmet medical needs exist.

''(e) CONSTRUCTION.—

''(1) PURPOSE.—The amendments made by the Food and Drug Administration Safety and Innovation Act to this section are intended to encourage the Secretary to utilize innovative and flexible approaches to the assessment of products under accelerated approval for treatments for patients with serious or life-threatening diseases or conditions and unmet medical needs.

''(2) CONSTRUCTION.—Nothing in this section shall be construed to alter the standards

of evidence under subsection (c) or (d) of section 505 (including the substantial evidence standard in section 505(d)) of this Act or under section 351(a) of the Public Health Service Act. Such sections and standards of evidence apply to the review and approval of products under this section, including whether a product is safe and effective. Nothing in this section alters the ability of the Secretary to rely on evidence that does not come from adequate and well-controlled investigations for the purpose of determining whether an endpoint is reasonably likely to predict clinical benefit as described in subsection (b)(1)(B).''.

(c) GUIDANCE; AMENDED REGULATIONS.—

(1) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue draft guidance to implement the amendments made by this section. In developing such guidance, the Secretary shall specifically consider issues arising under the accelerated approval and fast track processes under section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), for drugs designated for a rare disease or condition under section 526 of such Act (21 U.S.C. 360bb) and shall also consider any unique issues associated with very rare diseases.

(2) FINAL GUIDANCE.—Not later than 1 year after the issuance of draft guidance under paragraph (1), and after an opportunity for public comment, the Secretary shall issue final guidance.

(3) CONFORMING CHANGES.—The Secretary shall issue, as necessary, conforming amendments to the applicable regulations under title 21, Code of Federal Regulations, governing accelerated approval.

(4) NO EFFECT OF INACTION ON REQUESTS.—If the Secretary fails to issue final guidance or amended regulations as required by this subsection, such failure shall not preclude the review of, or action on, a request for designation or an application for approval submitted pursuant to section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b).

(d) INDEPENDENT REVIEW.—The Secretary may, in conjunction with other planned reviews, contract with an independent entity with expertise in assessing the quality and efficiency of biopharmaceutical development and regulatory review programs to evaluate the Food and Drug Administration's application of the processes described in section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), and the impact of such processes on the development and timely availability of innovative treatments for patients suffering from serious or life-threatening conditions. Any such evaluation shall include consultation with regulated industries, patient advocacy and disease research foundations, and relevant academic medical centers.

SEC. 902. BREAKTHROUGH THERAPIES.

(a) IN GENERAL.—Section 506 (21 U.S.C. 356), as amended by section 901, is further amended—

(1) by redesignating subsections (a) through (c) as subsections (b) through (d), respectively;

(2) by redesignating subsection (d) as subsection (f);

(3) by inserting before subsection (b), as so redesignated, the following:

''(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH THERAPY.—

''(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of such drug if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. (In this section, such a drug is referred to as a 'breakthrough therapy'.)

''(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a breakthrough therapy. A request for the designation may be made concurrently with, or at any time after, the submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

''(3) DESIGNATION.—

''(A) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a breakthrough therapy and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

''(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

''(i) holding meetings with the sponsor and the review team throughout the development of the drug;

''(ii) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the non-clinical and clinical data necessary for approval is as efficient as practicable;

''(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

''(iv) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

''(v) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.'';

(4) in subsection (f)(1), as so redesignated, by striking ''applicable to accelerated approval'' and inserting ''applicable to breakthrough therapies, accelerated approval, and''; and

(5) by adding at the end the following:

''(g) REPORT.—Beginning in fiscal year 2013, the Secretary shall annually prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make publicly available, with respect to this section for the previous fiscal year—

''(1) the number of drugs for which a sponsor requested designation as a breakthrough therapy;

''(2) the number of products designated as a breakthrough therapy; and

''(3) for each product designated as a breakthrough therapy, a summary of the actions taken under subsection (a)(3).''.

(b) GUIDANCE; AMENDED REGULATIONS.—

(1) IN GENERAL.—

(A) GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue draft guidance on implementing the requirements with respect to breakthrough therapies, as set forth in section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)), as amended by this section. The Secretary shall issue final guidance not later than 1 year after the close of the comment period for the draft guidance.

(B) AMENDED REGULATIONS.—

(i) IN GENERAL.—If the Secretary determines that it is necessary to amend the regulations under title 21, Code of Federal Regulations in order to implement the amendments made by this section to section 506(a) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall amend such regulations not later than 2 years after the date of enactment of this Act.

(ii) PROCEDURE.—In amending regulations under clause (i), the Secretary shall—

(I) issue a notice of proposed rulemaking that includes the proposed regulation;

(II) provide a period of not less than 60 days for comments on the proposed regulation; and

(III) publish the final regulation not less than 30 days before the effective date of the regulation.

(iii) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing the amendments made by section only as described in clause (ii).

(2) REQUIREMENTS.—Guidance issued under this section shall—

(A) specify the process and criteria by which the Secretary makes a designation under section 506(a)(3) of the Federal Food, Drug, and Cosmetic Act; and

(B) specify the actions the Secretary shall take to expedite the development and review of a breakthrough therapy pursuant to such designation under such section 506(a)(3), including updating good review management practices to reflect breakthrough therapies.

(c) INDEPENDENT REVIEW.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States, in consultation with appropriate experts, shall assess the manner by which the Food and Drug Administration has applied the processes described in section 506(a) of the Federal Food, Drug, and Cosmetic Act, as amended by this section, and the impact of such processes on the development and timely availability of innovative treatments for patients affected by serious or life-threatening conditions. Such assessment shall be made publicly available upon completion.

(d) CONFORMING AMENDMENTS.—Section 506B(e) (21 U.S.C. 356b) is amended by striking ''section 506(b)(2)(A)'' each place such term appears and inserting ''section 506(c)(2)(A)''.

SEC. 903. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by section 712, is further amended by adding at the end the following:

''SEC. 569. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

''(a) IN GENERAL.—For the purpose of promoting the efficiency of and informing the review by the Food and Drug Administration of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, the following shall apply:

''(1) CONSULTATION WITH STAKEHOLDERS.—Consistent with sections X.C and IX.E.4 of the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, as referenced in the letters described in section 101(b) of the Prescription

Drug User Fee Amendments of 2012, the Secretary shall ensure that opportunities exist, at a time the Secretary determines appropriate, for consultations with stakeholders on the topics described in subsection (c).

''(2) CONSULTATION WITH EXTERNAL EXPERTS.—The Secretary shall develop and maintain a list of external experts who, because of their special expertise, are qualified to provide advice on rare disease issues, including topics described in subsection (c). The Secretary may, when appropriate to address a specific regulatory question, consult such external experts on issues related to the review of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, including the topics described in subsection (c), when such consultation is necessary because the Secretary lacks specific scientific, medical, or technical expertise necessary for the performance of its regulatory responsibilities and the necessary expertise can be provided by the external experts.

''(b) EXTERNAL EXPERTS.—For purposes of subsection (a)(2), external experts are those who possess scientific or medical training that the Secretary lacks with respect to one or more rare diseases.

''(c) TOPICS FOR CONSULTATION.—Topics for consultation pursuant to this section may include—

''(1) rare diseases;

''(2) the severity of rare diseases;

''(3) the unmet medical need associated with rare diseases;

''(4) the willingness and ability of individuals with a rare disease to participate in clinical trials;

''(5) an assessment of the benefits and risks of therapies to treat rare diseases;

''(6) the general design of clinical trials for rare disease populations and subpopulations; and

''(7) demographics and the clinical description of patient populations.

''(d) CLASSIFICATION AS SPECIAL GOVERNMENT EMPLOYEES.—The external experts who are consulted under this section may be considered special government employees, as defined under section 202 of title 18, United States Code.

''(e) PROTECTION OF PROPRIETARY INFORMATION.—Nothing in this section shall be construed to alter the protections offered by laws, regulations, and policies governing disclosure of confidential commercial or trade secret information, and any other information exempt from disclosure pursuant to section 552(b) of title 5, United States Code, as such provisions would be applied to consultation with individuals and organizations prior to the date of enactment of this section.

''(f) OTHER CONSULTATION.—Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals and organizations as authorized prior to the date of enactment of this section.

''(g) NO RIGHT OR OBLIGATION.—Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder. Nothing in this section shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012. Nothing in this section is intended to increase the number of review cycles as in effect before the date of enactment of this section.''.

SEC. 904. ACCESSIBILITY OF INFORMATION ON PRESCRIPTION DRUG CONTAINER LABELS BY VISUALLY-IMPAIRED AND BLIND CONSUMERS.

(a) ESTABLISHMENT OF WORKING GROUP.—

(1) IN GENERAL.—The Architectural and Transportation Barriers Compliance Board (referred to in this section as the ''Access Board'') shall convene a stakeholder working group (referred to in this section as the ''working group'') to develop best practices on access to information on prescription drug container labels for individuals who are blind or visually impaired.

(2) MEMBERS.—The working group shall be comprised of representatives of national organizations representing blind and visually-impaired individuals, national organizations representing the elderly, and industry groups representing stakeholders, including retail, mail order, and independent community pharmacies, who would be impacted by such best practices. Representation within the working group shall be divided equally between consumer and industry advocates.

(3) BEST PRACTICES.—

(A) IN GENERAL.—The working group shall develop, not later than 1 year after the date of the enactment of this Act, best practices for pharmacies to ensure that blind and visually-impaired individuals have safe, consistent, reliable, and independent access to the information on prescription drug container labels.

(B) PUBLIC AVAILABILITY.—The best practices developed under subparagraph (A) may be made publicly available, including through the Internet websites of the working group participant organizations, and through other means, in a manner that provides access to interested individuals, including individuals with disabilities.

(C) LIMITATIONS.—The best practices developed under subparagraph (A) shall not be construed as accessibility guidelines or standards of the Access Board, and shall not confer any rights or impose any obligations on working group participants or other persons. Nothing in this section shall be construed to limit or condition any right, obligation, or remedy available under the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.) or any other Federal or State law requiring effective communication, barrier removal, or nondiscrimination on the basis of disability.

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

(A) the use of—

(i) Braille;

(ii) auditory means, such as—

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

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

(III) radio frequency identification tags;

(iii) enhanced visual means, such as—

(I) large font labels or large font ''duplicate'' labels that are affixed or matched to a prescription drug container;

(II) high-contrast printing; and

(III) sans-serf font; and

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

(B) whether there are technical, financial, manpower, or other factors unique to pharmacies with 20 or fewer retail locations which may pose significant challenges to the adoption of the best practices; and

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

(5) INFORMATION CAMPAIGN.—Upon completion of development of the best practices under subsection (a)(3), the National Council on Disability, in consultation with the working group, shall conduct an informational and educational campaign designed to inform individuals with disabilities, pharmacists, and the public about such best practices.

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

(b) GAO STUDY.—

(1) IN GENERAL.—Beginning 18 months after the completion of the development of best practices under subsection (a)(3)(A), the Comptroller General of the United States shall conduct a review of the extent to which pharmacies are utilizing such best practices, and the extent to which barriers to accessible information on prescription drug container labels for blind and visually-impaired individuals continue.

(2) REPORT.—Not later than September 30, 2016, the Comptroller General of the United States shall submit to Congress a report on the review conducted under paragraph (1). Such report shall include recommendations about how best to reduce the barriers experienced by blind and visually-impaired individuals to independently accessing information on prescription drug container labels.

(c) DEFINITIONS.—In this section—

(1) the term ''pharmacy'' includes a pharmacy that receives prescriptions and dispenses prescription drugs through an Internet website or by mail;

(2) the term ''prescription drug'' means a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and

(3) the term ''prescription drug container label'' means the label with the directions for use that is affixed to the prescription drug container by the pharmacist and dispensed to the consumer.

SEC. 905. RISK-BENEFIT FRAMEWORK.

Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: ''The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for premarket approval of a drug.''.

SEC. 906. INDEPENDENT STUDY ON MEDICAL INNOVATION INDUCEMENT MODEL.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into an agreement with the National Academies to provide expert consultation and conduct a study that evaluates the feasibility and possible consequences of the use of innovation inducement prizes to reward successful medical innovations. Under the agreement, the National Academies shall submit to the Secretary a report on such study not later than 15 months after the date of enactment of this Act.

(b) REQUIREMENTS.—

(1) IN GENERAL.—The study conducted under subsection (a) shall model at least 3 separate segments on the medical technologies market as candidate targets for the new incentive system and consider different medical innovation inducement prize design issues, including the challenges presented in the implementation of prizes for end products, open source dividend prizes, and prizes for upstream research.

(2) MARKET SEGMENTS.—The segments on the medical technologies market that shall be considered under paragraph (1) include—

(A) all pharmaceutical and biologic drugs and vaccines;

(B) drugs and vaccines used solely for the treatment of HIV/AIDS; and

(C) antibiotics.

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

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

(2) How large the innovation prize funds would have to be in order to induce at least as much research and development investment in innovation as is induced under the current system of time-limited market exclusivity, as in effect on the date of enactment of this Act.

(3) Whether a system of large innovation inducement prizes would be more or less expensive than the current system of time-limited market exclusivity, as in effect on the date of enactment of this Act, calculated over different time periods.

(4) Whether a system of large innovation inducement prizes would expand access to new products and improve health outcomes.

(5) The type of information and decision-making skills that would be necessary to manage end product prizes.

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

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

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

SEC. 907. ORPHAN PRODUCT GRANTS PROGRAM.

(a) REAUTHORIZATION OF PROGRAM.—Section 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended by striking ''2008 through 2012'' and inserting ''2013 through 2017''.

(b) HUMAN CLINICAL TESTING.—Section 5(b)(1)(A)(ii)) of the Orphan Drug Act (21 U.S.C. 360ee(b)(1)(A)(ii)) is amended by striking ''after the date such drug is designated under section 526 of such Act and''.

SEC. 908. REPORTING OF INCLUSION OF DEMOGRAPHIC SUBGROUPS IN CLINICAL TRIALS AND DATA ANALYSIS IN APPLICATIONS FOR DRUGS, BIOLOGICS, AND DEVICES.

(a) REPORT.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner, shall publish on the Internet website of the Food and Drug Administration a report, consistent with the regulations of the Food and Drug Administration pertaining to the protection of sponsors' confidential commercial information as of the date of enactment of this Act, addressing the extent to which clinical trial participation and the inclusion of safety and effectiveness data by demographic subgroups including sex, age, race, and ethnicity, is included in applications submitted to the Food and Drug Administration, and shall provide such publication to Congress.

(2) CONTENTS OF REPORT.—The report described in paragraph (1) shall contain the following:

(A) A description of existing tools to ensure that data to support demographic analyses are submitted in applications for drugs, biological products, and devices, and that these analyses are conducted by applicants consistent with applicable Food and Drug Administration requirements and Guidance for Industry. The report shall address how the Food and Drug Administration makes available information about differences in safety and effectiveness of medical products according to demographic subgroups, such as sex, age, racial, and ethnic subgroups, to healthcare providers, researchers, and patients.

(B) An analysis of the extent to which demographic data subset analyses on sex, age, race, and ethnicity is presented in applications for new drug applications for new molecular entities under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), in biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262), and in premarket approval applications under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) for products approved or licensed by the Food and Drug Administration, consistent with applicable requirements and Guidance for Industry, and consistent with the regulations of the Food and Drug Administration pertaining to the protection of sponsors' confidential commercial information as of the date of enactment of this Act.

(C) An analysis of the extent to which demographic subgroups, including sex, age, racial, and ethnic subgroups, are represented in clinical studies to support applications for approved or licensed new molecular entities, biological products, and devices.

(D) An analysis of the extent to which a summary of product safety and effectiveness data by demographic subgroups including sex, age, race, and ethnicity is readily available to the public in a timely manner by means of the product labeling or the Food and Drug Administration's Internet website.

(b) ACTION PLAN.—

(1) IN GENERAL.—Not later than 1 year after the publication of the report described in subsection (a), the Secretary, acting through the Commissioner, shall publish an action plan on the Internet website of the Food and Drug Administration, and provide such publication to Congress.

(2) CONTENT OF ACTION PLAN.—The plan described in paragraph (1) shall include—

(A) recommendations, as appropriate, to improve the completeness and quality of analyses of data on demographic subgroups in summaries of product safety and effectiveness data and in labeling;

(B) recommendations, as appropriate, on the inclusion of such data, or the lack of availability of such data in labeling;

(C) recommendations, as appropriate, to otherwise improve the public availability of such data to patients, healthcare providers, and researchers; and

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

(c) DEFINITIONS.—In this section:

(1) The term ''Commissioner'' means the Commissioner of Food and Drugs.

(2) The term ''device'' has the meaning given such term in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(3) The term ''drug'' has the meaning given such term in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)).

(4) The term ''biological product'' has the meaning given such term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(5) The term ''Secretary'' means the Secretary of Health and Human Services.

TITLE X—DRUG SHORTAGES

SEC. 1001. DRUG SHORTAGES.

(a) IN GENERAL.—Section 506C (21 U.S.C. 356c) is amended to read as follows:

''SEC. 506C. DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF LIFE-SAVING DRUGS.

''(a) IN GENERAL.—A manufacturer of a drug—

''(1) that is—

''(A) life-supporting;

''(B) life-sustaining;

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

''(D) a sterile injectable product; or

''(E) used in emergency medical care or during surgery; and

''(2) that is not a radio pharmaceutical drug product, a human tissue replaced by a recombinant product, a product derived from human plasma protein, or any other product as designated by the Secretary,

shall notify the Secretary, in accordance with subsection (b), of a permanent discontinuance in the manufacture of the drug or an interruption of the manufacture of the drug that could lead to a meaningful disruption in the supply of that drug in the United States.

''(b) TIMING.—A notice required under subsection (a) shall be submitted to the Secretary—

''(1) at least 6 months prior to the date of the discontinuance or interruption; or

''(2) if compliance with paragraph (1) is not possible, as soon as practicable.

''(c) EXPEDITED INSPECTIONS AND REVIEWS.—If, based on notifications described in subsection (a) or any other relevant information, the Secretary concludes that there is, or is likely to be, a drug shortage of a drug described in subsection (a), the Secretary may—

''(1) expedite the review of a supplement to a new drug application submitted under section 505(b), an abbreviated new drug application submitted under section 505(j), or a supplement to such an application submitted under section 505(j) that could help mitigate or prevent such shortage; or

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

''(d) COORDINATION.—

''(1) TASK FORCE AND STRATEGIC PLAN.—

''(A) IN GENERAL.—

''(i) TASK FORCE.—As soon as practicable after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall establish a Task Force to develop and implement a strategic plan for enhancing the Secretary's response to preventing and mitigating drug shortages.

''(ii) STRATEGIC PLAN.—The strategic plan described in clause (i) shall include—

''(I) plans for enhanced interagency and intraagency coordination, communication, and decisionmaking;

''(II) plans for ensuring that drug shortages are considered when the Secretary initiates a regulatory action that could precipitate a drug shortage or exacerbate an existing drug shortage;

''(III) plans for effective communication with outside stakeholders, including who the Secretary should alert about potential or actual drug shortages, how the communication should occur, and what types of information should be shared; and

''(IV) plans for considering the impact of drug shortages on research and clinical trials.

''(iii) CONSULTATION.—In carrying out this subparagraph, the Task Force shall ensure consultation with the appropriate offices within the Food and Drug Administration, including the Office of the Commissioner, the Center for Drug Evaluation and Research, the Office of Regulatory Affairs, and employees within the Department of Health and Human Services with expertise regarding drug shortages. The Secretary shall engage external stakeholders and experts as appropriate.

''(B) TIMING.—Not later than 1 year after the date of enactment Food and Drug Administration Safety and Innovation Act, the Task Force shall—

''(i) publish the strategic plan described in subparagraph (A); and

''(ii) submit such plan to Congress.

''(2) COMMUNICATION.—The Secretary shall ensure that, prior to any enforcement action

or issuance of a warning letter that the Secretary determines could reasonably be anticipated to lead to a meaningful disruption in the supply in the United States of a drug described under subsection (a), there is communication with the appropriate office of the Food and Drug Administration with expertise regarding drug shortages regarding whether the action or letter could cause, or exacerbate, a shortage of the drug.

''(3) ACTION.—If the Secretary determines, after the communication described in paragraph (2), that an enforcement action or a warning letter could reasonably cause or exacerbate a shortage of a drug described under subsection (a), then the Secretary shall evaluate the risks associated with the impact of such shortage upon patients and those risks associated with the violation involved before taking such action or issuing such letter, unless there is imminent risk of serious adverse health consequences or death to humans.

''(4) REPORTING BY OTHER ENTITIES.—The Secretary shall identify or establish a mechanism by which healthcare providers and other third-party organizations may report to the Secretary evidence of a drug shortage.

''(5) REVIEW AND CONSTRUCTION.—No determination, finding, action, or omission of the Secretary under this subsection shall—

''(A) be subject to judicial review; or

''(B) be construed to establish a defense to an enforcement action by the Secretary.

''(e) RECORDKEEPING AND REPORTING.—

''(1) RECORDKEEPING.—The Secretary shall maintain records related to drug shortages, including with respect to each of the following:

''(A) The number of manufacturers that submitted a notification to the Secretary under subsection (a) in each calendar year.

''(B) The number of drug shortages that occurred in each calendar year and a list of drug names, drug types, and classes that were the subject of such shortages.

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

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

''(ii) The Secretary shall include in the list under clause (i) the following:

''(I) The number of applications for which the Secretary expedited review under subsection (c)(1) in each calendar year.

''(II) The number of establishment inspections or reinspections that the Secretary expedited under subsection (c)(2) in each calendar year.

''(E) The number of notifications submitted to the Secretary under subsection (a) in each calendar year.

''(F) The names of manufacturers that the Secretary has learned did not comply with the notification requirement under subsection (a) in each calendar year.

''(G) The number of times in each calendar year that the Secretary determined under subsection (d)(3) that an enforcement action or a warning letter could reasonably cause or exacerbate a shortage of a drug described under subsection (a), but did not evaluate the risks associated with the impact of such shortage upon patients and those risks associated with the violation involved before taking such action or issuing such letter on the grounds that there was imminent risk of serious adverse health consequences or death to humans, and a summary of the determinations.

''(H) A summary of the communications made and actions taken under subsection (d) in each calendar year.

''(I) Any other information the Secretary deems appropriate to better prevent and mitigate drug shortages.

''(2) TREND ANALYSIS.—The Secretary is authorized to retain a third party to conduct a study, if the Secretary believes such a study would help clarify the causes, trends, or solutions related to drug shortages.

''(3) ANNUAL SUMMARY.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report summarizing, with respect to the 1-year period preceding such report, the information described in paragraph (1). Such report shall not include any information that is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section.

''(f) DEFINITIONS.—For purposes of this section—

''(1) the term 'drug'—

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

''(B) does not include biological products (as defined in section 351 of the Public Health Service Act), unless otherwise provided by the Secretary in the regulations promulgated under subsection (h);

''(2) the term 'drug shortage' or 'shortage', with respect to a drug, means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug; and

''(3) the term 'meaningful disruption'—

''(A) means a change in production that is reasonably likely to lead to a reduction in the supply of a drug by a manufacturer that is more than negligible and impacts the ability of the manufacturer to fill orders or meet expected demand for its product; and

''(B) does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

''(g) DISTRIBUTION.—To the maximum extent practicable, the Secretary may distribute information on drug shortages and on the permanent discontinuation of the drugs described in this section to appropriate provider and patient organizations, except that any such distribution shall not include any information that is exempt from disclosure under section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section.

''(h) REGULATIONS.—

''(1) IN GENERAL.—Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt a final regulation implementing this section.

''(2) INCLUSION OF BIOLOGICAL PRODUCTS.—

''(A) IN GENERAL.—The Secretary may by regulation apply this section to biological products (as defined in section 351 of the Public Health Service Act) if the Secretary determines such inclusion would benefit the public health.

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

''(i) consider whether the notification requirement under subsection (a) may be satisfied by submitting a notification to the Centers for Disease Control and Prevention under the vaccine shortage notification program of such Centers; and

''(ii) explain the determination made by the Secretary under clause (i) in the regulation.

''(3) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

''(A) issue a notice of proposed rulemaking that includes the proposed regulation;

''(B) provide a period of not less than 60 days for comments on the proposed regulation; and

''(C) publish the final regulation not less than 30 days before the regulation's effective date.

''(4) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing this section, the Secretary shall only promulgate regulations as described in paragraph (3).''.

(b) EFFECT OF NOTIFICATION.—The submission of a notification to the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') for purposes of complying with the requirement in section 506C(a) of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)) shall not be construed—

(1) as an admission that any product that is the subject of such notification violates any provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

(2) as evidence of an intention to promote or market the product for an indication or use for which the product has not been approved by the Secretary.

(c) INTERNAL REVIEW.—Not later than 2 years after the date of enactment of this Act, the Secretary shall—

(1) analyze and review the regulations promulgated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the guidances or policies issued under such Act related to drugs intended for human use, and the practices of the Food and Drug Administration regarding enforcing such Act related to manufacturing of such drugs, to identify any such regulations, guidances, policies, or practices that cause, exacerbate, prevent, or mitigate drug shortages (as defined in section 506C of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)); and

(2) determine how regulations, guidances, policies, or practices identified under paragraph (1) should be modified, streamlined, expanded, or discontinued in order to reduce or prevent such drug shortages, taking into consideration the effect of any changes on the public health.

(d) STUDY ON MARKET FACTORS CONTRIBUTING TO DRUG SHORTAGES AND STOCKPILING.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States, in consultation with the Secretary, the Department of Health and Human Services Office of the Inspector General, the Attorney General, and Chairman of the Federal Trade Commission, shall publish a report reviewing any findings that drug shortages (as so defined) have led market participants to stockpile affected drugs or sell them at significantly increased prices, the impact of such activities on Federal revenue, and any economic factors that have exacerbated or created a market for such actions.

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

(A) an analysis of the incidence of any of the activities described in paragraph (1) and the effect of such activities on the public health;

(B) an evaluation of whether in such cases there is a correlation between drugs in shortage and—

(i) the number of manufacturers producing such drugs;

(ii) the pricing structure, including Federal reimbursements, for such drugs before such drugs were in shortage, and to the extent possible, revenue received by each such manufacturer of such drugs;

(iii) pricing structure and revenue, to the extent possible, for the same drugs when sold under the conditions described in paragraph (1); and

(iv) the impact of contracting practices by market participants (including manufacturers, distributors, group purchasing organizations, and providers) on competition, access to drugs, and pricing of drugs;

(C) whether the activities described in paragraph (1) are consistent with applicable law; and

(D) recommendations to Congress on what, if any, additional reporting or enforcement actions are necessary.

(3) TRADE SECRET AND CONFIDENTIAL INFORMATION.—Nothing in this subsection alters or amends section 1905 of title 18, United States Code, or section 552(b)(4) of title 5, United States Code.

(e) GUIDANCE REGARDING REPACKAGING.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue guidance that clarifies the policy of the Food and Drug Administration regarding hospital pharmacies repackaging and safely transferring repackaged drugs among hospitals within a common health system during a drug shortage, as identified by the Secretary.

TITLE XI—OTHER PROVISIONS

Subtitle A—Reauthorizations

SEC. 1101. REAUTHORIZATION OF PROVISION RELATING TO EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

(a) IN GENERAL.—Section 505(u)(4) (21 U.S.C. 355(u)(4)) is amended by striking ''2012'' and inserting ''2017''.

(b) AMENDMENT.—Section 505(u)(1)(A)(ii)(II) (21 U.S.C. 355(u)(1)(A)(ii)(II)) is amended by inserting ''clinical'' after ''any''.

SEC. 1102. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

Section 566(f) (21 U.S.C. 360bbb–5(f)) is amended by striking ''2012'' and inserting ''2017''.

Subtitle B—Medical Gas Product Regulation

SEC. 1111. REGULATION OF MEDICAL GAS PRODUCTS.

(a) REGULATION.—Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter G—Medical Gas Products

''SEC. 575. DEFINITIONS.

''In this subchapter:

''(1) The term 'designated medical gas product' means any of the following:

''(A) Oxygen, that meets the standards set forth in an official compendium.

''(B) Nitrogen, that meets the standards set forth in an official compendium.

''(C) Nitrous oxide, that meets the standards set forth in an official compendium.

''(D) Carbon dioxide, that meets the standards set forth in an official compendium.

''(E) Helium, that meets the standards set forth in an official compendium.

''(F) Carbon monoxide, that meets the standards set forth in an official compendium.

''(G) Medical air, that meets the standards set forth in an official compendium.

''(H) Any other medical gas product deemed appropriate by the Secretary, unless any period of exclusivity under section 505(c)(3)(E)(ii) or 505(j)(5)(F)(ii), or the extension of any such period under section 505A, applicable to such medical gas product has not expired.

''(2) The term 'medical gas product' means a drug that—

''(A) is manufactured or stored in a liquefied, nonliquefied, or cryogenic state; and

''(B) is administered as a gas.

''SEC. 576. REGULATION OF MEDICAL GAS PRODUCTS.

''(a) CERTIFICATION OF DESIGNATED MEDICAL GAS PRODUCTS.—

''(1) SUBMISSION.—

''(A) IN GENERAL.—Beginning on the date of enactment of this section, any person may file with the Secretary a request for a certification of a designated medical gas product.

''(B) CONTENT.—A request under subparagraph (A) shall contain—

''(i) a description of the medical gas product;

''(ii) the name and address of the sponsor;

''(iii) the name and address of the facility or facilities where the gas product is or will be manufactured; and

''(iv) any other information deemed appropriate by the Secretary to determine whether the medical gas product is a designated medical gas product.

''(2) GRANT OF CERTIFICATION.—A certification described under paragraph (1)(A) shall be determined to have been granted unless, not later than 60 days after the filing of a request under paragraph (1), the Secretary finds that—

''(A) the medical gas product subject to the certification is not a designated medical gas product;

''(B) the request does not contain the information required under paragraph (1) or otherwise lacks sufficient information to permit the Secretary to determine that the gas product is a designated medical gas product; or

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

''(3) EFFECT OF CERTIFICATION.—

''(A) IN GENERAL.—

''(i) APPROVED USES.—A designated medical gas product for which a certification is granted under paragraph (2) is deemed, alone or in combination with another designated gas product or products as medically appropriate, to have in effect an approved application under section 505 or 512, subject to all applicable postapproval requirements, for the following indications for use:

''(I) Oxygen for the treatment or prevention of hypoxemia or hypoxia.

''(II) Nitrogen for use in hypoxic challenge testing.

''(III) Nitrous oxide for analgesia.

''(IV) Carbon dioxide for use in extracorporeal membrane oxygenation therapy or respiratory stimulation.

''(V) Helium for the treatment of upper airway obstruction or increased airway resistance.

''(VI) Medical air to reduce the risk of hyperoxia.

''(VII) Carbon monoxide for use in lung diffusion testing.

''(VIII) Any other indication for use for a designated medical gas product or combination of designated medical gas products deemed appropriate by the Secretary, unless any period of exclusivity under clause (iii) or (iv) of section 505(c)(3)(E), under clause (iii) or (iv) of section 505(j)(5)(F), or under section 527, or the extension of any such period under section 505A, applicable to such indication for use for such gas product or combination of products has not expired.

''(ii) LABELING.—The requirements established in sections 503(b)(4) and 502(f) shall be deemed to have been met for a designated medical gas product if the labeling on final use containers of such gas product bears the information required by section 503(b)(4) and a warning statement concerning the use of the gas product, as determined by the Secretary by regulation, as well as appropriate directions and warnings concerning storage and handling.

''(B) INAPPLICABILITY OF EXCLUSIVITY PROVISIONS.—

''(i) EFFECT ON INELIGIBILITY.—No designated medical gas product deemed under paragraph (3)(A)(i) to have in effect an approved application shall be eligible for any periods of exclusivity under sections 505(c), 505(j), or 527, or the extension of any such period under section 505A, on the basis of such deemed approval.

''(ii) EFFECT ON CERTIFICATION.—No period of exclusivity under sections 505(c), 505(j), or section 527, or the extension of any such period under section 505A, with respect to an application for a drug shall prohibit, limit, or otherwise affect the submission, grant, or effect of a certification under this section, except as provided in paragraph (3)(A)(i)(VIII).

''(4) WITHDRAWAL, SUSPENSION, OR REVOCATION OF APPROVAL.—

''(A) IN GENERAL.—Nothing in this subchapter limits the authority of the Secretary to withdraw or suspend approval of a drug, including a designated medical gas product deemed under this section to have in effect an approved application, under section 505 or section 512.

''(B) REVOCATION.—The Secretary may revoke the grant of a certification under this section if the Secretary determines that the request for certification contains any material omission or falsification.

''(b) PRESCRIPTION REQUIREMENT.—

''(1) IN GENERAL.—A designated medical gas product shall be subject to section 503(b)(1) unless the Secretary exercises the authority provided in section 503(b)(3) to remove such gas product from the requirements of section 503(b)(1) or the use in question is authorized pursuant to another provision of this Act relating to use of medical products in emergencies.

''(2) EXCEPTION FOR OXYGEN.—

''(A) IN GENERAL.—Notwithstanding paragraph (1), oxygen may be provided without a prescription for the following uses:

''(i) The use in the event of depressurization or other environmental oxygen deficiency.

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

''(B) LABELING.—For oxygen provided pursuant to subparagraph (A), the requirements established in section 503(b)(4) shall be deemed to have been met if the labeling of the oxygen bears a warning that the medical gas product can be used for emergency use only and for all other medical applications a prescription is required.

''(c) INAPPLICABILITY OF DRUGS FEES TO DESIGNATED MEDICAL GAS PRODUCTS.—A designated medical gas product deemed under this section to have in effect an approved application shall not be assessed fees under section 736(a) on the basis of such deemed approval.''.

SEC. 1112. REGULATIONS.

(a) REVIEW OF REGULATIONS.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall, after obtaining input from medical gas product manufacturers, and any other interested members of the public, submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding any changes to the Federal drug regulations in title 21, Code of Federal Regulations that the Secretary determines to be necessary.

(b) AMENDED REGULATIONS.—If the Secretary determines that changes to the Federal drug regulations in title 21, Code of Federal Regulations are necessary under subsection (a), the Secretary shall issue final regulations implementing such changes not later than 4 years after the date of enactment of this Act.

SEC. 1113. APPLICABILITY.

Nothing in this subtitle or the amendments made by this subtitle shall apply to—

(1) a drug that is covered by an application under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360b) approved prior to May 1, 2012; or

(2) any of the gases listed in subparagraphs (A) through (G) of section 575(1) of such Act (as added by section 1111), or any mixture of any such gases, for an indication that—

(A) is not included in, or is different from, those specified in subclauses (I) through (VII) of section 576(a)(3)(i) of such Act (as added by section 1111); and

(B) is approved on or after May 1, 2012, pursuant to an application submitted under section 505 or 512 of such Act.

Subtitle C—Miscellaneous Provisions

SEC. 1121. ADVISORY COMMITTEE CONFLICTS OF INTEREST.

Section 712 (21 U.S.C. 379d–1) is amended—

(1) in subsection (b)—

(A) by striking paragraph (2); and

(B) in paragraph (1)—

(i) by redesignating subparagraph (B) as paragraph (2) and moving such paragraph, as so redesignated, 2 ems to the left;

(ii) in subparagraph (A), by redesignating clauses (i) through (iii) as subparagraphs (A) through (C), respectively, and moving such subparagraphs, as so redesignated, 2 ems to the left;

(iii) in subparagraph (A), as so redesignated, by inserting '', including strategies to increase the number of special Government employees across medical and scientific specialties in areas where the Secretary would benefit from specific scientific, medical, or technical expertise necessary for the performance of its regulatory responsibilities'' before the semicolon at the end;

(iv) by striking ''(1) RECRUITMENT.—'' and inserting ''(1) RECRUITMENT IN GENERAL.—The Secretary shall—'';

(v) by striking ''(A) IN GENERAL.—The Secretary shall—'';

(vi) by redesignating clauses (i) through (iii) of paragraph (2) (as so redesignated) as subparagraphs (A) through (C), respectively, and moving such subparagraphs, as so redesignated, 2 ems to the left;

(vii) in paragraph (2) (as so redesignated), in the matter before subparagraph (A) (as so redesignated), by striking ''subparagraph (A)'' and inserting ''paragraph (1)''; and

(viii) by adding at the end the following:

''(3) RECRUITMENT THROUGH REFERRALS.—In carrying out paragraph (1), the Secretary shall, in order to further the goal of including in advisory committees highly qualified and specialized experts in the specific diseases to be considered by such advisory committees, at least every 180 days, request referrals from a variety of stakeholders, such as the Institute of Medicine, the National Institutes of Health, product developers, patient groups, disease advocacy organizations, professional societies, medical societies, including the American Academy of Medical Colleges, and other governmental organizations.'';

(2) by amending subsection (c)(2)(C) to read as follows:

''(C) CONSIDERATION BY SECRETARY.—The Secretary shall ensure that each determination made under subparagraph (B) considers the type, nature, and magnitude of the financial interests at issue and the public health interest in having the expertise of the member with respect to the particular matter before the advisory committee.'';

(3) in subsection (e), by inserting '', and shall make publicly available,'' after ''House of Representatives''; and

(4) by adding at the end the following:

''(g) GUIDANCE ON REPORTED FINANCIAL INTEREST OR INVOLVEMENT.—The Secretary shall issue guidance that describes how the Secretary reviews the financial interests and involvement of advisory committee members that are reported under subsection (c)(1) but that the Secretary determines not to meet the definition of a disqualifying interest under section 208 of title 18, United States Code for the purposes of participating in a particular matter.''.

SEC. 1122. GUIDANCE DOCUMENT REGARDING PRODUCT PROMOTION USING THE INTERNET.

Not later than 2 years after the date of enactment this Act, the Secretary of Health and Human Services shall issue guidance that describes Food and Drug Administration policy regarding the promotion, using the Internet (including social media), of medical products that are regulated by such Administration.

SEC. 1123. ELECTRONIC SUBMISSION OF APPLICATIONS.

Subchapter D of chapter VII (21 U.S.C. 379k et seq.) is amended by inserting after section 745 the following:

''SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.

''(a) DRUGS AND BIOLOGICS.—

''(1) IN GENERAL.—Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for comment, submissions under subsection (b), (i), or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act shall be submitted in such electronic format as specified by the Secretary in such guidance.

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

''(A) provide a timetable for establishment by the Secretary of further standards for electronic submission as required by such paragraph; and

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

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

''(b) DEVICES.—

''(1) IN GENERAL.—Beginning after the issuance of final guidance implementing this paragraph, pre-submissions and submissions for devices under section 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of this Act or section 351 of the Public Health Service Act, and any supplements to such pre-submissions or submissions, shall include an electronic copy of such pre-submissions or submissions.

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

''(A) provide standards for the electronic copy required under such paragraph; and

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

SEC. 1124. COMBATING PRESCRIPTION DRUG ABUSE.

(a) IN GENERAL.—To combat the significant rise in prescription drug abuse and the consequences of such abuse, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs (referred to in this section as the ''Commissioner'') and in coordination with other Federal agencies, as appropriate, shall review current Federal initiatives and identify gaps and opportunities with respect to ensuring the safe use and disposal of prescription drugs with the potential for abuse.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall post a report on the Internet website of the Food and Drug Administration on the findings of the review under subsection (a). Such report shall include findings and recommendations on—

(1) how best to leverage and build upon existing Federal and federally funded data sources, such as prescription drug monitoring program data and the sentinel initiative of the Food and Drug Administration under section 505(k)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(k)(3)), as it relates to collection of information relevant to adverse events, patient safety, and patient outcomes, to create a centralized data clearinghouse and early warning tool;

(2) how best to develop and disseminate widely best practices models and suggested standard requirements to States for achieving greater interoperability and effectiveness of prescription drug monitoring programs, especially with respect to provider participation, producing standardized data on adverse events, patient safety, and patient outcomes; and

(3) how best to develop provider, pharmacist, and patient education tools and a strategy to widely disseminate such tools and assess the efficacy of such tools.

(c) GUIDANCE ON ABUSE-DETERRENT PRODUCTS.—Not later than 6 months after the date of enactment of this Act, the Secretary, acting through the Commissioner, shall promulgate guidance on the development of abuse-deterrent drug products.

(d) STUDY AND REPORT ON PRESCRIPTION DRUG ABUSE.—Not later than 1 year after the date of enactment of this Act, the Secretary shall seek to enter into an agreement with the Institute of Medicine to conduct a study and report on prescription drug abuse. Such report shall evaluate trends in prescription drug abuse, assess opportunities to inform and educate the public, patients, and health care providers on issues related to prescription drug abuse and misuse, and identify potential barriers, if any, to prescription drug monitoring program participation and implementation.

SEC. 1125. TANNING BED LABELING.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall determine whether to amend the warning label requirements for sunlamp products to include specific requirements to more clearly and effectively convey the risks that such products pose for the development of irreversible damage to the eyes and skin, including skin cancer.

SEC. 1126. OPTIMIZING GLOBAL CLINICAL TRIALS.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by section 903, is further amended by adding at the end the following:

''SEC. 569A. OPTIMIZING GLOBAL CLINICAL TRIALS.

''(a) IN GENERAL.—The Secretary shall—

''(1) work with other regulatory authorities of similar standing, medical research companies, and international organizations to foster and encourage uniform, scientifically-driven clinical trial standards with respect to medical products around the world; and

''(2) enhance the commitment to provide consistent parallel scientific advice to manufacturers seeking simultaneous global development of new medical products in order to—

''(A) enhance medical product development;

''(B) facilitate the use of foreign data; and

''(C) minimize the need to conduct duplicative clinical studies, preclinical studies, or non-clinical studies.

''(b) MEDICAL PRODUCT.—In this section, the term 'medical product' means a drug, as defined in subsection (g) of section 201, a device, as defined in subsection (h) of such section, or a biological product, as defined in section 351(i) of the Public Health Service Act.

''(c) SAVINGS CLAUSE.—Nothing in this section shall alter the criteria for evaluating the safety or effectiveness of a medical product under this Act.

''SEC. 569B. USE OF CLINICAL INVESTIGATION DATA FROM OUTSIDE THE UNITED STATES.

''(a) IN GENERAL.—In determining whether to approve, license, or clear a drug or device pursuant to an application submitted under this chapter, the Secretary shall accept data from clinical investigations conducted outside of the United States, including the European Union, if the applicant demonstrates that such data are adequate under applicable standards to support approval, licensure, or clearance of the drug or device in the United States.

''(b) NOTICE TO SPONSOR.—If the Secretary finds under subsection (a) that the data from clinical investigations conducted outside the United States, including in the European Union, are inadequate for the purpose of making a determination on approval, clearance, or licensure of a drug or device pursuant to an application submitted under this chapter, the Secretary shall provide written notice to the sponsor of the application of such finding and include the rationale for such finding.''.

SEC. 1127. ADVANCING REGULATORY SCIENCE TO PROMOTE PUBLIC HEALTH INNOVATION.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall develop a strategy and implementation plan for advancing regulatory science for medical products in order to promote the public health and advance innovation in regulatory decisionmaking.

(b) REQUIREMENTS.—The strategy and implementation plan developed under subsection (a) shall be consistent with the user fee performance goals in the Prescription Drug User Fee Agreement commitment letter, the Generic Drug User Fee Agreement commitment letter, and the Biosimilar User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 13, 2012, and the Medical Device User Fee Agreement commitment letter transmitted by the Secretary to Congress on April 20, 2012, and shall—

(1) identify a clear vision of the fundamental role of efficient, consistent, and predictable, science-based decisions throughout regulatory decisionmaking of the Food and Drug Administration with respect to medical products;

(2) identify the regulatory science priorities of the Food and Drug Administration directly related to fulfilling the mission of the agency with respect to decisionmaking concerning medical products and allocation of resources towards such regulatory science priorities;

(3) identify regulatory and scientific gaps that impede the timely development and review of, and regulatory certainty with respect to, the approval, licensure, or clearance of medical products, including with respect to companion products and new technologies, and facilitating the timely introduction and adoption of new technologies and methodologies in a safe and effective manner;

(4) identify clear, measurable metrics by which progress on the priorities identified under paragraph (2) and gaps identified under paragraph (3) will be measured by the Food and Drug Administration, including metrics specific to the integration and adoption of advances in regulatory science described in paragraph (5) and improving medical product decisionmaking, in a predictable and science-based manner; and

(5) set forth how the Food and Drug Administration will ensure that advances in regulatory science for medical products are adopted, as appropriate, on an ongoing basis and in an manner integrated across centers, divisions, and branches of the Food and Drug Administration, including by senior managers and reviewers, including through the—

(A) development, updating, and consistent application of guidance documents that support medical product decisionmaking; and

(B) the adoption of the tools, methods, and processes under section 566 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–5).

(c) ANNUAL PERFORMANCE REPORTS.—As part of the annual performance reports submitted to Congress under sections 736B(a) (as amended by section 104), 738A(a) (as amended by section 204), 744C(a) (as added by section 303), and 744I(a) (as added by section 403) of the Federal Food, Drug, and Cosmetic Act for each of fiscal years 2013 through 2017, the Secretary shall annually report on the progress made with respect to—

(1) advancing the regulatory science priorities identified under paragraph (2) of subsection (b) and resolving the gaps identified under paragraph (3) of such subsection, including reporting on specific metrics identified under paragraph (4) of such subsection;

(2) the integration and adoption of advances in regulatory science as set forth in paragraph (5) of such subsection; and

(3) the progress made in advancing the regulatory science goals outlined in the Prescription Drug User Fee Agreement commitment letter, the Generic Drug User Fee Agreement commitment letter, and the Biosimilar User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 13, 2012, and the Medical Device User Fee Agreement transmitted by the Secretary to Congress on April 20, 2012.

(d) INDEPENDENT ASSESSMENT.—Not later than January 1, 2016, the Comptroller General of the United States shall submit to Congress a report—

(1) detailing the progress made by the Food and Drug Administration in meeting the priorities and addressing the gaps identified in subsection (b), including any outstanding gaps; and

(2) containing recommendations, as appropriate, on how regulatory science initiatives for medical products can be strengthened and improved to promote the public health and advance innovation in regulatory decisionmaking.

(e) MEDICAL PRODUCT.—In this section, the term ''medical product'' means a drug, as defined in subsection (g) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), a device, as defined in subsection (h) of such section, or a biological product, as defined in section 351(i) of the Public Health Service Act.

SEC. 1128. INFORMATION TECHNOLOGY.

(a) HHS REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) report to Congress on—

(A) the milestones and a completion date for developing and implementing a comprehensive information technology strategic plan to align the information technology systems modernization projects with the strategic goals of the Food and Drug Administration, including results-oriented goals, strategies, milestones, performance measures;

(B) efforts to finalize and approve a comprehensive inventory of the information technology systems of the Food and Drug Administration that includes information describing each system, such as costs, system function or purpose, and status information, and incorporate use of the system portfolio into the information investment management process of the Food and Drug Administration;

(C) the ways in which the Food and Drug Administration uses the plan described in subparagraph (A) to guide and coordinate the modernization projects and activities of the Food and Drug Administration, including the interdependencies among projects and activities; and

(D) the extent to which the Food and Drug Administration has fulfilled or is implementing recommendations of the Government Accountability Office with respect to the Food and Drug Administration and information technology; and

(2) develop—

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

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

(b) GAO REPORT.—Not later than January 1, 2016, the Comptroller General of the United States shall issue a report regarding the strategic plan described in subsection (a)(1)(A) and related actions carried out by the Food and Drug Administration. Such report shall assess the progress the Food and Drug Administration has made on—

(1) the development and implementation of a comprehensive information technology strategic plan, including the results-oriented goals, strategies, milestones, and performance measures identified in subsection (a)(1)(A);

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

(3) the extent to which the Food and Drug Administration has fulfilled recommendations of the Government Accountability Office with respect to such agency and information technology.

SEC. 1129. REPORTING REQUIREMENTS.

Subchapter A of chapter VII (21 U.S.C. 371 et seq.), as amended by section 208, is further amended by adding at the end the following:

''SEC. 715. REPORTING REQUIREMENTS.

''(a) NEW DRUGS.—Beginning with fiscal year 2013 and ending with fiscal year 2017, not later than 120 days after the end of each fiscal year for which fees are collected under part 2 of subchapter C, the Secretary shall prepare and submit to the Committee on Health Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning, for all applications for approval of a new drug under section 505(b) of this Act or a new biological product under section 351(a) of the Public Health Service Act filed in the previous fiscal year—

''(1) the number of such applications that met the goals identified for purposes of part 2 of subchapter C in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record;

''(2) the percentage of such applications that were approved;

''(3) the percentage of such applications that were issued complete response letters;

''(4) the percentage of such applications that were subject to a refuse-to-file action;

''(5) the percentage of such applications that were withdrawn; and

''(6) the average total time to decision by the Secretary for all applications for approval of a new drug under section 505(b) of this Act or a new biological product under section 351(a) of the Public Health Service Act filed in the previous fiscal year, including the number of calendar days spent during the review by the Food and Drug Administration and the number of calendar days spent by the sponsor responding to a complete response letter.''.

''(b) GENERIC DRUGS.—Beginning with fiscal year 2013 and ending after fiscal year 2017, not later than 120 days after the end of each fiscal year for which fees are collected under part 7 of subchapter C, the Secretary shall prepare and submit to the Committee on Health Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning, for all applications for approval of a generic drug under section 505(j), amendments to such applications, and prior approval supplements with respect to such applications filed in the previous fiscal year—

''(1) the number of such applications that met the goals identified for purposes of part 7 of subchapter C, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record;

''(2) the average total time to decision by the Secretary for applications for approval of a generic drug under section 505(j), amendments to such applications, and prior approval supplements with respect to such applications filed in the previous fiscal year, including the number of calendar days spent during the review by the Food and Drug Administration and the number of calendar days spent by the sponsor responding to a complete response letter;

''(3) the total number of applications under section 505(j), amendments to such applications, and prior approval supplements with respect to such applications that were pending with the Secretary for more than 10 months on the date of enactment of the Food and Drug Administration Safety and Innovation Act; and

''(4) the number of applications described in paragraph (3) on which the Food and Drug Administration took final regulatory action in the previous fiscal year.

''(c) BIOSIMILAR BIOLOGICAL PRODUCTS.—

''(1) IN GENERAL.—Beginning with fiscal year 2014, not later than 120 days after the end of each fiscal year for which fees are collected under part 8 of subchapter C, the Secretary shall prepare and submit to the Committee on Health Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning—

''(A) the number of applications for approval filed under section 351(k) of the Public Health Service Act; and

''(B) the percentage of applications described in subparagraph (A) that were approved by the Secretary.

''(2) ADDITIONAL INFORMATION.—As part of the performance report described in paragraph (1), the Secretary shall include an explanation of how the Food and Drug Administration is managing the biological product review program to ensure that the user fees collected under part 2 are not used to review an application under section 351(k) of the Public Health Service Act.''.

SEC. 1130. STRATEGIC INTEGRATED MANAGEMENT PLAN.

(a) STRATEGIC INTEGRATED MANAGEMENT PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall submit to Congress a strategic integrated management plan for the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health. Such strategic management plan shall—

(1) identify strategic institutional goals and priorities for the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health;

(2) describe the actions the Secretary will take to recruit, retain, train, and continue to develop the workforce at the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health to fulfill the public health mission of the Food and Drug Administration; and

(3) identify results-oriented, outcome-based measures that the Secretary will use to measure the progress of achieving the strategic goals and priorities identified under paragraph (1) and the effectiveness of the actions identified under paragraph (2), including metrics to ensure that managers and reviewers of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health are familiar with and appropriately and consistently apply the requirements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including new requirements under parts 2, 3, 7, and 8 of subchapter C of title VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.).

(b) REPORT.—Not later than January 1, 2016, the Comptroller General of the United States shall issue a report regarding the strategic management plan described in subsection (a) and related actions carried out by the Food and Drug Administration. Such report shall—

(1) assess the effectiveness of the actions described in subsection (a)(2) in recruiting, retaining, training, and developing the workforce at the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health in fulfilling the public health mission of the Food and Drug Administration;

(2) assess the effectiveness of the measures identified under subsection (a)(3) in gauging progress against the strategic goals and priorities identified under subsection (a)(1);

(3) assess the extent to which the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health are using the identified results-oriented set of performance measures in tracking their workload by strategic goals and the effectiveness of such measures;

(4) assess the extent to which performance information is collected, analyzed, and acted on by managers; and

(5) make recommendations, as appropriate, regarding how the strategic management plan and related actions of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health could be improved to fulfill the public health mission of the Food and Drug Administration in as efficient and effective manner as possible.

SEC. 1131. DRUG DEVELOPMENT AND TESTING.

(a) IN GENERAL.—Section 505–1 (21 U.S.C. 355–1) is amended by adding at the end the following:

''(k) DRUG DEVELOPMENT AND TESTING.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, if a drug is a covered drug, no elements to ensure safe use shall prohibit, or be construed or applied to prohibit, supply of such drug to any eligible drug developer for the purpose of conducting testing necessary to support an application under subsection (b)(2) or (j) of section 505 of this Act or section 351(k) of the Public Health Service Act, if the Secretary has issued a written notice described in paragraph (2), and the eligible drug developer has agreed to comply with the terms of the notice.

''(2) WRITTEN NOTICE.—For purposes of this subsection, the Secretary shall, within a reasonable period of time, consider and respond to a request by an eligible drug developer for a written notice authorizing the supply of a covered drug for purposes of testing as described in paragraph (1), and the Secretary shall issue a written notice to such eligible drug developer and the holder of an application for a covered drug authorizing the supply of such drug to such eligible drug developer for purposes of testing if—

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

''(B) in the event the eligible drug developer is conducting bioequivalence or other clinical testing, the eligible drug developer has submitted, and the Secretary has approved, a protocol that includes protections that the Secretary finds will provide assurance of safety comparable to the assurance of safety provided by the elements to ensure safe use in the risk evaluation and mitigation strategy for the covered drug as applicable to such testing; and

''(C) the eligible drug developer is in compliance with applicable laws and regulations related to such testing, including any applicable requirements related to Investigational New Drug Applications or informed consent.

''(3) ADDITIONAL REQUIRED ELEMENT.—The Secretary shall require as an element of each risk evaluation and mitigation strategy with elements to ensure safe use approved by the Secretary that the holder of an application for a covered drug shall not restrict the resale of the covered drug to an eligible drug developer that receives a written notice from the Secretary under paragraph (2) unless, at any time, the Secretary provides written notice to the holder of the application directing otherwise based on a shortage of such drug for patients, national security concerns related to access to such drug, or such other reason as the Secretary may specify.

''(4) VIOLATION AND PENALTIES.—For purposes of subsection (f)(8) and sections 301, 303(f)(4), 502(y), and 505(p), it shall be a violation of the risk evaluation and mitigation strategy for the holder of the application for a covered drug to violate the element described in paragraph (3), or in the case of a

holder of an application that is a sole distributor or supplier of a covered drug, to prevent the sale thereof after receipt of a written notice by the Secretary issued under paragraph (2). The Secretary shall provide written notice to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives within 30 days of the Secretary becoming aware that a holder of an application of a covered drug has restricted the sale of such a covered drug to any eligible drug developer after receipt of written notice as provided in paragraph (2).

''(5) LIABILITY.—Unless the holder of the application for a covered drug and the eligible developer are the same entity, the holder of an application for a covered drug shall not be liable for any claim arising out of the eligible drug developer's testing necessary to support an application under subsection (b)(2) or (j) of section 505 of this Act or section 351(k) of the Public Health Service Act for a drug obtained under this subsection. Nothing in this subsection shall be construed to expand or limit the liability of the eligible drug developer or the holder of an application for a covered drug for any other claim.

''(6) CERTIFICATION.—In any request for supply of a covered drug for purposes of testing as described in paragraph (1), an eligible drug developer shall certify to the Secretary that—

''(A) the eligible drug developer will comply with all conditions the Secretary considers necessary, any protocol approved by the Secretary, and all applicable laws and regulations pertaining to such testing; and

''(B) the eligible drug developer intends to submit an application under subsection (b)(2) or (j) of section 505 of this Act or section 351(k) of the Public Health Service Act for the drug for which it is requesting written notice pursuant to paragraph (2), and will use the covered drug only for the purpose of conducting testing to support such an application.

''(7) DEFINITIONS.—

''(A) COVERED DRUG.—Notwithstanding subsection (b)(2), for purposes of this subsection, the term 'covered drug' means a drug, including a biological product licensed under section 351(a) of the Public Health Service Act, that is subject to a risk evaluation and mitigation strategy with elements to ensure safe use under subsection (f), or a drug, including a biological product licensed under section 351(a) of the Public Health Service Act, required to have a risk evaluation and mitigation strategy with elements to ensure safe use under section 909(b) of the Food and Drug Administration Amendments Act of 2007.

''(B) ELIGIBLE DRUG DEVELOPER.—For purposes of this subsection, the term 'eligible drug developer' means a sponsor that has submitted, or intends to submit, an application under subsection (b)(2) or (j) of section 505 of this Act or section 351(k) of the Public Health Service Act to market a version of the covered drug in the United States.

''(8) EFFECT ON OTHER LAW.—Notwithstanding the provisions of this subsection, the antitrust statutes enforced by the Federal Trade Commission, including the Federal Trade Commission Act (15 U.S.C. 41–58), the Sherman Act (15 U.S.C. 1–7), and any other statute properly under such Commission's jurisdiction, shall apply to the conduct described in this subsection to the same extent as such statutes did on the day before the date of enactment of this subsection.''.

(b) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) Section 505–1(c)(2) (21 U.S.C. 355–1(c)(2)) is amended by striking ''(e) and (f)'' and inserting ''(e), (f), and (k)(3)''.

(2) Section 502(y) (21 U.S.C. 352(y)) is amended by striking '''(d), (e), or (f) of section 505–1'' and inserting ''(d), (e), (f), or (k)(3) of section 505–1''.

SEC. 1132. PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSIONS.

Subchapter E of chapter V (21 U.S.C. 360bbb et seq.), as amended by section 1126, is further amended by adding at the end the following:

''SEC. 569C. PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSION.

''(a) IN GENERAL.—The Secretary shall develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions, including by—

''(1) fostering participation of a patient representative who may serve as a special government employee in appropriate agency meetings with medical product sponsors and investigators; and

''(2) exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.

''(b) FINANCIAL INTEREST.—In this section, the term 'financial interest' means a financial interest under section 208(a) of title 18, United States Code.''.

SEC. 1133. NANOTECHNOLOGY REGULATORY SCIENCE PROGRAM.

(a) IN GENERAL.—Chapter X (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

''SEC. 1013. NANOTECHNOLOGY REGULATORY SCIENCE PROGRAM.

''(a) IN GENERAL.—Not later than 180 days after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary, in consultation as appropriate with the Secretary of Agriculture, shall establish within the Food and Drug Administration a Nanotechnology Regulatory Science Program (referred to in this section as the 'program') to enhance scientific knowledge regarding nanomaterials included or intended for inclusion in products regulated under this Act or other statutes administered by the Food and Drug Administration, to address issues relevant to the regulation of those products, including the potential toxicology of such materials, the effects of such materials on biological systems, and interaction of such materials with biological systems.

''(b) PROGRAM PURPOSES.—The purposes of the program established under subsection (a) may include—

''(1) assessing scientific literature and data on general nanomaterials interactions with biological systems and on specific nanomaterials of concern to the Food and Drug Administration;

''(2) in cooperation with other Federal agencies, developing and organizing information using databases and models that will facilitate the identification of generalized principles and characteristics regarding the behavior of classes of nanomaterials with biological systems;

''(3) promoting Food and Drug Administration programs and participate in collaborative efforts, to further the understanding of the science of novel properties of nanomaterials that might contribute to toxicity;

''(4) promoting and participating in collaborative efforts to further the understanding of measurement and detection methods for nanomaterials;

''(5) collecting, synthesizing, interpreting, and disseminating scientific information and data related to the interactions of nanomaterials with biological systems;

''(6) building scientific expertise on nanomaterials within the Food and Drug Administration, including field and laboratory expertise, for monitoring the production and presence of nanomaterials in domestic and imported products regulated under this Act;

''(7) ensuring ongoing training, as well as dissemination of new information within the centers of the Food and Drug Administration, and more broadly across the Food and Drug Administration, to ensure timely, informed consideration of the most current science pertaining to nanomaterials;

''(8) encouraging the Food and Drug Administration to participate in international and national consensus standards activities pertaining to nanomaterials; and

''(9) carrying out other activities that the Secretary determines are necessary and consistent with the purposes described in paragraphs (1) through (8).

''(c) PROGRAM ADMINISTRATION.—

''(1) DESIGNATED INDIVIDUAL.—In carrying out the program under this section, the Secretary, acting through the Commissioner of Food and Drugs, may designate an appropriately qualified individual who shall supervise the planning, management, and coordination of the program.

''(2) DUTIES.—The duties of the individual designated under paragraph (1) may include—

''(A) developing a detailed strategic plan for achieving specific short- and long-term technical goals for the program;

''(B) coordinating and integrating the strategic plan with activities by the Food and Drug Administration and other departments and agencies participating in the National Nanotechnology Initiative; and

''(C) developing Food and Drug Administration programs, contracts, memoranda of agreement, joint funding agreements, and other cooperative arrangements necessary for meeting the long-term challenges and achieving the specific technical goals of the program.

''(d) REPORT.—Not later than March 15, 2015, the Secretary shall publish on the Internet Web site of the Food and Drug Administration a report on the program carried out under this section. Such report shall include—

''(1) a review of the specific short- and long-term goals of the program;

''(2) an assessment of current and proposed funding levels for the program, including an assessment of the adequacy of such funding levels to support program activities; and

''(3) a review of the coordination of activities under the program with other departments and agencies participating in the National Nanotechnology Initiative.

''(e) EFFECT OF SECTION.—Nothing in this section shall affect the authority of the Secretary under any other provision of this Act or other statutes administered by the Food and Drug Administration.''.

(b) EFFECTIVE DATE; SUNSET.—The Nanotechnology Regulatory Science Program authorized under section 1013 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) shall take effect on October 1, 2012, or the date of the enactment of this Act, whichever is later. Such Program shall cease to be effective October 1, 2017.

SEC. 1134. ONLINE PHARMACY REPORT TO CONGRESS.

Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes any problems posed by pharmacy Internet websites that violate Federal or State law, including—

(1) the methods by which Internet websites are used to sell prescription drugs in violation of Federal or State law or established industry standards;

(2) the harmful health effects that patients experience when they consume prescription drugs purchased through such pharmacy Internet websites;

(3) efforts by the Federal Government and State and local governments to investigate and prosecute the owners or operators of pharmacy Internet websites, to address the threats such websites pose, and to protect patients;

(4) the level of success that Federal, State, and local governments have experienced in investigating and prosecuting such cases;

(5) whether the law, as in effect on the date of the report, provides sufficient authorities to Federal, State, and local governments to investigate and prosecute the owners and operators of pharmacy Internet websites;

(6) additional authorities that could assist Federal, State, and local governments in investigating and prosecuting the owners and operators of pharmacy Internet websites;

(7) laws, policies, and activities that would educate consumers about how to distinguish pharmacy Internet websites that comply with Federal and State laws and established industry standards from those pharmacy Internet websites that do not comply with such laws and standards; and

(8) laws, policies, and activities that would encourage private sector actors to take steps to address the prevalence of illegitimate pharmacy Internet websites.

SEC. 1135. MEDICATION AND DEVICE ERRORS.

The Secretary of Health and Human Services shall continue and further coordinate activities of the Department of Health and Human Services related to the prevention of medication and device errors, including consideration of medication and device errors that affect the pediatric patient population. In developing initiatives to address medication and device errors, the Secretary shall consider the root causes of medication and device errors, including pediatric medication and device errors, in the clinical setting and consult with relevant stakeholders on effective strategies to reduce and prevent medication and device errors in the clinical setting.

SEC. 1136. COMPLIANCE PROVISION.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go-Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this Act, submitted for printing in the Congressional Record by the Chairman of the Senate Budget Committee, provided that such statement has been submitted prior to the vote on passage.

SA 2123. Mr. REID (for Mr. JOHNSON of South Dakota (for himself and Mr. SHELBY)) proposed an amendment 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:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Iran Sanctions, Accountability, and Human Rights Act of 2012''.

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

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Successive Presidents of the United States have determined that the pursuit of nuclear weapons capabilities by the Government of Iran presents a danger to the United States, its friends and allies, and to global security.

(2) Successive Congresses have recognized the threat that the Government of Iran and its policies present to the United States, its friends and allies, and to global security, and responded with successive bipartisan legislative initiatives, including most recently the enactment of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8501 et seq.) on July 1, 2010.

(3) If the Government of Iran achieves a nuclear weapons capability, it would pose a threat to the United States and allies and friends of the United States, particularly Israel, destabilize the Middle East, increase the threat of nuclear terrorism, and significantly undermine global nonproliferation efforts.

(4) The United States and its allies in the international community recognize the threat posed by the pursuit of nuclear weapons capabilities by the Government of Iran and have imposed significant sanctions against the Government of Iran, including through the enactment of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 in the United States and the adoption of a series of successive, increasingly stringent United Nations Security Council resolutions. While such efforts, together with others, have served to slow the development of Iran's nuclear program, they have not yet deterred Iran from its nuclear ambitions, and international efforts to do so must be intensified.

SEC. 3. DEFINITIONS.

In this Act:

(1) APPROPRIATE CONGRESSIONAL COMMITTEES.—The term ''appropriate congressional committees'' has the meaning given that term in section 14 of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note).

(2) CREDIBLE INFORMATION.—The term ''credible information'' has the meaning given that term in section 14 of the Iran Sanctions Act of 1996, as amended by section 205 of this Act.

(3) KNOWINGLY.—The term ''knowingly'' has the meaning given that term in section 14 of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note).

(4) UNITED STATES PERSON.—The term ''United States person'' has the meaning given that term in section 101 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8511).

TITLE I—EXPANSION OF MULTILATERAL SANCTIONS REGIME WITH RESPECT TO IRAN

SEC. 101. POLICY OF THE UNITED STATES WITH RESPECT TO DEVELOPMENT OF NUCLEAR WEAPONS CAPABILITIES BY IRAN.

It shall be the policy of the United States—

(1) to prevent the Government of Iran from—

(A) acquiring or developing nuclear weapons;

(B) developing its advanced conventional weapons and ballistic missile capabilities; and

(C) continuing its support for terrorist organizations and other activities aimed at undermining and destabilizing its neighbors and other countries; and

(2) to fully implement all multilateral and bilateral sanctions against Iran, as part of larger multilateral and bilateral diplomatic efforts, in order to compel the Government of Iran—

(A) to abandon efforts to acquire a nuclear weapons capability;

(B) to abandon and dismantle its ballistic missile and unconventional weapons programs; and

(C) to cease all support for terrorist organizations and other terrorist activities aimed at undermining and destabilizing its neighbors and other countries.

SEC. 102. SENSE OF CONGRESS ON EXPANSION OF MULTILATERAL SANCTIONS REGIME AND IMPLEMENTATION OF SANCTIONS LAWS.

It is the sense of Congress that the goal of compelling Iran to abandon efforts to acquire a nuclear weapons capability and other threatening activities can be effectively achieved through—

(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 or expanded by this Act or amendments made by this Act.

SEC. 103. DIPLOMATIC EFFORTS TO EXPAND MULTILATERAL SANCTIONS REGIME.

(a) MULTILATERAL NEGOTIATIONS.—In order to further the policy set forth in section 101, Congress urges the President to intensify diplomatic efforts, both in appropriate international fora such as the United Nations and bilaterally with allies of the United States, to expand the multilateral sanctions regime with respect to Iran, including—

(1) expanding the United Nations Security Council sanctions regime to include—

(A) a prohibition on the issuance of visas to any official of the Government of Iran who is involved in—

(i) human rights violations in or outside of Iran;

(ii) the development of a nuclear weapons program and a ballistic missile capability in Iran; or

(iii) support by the Government of Iran for terrorist organizations, including Hamas and Hezbollah; and

(B) a requirement that each member country of the United Nations prohibit the Islamic Republic of Iran Shipping Lines from landing at seaports, and cargo flights of Iran Air from landing at airports, in that country because of the role of those organizations in proliferation and illegal arms sales;

(2) expanding the range of sanctions imposed with respect to Iran by allies of the United States;

(3) expanding efforts to limit the development of petroleum resources and the importation of refined petroleum products by Iran;

(4) developing additional initiatives to—

(A) increase the production of crude oil in countries other than Iran; and

(B) assist countries that purchase or otherwise obtain crude oil or petroleum products from Iran to reduce their dependence on crude oil and petroleum products from Iran; and

(5) eliminating the revenue generated by the Government of Iran from the sale of petrochemical products produced in Iran to other countries.

(b) REPORTS TO CONGRESS.—Not later than 180 days after the date of the enactment of this Act, and every 180 days thereafter, the President shall submit to the appropriate congressional committees a report on the extent to which diplomatic efforts described in subsection (a) have been successful that includes—

(1) an identification of the countries that have agreed to impose additional sanctions or take other measures to further the policy set forth in section 101 and a description of those measures;

(2) an identification of the countries that have not agreed to impose such sanctions or measures;

(3) recommendations for additional measures that the United States could take to further the policy set forth in section 101; and

(4) a description of any decision by the World Trade Organization with respect to whether the imposition by any country of any sanction with respect to Iran is inconsistent with the obligations of that country as a member of the World Trade Organization or under the General Agreement on Tariffs and Trade, done at Geneva October 30, 1947.

SEC. 104. SENSE OF CONGRESS REGARDING THE IMPOSITION OF SANCTIONS WITH RESPECT TO IRAN.

It is the sense of Congress that all efforts should be made by the President to maximize the effects of existing sanctions with respect to Iran and the United States should take all necessary measures to preserve robust information-sharing activities.

TITLE II—EXPANSION OF SANCTIONS RELATING TO THE ENERGY SECTOR OF IRAN AND PROLIFERATION OF WEAPONS OF MASS DESTRUCTION BY IRAN

Subtitle A—Expansion of Iran Sanctions Act of 1996

SEC. 201. IMPOSITION OF SANCTIONS WITH RESPECT TO JOINT VENTURES WITH THE GOVERNMENT OF IRAN RELATING TO DEVELOPING PETROLEUM RESOURCES.

Section 5(a) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) is amended—

(1) in the subsection heading, by striking ''WITH RESPECT TO'' and all that follows through ''TO IRAN'' and inserting ''RELATING TO THE ENERGY SECTOR OF IRAN''; and

(2) by adding at the end the following:

''(4) JOINT VENTURES WITH IRAN RELATING TO DEVELOPING PETROLEUM RESOURCES.—

''(A) IN GENERAL.—Except as provided in subparagraph (B) and subsection (f), the President shall impose 3 or more of the sanctions described in section 6(a) with respect to a person if the President determines that the person knowingly participates, on or after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, in a joint venture with respect to the development of petroleum resources outside of Iran if—

''(i) the joint venture is established on or after January 1, 2002; and

''(ii)(I) the Government of Iran is a substantial partner or investor in the joint venture; or

''(II) Iran could, through a direct operational role in the joint venture or by other means, receive technological knowledge or equipment not previously available to Iran that could directly and significantly contribute to the enhancement of Iran's ability to develop petroleum resources in Iran.

''(B) APPLICABILITY.—Subparagraph (A) shall not apply with respect to participation in a joint venture established on or after January 1, 2002, and before the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012 if the person participating in the joint venture terminates that participation not later than the date that is 180 days after such date of enactment.''.

SEC. 202. IMPOSITION OF SANCTIONS WITH RESPECT TO THE PROVISION OF GOODS, SERVICES, TECHNOLOGY, OR SUPPORT FOR THE ENERGY OR PETROCHEMICAL SECTORS OF IRAN.

Section 5(a) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note), as amended by section 201, is further amended by adding at the end the following:

''(5) SUPPORT FOR THE DEVELOPMENT OF PETROLEUM RESOURCES AND REFINED PETROLEUM PRODUCTS IN IRAN.—

''(A) IN GENERAL.—Except as provided in subsection (f), the President shall impose 3 or more of the sanctions described in section 6(a) with respect to a person if the President determines that the person knowingly, on or after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, sells, leases, or provides to Iran goods, services, technology, or support described in subparagraph (B)—

''(i) any of which has a fair market value of $1,000,000 or more; or

''(ii) that, during a 12-month period, have an aggregate fair market value of $5,000,000 or more.

''(B) GOODS, SERVICES, TECHNOLOGY, OR SUPPORT DESCRIBED.—Goods, services, technology, or support described in this subparagraph are goods, services, technology, or support that could directly and significantly contribute to the maintenance or enhancement of Iran's—

''(i) ability to develop petroleum resources located in Iran; or

''(ii) domestic production of refined petroleum products, including any direct and significant assistance with respect to the construction, modernization, or repair of petroleum refineries or directly associated infrastructure, including port facilities, railroads, or roads, if the predominant use of those facilities, railroads, or roads is for the transportation of refined petroleum products.

''(6) DEVELOPMENT AND PURCHASE OF PETROCHEMICAL PRODUCTS FROM IRAN.—

''(A) IN GENERAL.—Except as provided in subsection (f), the President shall impose 3 or more of the sanctions described in section 6(a) with respect to a person if the President determines that the person knowingly, on or after the date of the enactment of Iran Sanctions, Accountability, and Human Rights Act of 2012, sells, leases, or provides to Iran goods, services, technology, or support described in subparagraph (B)—

''(i) any of which has a fair market value of $250,000 or more; or

''(ii) that, during a 12-month period, have an aggregate fair market value of $1,000,000 or more.

''(B) GOODS, SERVICES, TECHNOLOGY, OR SUPPORT DESCRIBED.—Goods, services, technology, or support described in this subparagraph are goods, services, technology, or support that could directly and significantly contribute to the maintenance or expansion of Iran's domestic production of petrochemical products.''.

SEC. 203. IMPOSITION OF SANCTIONS WITH RESPECT TO JOINT VENTURES WITH THE GOVERNMENT OF IRAN RELATING TO MINING, PRODUCTION, OR TRANSPORTATION OF URANIUM.

Section 5(b) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) is amended—

(1) in paragraph (1)—

(A) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and moving such clauses, as so redesignated, 2 ems to the right;

(B) by striking ''a person has, on or after'' and inserting the following: ''a person has—

''(A) on or after'';

(C) in subparagraph (A)(ii), as redesignated, by striking the period and inserting ''; or''; and

(D) by adding at the end the following:

''(B) except as provided in paragraph (3), knowingly participated, on or after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, in a joint venture—

''(i) with—

''(I) the Government of Iran;

''(II) an entity incorporated in Iran or subject to the jurisdiction of the Government of Iran; or

''(III) a person acting on behalf of or at the direction of, or owned or controlled by, the Government of Iran or an entity described in subclause (II); and

''(ii) that involves any activity relating to the mining, production, or transportation of uranium.''; and

(2) by adding at the end the following:

''(3) APPLICABILITY OF SANCTIONS WITH RESPECT TO JOINT VENTURES RELATING TO THE MINING, PRODUCTION, OR TRANSPORTATION OF URANIUM.—

''(A) IN GENERAL.—Paragraph (1)(B) shall apply with respect to participation, on or after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, in—

''(i) a joint venture established on or after such date of enactment; and

''(ii) except as provided in subparagraph (B), a joint venture established before such date of enactment.

''(B) EXCEPTION.—Paragraph (1)(B) shall not apply with respect to participation in a joint venture described in subparagraph (A)(ii) if the person participating in the joint venture terminates that participation not later than the date that is 180 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012.''.

SEC. 204. EXPANSION OF SANCTIONS AVAILABLE UNDER THE IRAN SANCTIONS ACT OF 1996.

(a) IN GENERAL.—Section 6(a) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) is amended—

(1) by redesignating paragraph (9) as paragraph (11); and

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

''(9) EXCLUSION OF CORPORATE OFFICERS.—The President may direct the Secretary of State to deny a visa to, and the Secretary of Homeland Security to exclude from the United States, any alien that the President determines is a corporate officer or principal of, or a shareholder with a controlling interest in, a sanctioned person.

''(10) SANCTIONS ON PRINCIPAL EXECUTIVE OFFICERS.—The President may impose on the principal executive officer or officers of any sanctioned person, or on persons performing similar functions and with similar authorities as such officer or officers, any of the sanctions under this subsection.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on the date of the enactment of this Act and apply with respect to activities described in section 5 of the Iran Sanctions Act of 1996, as amended by this Act, commenced on or after such date of enactment.

SEC. 205. EXPANSION OF DEFINITIONS UNDER THE IRAN SANCTIONS ACT OF 1996.

(a) IN GENERAL.—Section 14 of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) is amended by adding at the end the following:

''(19) CREDIBLE INFORMATION.—The term 'credible information', with respect to a person—

''(A) includes—

''(i) a public announcement by the person that the person has engaged in an activity described in section 5; and

''(ii) information set forth in a report to stockholders of the person indicating that the person has engaged in such an activity; and

''(B) may include, in the discretion of the President—

''(i) an announcement by the Government of Iran that the person has engaged in such an activity; or

''(ii) information indicating that the person has engaged in such an activity that is set forth in—

''(I) a report of the Government Accountability Office, the Energy Information Administration, or the Congressional Research Service; or

''(II) a report or publication of a similarly reputable governmental organization.

''(20) PETROCHEMICAL PRODUCT.—The term 'petrochemical product' includes any aromatic, olefin, or synthesis gas, and any derivative of such a gas, including ethylene, propylene, butadiene, benzene, toluene, xylene, ammonia, methanol, and urea.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act and apply with respect to activities described in section 5 of the Iran Sanctions Act of 1996, as amended by this Act, commenced on or after such date of enactment.

Subtitle B—Additional Measures Relating to Sanctions Against Iran

SEC. 211. IMPOSITION OF SANCTIONS WITH RESPECT TO THE PROVISION OF VESSELS OR SHIPPING SERVICES TO TRANSPORT CERTAIN GOODS RELATED TO PROLIFERATION OR TERRORISM ACTIVITIES TO IRAN.

(a) IN GENERAL.—Except as provided in subsection (c), if the President determines that a person, on or after the date of the enactment of this Act, knowingly provides a vessel, insurance or reinsurance, or any other shipping service for the transportation to or from Iran of goods that could materially contribute to the activities of the Government of Iran with respect to the proliferation of weapons of mass destruction or support for acts of international terrorism, the President shall, pursuant to Executive Order 13382 (70 Fed. Reg. 38567; relating to blocking of property of weapons of mass destruction proliferators and their supporters) or Executive Order 13224 (66 Fed. Reg. 49079; relating to blocking property and prohibiting transactions with persons who commit, threaten to commit, or support terrorism), or otherwise pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.), block and prohibit all transactions in all property and interests in property of the persons specified in subsection (b) if such property and interests in property are in the United States, come within the United States, or are or come within the possession or control of a United States person.

(b) PERSONS SPECIFIED.—The persons specified in this subsection are—

(1) the person that provided a vessel, insurance or reinsurance, or other shipping service described in subsection (a); and

(2) any person that—

(A) is a successor entity to the person referred to in paragraph (1);

(B) owns or controls the person referred to in paragraph (1), if the person that owns or controls the person referred to in paragraph (1) had actual knowledge or should have known that the person referred to in paragraph (1) provided the vessel, insurance or reinsurance, or other shipping service; or

(C) is owned or controlled by, or under common ownership or control with, the person referred to in paragraph (1), if the person owned or controlled by, or under common ownership or control with (as the case may be), the person referred to in paragraph (1)

knowingly engaged in the provision of the vessel, insurance or reinsurance, or other shipping service.

(c) WAIVER.—The President may waive the requirement to impose sanctions with respect to a person under subsection (a) on or after the date that is 30 days after the President—

(1) determines that such a waiver is in the national security interests of the United States; and

(2) submits to the appropriate congressional committees a report that contains the reasons for that determination.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the President to designate persons for the imposition of sanctions pursuant to Executive Order 13382 (70 Fed. Reg. 38567; relating to the blocking of property of weapons of mass destruction proliferators and their supporters) or Executive Order 13224 (66 Fed. Reg. 49079; relating to blocking property and prohibiting transactions with persons who commit, threaten to commit, or support terrorism), or otherwise pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).

SEC. 212. IMPOSITION OF SANCTIONS WITH RESPECT TO SUBSIDIARIES AND AGENTS OF PERSONS SANCTIONED BY UNITED NATIONS SECURITY COUNCIL RESOLUTIONS.

(a) IN GENERAL.—Section 104(c)(2)(B) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(B)) is amended—

(1) by striking ''of a person subject'' and inserting the following: ''of—

''(i) a person subject'';

(2) in clause (i), as redesignated, by striking the semicolon and inserting ''; or''; and

(3) by adding at the end the following:

''(ii) a person acting on behalf of or at the direction of, or owned or controlled by, a person described in clause (i);''.

(b) REGULATIONS.—Not later than 90 days after the date of the enactment of this Act, the Secretary of the Treasury shall make such revisions to the regulations prescribed under section 104 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513) as are necessary to carry out the amendments made by subsection (a).

SEC. 213. LIABILITY OF PARENT COMPANIES FOR VIOLATIONS OF SANCTIONS BY FOREIGN SUBSIDIARIES.

(a) DEFINITIONS.—In this section:

(1) ENTITY.—The term ''entity'' means a partnership, association, trust, joint venture, corporation, or other organization.

(2) OWN OR CONTROL.—The term ''own or control'' means, with respect to an entity—

(A) to hold more than 50 percent of the equity interest by vote or value in the entity;

(B) to hold a majority of seats on the board of directors of the entity; or

(C) to otherwise control the actions, policies, or personnel decisions of the entity.

(b) PROHIBITION.—Not later than 60 days after the date of the enactment of this Act, the President shall prohibit an entity owned or controlled by a United States person and established or maintained outside the United States from engaging in any transaction directly or indirectly with the Government of Iran or any person subject to the jurisdiction of that Government that would be prohibited by an order or regulation issued pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) if the transaction were engaged in by a United States person or in the United States.

(c) CIVIL PENALTY.—The civil penalties provided for in section 206(b) of the International Emergency Economic Powers Act (50 U.S.C. 1705(b)) shall apply to a United States person to the same extent that such penalties apply to a person that commits an unlawful act described in section 206(a) of that Act if an entity owned or controlled by the United States person and established or maintained outside the United States violates, attempts to violate, conspires to violate, or causes a violation of any order or regulation issued to implement subsection (b).

(d) APPLICABILITY.—Subsection (c) shall not apply with respect to a transaction described in subsection (b) by an entity owned or controlled by a United States person and established or maintained outside the United States if the United States person divests or terminates its business with the entity not later than the date that is 180 days after the date of the enactment of this Act.

SEC. 214. DISCLOSURES TO THE SECURITIES AND EXCHANGE COMMISSION RELATING TO SANCTIONABLE ACTIVITIES.

(a) IN GENERAL.—Section 13 of the Securities Exchange Act of 1934 (15 U.S.C. 78m) is amended by adding at the end the following new subsection:

''(r) DISCLOSURE OF CERTAIN ACTIVITIES RELATING TO IRAN.—

''(1) IN GENERAL.—Each issuer required to file an annual or quarterly report under subsection (a) shall disclose in that report the information required by paragraph (2) if, during the period covered by the report, the issuer or any affiliate of the issuer—

''(A) knowingly engaged in an activity described in section 5 of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note);

''(B) knowingly engaged in an activity described in subsection (c)(2) of section 104 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513) or a transaction described in subsection (d)(1) of that section;

''(C) knowingly engaged in an activity described in section 105A(b)(2) of that Act; or

''(D) knowingly conducted any transaction or dealing with—

''(i) any person the property and interests in property of which are blocked pursuant to Executive Order 13224 (66 Fed. Reg. 49079; relating to blocking property and prohibiting transactions with persons who commit, threaten to commit, or support terrorism);

''(ii) any person the property and interests in property of which are blocked pursuant to Executive Order 13382 (70 Fed. Reg. 38567; relating to blocking of property of weapons of mass destruction proliferators and their supporters); or

''(iii) any person identified under section 560.304 of title 31, Code of Federal Regulations (relating to the definition of the Government of Iran).

''(2) INFORMATION REQUIRED.—If an issuer or an affiliate of the issuer has engaged in any activity described in paragraph (1), the issuer shall disclose a detailed description of each such activity, including—

''(A) the nature and extent of the activity;

''(B) the gross revenues and net profits, if any, attributable to the activity; and

''(C) whether the issuer or the affiliate of the issuer (as the case may be) intends to continue the activity.

''(3) NOTICE OF DISCLOSURES.—If an issuer reports under paragraph (1) that the issuer or an affiliate of the issuer has knowingly engaged in any activity described in that paragraph, the issuer shall separately file with the Commission, concurrently with the annual or quarterly report under subsection (a), a notice that the disclosure of that activity has been included in that annual or quarterly report that identifies the issuer and contains the information required by paragraph (2).

''(4) PUBLIC DISCLOSURE OF INFORMATION.—Upon receiving a notice under paragraph (3) that an annual or quarterly report includes a disclosure of an activity described in paragraph (1), the Commission shall promptly—

''(A) transmit the report to—

''(i) the President;

''(ii) the Committee on Foreign Affairs and the Committee on Financial Services of the House of Representatives; and

''(iii) the Committee on Foreign Relations and the Committee on Banking, Housing, and Urban Affairs of the Senate; and

''(B) make the information provided in the disclosure and the notice available to the public by posting the information on the Internet website of the Commission.

''(5) INVESTIGATIONS.—Upon receiving a report under paragraph (4), the President shall—

''(A) initiate an investigation into the possible imposition of sanctions under the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note), section 104 or 105A of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, an Executive Order specified in clause (i) or (ii) of paragraph (1)(D), or any other provision of law relating to the imposition of sanctions with respect to Iran, as applicable; and

''(B) not later than 180 days after initiating such an investigation, make a determination with respect to whether sanctions should be imposed with respect to the issuer or the affiliate of the issuer (as the case may be).

''(6) SUNSET.—The provisions of this subsection shall terminate on the date that is 30 days after the date on which the President makes the certification described in section 401(a) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8551(a)).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect with respect to reports required to be filed with the Securities and Exchange Commission after the date that is 180 days after the date of the enactment of this Act.

SEC. 215. IDENTIFICATION OF, AND IMMIGRATION RESTRICTIONS ON, SENIOR OFFICIALS OF THE GOVERNMENT OF IRAN AND THEIR FAMILY MEMBERS.

(a) IDENTIFICATION.—Not later than 180 days after the date of the enactment of this Act, and annually thereafter, the President shall publish a list of each individual the President determines is—

(1) a senior official of the Government of Iran described in subsection (b) that is involved in Iran's—

(A) illicit nuclear activities or proliferation of weapons of mass destruction or delivery systems for weapons of mass destruction;

(B) support for international terrorism; or

(C) commission of serious human rights abuses against citizens of Iran or their family members; or

(2) a family member of such an official.

(b) SENIOR OFFICIALS OF THE GOVERNMENT OF IRAN DESCRIBED.—A senior official of the Government of Iran described in this subsection is any senior official of that Government, including—

(1) the Supreme Leader of Iran, Ali Khamenei;

(2) the President of Iran, Mahmoud Ahmadinejad;

(3) a member of the Cabinet of the Government of Iran;

(4) a member of the Assembly of Experts;

(5) a senior member of the Intelligence Ministry of Iran; or

(6) a member of Iran's Revolutionary Guard Corps with the rank of brigadier general or higher, including a member of a paramilitary organization such as Ansar-e-Hezbollah or Basij-e Motaz'afin.

(c) RESTRICTIONS ON VISAS AND ADJUSTMENTS IN IMMIGRATION STATUS.—The Secretary of State and the Secretary of Homeland Security may not grant an individual on the list required by subsection (a) immigration status in, or admit the individual to, the United States.

(d) WAIVER.—The President may waive the application of subsection (a) or (c) with respect to an individual if the President—

(1) determines that such a waiver is—

(A) in the national interests of the United States; or

(B) necessary to permit the United States to comply with the Agreement between the United Nations and the United States of America regarding the Headquarters of the United Nations, signed June 26, 1947, and entered into force November 21, 1947; and

(2) not less than 7 days before the waiver takes effect, notifies Congress of the waiver and the reason for the waiver.

SEC. 216. REPORTS ON, AND AUTHORIZATION OF IMPOSITION OF SANCTIONS WITH RESPECT TO, THE PROVISION OF FINANCIAL COMMUNICATIONS SERVICES TO THE CENTRAL BANK OF IRAN AND SANCTIONED IRANIAN FINANCIAL INSTITUTIONS.

(a) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) the President has been engaged in diplomatic efforts to multilateralize sanctions against Iran to restrict the access of the Government of Iran to the global financial system;

(2) the President should intensify those efforts and, in particular, efforts to ensure that global financial communications services providers, such as the Society for Worldwide Interbank Financial Telecommunication (in this section referred to as ''SWIFT''), cut off services to Iranian financial institutions designated for the imposition of sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.); and

(3) at a time when financial institutions around the world are severing their ties with such Iranian financial institutions, it is inconsistent and troubling that financial communications services providers continue to service those financial institutions, particularly with respect to the Belgian cooperative SWIFT, which—

(A) is subject to the prohibition of the European Union on providing economic resources to financial institutions designated for the imposition of sanctions by the European Union; and

(B) notes in its own corporate rules that it reserves the right to expel a SWIFT customer that may adversely affect SWIFT's ''reputation, brand, or goodwill'', for instance if the SWIFT customer is subject to sanctions (such as by the United Nations or the European Union), as is the case with Iranian financial institutions.

(b) REPORT ON THE PROVISION OF FINANCIAL COMMUNICATIONS SERVICES TO SANCTIONED IRANIAN FINANCIAL INSTITUTIONS.—Not later than 60 days after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the appropriate congressional committees a list of all known entities (including SWIFT) that provide financial communications services to, or that enable or facilitate access to such 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)).

(c) REPORT ON EFFORTS TO TERMINATE THE PROVISION BY SWIFT OF SERVICES FOR SANCTIONED IRANIAN FINANCIAL INSTITUTIONS.—Not later than 90 days after the date of the enactment of this Act, the Secretary of the Treasury shall submit to the appropriate congressional committees a report on the status of efforts to ensure that SWIFT has terminated the provision of financial communications services to, and the enabling and facilitation of access to such services for, the Central Bank of Iran and Iranian financial institutions designated for the imposition of sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).

(d) AUTHORIZATION FOR THE IMPOSITION OF SANCTIONS.—If, on or after the date that is 90 days after the date of the enactment of this Act, a global financial communications services provider has not terminated the provision of financial communications services to, and the enabling and facilitation of access to such services for, the Central Bank of Iran and any financial institution described in paragraph (2)(E)(ii) of section 104(c) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)), the President may impose sanctions pursuant to that section or the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) with respect to the financial communications services provider and the directors of, and shareholders with a significant interest in, the provider.

SEC. 217. GOVERNMENT ACCOUNTABILITY OFFICE REPORT ON FOREIGN ENTITIES THAT INVEST IN THE ENERGY SECTOR OF IRAN OR EXPORT REFINED PETROLEUM PRODUCTS TO IRAN.

(a) INITIAL REPORT.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the appropriate congressional committees a report—

(A) listing all foreign investors in the energy sector of Iran during the period specified in paragraph (2), including—

(i) all entities that exported gasoline and other refined petroleum products to Iran;

(ii) all entities involved in providing refined petroleum products to Iran, including—

(I) entities that provided ships to transport refined petroleum products to Iran; and

(II) entities that provided insurance or reinsurance for shipments of refined petroleum products to Iran; and

(iii) all entities involved in commercial transactions of any kind, including joint ventures anywhere in the world, with Iranian energy companies; and

(B) identifying the countries in which gasoline and other refined petroleum products exported to Iran during the period specified in paragraph (2) were produced or refined.

(2) PERIOD SPECIFIED.—The period specified in this paragraph is the period beginning on January 1, 2006, and ending on the date that is 150 days after the date of the enactment of this Act.

(b) UPDATED REPORTS.—Not later than one year after submitting the report required by subsection (a), and annually thereafter, the Comptroller General of the United States shall submit to the appropriate congressional committees a report containing the matters required in the report under subsection (a)(1) for the one-year period beginning on the date that is 30 days before the date on which the preceding report was required to be submitted by this section.

SEC. 218. REPORTING ON THE IMPORTATION TO AND EXPORTATION FROM IRAN OF CRUDE OIL AND REFINED PETROLEUM PRODUCTS.

Section 110(b) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8518(b)) is amended by striking ''a report containing the matters'' and all that follows through the period at the end and inserting the following: ''a report, covering the 180-day period beginning on the date that is 30 days before the date on which the preceding report was required to be submitted by this section, that—

''(1) contains the matters required in the report under subsection (a)(1); and

''(2) identifies—

''(A) the volume of crude oil and refined petroleum products imported to and exported from Iran (including through swaps and similar arrangements);

''(B) the persons selling and transporting crude oil and refined petroleum products described in subparagraph (A), the countries with primary jurisdiction over those persons, and the countries in which those products were refined;

''(C) the sources of financing for imports to Iran of crude oil and refined petroleum products described in subparagraph (A); and

''(D) the involvement of foreign persons in efforts to assist Iran in—

''(i) developing upstream oil and gas production capacity;

''(ii) importing advanced technology to upgrade existing Iranian refineries;

''(iii) converting existing chemical plants to petroleum refineries; or

''(iv) maintaining, upgrading, or expanding refineries or constructing new refineries.''.

TITLE III—SANCTIONS WITH RESPECT TO IRAN'S REVOLUTIONARY GUARD CORPS

Subtitle A—Identification of, and Sanctions With Respect to, Officials, Agents, Affiliates, and Supporters of Iran's Revolutionary Guard Corps and Other Sanctioned Persons

SEC. 301. IDENTIFICATION OF, AND IMPOSITION OF SANCTIONS WITH RESPECT TO, OFFICIALS, AGENTS, AND AFFILIATES OF IRAN'S REVOLUTIONARY GUARD CORPS.

(a) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, and as appropriate thereafter, the President shall—

(1) identify foreign persons that are officials, agents, or affiliates of Iran's Revolutionary Guard Corps; and

(2) for each foreign person identified under paragraph (1) that is not already designated for the imposition of sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.)—

(A) designate that foreign person for the imposition of sanctions pursuant to that Act; and

(B) block and prohibit all transactions in all property and interests in property of that foreign person if such property and interests in property are in the United States, come within the United States, or are or come within the possession or control of a United States person.

(b) PRIORITY FOR INVESTIGATION.—In identifying foreign persons pursuant to subsection (a)(1) as officials, agents, or affiliates of Iran's Revolutionary Guard Corps, the President shall give priority to investigating—

(1) foreign persons identified under section 560.304 of title 31, Code of Federal Regulations (relating to the definition of the Government of Iran); and

(2) foreign persons for which there is a reasonable basis to find that the person has conducted or attempted to conduct one or more sensitive transactions or activities described in subsection (c).

(c) SENSITIVE TRANSACTIONS AND ACTIVITIES DESCRIBED.—A sensitive transaction or activity described in this subsection is—

(1) a financial transaction or series of transactions valued at more than $1,000,000 in the aggregate in any 12-month period involving a non-Iranian financial institution;

(2) a transaction to facilitate the manufacture, importation, exportation, or transfer of items needed for the development by Iran of

nuclear, chemical, biological, or advanced conventional weapons, including ballistic missiles;

(3) a transaction relating to the manufacture, procurement, or sale of goods, services, and technology relating to Iran's energy sector, including a transaction relating to the development of the energy resources of Iran, the exportation of petroleum products from Iran, the importation of refined petroleum to Iran, or the development of refining capacity available to Iran;

(4) a transaction relating to the manufacture, procurement, or sale of goods, services, and technology relating to Iran's petrochemical sector; or

(5) a transaction relating to the procurement of sensitive technologies (as defined in section 106(c) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8515(c))).

(d) EXCLUSION FROM UNITED STATES.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary of State shall deny a visa to, and the Secretary of Homeland Security shall exclude from the United States, any alien who, on or after the date of the enactment of this Act, is a foreign person designated pursuant to subsection (a) for the imposition of sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).

(2) REGULATORY EXCEPTIONS TO COMPLY WITH INTERNATIONAL OBLIGATIONS.—The requirement to deny visas to and exclude aliens from the United States pursuant to paragraph (1) shall be subject to such regulations as the President may prescribe, including regulatory exceptions to permit the United States to comply with the Agreement between the United Nations and the United States of America regarding the Headquarters of the United Nations, signed June 26, 1947, and entered into force November 21, 1947, and other applicable international obligations.

(e) WAIVER OF IMPOSITION OF SANCTIONS.—

(1) IN GENERAL.—The President may waive the application of subsection (a)(2) or (d) with respect to a foreign person if the President—

(A) determines that it is in the national security interests of the United States to do so; and

(B) submits to the appropriate congressional committees a report that—

(i) identifies the foreign person with respect to which the waiver applies; and

(ii) sets forth the reasons for the determination.

(2) FORM OF REPORT.—A report submitted under paragraph (1)(B) shall be submitted in unclassified form but may contain a classified annex.

(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to remove any sanction of the United States in force with respect to Iran's Revolutionary Guard Corps as of the date of the enactment of this Act.

SEC. 302. IDENTIFICATION OF, AND IMPOSITION OF SANCTIONS WITH RESPECT TO, PERSONS THAT SUPPORT OR CONDUCT CERTAIN TRANSACTIONS WITH IRAN'S REVOLUTIONARY GUARD CORPS OR OTHER SANCTIONED PERSONS.

(a) IDENTIFICATION.—

(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, and every 180 days thereafter, the President shall submit to the appropriate congressional committees a report identifying foreign persons that the President determines, on or after the date of the enactment of this Act, knowingly—

(A) materially assist, sponsor, or provide financial, material, or technological support for, or goods or services in support of, Iran's Revolutionary Guard Corps or any of its officials, agents, or affiliates the property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.);

(B) engage in a significant transaction or transactions with Iran's Revolutionary Guard Corps or any such official, agent, or affiliate; or

(C) engage in a significant transaction or transactions with—

(i) a person subject to financial sanctions pursuant to United Nations Security Council Resolution 1737 (2006), 1747 (2007), 1803 (2008), or 1929 (2010), or any other resolution that is adopted by the Security Council and imposes sanctions with respect to Iran or modifies such sanctions; or

(ii) a person acting on behalf of or at the direction of, or owned or controlled by, a person described in clause (i).

(2) FORM OF REPORT.—A report submitted under paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

(3) BARTER TRANSACTIONS.—For purposes of paragraph (1), the term ''transaction'' includes a barter transaction.

(b) IMPOSITION OF SANCTIONS.—If the President determines under subsection (a)(1) that a foreign person has knowingly engaged in an activity described in that subsection, the President—

(1) shall impose 3 or more of the sanctions described in section 6(a) of the Iran Sanctions Act of 1996, as amended by section 204 of this Act; and

(2) may impose additional sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) with respect to the person.

(c) TERMINATION.—The President may terminate a sanction imposed with respect to a foreign person pursuant to subsection (b) if the President determines that the person—

(1) no longer engages in the activity for which the sanction was imposed; and

(2) has provided assurances to the President that the person will not engage in any activity described in subsection (a)(1) in the future.

(d) WAIVER OF IMPOSITION OF SANCTIONS.—

(1) IN GENERAL.—The President may waive the imposition of sanctions under subsection (b) with respect to a foreign person if the President—

(A)(i) determines that the person has ceased the activity for which sanctions would otherwise be imposed and has taken measures to prevent a recurrence of the activity; or

(ii) determines that it is in the national security interests of the United States to do so; and

(B) submits to the appropriate congressional committees a report that—

(i) identifies the foreign person with respect to which the waiver applies;

(ii) describes the activity that would otherwise subject the foreign person to the imposition of sanctions under subsection (b); and

(iii) sets forth the reasons for the determination.

(2) FORM OF REPORT.—A report submitted under paragraph (1)(B) shall be submitted in unclassified form but may contain a classified annex.

(e) WAIVER OF IDENTIFICATIONS AND DESIGNATIONS.—Notwithstanding any other provision of this subtitle and subject to paragraph (2), the President shall not be required to make any identification of a foreign person under subsection (a) or any identification or designation of a foreign person under section 301(a) if the President—

(1) determines that doing so would cause damage to the national security of the United States, including through the divulgence of sources or methods of obtaining intelligence or other critical classified information; and

(2) notifies the appropriate congressional committees of the exercise of the authority provided under this subsection.

(f) APPLICATION OF PROVISIONS OF IRAN SANCTIONS ACT OF 1996.—The following provisions of the Iran Sanctions Act of 1996, as amended by this Act, apply with respect to the imposition under subsection (b)(1) of sanctions relating to activities described in subsection (a)(1) to the same extent that such provisions apply with respect to the imposition of sanctions under section 5(a) of the Iran Sanctions Act of 1996:

(1) Subsections (c) and (e) of section 4.
(2) Subsections (c), (d), and (f) of section 5.
(3) Section 8.
(4) Section 9.
(5) Section 11.
(6) Section 12.
(7) Subsection (b) of section 13.
(8) Section 14.

SEC. 303. RULE OF CONSTRUCTION.

Nothing in this subtitle shall be construed to limit the authority of the President to designate foreign persons for the imposition of sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).

Subtitle B—Additional Measures Relating to Iran's Revolutionary Guard Corps

SEC. 311. EXPANSION OF PROCUREMENT PROHIBITION TO FOREIGN PERSONS THAT ENGAGE IN CERTAIN TRANSACTIONS WITH IRAN'S REVOLUTIONARY GUARD CORPS.

(a) IN GENERAL.—Section 6(b)(1) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) is amended—

(1) by striking ''Not later than 90 days'' and inserting the following:

''(A) CERTIFICATIONS RELATING TO ACTIVITIES DESCRIBED IN SECTION 5.—Not later than 90 days''; and

(2) by adding at the end the following:

''(B) CERTIFICATIONS RELATING TO TRANSACTIONS WITH IRAN'S REVOLUTIONARY GUARD CORPS.—Not later than 90 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, the Federal Acquisition Regulation shall be revised to require a certification from each person that is a prospective contractor that the person, and any person owned or controlled by the person, does not knowingly engage in a significant transaction or transactions with Iran's Revolutionary Guard Corps or any of its officials, agents, or affiliates the property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.).''.

(b) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) Section 6(b) of the Iran Sanctions Act of 1996, as amended by subsection (a), is further amended—

(A) in paragraph (1)(A), as redesignated, by striking ''issued pursuant to section 25 of the Office of Federal Procurement Policy Act (41 U.S.C. 421)'';

(B) in paragraph (2)—

(i) in subparagraph (A), by striking ''the revision'' and inserting ''the applicable revision''; and

(ii) in subparagraph (B), by striking ''issued pursuant to section 25 of the Office of Federal Procurement Policy Act (41 U.S.C. 421)'';

(C) by striking paragraph (6) and inserting the following:

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

''(A) EXECUTIVE AGENCY.—The term 'executive agency' has the meaning given that term in section 133 of title 41, United States Code.

''(B) FEDERAL ACQUISITION REGULATION.—The term 'Federal Acquisition Regulation' means the regulation issued pursuant to section 1303(a)(1) of title 41, United States Code.''; and

(D) in paragraph (7)—

(i) by striking ''The revisions to the Federal Acquisition Regulation required under paragraph (1)'' and inserting the following:

''(A) CERTIFICATIONS RELATING TO ACTIVITIES DESCRIBED IN SECTION 5.—The revisions to the Federal Acquisition Regulation required under paragraph (1)(A)''; and

(ii) by adding at the end the following:

''(B) CERTIFICATIONS RELATING TO TRANSACTIONS WITH IRAN'S REVOLUTIONARY GUARD CORPS.—The revisions to the Federal Acquisition Regulation required under paragraph (1)(B) shall apply with respect to contracts for which solicitations are issued on or after the date that is 90 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012.''.

(2) Section 101(3) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8511(3)) is amended by striking ''section 4 of the Office of Federal Procurement Policy Act (41 U.S.C. 403)'' and inserting ''section 133 of title 41, United States Code''.

SEC. 312. DETERMINATIONS OF WHETHER THE NATIONAL IRANIAN OIL COMPANY AND THE NATIONAL IRANIAN TANKER COMPANY ARE AGENTS OR AFFILIATES OF IRAN'S REVOLUTIONARY GUARD CORPS.

(a) IN GENERAL.—Section 104(c) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)) is amended by adding at the end the following:

''(4) DETERMINATIONS REGARDING NIOC AND NITC.—

''(A) DETERMINATIONS.—For purposes of paragraph (2)(E)(i), the Secretary of the Treasury shall, not later than 60 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012—

''(i) determine whether the NIOC or the NITC is an agent or affiliate of Iran's Revolutionary Guard Corps; and

''(ii) submit to the appropriate congressional committees a report on the determinations made under clause (i), together with the reasons for those determinations.

''(B) FORM OF REPORT.—A report submitted under subparagraph (A)(ii) shall be submitted in unclassified form but may contain a classified annex.

''(C) APPLICABILITY WITH RESPECT TO PETROLEUM TRANSACTIONS.—

''(i) APPLICATION OF SANCTIONS.—Except as provided in clause (ii), the regulations prescribed under paragraph (1) shall apply to a transaction for the purchase of petroleum or petroleum products from, or to financial services relating to such a transaction for, the NIOC or the NITC on or after the date that is 180 days after the date of the enactment of the National Defense Authorization Act for Fiscal Year 2012 (Public Law 112–81) only if the President has determined, pursuant to section 1245(d)(4)(B) of that Act, that there is a sufficient supply of petroleum and petroleum products produced in countries other than Iran to permit purchasers of petroleum and petroleum products from Iran to reduce significantly in volume their purchases from Iran.

''(ii) EXCEPTION FOR CERTAIN COUNTRIES.—The regulations prescribed under paragraph (1) shall not apply to a foreign financial institution that facilitates a significant transaction or transactions for the purchase of petroleum or petroleum products from, or that provides significant financial services relating to such a transaction for, the NIOC or the NITC if the President determines and reports to Congress, not later than 90 days after the date on which the President makes the determination required by section 1245(d)(4)(B) of the National Defense Authorization Act for Fiscal Year 2012, and every 180 days thereafter, that the country with primary jurisdiction over the foreign financial institution has significantly reduced its volume of crude oil purchases from Iran during the period beginning on the date on which the President submitted the last report with respect to the country under this clause.

''(D) DEFINITIONS.—In this paragraph:

''(i) NIOC.—The term 'NIOC' means the National Iranian Oil Company.

''(ii) NITC.—The term 'NITC' means the National Iranian Tanker Company.''.

(b) CONFORMING AMENDMENTS.—Section 104(g) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(g)) is amended by striking ''subsection (c)(1)'' each place it appears and inserting ''paragraph (1) or (4) of subsection (c)''.

TITLE IV—MEASURES RELATING TO HUMAN RIGHTS ABUSES IN IRAN

Subtitle A—Expansion of Sanctions Relating to Human Rights Abuses in Iran

SEC. 401. IMPOSITION OF SANCTIONS WITH RESPECT TO THE TRANSFER OF GOODS OR TECHNOLOGIES TO IRAN THAT ARE LIKELY TO BE USED TO COMMIT HUMAN RIGHTS ABUSES.

(a) IN GENERAL.—The Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8501 et seq.) is amended by inserting after section 105 the following:

''SEC. 105A. IMPOSITION OF SANCTIONS WITH RESPECT TO THE TRANSFER OF GOODS OR TECHNOLOGIES TO IRAN THAT ARE LIKELY TO BE USED TO COMMIT HUMAN RIGHTS ABUSES.

''(a) IN GENERAL.—The President shall impose sanctions in accordance with subsection (c) with respect to each person on the list required by subsection (b).

''(b) LIST.—

''(1) IN GENERAL.—Not later than 90 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, the President shall submit to the appropriate congressional committees a list of persons that the President determines have knowingly engaged in an activity described in paragraph (2) on or after such date of enactment.

''(2) ACTIVITY DESCRIBED.—

''(A) IN GENERAL.—A person engages in an activity described in this paragraph if the person—

''(i) transfers, or facilitates the transfer of, goods or technologies described in subparagraph (C) to Iran; or

''(ii) provides services with respect to goods or technologies described in subparagraph (C) after such goods or technologies are transferred to Iran.

''(B) APPLICABILITY TO CONTRACTS AND OTHER AGREEMENTS.—A person engages in an activity described in subparagraph (A) without regard to whether the activity is carried out pursuant to a contract or other agreement entered into before, on, or after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012.

''(C) GOODS OR TECHNOLOGIES DESCRIBED.—Goods or technologies described in this subparagraph are goods or technologies that the President determines are likely to be used by the Government of Iran or any of its agencies or instrumentalities to commit serious human rights abuses against the people of Iran, including—

''(i) firearms or ammunition (as those terms are defined in section 921 of title 18, United States Code), rubber bullets, police batons, pepper or chemical sprays, stun grenades, electroshock weapons, tear gas, water cannons, or surveillance technology; or

''(ii) sensitive technology (as defined in section 106(c)).

''(3) SPECIAL RULE TO ALLOW FOR TERMINATION OF SANCTIONABLE ACTIVITY.—The President shall not be required to include a person on the list required by paragraph (1) if the President certifies in writing to the appropriate congressional committees that—

''(A) the person is no longer engaging in, or has taken significant verifiable steps toward stopping, the activity described in paragraph (2) for which the President would otherwise have included the person on the list; and

''(B) the President has received reliable assurances that the person will not knowingly engage in any activity described in paragraph (2) in the future.

''(4) UPDATES OF LIST.—The President shall submit to the appropriate congressional committees an updated list under paragraph (1)—

''(A) each time the President is required to submit an updated list to those committees under section 105(b)(2)(A); and

''(B) as new information becomes available.

''(5) FORM OF REPORT; PUBLIC AVAILABILITY.—

''(A) FORM.—The list required by paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

''(B) PUBLIC AVAILABILITY.—The unclassified portion of the list required by paragraph (1) shall be made available to the public and posted on the websites of the Department of the Treasury and the Department of State.

''(c) APPLICATION OF SANCTIONS.—

''(1) IN GENERAL.—Subject to paragraph (2), the President shall impose sanctions described in section 105(c) with respect to a person on the list required by subsection (b).

''(2) TRANSFERS TO IRAN'S REVOLUTIONARY GUARD CORPS.—In the case of a person on the list required by subsection (b) for transferring, or facilitating the transfer of, goods or technologies described in subsection (b)(2)(C) to Iran's Revolutionary Guard Corps, or providing services with respect to such goods or technologies after such goods or technologies are transferred to Iran's Revolutionary Guard Corps, the President shall—

''(A) impose sanctions described in section 105(c) with respect to the person; and

''(B) impose such other sanctions from among the sanctions described in section 6(a) of the Iran Sanctions Act of 1996 (Public Law 104–172; 50 U.S.C. 1701 note) as the President determines appropriate.''.

(b) CLERICAL AMENDMENT.—The table of contents for the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 is amended by inserting after the item relating to section 105 the following:

''Sec. 105A. Imposition of sanctions with respect to the transfer of goods or technologies to Iran that are likely to be used to commit human rights abuses.''.

SEC. 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 further amended by inserting after section 105A the following:

''SEC. 105B. IMPOSITION OF SANCTIONS WITH RESPECT TO PERSONS WHO ENGAGE IN CENSORSHIP OR OTHER RELATED ACTIVITIES AGAINST CITIZENS OF IRAN.

''(a) IN GENERAL.—The President shall impose sanctions described in section 105(c)

with respect to each person on the list required by subsection (b).

''(b) LIST OF PERSONS WHO ENGAGE IN CENSORSHIP.—

''(1) IN GENERAL.—Not later than 90 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, the President shall submit to the appropriate congressional committees a list of persons that the President determines have 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, Accountability, and Human Rights Act of 2012; or

''(B) commenced before such date of enactment, 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)—

''(A) each time the President is required to submit an updated list to those committees under section 105(b)(2)(A); and

''(B) as new information becomes available.

''(4) FORM OF REPORT; PUBLIC AVAILABILITY.—

''(A) FORM.—The list required by paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

''(B) PUBLIC AVAILABILITY.—The unclassified portion of the list required by paragraph (1) shall be made available to the public and posted on the websites of the Department of the Treasury and the Department of State.''.

(b) CLERICAL AMENDMENT.—The table of contents for the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, as amended by section 401, is further amended by inserting after the item relating to section 105A the following:

''Sec. 105B. Imposition of sanctions with respect to persons who engage in censorship or other related activities against citizens of Iran.''.

(c) CONFORMING AMENDMENTS.—Section 401(b)(1) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8551(b)(1)) is amended—

(1) by inserting '', 105A(a), or 105B(a)'' after ''105(a)''; and

(2) by inserting '', 105A(b), or 105B(b)'' after ''105(b)''.

Subtitle B—Additional Measures to Promote Human Rights in Iran

SEC. 411. EXPEDITED CONSIDERATION OF REQUESTS FOR AUTHORIZATION OF CERTAIN HUMAN RIGHTS-, HUMANITARIAN-, AND DEMOCRACY-RELATED ACTIVITIES WITH RESPECT TO IRAN.

(a) REQUIREMENT.—The Office of Foreign Assets Control, in consultation with the Department of State, shall establish an expedited process for the consideration of complete requests for authorization to engage in human rights-, humanitarian-, or democracy-related activities relating to Iran that are submitted by—

(1) entities receiving funds from the Department of State to engage in the proposed activity;

(2) the Broadcasting Board of Governors; and

(3) other appropriate agencies of the United States Government.

(b) PROCEDURES.—Requests for authorization under subsection (a) shall be submitted to the Office of Foreign Assets Control in conformance with the agency's regulations, including section 501.801 of title 31, Code of Federal Regulations (commonly known as the Reporting, Procedures and Penalties Regulations). Applicants must fully disclose the parties to the transactions as well as describe the activities to be undertaken. License applications involving the exportation or reexportation of goods, technology, or software to Iran must provide a copy of an official Commodity Classification issued by the Department of Commerce, Bureau of Industry and Security, as part of the license application.

(c) FOREIGN POLICY REVIEW.—The Department of State shall complete a foreign policy review of a request for authorization under subsection (a) not later than 30 days after the request is referred to the Department by the Office of Foreign Assets Control.

(d) LICENSE DETERMINATIONS.—License determinations for complete requests for authorization under subsection (a) shall be made not later than 90 days after receipt by the Office of Foreign Assets Control, with the following exceptions:

(1) Any requests involving the exportation or reexportation to Iran of goods, technology, or software listed on the Commerce Control List maintained pursuant to part 774 of the Export Administration Regulations shall be processed in a manner consistent with the Iran-Iraq Arms Non-Proliferation Act of 1992 (title XVI of Public Law 102–484) and other applicable provisions of law.

(2) Any other requests presenting novel or extraordinary circumstances.

(e) REGULATIONS.—The Secretary of the Treasury may prescribe such regulations as are appropriate to carry out this section.

SEC. 412. COMPREHENSIVE STRATEGY TO PROMOTE INTERNET FREEDOM AND ACCESS TO INFORMATION IN IRAN.

Not later than 90 days after the date of the enactment of this Act, the President shall submit to the appropriate congressional committees a comprehensive strategy developed in consultation with the Department of State, the Department of the Treasury, and other Federal agencies, as appropriate, to—

(1) assist the people of Iran to produce, access, and share information freely and safely via the Internet, including in Farsi and regional languages;

(2) support the development of countercensorship technologies that enable the citizens of Iran to undertake Internet activities without interference from the Government of Iran;

(3) increase the capabilities and availability of secure communications through connective technology among human rights and democracy activists in Iran;

(4) provide resources for digital safety training for media and academic and civil society organizations in Iran;

(5) provide accurate and substantive Internet content in local languages in Iran;

(6) increase emergency resources for the most vulnerable human rights advocates seeking to organize, share information, and support human rights in Iran;

(7) expand surrogate radio, television, live stream, and social network communications inside Iran, including Voice of America's Persian News Network and Radio Free Europe/Radio Liberty's Radio Farda, to provide hourly live news update programming and breaking news coverage capability 24 hours a day and 7 days a week;

(8) expand activities to safely assist and train human rights, civil society, and democracy activists in Iran to operate effectively and securely;

(9) identify and utilize all available resources to overcome attempts by the Government of Iran to jam or otherwise deny international satellite broadcasting signals; and

(10) expand worldwide United States embassy and consulate programming for and outreach to Iranian dissident communities.

SEC. 413. SENSE OF CONGRESS ON POLITICAL PRISONERS.

It is the sense of Congress that—

(1) the Secretary of State should support efforts to research and identify prisoners of conscience and cases of human rights abuses in Iran;

(2) the United States Government should—

(A) offer refugee status or political asylum in the United States to political dissidents in Iran if requested and consistent with the laws and national security interests of the United States; and

(B) offer to assist, through the United Nations High Commissioner for Refugees, with the relocation of such political prisoners to other countries if requested, as appropriate and with appropriate consideration for United States national security interests; and

(3) the Secretary of State should publicly call for the release of Iranian dissidents by name and raise awareness with respect to individual cases of Iranian dissidents and prisoners of conscience, as appropriate and if requested by the dissidents or prisoners themselves or their families.

TITLE V—MISCELLANEOUS

SEC. 501. EXCLUSION OF CITIZENS OF IRAN SEEKING EDUCATION RELATING TO THE NUCLEAR AND ENERGY SECTORS OF IRAN.

(a) IN GENERAL.—The Secretary of State shall deny a visa to, and the Secretary of Homeland Security shall exclude from the United States, any alien who is a citizen of Iran that the Secretary of State determines seeks to enter the United States to participate in coursework at an institution of higher education (as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a))) to prepare the alien for a career in the energy sector of Iran or in nuclear science or nuclear engineering or a related field in Iran.

(b) APPLICABILITY.—Subsection (a) applies with respect to visa applications filed on or after the date of the enactment of this Act.

SEC. 502. TECHNICAL CORRECTION.

(a) IN GENERAL.—Section 1245(d)(2) of the National Defense Authorization Act for Fiscal Year 2012 (Public Law 112–81) is amended—

(1) in the paragraph heading, by inserting ''AGRICULTURAL COMMODITIES,'' after ''SALES OF''; and

(2) in the text, by inserting ''agricultural commodities,'' after ''sale of''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect as if included in the National Defense Authorization Act for Fiscal Year 2012 (Public Law 112–81).

SEC. 503. INTERESTS IN FINANCIAL ASSETS OF IRAN.

(a) INTERESTS IN BLOCKED ASSETS.—Notwithstanding 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 interest 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 institution. 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 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 securities intermediary that directly or indirectly holds the interest for the benefit of Iran, in securities or other financial assets that are represented by certificates or are in other physical form and are immobilized, custodized, 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 securities intermediary 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.

(c) DETERMINATION OF WHETHER SECURITIES OR OTHER ASSETS ARE HELD OR CREDITED TO A SECURITIES ACCOUNT IN THE UNITED STATES.—For purposes of this section, an interest in securities or other financial assets is held and credited to a securities account in the United States by a securities intermediary if the securities intermediary is located in the United States. A securities intermediary is conclusively presumed to be located in the United States if it is regulated in its capacity as a securities intermediary under the laws of the United States.

(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 interest in that 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 attachments and proceedings 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 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.

(f) DEFINITIONS.—In this section:

(1) BLOCKED ASSET.—The term ''blocked asset''—

(A) means any asset seized or frozen by the United States under section 5(b) of the Trading With the Enemy Act (50 U.S.C. App. 5(b)) or under section 202 or 203 of the International Emergency Economic Powers Act (50 U.S.C. 1701 and 1702); and

(B) does not include property that—

(i) is subject to a license issued by the United States Government for final payment, transfer, or disposition by or to a person subject to the jurisdiction of the United States in connection with a transaction for which the issuance of the license has been specifically required by a provision of law other than the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) or the United Nations Participation Act of 1945 (22 U.S.C. 287 et seq.); or

(ii) is property subject to the Vienna Convention on Diplomatic Relations or the Vienna Convention on Consular Relations, or that enjoys equivalent privileges and immunities under the laws of the United States, and is being used exclusively for diplomatic or consular purposes.

(2) CLEARING CORPORATION.—The term ''clearing corporation'' means—

(A) a clearing agency (as defined in section 3(a)(23) of the Securities Exchange Act of 1934 (15 U.S.C. 78c(a)(23)));

(B) a Federal reserve bank; or

(C) any other person that provides clearance or settlement services with respect to financial assets that would require it to register as a clearing agency under the Federal securities laws but for an exclusion or exemption from the registration requirement under section 3(a)(23)(B) of the Securities Exchange Act of 1934, if its activities as a clearing corporation, including promulgation of rules, are subject to regulation by a Federal or State governmental authority.

(3) FINANCIAL ASSET; SECURITY.—The terms ''financial asset'' and ''security'' have the meanings given those terms in the Uniform Commercial Code.

(4) IRAN.—The term ''Iran'' means the Government of Iran, including the central bank or monetary authority of that Government and any agency or instrumentality of that Government.

(5) PROPERTY SUBJECT TO THE VIENNA CONVENTION ON DIPLOMATIC RELATIONS OR THE VIENNA CONVENTION ON CONSULAR RELATIONS.—The term ''property subject to the Vienna Convention on Diplomatic Relations or the Vienna Convention on Consular Relations'' means any property the attachment in aid of execution or execution of which would result in a violation of an obligation of the United States under the Vienna Convention on Diplomatic Relations, done at Vienna April 18, 1961, or the Convention on Consular Relations, done at Vienna April 24, 1963.

(6) SECURITIES INTERMEDIARY.—The term ''securities intermediary'' means—

(A) a clearing corporation; or

(B) a person, including a bank or broker, that in the ordinary course of its business maintains securities accounts for others and is acting in that capacity.

(7) UNITED STATES.—The terms ''United States'' includes all territory and waters, continental or insular, subject to the jurisdiction of the United States.

SEC. 504. REPORT ON MEMBERSHIP OF IRAN IN INTERNATIONAL ORGANIZATIONS.

Not later than 180 days after the date of the enactment of this Act, and annually thereafter not later than September 1, the Secretary of State shall submit to Congress a report listing the international organizations of which Iran is a member and detailing the amount that the United States contributes to each such organization on an annual basis.

TITLE VI—GENERAL PROVISIONS

SEC. 601. TECHNICAL IMPLEMENTATION; PENALTIES.

(a) IMPLEMENTATION.—The President may exercise all authorities provided under sections 203 and 205 of the International Emergency Economic Powers Act (50 U.S.C. 1702 and 1704) to carry out—

(1) sections 211, 213, and 216, subtitle A of title III, and title VII of this Act; and

(2) sections 105A and 105B of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, as added by subtitle A of title IV of this Act.

(b) PENALTIES.—

(1) IN GENERAL.—The penalties provided for in subsections (b) and (c) of section 206 of the International Emergency Economic Powers Act (50 U.S.C. 1705) shall apply to a person that violates, attempts to violate, conspires to violate, or causes a violation of a provision specified in paragraph (2) of this subsection, or an order or regulation prescribed under such a provision, to the same extent that such penalties apply to a person that commits an unlawful act described in section 206(a) of that Act.

(2) PROVISIONS SPECIFIED.—The provisions specified in this paragraph are the following:

(A) Sections 211 and 216, subtitle A of title III, and title VII of this Act.

(B) Sections 105A and 105B of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, as added by subtitle A of title IV of this Act.

SEC. 602. APPLICABILITY TO CERTAIN INTELLIGENCE ACTIVITIES.

Nothing in this Act or the amendments made by this Act shall apply to the authorized intelligence activities of the United States.

SEC. 603. TERMINATION.

The provisions of sections 211, 213, 215, 216, 217, and 501, title I, and subtitle A of title III shall terminate on the date that is 30 days after the date on which the President makes the certification described in section 401(a) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8551(a)).

TITLE VII—SANCTIONS WITH RESPECT TO HUMAN RIGHTS ABUSES IN SYRIA

SEC. 701. SHORT TITLE.

This title may be cited as the ''Syria Human Rights Accountability Act of 2012''.

SEC. 702. IMPOSITION OF SANCTIONS WITH RESPECT TO CERTAIN PERSONS WHO ARE RESPONSIBLE FOR OR COMPLICIT IN HUMAN RIGHTS ABUSES COMMITTED AGAINST CITIZENS OF SYRIA OR THEIR FAMILY MEMBERS.

(a) IN GENERAL.—The President shall impose sanctions described in subsection (c) with respect to each person on the list required by subsection (b).

(b) LIST OF PERSONS WHO ARE RESPONSIBLE FOR OR COMPLICIT IN CERTAIN HUMAN RIGHTS ABUSES.—

(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the President shall submit to the appropriate congressional committees a list of persons who are officials of the Government of Syria or persons acting on behalf of that Government that the President determines, based on credible evidence, are responsible for or complicit in, or responsible for ordering, controlling, or otherwise directing, the commission of serious human rights abuses against citizens of Syria or their family members, regardless of whether such abuses occurred in Syria.

(2) UPDATES OF LIST.—The President shall submit to the appropriate congressional committees an updated list under paragraph (1)—

(A) not later than 270 days after the date of the enactment of this Act and every 180 days thereafter; and

(B) as new information becomes available.

(3) FORM OF REPORT; PUBLIC AVAILABILITY.—

(A) FORM.—The list required by paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

(B) PUBLIC AVAILABILITY.—The unclassified portion of the list required by paragraph (1) shall be made available to the public and posted on the websites of the Department of the Treasury and the Department of State.

(4) CONSIDERATION OF DATA FROM OTHER COUNTRIES AND NONGOVERNMENTAL ORGANIZATIONS.—In preparing the list required by paragraph (1), the President shall consider credible data already obtained by other countries and nongovernmental organizations, including organizations in Syria, that

monitor the human rights abuses of the Government of Syria.

(c) SANCTIONS DESCRIBED.—The sanctions described in this subsection are sanctions pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.), including blocking of property and restrictions or prohibitions on financial transactions and the exportation and importation of property, subject to such regulations as the President may prescribe.

SEC. 703. IMPOSITION OF SANCTIONS WITH RESPECT TO THE TRANSFER OF GOODS OR TECHNOLOGIES TO SYRIA THAT ARE LIKELY TO BE USED TO COMMIT HUMAN RIGHTS ABUSES.

(a) IN GENERAL.—The President shall impose sanctions described in section 702(c) with respect to—

(1) each person on the list required by subsection (b); and

(2) any person that—

(A) is a successor entity to a person on the list;

(B) owns or controls a person on the list, if the person that owns or controls the person on the list had actual knowledge or should have known that the person on the list engaged in the activity described in subsection (b)(2) for which the person was included in the list; or

(C) is owned or controlled by, or under common ownership or control with, the person on the list, if the person owned or controlled by, or under common ownership or control with (as the case may be), the person on the list knowingly engaged in the activity described in subsection (b)(2) for which the person was included in the list.

(b) LIST.—

(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the President shall submit to the appropriate congressional committees a list of persons that the President determines have knowingly engaged in an activity described in paragraph (2) on or after such date of enactment.

(2) ACTIVITY DESCRIBED.—

(A) IN GENERAL.—A person engages in an activity described in this paragraph if the person—

(i) transfers, or facilitates the transfer of, goods or technologies described in subparagraph (C) to Syria; or

(ii) provides services with respect to goods or technologies described in subparagraph (C) after such goods or technologies are transferred to Syria.

(B) APPLICABILITY TO CONTRACTS AND OTHER AGREEMENTS.—A person engages in an activity described in subparagraph (A) without regard to whether the activity is carried out pursuant to a contract or other agreement entered into before, on, or after the date of the enactment of this Act.

(C) GOODS OR TECHNOLOGIES DESCRIBED.—Goods or technologies described in this subparagraph are goods or technologies that the President determines are likely to be used by the Government of Syria or any of its agencies or instrumentalities to commit human rights abuses against the people of Syria, including—

(i) firearms or ammunition (as those terms are defined in section 921 of title 18, United States Code), rubber bullets, police batons, pepper or chemical sprays, stun grenades, electroshock weapons, tear gas, water cannons, or surveillance technology; or

(ii) sensitive technology.

(D) SENSITIVE TECHNOLOGY DEFINED.—

(i) IN GENERAL.—For purposes of subparagraph (C), the term ''sensitive technology'' means hardware, software, telecommunications equipment, or any other technology, that the President determines is to be used specifically—

(I) to restrict the free flow of unbiased information in Syria; or

(II) to disrupt, monitor, or otherwise restrict speech of the people of Syria.

(ii) EXCEPTION.—The term ''sensitive technology'' does not include information or informational materials the exportation of which the President does not have the authority to regulate or prohibit pursuant to section 203(b)(3) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)(3)).

(3) SPECIAL RULE TO ALLOW FOR TERMINATION OF SANCTIONABLE ACTIVITY.—The President shall not be required to include a person on the list required by paragraph (1) if the President certifies in writing to the appropriate congressional committees that—

(A) the person is no longer engaging in, or has taken significant verifiable steps toward stopping, the activity described in paragraph (2) for which the President would otherwise have included the person on the list; and

(B) the President has received reliable assurances that the person will not knowingly engage in any activity described in paragraph (2) in the future.

(4) UPDATES OF LIST.—The President shall submit to the appropriate congressional committees an updated list under paragraph (1)—

(A) not later than 270 days after the date of the enactment of this Act and every 180 days thereafter; and

(B) as new information becomes available.

(5) FORM OF REPORT; PUBLIC AVAILABILITY.—

(A) FORM.—The list required by paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

(B) PUBLIC AVAILABILITY.—The unclassified portion of the list required by paragraph (1) shall be made available to the public and posted on the websites of the Department of the Treasury and the Department of State.

SEC. 704. IMPOSITION OF SANCTIONS WITH RESPECT TO PERSONS WHO ENGAGE IN CENSORSHIP OR OTHER FORMS OF REPRESSION IN SYRIA.

(a) IN GENERAL.—The President shall impose sanctions described in section 702(c) with respect to each person on the list required by subsection (b).

(b) LIST OF PERSONS WHO ENGAGE IN CENSORSHIP.—

(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the President shall submit to the appropriate congressional committees a list of persons that the President determines have engaged in censorship, or activities relating to censorship, in a manner that prohibits, limits, or penalizes the legitimate exercise of freedom of expression by citizens of Syria.

(2) UPDATES OF LIST.—The President shall submit to the appropriate congressional committees an updated list under paragraph (1)—

(A) not later than 270 days after the date of the enactment of this Act and every 180 days thereafter; and

(B) as new information becomes available.

(3) FORM OF REPORT; PUBLIC AVAILABILITY.—

(A) FORM.—The list required by paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

(B) PUBLIC AVAILABILITY.—The unclassified portion of the list required by paragraph (1) shall be made available to the public and posted on the websites of the Department of the Treasury and the Department of State.

SEC. 705. WAIVER.

The President may waive the requirement to include a person on a list required by section 702, 703, or 704 or to impose sanctions pursuant to any such section if the President—

(1) determines that such a waiver is in the national security interests of the United States; and

(2) submits to the appropriate congressional committees a report on the reasons for that determination.

SEC. 706. TERMINATION.

(a) IN GENERAL.—The provisions of this title and any sanctions imposed pursuant to this title shall terminate on the date on which the President submits to the appropriate congressional committees—

(1) the certification described in subsection (b); and

(2) a certification that—

(A) the Government of Syria is democratically elected and representative of the people of Syria; or

(B) a legitimate transitional government of Syria is in place.

(b) CERTIFICATION DESCRIBED.—A certification described in this subsection is a certification by the President that the Government of Syria—

(1) has unconditionally released all political prisoners;

(2) has ceased its practices of violence, unlawful detention, torture, and abuse of citizens of Syria engaged in peaceful political activity;

(3) has ceased its practice of procuring sensitive technology designed to restrict the free flow of unbiased information in Syria, or to disrupt, monitor, or otherwise restrict the right of citizens of Syria to freedom of expression;

(4) has ceased providing support for foreign terrorist organizations and no longer allows such organizations, including Hamas, Hezbollah, and Palestinian Islamic Jihad, to maintain facilities in territory under the control of the Government of Syria; and

(5) has ceased the development and deployment of medium- and long-range surface-to-surface ballistic missiles;

(6) is not pursuing or engaged in the research, development, acquisition, production, transfer, or deployment of biological, chemical, or nuclear weapons, and has provided credible assurances that it will not engage in such activities in the future; and

(7) has agreed to allow the United Nations and other international observers to verify that the Government of Syria is not engaging in such activities and to assess the credibility of the assurances provided by that Government.

(c) SUSPENSION OF SANCTIONS AFTER ELECTION OF DEMOCRATIC GOVERNMENT.—If the President submits to the appropriate congressional committees the certification described in subsection (a)(2), the President may suspend the provisions of this title and any sanctions imposed under this title for not more than one year to allow time for a certification described in subsection (b) to be submitted.

SA 2124. Mr. REID (for Mr. JOHNSON of South Dakota (for himself and Mr. SHELBY)) proposed an amendment to amendment SA 2123 proposed by Mr. REID (for Mr. JOHNSON of South Dakota (for himself and Mr. SHELBY)) 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:

SEC. 102. SENSE OF CONGRESS ON ENFORCEMENT OF MULTILATERAL SANCTIONS REGIME AND EXPANSION AND IMPLEMENTATION OF SANCTIONS LAWS.

It is the sense of Congress that the goal of compelling Iran to abandon efforts to acquire a nuclear weapons capability and other threatening activities can be effectively achieved through a comprehensive policy that includes economic sanctions, diplomacy, and military planning, capabilities and options, and that this objective is consistent with the one stated by President Barack Obama in the 2012 State of the Union Address: ''Let there be no doubt: America is determined to prevent Iran from getting a nuclear weapon, and I will take no options off the table to achieve that goal''. Among these economic sanctions are—

(1) prompt enforcement of the current multilateral sanctions regime with respect to Iran;

(2) full, timely, and vigorous implementation of all sanctions enacted into law, including sanctions imposed or expanded by this Act or amendments made by this Act, through—

(A) intensified monitoring by the President and his designees, including the Secretary of the Treasury and the Secretary of State, along with senior officials in the intelligence community, as appropriate;

(B) more extensive use of extraordinary authorities provided for under the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) and other sanctions laws;

(C) reallocation of resources to provide the personnel necessary, within the Department of the Treasury, the Department of State, and the Department of Defense, and, where appropriate, the intelligence community, to apply and enforce sanctions; and

(D) expanded cooperation with international sanctions enforcement efforts;

(3) urgent consideration of the expansion of existing sanctions with respect to such areas as—

(A) the provision of energy-related services to Iran;

(B) the provision of insurance and reinsurance services to Iran;

(C) the provision of shipping services to Iran;

(D) those Iranian financial institutions not currently designated for the imposition of sanctions that may be acting as intermediaries for Iranian financial institutions that are designated for the imposition of sanctions; and

(4) a focus on countering Iran's efforts to evade sanctions, including—

(A) the activities of telecommunications, Internet, and satellite service providers, within and outside of Iran, to ensure that such providers are not participating in or facilitating, directly or indirectly, the evasion of the sanctions regime with respect to Iran or violations of the human rights of the people of Iran;

(B) the activities of financial institutions or other businesses or government agencies, within or outside of Iran, not yet designated for the imposition of sanctions; and

(C) urgent and ongoing evaluation of Iran's energy, national security, financial, and telecommunications sectors, to gauge the effects of, and possible defects in, particular sanctions, with prompt efforts to correct any gaps in the existing sanctions regime with respect to Iran.

On page 30, line 12, insert ''that includes a disclosure of an activity described in paragraph (1) (other than an activity described in subparagraph (D)(iii) of that paragraph)'' after ''paragraph (4)''.

On page 33, strike lines 1 through 20, and insert the following:

(c) RESTRICTIONS ON VISAS AND ADJUSTMENTS IN IMMIGRATION STATUS.—Except as provided in subsection (d), the Secretary of State and the Secretary of Homeland Security may not grant an individual on the list required by subsection (a) immigration status in, or admit the individual to, the United States.

(d) EXCEPTION TO COMPLY WITH UNITED NATIONS HEADQUARTERS AGREEMENT.—Subsection (c) shall not apply to an individual if admitting the individual to the United States is necessary to permit the United States to comply with the Agreement between the United Nations and the United States of America regarding the Headquarters of the United Nations, signed June 26, 1947, and entered into force November 21, 1947.

(e) WAIVER.—The President may waive the application of subsection (a) or (c) with respect to an individual if the President—

(1) determines that such a waiver is in the national interest of the United States; and

(2) not less than 7 days before the waiver takes effect, notifies Congress of the waiver and the reason for the waiver.

Beginning on page 34, strike line 1 and all that follows through page 37, line 5, and insert the following:

SEC. 216. REPORTS ON, AND AUTHORIZATION OF IMPOSITION OF SANCTIONS WITH RESPECT TO, THE PROVISION OF SPECIALIZED FINANCIAL MESSAGING SERVICES TO THE CENTRAL BANK OF IRAN AND OTHER SANCTIONED IRANIAN FINANCIAL INSTITUTIONS.

(a) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) providers of specialized financial messaging services are a critical link to the international financial system;

(2) the European Union is to be commended for strengthening the multilateral sanctions regime against Iran by deciding that specialized financial messaging services may not be provided to the Central Bank of Iran and other sanctioned Iranian financial institutions by persons subject to the jurisdiction of the European Union; and

(3) the loss of access by sanctioned Iranian financial institutions to specialized financial messaging services must be maintained.

(b) REPORTS REQUIRED.—

(1) IN GENERAL.—Not later than 60 days after the date of the enactment of this Act, and every 90 days thereafter, the Secretary of the Treasury shall submit to the appropriate congressional committees a report that contains—

(A) a list of all persons that the Secretary has identified that directly provide specialized financial messaging services to, or enable or facilitate direct or indirect access to such messaging services for, the Central Bank of Iran or a financial institution described in section 104(c)(2)(E)(ii) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(E)(ii)); and

(B) a detailed assessment of the status of efforts by the Secretary to end the direct provision of such messaging services to, and the enabling or facilitation of direct or indirect access to such messaging services for, the Central Bank of Iran or a financial institution described in section 104(c)(2)(E)(ii) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(E)(ii)).

(2) ENABLING OR FACILITATION OF ACCESS TO SPECIALIZED FINANCIAL MESSAGING SERVICES THROUGH INTERMEDIARY FINANCIAL INSTITUTIONS.—For purposes of paragraph (1) and subsection (c), enabling or facilitating direct or indirect access to specialized financial messaging services for the Central Bank of Iran or a financial institution described in section 104(c)(2)(E)(ii) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(E)(ii)) includes doing so by serving as an intermediary financial institution with access to such messaging services.

(3) FORM OF REPORT.—A report submitted under paragraph (1) shall be submitted in unclassified form but may contain a classified annex.

(c) AUTHORIZATION OF THE IMPOSITION OF SANCTIONS.—

(1) IN GENERAL.—Except as provided in paragraph (2), if, on or after the date that is 90 days after the date of the enactment of this Act, a person continues to knowingly and directly provide specialized financial messaging services to, or knowingly enable or facilitate direct or indirect access to such messaging services for, the Central Bank of Iran or a financial institution described in paragraph (2)(E)(ii) of section 104(c) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)), the President may impose sanctions pursuant to that section or the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) with respect to the person.

(2) EXCEPTION.—The President may not impose sanctions pursuant to paragraph (1) with respect to a person for directly providing specialized financial messaging services to, or enabling or facilitating direct or indirect access to such messaging services for, the Central Bank of Iran or a financial institution described in section 104(c)(2)(E)(ii) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(E)(ii)) if—

(A) the person is subject to a sanctions regime under its governing foreign law that requires it to eliminate the knowing provision of such messaging services to, and the knowing enabling and facilitation of direct or indirect access to such messaging services for—

(i) the Central Bank of Iran; and

(ii) a group of Iranian financial institutions identified under such governing foreign law for purposes of that sanctions regime if the President determines that—

(I) the group is substantially similar to the group of financial institutions described in section 104(c)(2)(E)(ii) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8513(c)(2)(E)(ii)); and

(II) the differences between those groups of financial institutions do not adversely affect the national interest of the United States; and

(B) the person has, pursuant to that sanctions regime, terminated the knowing provision of such messaging services to, and the knowing enabling and facilitation of direct or indirect access to such messaging services for, the Central Bank of Iran and each Iranian financial institution identified under such governing foreign law for purposes of that sanctions regime.

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 New Year, President Barack Obama described censorship of the Internet and monitoring of computers and

cell phones by the Government of Iran as depriving the people of Iran of ''the information they want [and] stopping the free flow of information and ideas into the country''. The President concluded that ''in recent weeks, Internet restrictions have become so severe that Iranians cannot communicate freely with their loved ones within Iran, or beyond its borders, [so that] an electronic curtain has fallen around Iran.''.

(3) At a time when growing numbers of Iranians turn to the Internet as a source for news and political debate, the response of the Government of Iran has combined increasingly pervasive jamming and filtering of the Internet, blocking of email, social networking and other websites, and interception of Internet, telephonic, and mail communications.

(4) The March 2012 Report of the United Nations Human Rights Council Special Rapporteur on Iran details the Government of Iran's widespread human rights abuses and censorship, its chronic disregard of due process, and its equally chronic harassment, abuse, and intimidation of the people of Iran.

(5) There has been no independent investigation into the months of violence that followed Iran's fraudulent 2009 presidential election, violence that included the beatings of scores of Tehran University students by security forces using weapons, such as chains, metal rods, and electrified batons, and the subsequent imprisonment of many students, some of whom died in captivity.

(6) The Government of Iran has failed to cooperate with human rights investigations by the Special Rapporteur, and its failure to cooperate in those and similar investigations has been criticized in reports of the United Nations Secretary-General, General Assembly, and Human Rights Council, even as human rights abuses continue.

SEC. 402. SENSE OF CONGRESS.

It is the sense of Congress that—

(1) the Government of Iran, especially Iran's Revolutionary Guard Corps, continues to engage in serious, systematic, and ongoing violations of human rights and the rise in the level of such violations after the 2009 presidential elections has not abated;

(2) the Government of Iran is engaging in a systematic campaign to prevent news, entertainment, and opinions from reaching media that are not subject to government control and to eliminate any free Internet or other electronic media discussion among the people of Iran; and

(3) the Government of Iran has refused to cooperate with international organizations, including the United Nations, seeking to investigate or to alleviate those conditions.

On page 58, line 7, strike ''**401**'' and insert ''**403**''.

On page 59, line 12, insert '', any entity organized under the laws of Iran or otherwise subject to the jurisdiction of the Government of Iran, or any national of Iran, for use in or with respect to Iran'' after ''Iran''.

On page 59, line 13, insert ''(including services relating to hardware, software, and specialized information, and professional consulting, engineering, and support services)'' after ''services''.

On page 60, line 6, insert ''(or by any other person on behalf of the Government of Iran or any of such agencies or instrumentalities)'' after ''instrumentalities''.

On page 63, line 1, strike ''**402**'' and insert ''**404**''.

On page 63, strike line 19 and all that follows through page 64, line 12, and insert the following:

''(1) IN GENERAL.—Not later than 90 days after the date of the enactment of the Iran Sanctions, Accountability, and Human Rights Act of 2012, the President shall submit to the appropriate congressional committees a list of persons that the President determines have, on or after June 12, 2009, engaged in censorship or other activities that—

''(A) prohibit, limit, or penalize the exercise of freedom of expression or assembly by citizens of Iran; or

''(B) limit access to print or broadcast media, including the facilitation or support of intentional frequency manipulation by the Government of Iran that would jam or restrict an international signal or the failure to prohibit intentional frequency manipulation by the Government of Iran that would jam or restrict an international signal by satellite service providers that provide satellite services to the Government of Iran or an entity owned or controlled by the Government of Iran.

On page 64, line 13, strike ''(3)'' and insert ''(2)''.

On page 64, line 21, strike ''(4)'' and insert ''(3)''.

Beginning on page 72, strike line 7 and all that follows through page 78, line 6, and insert the following:

SEC. 503. INTERESTS IN CERTAIN FINANCIAL ASSETS OF IRAN.

(a) INTERESTS IN BLOCKED ASSETS.—Notwithstanding any other provision of law, including any provision of law relating to sovereign immunity, and preempting any inconsistent provision of State law, a financial asset that is—

(1) property in the United States of a foreign securities intermediary doing business in the United States,

(2) a blocked asset (whether or not subsequently unblocked) that is property described in subsection (b), and

(3) equal in value to a financial asset of Iran, including an asset of the central bank or monetary authority of the Government of Iran or any agency or instrumentality of that Government, that such foreign securities intermediary or a related intermediary holds abroad,

shall be available for all attachments and other proceedings in aid of execution, with respect to judgments entered against Iran for damages for personal injury or death caused by an act of torture, extrajudicial killing, aircraft sabotage, or hostage-taking, or the provision of material support or resources for such an act.

(b) PROPERTY DESCRIBED.—Property described in this subsection is property that is identified in and the subject of proceedings in the United States District Court for the Southern District of New York in *Peterson et al.* v. *Islamic Republic of Iran et al.*, Case No. 10 Civ. 4518 (BSJ) (GWG).

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the availability, or lack thereof, of a right to satisfy a judgment in any other action against a terrorist party in any proceedings other than proceedings referred to in subsection (b).

(d) DEFINITIONS.—In this section:

(1) BLOCKED ASSET.—The term ''blocked asset''—

(A) means any asset seized or frozen by the United States under section 5(b) of the Trading With the Enemy Act (50 U.S.C. App. 5(b)) or under section 202 or 203 of the International Emergency Economic Powers Act (50 U.S.C. 1701 and 1702); and

(B) does not include property that—

(i) is subject to a license issued by the United States Government for final payment, transfer, or disposition by or to a person subject to the jurisdiction of the United States in connection with a transaction for which the issuance of the license has been specifically required by a provision of law other than the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) or the United Nations Participation Act of 1945 (22 U.S.C. 287 et seq.); or

(ii) is property subject to the Vienna Convention on Diplomatic Relations or the Vienna Convention on Consular Relations, or that enjoys equivalent privileges and immunities under the laws of the United States, and is being used exclusively for diplomatic or consular purposes.

(2) FINANCIAL ASSET; SECURITIES INTERMEDIARY.—The terms ''financial asset'' and ''securities intermediary'' have the meanings given those terms in the Uniform Commercial Code, but the former includes cash.

(3) IRAN.—The term ''Iran'' means the Government of Iran, including the central bank or monetary authority of that Government and any agency or instrumentality of that Government.

(4) PERSON.—

(A) IN GENERAL.—The term ''person'' means an individual or entity.

(B) ENTITY.—The term ''entity'' means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization.

(5) TERRORIST PARTY.—The term ''terrorist party'' has the meaning given that term in section 201(d) of the Terrorism Risk Insurance Act of 2002 (28 U.S.C. 1610 note).

(6) UNITED STATES.—The term ''United States'' includes all territory and waters, continental, or insular, subject to the jurisdiction of the United States.

On page 78, between lines 15 and 16, insert the following:

SEC. 505. INCREASED CAPACITY FOR EFFORTS TO COMBAT UNLAWFUL OR TERRORIST FINANCING.

(a) AUTHORIZATION OF APPROPRIATIONS FOR OFFICE OF TERRORISM AND FINANCIAL INTELLIGENCE AND BUREAU OF INDUSTRY AND SECURITY.—Section 109 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8517) is amended—

(1) in subsection (b)(2), by striking ''and 2013'' and inserting ''through 2016''; and

(2) in subsection (d)(2), by striking ''and 2013'' and inserting ''through 2016''.

(b) AUTHORIZATION OF APPROPRIATIONS FOR FINANCIAL CRIMES ENFORCEMENT NETWORK.—Section 310(d)(1) of title 31, United States Code, is amended by striking ''and 2013'' and inserting ''through 2016''.

On page 80, between lines 5 and 6, insert the following:

SEC. 603. RULE OF CONSTRUCTION WITH RESPECT TO USE OF FORCE AGAINST IRAN AND SYRIA.

Nothing in this Act or the amendments made by this Act shall be construed as a declaration of war or an authorization of the use of force against Iran or Syria.

On page 80, line 6, strike ''603'' and insert ''604''.

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; as follows:

At the end of title XI, add the following:

SEC. 11___. ENSURING ADEQUATE INFORMATION REGARDING PHARMACEUTICALS FOR ALL POPULATIONS, PARTICULARLY UNDERREPRESENTED SUBPOPULATIONS, INCLUDING RACIAL SUBGROUPS.

(a) COMMUNICATION PLAN.—The Secretary of Health and Human Services (referred to in

this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall review and modify, as necessary, the Food and Drug Administration's communication plan to inform and educate health care providers, patients, and payors on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

(b) CONTENT.—The communication plan described under subsection (a)—

(1) shall take into account—

(A) the goals and principles set forth in the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities issued by the Department of Health and Human Services;

(B) the nature of the medical product; and

(C) health and disease information available from other agencies within such Department, as well as any new means of communicating health and safety benefits and risks related to medical products;

(2) taking into account the nature of the medical product, shall address the best strategy for communicating safety alerts, labeled indications for the medical products, changes to the label or labeling of medical products (including black box warnings, health advisories, health and safety benefits and risks), particular actions to be taken by healthcare professionals and patients, any information identifying particular subpopulations, and any other relevant information as determined appropriate to enhance communication, including varied means of electronic communication; and

(3) shall include a process for implementation of any improvements or other modifications determined to be necessary.

(c) ISSUANCE AND POSTING OF COMMUNICATION PLAN.—

(1) COMMUNICATION PLAN.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall issue the communication plan described under this section.

(2) POSTING OF COMMUNICATION PLAN ON THE OFFICE OF MINORITY HEALTH WEBSITE.—The Secretary, acting through the Commissioner of Food and Drugs, shall publicly post the communication plan on the Internet website of the Office of Minority Health of the Food and Drug Administration, and provide links to any other appropriate webpage, and seek public comment on the communication plan.

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. 11___. COMPLIANCE DATE FOR RULE RELATING TO SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE.

In accordance with the final rule issued by the Commissioner of Food and Drug entitled ''Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Delay of Compliance Dates'' (77 Fed. Reg. 27591 (May 11, 2012)), a product subject to the final rule issued by the Commissioner entitled ''Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use'' (76 Fed. Reg. 35620 (June 17, 2011)), shall comply with such rule not later than—

(1) December 17, 2013, for products subject to such rule with annual sales of less than $25,000 and

(2) December 17, 2012, for all other products subject to such rule.

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

Ms. 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 stroke and recognizing May as ''National Pediatric Stroke Awareness Month.''

There being no objection, the Senate proceeded to consider the resolution.

Mr. BROWN of Ohio. Madam President, I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, the motions to reconsider be laid upon the table, with no intervening action or debate, and any related statements be printed in the RECORD.

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

The resolution (S. Res. 468) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

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 a 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 between 20 percent and 40 percent of children who suffer a stroke die as a result;

Whereas stroke recurs 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 24 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 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 have a 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'';

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

(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 prognoses for children who suffer strokes.

HONORING THE ENTREPRENEURIAL SPIRIT OF SMALL BUSINESS

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 in the United States during National 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 AYOTTE, Senator RISCH, 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 to recognize this week, or 1 week in the year, as Small Business Week. So that is what our resolution, which was submitted earlier today, does.

I hope Leaders MCCONNELL and REID will take up this resolution and pass it so we can honor the 28 million small businesses that exist today in America. We have been doing everything we can, and I am very proud, as the chairman of the Small Business Committee, that we have worked in a bipartisan fashion for the most part trying to give our businesses, first of all, the recognition that 9 out of 10 new jobs created were created by a small number, a very small number, of small businesses that are fast growing. They are the new job creators. These are the businesses that are going to be putting this recession behind us. These are the businesses that are innovating and adapting and changing and being more strategic and smarter, looking for those opportunities in all areas and in all geographic parts of our Nation.

Over the past few months my committee has held three very special roundtables to explore strategies, tools, and methods to strengthen what I like to call the ecosystem of entrepreneurship. Much like a rain forest or desert or much like the ocean itself, that is an environment where many creatures or organisms have to live and interact. The same is true of our financial ecosystem, the political ecosystem. Society itself is an ecosystem where small businesses have to function.

In order for them to be healthy, there have to be the right nutrients, if you will, present. So we have explored in our committee what—we know the United States does this well. We do it better than any country on Earth. That is one of the great strengths of America; we foster that entrepreneurship, free but fair markets, well regulated, not too lightly, not too heavily. Sometimes we go a little overboard and we need to pull back. Sometimes we do not regulate enough and we need to step up. But that is what we have been exploring.

In fact, we have broken our roundtables into domains: Do our small businesses have enough access to capital? Do our small businesses truly have access to grow global markets? What did we learn this year? We learned that less than 12 percent of all small businesses in America export. With the market growing overseas and only the small percentage of the world market being now in the United States—we were at one time the biggest market, when China was closed, 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 the loan from the bank 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 remarket 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; there are clear 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 IBM, GE, 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 most certainly can 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 comes to contracting with minority and women-owned businesses, which make up a significant and growing area. It is very exiting as more women enter not just the workforce but decide they want their flexibility. They want to set their own hours. 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 areas 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 at our universities, to where 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 visa privileges 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 do not 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 heavy, too burdensome, and 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 have 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 pricetag 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 encouraging, by granting some 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 look forward to working with my 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 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, the granddaddy 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—actually people of all ages, 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, although 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 them in Delaware. That is what it 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 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 market to create wealth and opportunity for the United States and the world.

I am happy to be chair of the Small Business Committee. For small business and economic 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 will be 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:

S. RES. 469

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 all exporters and produce 31 percent 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 free and competitive enterprise, to ensure that a fair proportion of the total Federal Government purchases, contracts, 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 every year since 1963, 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 of owning 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 key part 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 efficient 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.

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.

APPOINTMENTS

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.

NOMINATIONS

Executive nominations received by the Senate:

THE JUDICIARY

THOMAS M. DURKIN, 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 EXPECTING SEPTEMBER 7, 2013, VICE LANE CARSON, RESIGNED.

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

BRUCE R. SIEVERS, 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

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.